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The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF AGRICULTURE

Rural Housing Service

7 CFR Part 3555

[Docket No. RHS–26–SFH–0364]

RIN 0575–AD47

Single Family Housing Guaranteed Loan Program-Limited Party Concessions

AGENCY: Rural Housing Service (RHS), U.S. Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: Rural Housing Service (RHS or the Agency), a Rural Development (RD) agency of the United States Department of Agriculture (USDA), amends the Single Family Housing Guaranteed Loan Program (SFHGLP) regulation to clarify real estate commission fees are not included in the limit on interested party concessions.

DATES: This final rule is effective November 9, 2026.

FOR FURTHER INFORMATION CONTACT: Laurie Mohr, Finance & Loan Analyst, Single Family Housing Guaranteed Loan Division, Rural Development, U.S. Department of Agriculture, STOP 0784, Room 2250, South Agriculture Building, 1400 Independence Avenue SW, Washington, DC 20250–0784, email: *laurie.mohr@usda.gov,* or Phone: 314–679–6917.

SUPPLEMENTARY INFORMATION:

Abbreviations

CFR Code of Federal Regulations
FR Federal Register
RHS Rural Housing Service
§ Section
SFH Single Family Housing
SFHGLP Single Family Housing Guaranteed Loan Program
USDA U.S. Department of Agriculture

Statutory Authority

SFHGLP is authorized by Section 502(h) of Title V of the Housing Act of 1949 (42 U.S.C. 1472(h)), as amended; and is implemented by 7 CFR part 3555.

Background

RHS offers programs to develop and enhance housing and critical community infrastructure in rural areas. RHS provides loans, grants, and loan guarantees for single and multi-family housing, childcare centers, emergency service facilities, hospitals, libraries, nursing homes, schools, and housing for agricultural workers, among other essential projects. RHS partners with non-profits, tribal governments, and state/federal agencies to provide technical assistance and supplementary financing to local communities.

Section 502(h) of the Housing Act of 1949 (42 U.S.C. 1472(h)) authorizes RHS to provide Single Family Housing (SFH) loan guarantees, providing low- and moderate-income individuals in rural areas an opportunity to own decent, safe, and sanitary dwelling and related facilities. Providing affordable homeownership opportunities promotes prosperity, which in turn creates thriving communities and improves the quality of life in rural areas.

Discussion of Public Comments

RHS published a proposed rule on April 20, 2026 (91 FR 20941) to amend SFHGLP regulation at 7 CFR part 3555. RHS received comments from 11 respondents, including individuals, interested parties, and one association.

The following summary presents the relevant comments:

Public Comment: Ten respondents replied they were in favor of the proposed rule, indicating real estate commission fees should not be included in the limit on interested party concessions.

Agency's Response: RHS appreciates the commenters' support and has determined no action is required.

Public Comment: One respondent agreed the proposal may offer benefits to homebuyers but cautioned the provision could be susceptible to misuse, potentially resulting in improper rebates to homebuyers.

Agency's Response: RHS appreciates this comment. Lenders must follow all consumer financial protection laws and standards enforced by the Consumer Financial Protection Bureau (CFPB) when originating and closing mortgage loans. RHS regulations also prohibit applicants from receiving cash back at closing beyond out-of-pocket costs.

In addition, lenders must set fees and charges which are reasonable and customary pursuant to 7 CFR 3555.101(b)(6), must comply with point and fee limits established by the CFPB, and may not charge amounts higher than those charged to other applicants for comparable transactions. Based on these existing safeguards, RHS has determined no action is required.

Summary of Changes to Rule

RHS amends its regulations to clarify real estate commission fees are excluded from the interested party concession limitation, aligning the policy with prevailing mortgage industry standards. Excluding real estate commission fees from the six percent seller concession limitation allows sellers to contribute more toward borrower closing costs, necessary repairs, or other permissible transaction expenses. This change enables applicants to retain more of their own funds for future investments, home improvements, or the purchase of goods and services, thereby supporting economic activity.

This final rule implements the changes published in the proposed rule (91 FR 20941; April 20, 2026), as follows:

(1) Amend 7 CFR 3555.102(h) by revising the definition of seller concessions to read as follows:

Seller concessions. Purchasing a home if the seller, or other interested third party, contributes more than 6 percent, unless otherwise provided by the Agency, of the property's sales price toward the purchaser's mortgage financing costs, closing costs, escrow accounts, furniture, or other giveaways. Real estate commission fees are excluded from the 6 percent seller concession limitation.

Executive Orders and Statutory Regulatory Review Requirements

Executive Order 12372, Intergovernmental Review of Federal Programs

This program is not subject to the requirements of Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' as implemented under USDA's regulations.

Executive Order 12866, Regulatory Planning and Review

This final rule has been determined to be not significant under section 3(f) of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

This final rule was reviewed under Executive Order 12988. In accordance with this rule: (1) unless otherwise specifically provided, all State and local laws that conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule except as specifically prescribed in the rule; and (3) administrative proceedings of the National Appeals Division of the Department of Agriculture (7 CFR part 11) must be exhausted before bringing suit in court that challenges action taken under this rule.

Executive Order 13132, Federalism

The policies contained in this final rule do not have any substantial direct effect on states, on the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. This rule does not impose substantial direct compliance costs on state and local governments. Therefore, consultation with the state is not required.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final rule was reviewed in accordance with the requirements of Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments''. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Consultation is also required for any regulation that preempts tribal law or that imposes substantial direct compliance costs on Indian tribal governments and that is not required by statute.

The Agency has determined that this rule does not have tribal implications that require formal tribal consultation under Executive Order 13175. If a Tribe requests consultation, the Rural Housing Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

Assistance Listing Number

The program affected by this final rule is listed in the Assistance Listing (AL) Number 10.410, Very Low- to Moderate-Income Housing Loans (Section 502 Rural Housing Loans).

Civil Rights Impact Analysis

RD has reviewed this final rule in accordance with USDA Regulation 4300–4, Civil Rights Impact Analysis,'' to identify any major civil rights impacts the rule might have on program participants on the basis of age, race, color, national origin, sex, disability, political beliefs, marital status, familial status, parental status, veteran status, religion, reprisal and/or resulting from all or a part of an individual's income being derived from any public assistance program. This final rule is within a Guarantee-based program. Guarantees are not covered under Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and Title IX of the Education Amendments Act of 1972, as amended, when the Federal assistance does not include insurance or interest credit loans. Lenders must comply with other applicable Federal laws, including Equal Employment Opportunities, the Equal Credit Opportunity Act, the Fair Housing Act, and the Civil Rights Act of 1964. Guaranteed loans that involve the construction of or addition to facilities that accommodate the public must comply with the Architectural Barriers Act Accessibility Standard. The borrower and lender are responsible for ensuring compliance with these requirements.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this final rule as not a major rule, as defined by 5 U.S.C. 804(2).

E-Government Act Compliance

Rural Development is committed to the E-Government Act, which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible and to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

National Environmental Policy Act

In accordance with the National Environmental Policy Act of 1969, Public Law 91–190, this rule was reviewed in accordance with 7 CFR part 1b (''National Environmental Policy Act''). The Agency has determined that (i) this action meets the criteria established in 7 CFR 1b.4(c)(31) and (ii) no extraordinary circumstances exist. Therefore, the Agency has determined that the action does not have a significant effect on the human environment, and therefore neither an Environmental Assessment nor an Environmental Impact Statement is required.

Paperwork Reduction Act

This final rule contains no new reporting or recordkeeping burden under OMB Control Number 0575–0179 that would require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Regulatory Flexibility Act

This final rule was reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). The undersigned has determined and certified by signature on this document that this rule will not have a significant economic impact on a substantial number of small entities since this rulemaking action does not involve a new or expanded program, nor does it require any more action on the part of a small business than required of a large entity.

The Reform Act for Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and on the private sector. Under section 202 of the UMRA, the Agency generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''federal mandates'' that may result in expenditures to state, local, or tribal Governments, in the aggregate, or to the private sector, of $100 million, or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Agency to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule.

This final rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for state, local, and tribal governments, or for the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Non-Discrimination Policy

In accordance with Federal civil rights laws and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the State or local Agency that administers the program or contact USDA through the Telecommunications Relay Service at 711 (voice and TTY). Additionally, program information may be made available in languages other than English.

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List of Subjects in 7 CFR Part 3555

Administrative practice and procedure, Conflicts of interest, Credit, Environmental impact statements, Fair housing, Flood insurance, Housing, Loan programs—housing and community development, Low- and moderate-income housing, Manufactured homes, Mortgages, Reporting and recordkeeping requirements, Rural areas.

For the reasons discussed in the preamble, RHS amends 7 CFR part 3555 as follows:

PART 3555—GUARANTEED RURAL HOUSING PROGRAM

■ 1. The authority citation for 7 CFR Part 3555 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 1471 *et seq.*

Subpart C—Loan Requirements

■ 2. Amend § 3555.102 by revising paragraph (h) to read as follows:

§ 3555.102 Loan restrictions.

* * * * *

(h) *Seller concessions.* Purchasing a home if the seller, or other interested third party, contributes more than 6 percent, unless otherwise provided by the Agency, of the property's sales price toward the purchaser's mortgage financing costs, closing costs, escrow accounts, furniture, or other giveaways. Real estate commission fees are excluded from the 6 percent seller concession limitation.

George Kelly,

Administrator, Rural Housing Service.

[FR Doc. 2026–22772 Filed 11–6–26; 8:45 am]

BILLING CODE 3410–XV–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–7230; Project Identifier MCAI–2026–00185–R; Amendment 39–23512; AD 2026–22–10]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters Deutschland GmbH (AHD) Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2024–04–10 which applied to all Airbus Helicopters Deutschland GmbH (AHD) Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, and EC635T2+ helicopters. AD 2024–04–10 required repetitively inspecting certain part-numbered tail rotor (T/R) blades for a crack and, depending on the results, removing any cracked T/R blade from service. AD 2024–04–10 also prohibits installing certain T/R blades on any helicopter unless certain requirements are met. Since AD 2024–04–10 was issued, it was determined that inspection Method A should be discontinued and that additional limitations shall be provided. This AD retains the actions of AD 2024–04–10 and requires repetitively inspecting a certain tail rotor blade (TRB) assembly for cracks and, depending on the results, removing any cracked TRB assembly from service and replacing an affected part as terminating action for the repetitive inspections. This AD also prohibits installing an affected TRB assembly on any helicopter unless certain requirements are met. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 14, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 14, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–7230; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2026–7230.

FOR FURTHER INFORMATION CONTACT: Soban Saeed, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4123; email: *soban.saeed@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2024–04–10, Amendment 39–22689 (89 FR 15431, March 4, 2024), (AD 2024–04–10). AD 2024–04–10 applied to all AHD Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, and EC635T2+ helicopters. AD 2024–04–10 required repetitively inspecting T/R blades having part number (P/N) L642A2002111 or P/N L642A2002112 installed for a crack and, depending on the results, removing any cracked T/R blade from service. AD 2024–04–10 also prohibited installing certain T/R blades on any helicopter unless certain requirements are met. The FAA issued AD 2024–04–10 to detect and address cracks in affected T/R blades. The unsafe condition, if not addressed, could result in separation of a T/R blade assembly and subsequently reduced control of the helicopter.

The NPRM was published in the **Federal Register** on July 30, 2026 (91 FR 47994). The NPRM was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued EASA AD 2026–0032, dated February 19, 2026 (EASA AD 2026–0032) (also referred to as the MCAI). The MCAI states that a determination was made by the manufacturer that a previously approved inspection method (Method A) should be discontinued. Method A consisted of a dye-penetrant (with increased temperature) inspection.

In the NPRM, the FAA proposed to retain the requirements of AD 2024–04–10 and also proposed to require repetitively inspecting a certain TRB assembly for cracks and, depending on the results, removing any cracked TRB assembly from service and replacing an affected part as terminating action for the repetitive inspections. In the NPRM, the FAA also proposed to prohibit installing an affected TRB assembly on any helicopter unless certain requirements are met.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–7230.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2026–0032, which specifies procedures for repetitively inspecting the affected TRB assembly for cracks and, if any crack is detected, replacing the affected TRB assembly with a serviceable part. EASA AD 2026–0032 prohibits installing a certain TRB assembly on any helicopter unless certain requirements are met and specifies that replacing an affected TRB assembly with an eligible TRB assembly that is not an affected part is terminating action for certain repetitive inspections.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Differences Between This AD and the MCAI

The MCAI applies to Airbus Helicopters Model EC635 P2+, EC635 P3, EC635 T1, and EC635 T3 helicopters, whereas this AD does not because those models do not have an FAA type certificate.

The MCAI specifies inspecting cracks by performing a visual inspection, dye-penetrant inspection, eddy current inspection, or fluorescent penetrant inspection, whereas this AD requires inspection methods under certain scenarios as outlined in the regulatory text of this AD, which are also described in a Note in the regulatory text of this AD.

Costs of Compliance

The FAA estimates that this AD affects 359 helicopters of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect one affected TRB assembly (up to 10 per helicopter).	3 work-hours × $85 per hour = $255.	$50	Up to $305	Up to $109,495.

The FAA estimates the following costs to do any replacements that will be required based on the results of the inspection. The agency has no way of determining the number of helicopters that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace one TRB assembly (up to 10 per helicopter).	3 work-hours × $85 per hour = $255.	$4,900 per TRB assembly	Up to $51,550.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—Airworthiness Directives

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2024–04–10, Amendment 39–22689 (89 FR 15431, March 4, 2024); and

■ b. Adding the following new airworthiness directive:

2026–22–10 Airbus Helicopters Deutschland GmbH (AHD):

Amendment 39–23512; Docket No. FAA–2026–7230; Project Identifier MCAI–2026–00185–R.

(a) Effective Date

This airworthiness directive (AD) is effective December 14, 2026.

(b) Affected ADs

This AD replaces AD 2024–04–10, Amendment 39–22689 (89 FR 15431, March 4, 2024) (AD 2024–04–10).

(c) Applicability

This AD applies to all Airbus Helicopters Deutschland GmbH (AHD) Model EC135P1, EC135P2, EC135P2+, EC135P3, EC135T1, EC135T2, EC135T2+, EC135T3, and EC635T2+ helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 6410, Tail rotor blades.

(e) Unsafe Condition

This AD was prompted by a report of a separated tail rotor blade (TRB) assembly due to a crack in the TRB assembly caused by intergranular corrosion. The FAA is issuing this AD to detect and address cracks in the TRB assembly. The unsafe condition, if not addressed, could result in separation of a TRB assembly and reduced control of the helicopter.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency AD 2026–0032, dated February 19, 2026 (EASA AD 2026–0032).

(h) Exceptions to EASA AD 2026–0032

(1) Where EASA AD 2026–0032 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2026–0032 refers to January 29, 2024 (the effective date of EASA Emergency AD 2024–0028–E), this AD requires using March 19, 2024 (the effective date of AD 2024–04–10).

(3) Where EASA AD 2026–0032 refers to flight hours, this AD requires using hours time-in-service (TIS).

(4) Where paragraph (1) of EASA AD 2026–0032 specifies ''Before an affected part exceeds 685 FH [flight hours] since first installation on a helicopter'', this AD requires replacing that text with ''Before an affected part accumulates 685 hours TIS since first installation on a helicopter, or within 10 hours TIS after March 19, 2024 (the effective date of AD 2024–04–10), whichever occurs later''.

(5) Where paragraph 4.3 of the material referenced in EASA AD 2026–0032 recommends type II visible dye inspections, this AD requires the inspection methods in paragraphs (h)(5)(i), (ii), or (iii) of this AD, as applicable:

(i) If the affected part has previously been inspected using a type II visible dye method, perform type II visible dye (Method B of the material referenced in EASA AD 2026–0032) or eddy current inspections, instead of fluorescent penetrant inspections.

(ii) If the affected part has not previously been inspected using a type II visible dye inspection, perform eddy current or fluorescent penetrant inspections, instead of type II visible dye inspections.

(iii) If you cannot determine whether the affected part has previously been inspected by a type II visible dye method, clean all surfaces to be inspected and perform an eddy current or a fluorescent penetrant inspection, instead of a type II visible dye inspection.

Note 1 to paragraph (h)(5): The FAA reminds operators of the airworthiness concern regarding type II visible dye inspections of critical parts discussed in FAA Special Airworthiness Information Bulletin (SAIB) CE–18–26R1, dated October 30, 2018 (SAIB CE–18–26R1). SAIB CE–18–26R1 explains the risks associated with using type II visible dye inspection methods, including the prohibition in ASTM E1417 on the use of type II visible dye penetrant prior to the use of type I fluorescent penetrant on the same surface. SAIB CE–18–26R1 also advises of the importance of pre- and post-inspection cleaning to ensure proper detection of cracks. You can find SAIB CE–18–26R1 at *drs.faa.gov*.

Note 2 to paragraph (h)(5): The material referenced in EASA AD 2026–0032 identifies a type II visible dye inspection as Method A (not allowed) or Method B; eddy current inspection as Method C; fluorescent penetrant inspection as Method D; and visual inspection as Method E.

Note 3 to paragraph (h)(5): When entering compliance with the applicable paragraph of the AD into the helicopter maintenance records, documenting that a type II visible dye inspection was performed improves the accuracy of maintenance records.

(6) This AD does not adopt paragraph (3) of EASA AD 2026–0032.

(7) This AD does not adopt the ''Remarks'' section of EASA AD 2026–0032.

(i) No Reporting or Returning of Parts

Where the material referenced in EASA AD 2026–0032 specifies to submit certain information and to send removed parts to the manufacturer, this AD does not include those actions.

(j) Special Flight Permits

Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (l) of this AD and email to *AMOC@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager

of the local flight standards district office/certificate holding district office.

(l) Additional Information

For more information about this AD, contact Soban Saeed, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946–4123; email: *soban.saeed@faa.gov.*

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2026–0032, dated February 19, 2026.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on October 30, 2026.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2026–22776 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–1335; Project Identifier AD–2025–00825–T; Amendment 39–23511; AD 2026–22–09]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. This AD was prompted by reports that the low range radio altimeter (LRRA) system has an increased rate of non-computed data (NCD) outputs at low altitudes during approach and landing, which could cause unreliable altimeter function. This AD requires replacing the left and right LRRA transmit and receive coaxial cables with larger gauge coaxial cables. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 14, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 14, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–1335; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2026–1335.

FOR FURTHER INFORMATION CONTACT: Frank Carreras, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3539; email: *Frank.Carreras@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. The NPRM was published in the **Federal Register** on February 24, 2026 (91 FR 8794). The NPRM was prompted by reports that the LRRA system has an increased rate of NCD outputs at low altitudes during approach and landing, which could cause unreliable altimeter function. In the NPRM, the FAA proposed to require replacing the left and right LRRA transmit and receive coaxial cables with larger gauge coaxial cables. The FAA is issuing this AD to address unreliable data output or in-service disruptions of LRRA functions. The unsafe condition, if not addressed, could result in loss of continued safe flight and landing.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International (ALPA) and Boeing who supported the NPRM without change.

The FAA received additional comments from seven commenters, including Air Canada, American Airlines (American), EVA Air, the Foundation for Aviation Safety, Turkish Airlines, United Airlines (United), and an anonymous commenter. The following presents those comments and the FAA's response.

Request To Reference Revised Service Information

Air Canada and United requested the FAA revise the proposed AD to specify that Boeing Alert Service Bulletin B787–81205–SB340062–00, Issue 002, dated August 11, 2025 (Issue 002 of the Service Bulletin) may be used to accomplish the proposed actions. United noted that Issue 002 of the Service Bulletin corrects the required material kits and consumables and updates the installation instructions.

EVA Air requested that the FAA confirm accomplishment of Boeing Alert Requirements Bulletin B787–81205–SB340062–00 RB, Issue 002, dated August 11, 2025 (Issue 002 of the Requirements Bulletin), is acceptable for compliance with the proposed AD. EVA stated it identified multiple deviations and practical implementation issues with Boeing Alert Requirements Bulletin B787–81205–SB340062–00 RB, Issue 001, dated December 23, 2024 (Issue 001 of the Requirements Bulletin).

Turkish Airlines requested that the FAA revise the applicability of the proposed AD to reference Issue 002 of the Requirements Bulletin. Turkish Airlines stated that, due to technical problems in Issue 001 of the Requirements Bulletin, it accomplished some actions using Issue 001 along with approved repair data, and continued implementation using Issue 002 of the Requirements Bulletin.

The FAA agrees that Issue 002 of the Service Bulletin may be used for accomplishing the actions required by

this AD. Tables 1 and 2 of the Accomplishment Instructions of Issue 001 of the Requirements Bulletin refer to Issue 001 of the Service Bulletin or ''later approved issues'' as accepted procedures. Further, the FAA reviewed Issue 002 of the Service Bulletin, which updates work instructions for Group 4 airplanes, revises task tables and illustrations, and updates industry support information without expanding the scope of the AD. Therefore, operators may use the procedures in Issue 002 of the Service Bulletin for compliance with requirements of this AD. The FAA has determined no change to this AD is necessary in regard to Air Canada's and United's requests.

The FAA disagrees with EVA Air's and Turkish Airline's requests. Changes in Issue 002 of the Service Bulletin do not affect the required for compliance (RC) steps in Issue 001 of the Requirements Bulletin. Therefore, Boeing has not released Issue 002 of the Requirements Bulletin. However, as noted in the previous paragraph, later approved issues of the service bulletin provide accepted procedures, and this meets the intent of the requests from EVA Air and Turkish Airlines.

Request To Extend Compliance Time

American, Turkish Airlines, and an anonymous commenter requested that the FAA extend the compliance time of the proposed AD. American stated that Boeing quoted a lead time exceeding 500 days for the required cables, which would shorten the available time to accomplish the proposed requirements. Turkish Airlines stated that it shared its kit needs with Boeing in March 2025 but continued to experience kit supply problems. The anonymous commenter stated that moving the compliance date slightly after the effective date of the final rule would allow operators adequate time to incorporate the required modifications into scheduled maintenance cycles without unnecessary operational disruption.

The FAA disagrees with extending the compliance time. In developing an appropriate compliance time for this action, the FAA considered the recommendations of the manufacturer, the urgency associated with the subject unsafe condition, the availability of required parts, and the practical aspect of accomplishing the required modification within a period of time that corresponds to the normal scheduled maintenance for most affected operators. Further, the FAA has determined that operators have sufficient time within the 5-year compliance period to accomplish the required coaxial cable installation. However, under the provisions of paragraph (i) of this AD, the FAA will consider requests for approval of an extension of the compliance time if sufficient data are submitted to substantiate that the new compliance time would provide an acceptable level of safety. The FAA has not changed this AD in regard to this comment.

Request To Reduce Compliance Time

The Foundation for Aviation Safety noted that the unsafe condition is critical and questioned whether it is necessary to allow up to five years to accomplish the proposed actions that are estimated to take approximately 28 hours.

As discussed in the previous comment, the FAA has determined that the compliance time, as proposed, represents an appropriate amount of time in which the required actions can be performed in a timely manner within the affected fleet while still maintaining an adequate level of safety. The FAA has not changed this AD in regard to this comment.

Request To Allow Continued Operation Under Visual Flight Rules (VFR)

An anonymous commenter requested that the FAA consider permitting continued operation of affected airplanes on routes where both the departure and arrival airports are forecasted to maintain VFR conditions, since pilots operating under VFR rely primarily on visual references rather than sole dependence on radio altimeter data during approach and landing. The commenter stated this approach would maintain safety objectives while minimizing economic and scheduling impacts on operators and passengers during the transition period.

The FAA disagrees because the FAA has determined that LRRA coaxial cables must be replaced to address the unsafe condition. The LRRA is needed for everyday operations including continued operation of affected aircraft on routes where both departure and arrival airports are forecast to maintain VFR conditions. Further, this AD does not prohibit operations of the affected airplanes. The FAA has not changed this AD in regard to this comment.

Additional Changes Made to This Final Rule

Issue 002 of the Service Bulletin includes an update to the estimated work-hours. Therefore, the FAA has revised the Costs of Compliance section in this final rule.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin B787–81205–SB340062–00 RB, Issue 001, dated December 23, 2024. This material specifies procedures for replacing the existing left and right BMS13–65 Type 0G LRRA transmit and receive coaxial cables with larger gauge Type 0J coaxial cables. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 169 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement	31 work-hours × $85 per hour = $2,635	$15,170	$17,805	$3,009,045

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2026–22–09 The Boeing Company: Amendment 39–23511; Docket No. FAA–2026–1335; Project Identifier AD–2025–00825–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 14, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8, 787–9, and 787–10 airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin B787–81205–SB340062–00 RB, Issue 001, dated December 23, 2024.

(d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

(e) Unsafe Condition

This AD was prompted by reports that the low range radio altimeter (LRRA) system has an increased rate of non-computed data (NCD) outputs at low altitudes during approach and landing. The FAA is issuing this AD to address unreliable data output or in-service disruptions of LRRA functions. The unsafe condition, if not addressed, could result in loss of continued safe flight and landing.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin B787–81205–SB340062–00 RB, Issue 001, dated December 23, 2024, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin B787–81205–SB340062–00 RB, Issue 001, dated December 23, 2024.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin B787–81205–SB340062–00, Issue 01, dated December 23, 2024, which is referred to in Boeing Alert Requirements Bulletin B787–81205–SB340062–00 RB, Issue 001, dated December 23, 2024.

(h) Exception to Requirements Bulletin Specifications

Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin B787–81205–SB340062–00 RB, Issue 001, dated December 23, 2024, refer to the Issue 001 date of Requirements Bulletin B787–81205–SB340062–00 RB, this AD requires using the effective date of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *AMOC@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Additional Information

(1) For more information about this AD, contact Frank Carreras, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3539; email: *Frank.Carreras@faa.gov.*

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (k)(AD.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Requirements Bulletin B787–81205–SB340062–00 RB, Issue 001, dated December 23, 2024.

(ii) [Reserved]

(3) For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com*.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*.

Issued on October 27, 2026.

Brian Knaup,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2026–22817 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–7219; Project Identifier MCAI–2024–00404–E; Amendment 39–23509; AD 2026–22–07]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Rolls-Royce Deutschland Ltd & Co KG (RRD) Model BR700–725A1–12 engines. This AD was prompted by the manufacturer revising the airworthiness limitations section (ALS) of the existing time limits manual (TLM) to introduce new or more restrictive airworthiness limitations and associated thresholds and intervals for life-limited parts. This AD requires revising the ALS of the operator's existing approved engine maintenance or inspection program, as applicable, to incorporate new or more restrictive instructions and associated thresholds and intervals for life-limited parts. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 14, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 14, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–7219; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2026–7219.

FOR FURTHER INFORMATION CONTACT: Barbara Caufield, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all RRD Model BR700–725A1–12 engines. The NPRM was published in the **Federal Register** on July 15, 2026 (91 FR 43343). The NPRM was prompted by EASA AD 2024–0136, dated July 11, 2024, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2024–0136) (also referred to as the MCAI). The MCAI states that the manufacturer revised the ALS of the existing TLM to introduce new or more restrictive airworthiness limitations and associated thresholds and intervals for life-limited parts.

In the NPRM, the FAA proposed to require revising the ALS of the operator's existing approved engine maintenance or inspection program, as applicable, to incorporate new or more restrictive instructions and associated thresholds and intervals for life-limited parts. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–7219.

Discussion of Final Airworthiness Directive

Comments

The FAA received one comment from an anonymous commenter. The following presents the comment received on the NPRM and the FAA's response to the comment.

Request To Include Non-Destructive Testing Inspections

An individual commenter stated that the FAA focuses primarily on removing parts once they reach the new cycle limit but fails to mandate intermediate non-destructive testing inspections for components approaching the new threshold. The commenter noted that without requiring inspections prior to part removal, the FAA leaves an undetected safety risk for engines that may already have micro-cracks propagating toward failure before reaching the new lower limit. The FAA infers that the commenter is requesting that non-destructive testing inspections be required for parts approaching their life-limit threshold.

The FAA disagrees with this request because the airworthiness limitations section includes inspections at piece part opportunity and life limits which are designed to appropriately mitigate the risk associated with the unsafe condition. The FAA did not change this AD as a result of this comment.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0136, which specifies procedures for revising the ALS of the existing approved engine maintenance or inspection program, as applicable, to incorporate new or more restrictive tasks and limitations and associated thresholds and intervals for life-limited parts. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Differences Between This AD and the MCAI

Where paragraph (3) of EASA AD 2024–0136 specifies revising the approved Aircraft Maintenance Programme within 12 months after the effective date of EASA AD 2024–0136, this AD requires revising the ALS of the existing approved engine maintenance or inspection program, as applicable, within 30 days after the effective date of this AD.

Costs of Compliance

The FAA estimates that this AD affects 758 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise the ALS	1 work-hour × $85 per hour = $85	$0	$85	$64,430

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2026–22–07 Rolls-Royce Deutschland Ltd & Co KG: Amendment 39–23509; Docket No. FAA–2026–7219; Project Identifier MCAI–2024–00404–E.

(a) Effective Date

This airworthiness directive (AD) is effective December 14, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Rolls-Royce Deutschland Ltd & Co KG Model BR700–725A1–12 engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by the manufacturer revising the airworthiness limitations section of the existing time limits manual to introduce new or more restrictive airworthiness limitations and associated thresholds and intervals for life-limited parts. The FAA is issuing this AD to prevent failure of critical rotating parts. The unsafe condition, if not addressed, could result in failure of one or more engines, loss of thrust control, and loss of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Except as specified in paragraph (h) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2024–0136, dated July 11, 2024 (AD 2024–0136).

(h) Exceptions to EASA AD 2024–0136

(1) Where EASA AD 2024–0136 requires compliance from its effective date, this AD requires using the effective date of this AD.

(2) This AD does not require compliance with paragraphs (1), (2), (4), and (5) of EASA AD 2024–0136.

(3) Where paragraph (3) of EASA AD 2024–0136 specifies ''Within 12 months after the effective date of this AD, revise the approved AMP,'' replace that text with ''Within 30 days after the effective date of this AD, revise the airworthiness limitations section of the existing approved engine maintenance or inspection program, as applicable''.

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0136 is on or before the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2024–0136 or within 30 days after the effective date of this AD, whichever occurs later.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0136.

(i) Provisions for Alternative Actions and Intervals

No alternative actions and associated thresholds and intervals, including life limits, are allowed for compliance with paragraph (g) of this AD unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2024–0136.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, AIR–520 Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the AIR–520 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: *AMOC@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Barbara Caufield, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des

Moines, WA 98198; phone: (781) 238–7146; email: *barbara.caufield@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0136, dated July 11, 2024.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on October 26, 2026.

Brian Knaup,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2026–22774 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2025–7226; Project Identifier MCAI–2025–01346–R; Amendment 39–23510; AD 2026–22–08]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Helicopters (AH) Model EC130B4 helicopters. This AD was prompted by reports of weaknesses in the locking mechanisms on the left-hand side swinging and sliding door. This AD requires modifying the swing door star support and sliding door star support stringer. This AD also prohibits installing an affected composite door on any helicopter unless certain requirements are met. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 14, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 14, 2026.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2025–7226; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For European Union Aviation Safety Agency (EASA) material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT: Thanh Tran, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (562) 275–5304; email: *thanh.b.tran@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus Helicopters Model EC130B4 helicopters. The NPRM was published in the **Federal Register** on July 23, 2026 (91 FR 46325). The NPRM was prompted by an MCAI issued by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued EASA AD 2024–0232, dated December 5, 2024 (EASA AD 2024–0232), (also referred to as the MCAI). The MCAI states that several incidents on the left-hand side swing and sliding doors have revealed some weaknesses in the locking mechanism. Additionally, the MCAI states that AH [Airbus Helicopters] Model EC130B4 helicopters that have embodied EC MOD [modification] 07 3796 were erroneously excluded from the applicability of a previously issued EASA AD.

In the NPRM, the FAA proposed to require, for all AH Model EC130B4 helicopters, modifying the swing door star support and sliding door star support stringer and proposed to prohibit installing an affected composite door on any helicopter unless certain requirements are met. The FAA is issuing this AD to address failure of the sliding door star support, which could inhibit the operation of the sliding door from the inside, and delay the evacuation of passengers during an emergency.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–7226.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from one anonymous commenter. The commenter supported the NPRM without change.

Conclusion

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0232, which specifies procedures for modifying the door locking/unlocking mechanism by installing a reinforcing bracket and replacing rod ends and prohibits installing a composite door on any helicopter unless this modification is accomplished. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Differences Between This AD and the MCAI

EASA AD 2024–0232 specifies to accomplish the modification of the locking/unlocking mechanism within 24 months. This AD requires the modification to be accomplished within 460 hours time-in-service (TIS) based on an average of 230 hours TIS per year. The FAA has determined this compliance time represents the maximum interval of time allowable for the affected helicopters to continue to safely operate before the modification is done.

Costs of Compliance

The FAA estimates that this AD affects 214 helicopters of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Perform modification	20 work-hours × $85 per hour = $1,700	$642	$2,342	$501,188

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2026–22–08 Airbus Helicopters: Amendment 39–23510; Docket No. FAA–2025–7226; Project Identifier MCAI–2025–01346–R.

(a) Effective Date

This airworthiness directive (AD) is effective December 14, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Helicopters Model EC130B4 helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 5200, Doors.

(e) Unsafe Condition

This AD was prompted by reports of weaknesses in the locking mechanisms on the left-hand side swing and sliding doors. The FAA is issuing this AD to address failure of the sliding door star support, which could inhibit the operation of the sliding door from the inside, and delay the evacuation of passengers during an emergency.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency AD 2024–0232, dated December 5, 2024 (EASA AD 2024–0232).

(h) Exceptions to EASA AD 2024–0232

(1) Where EASA AD 2024–0232 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (1) of EASA AD 2024–0232 specifies to complete the actions within 24 months after its effective date, this AD requires completion within 460 hours time-in-service after the effective date of this AD.

(3) Where the material referenced in EASA AD 2024–0232 specifies performing a dye penetrant inspection, for the purposes of this AD, it is not permitted to use Type 2 colored dye penetrant for inspections required by paragraph (g) of this AD.

(4) Where the material referenced in EASA AD 2024–0232 specifies discarding certain parts, this AD requires removing those parts from service.

(5) Where the material referenced in EASA AD 2024–0232 specifies ''check'', this AD requires replacing that text with ''inspect''.

(6) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0232.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2024–0232 specifies to submit certain information to the manufacturer, this AD does not require that action.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: *AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Thanh Tran, Aviation Safety

Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (562) 275–5304; email: *thanh.b.tran@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0232, dated December 5, 2024.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on October 26, 2026.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2026–22780 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–13797; Project Identifier AD–2026–01052–E; Amendment 39–23515; AD 2026–22–13]

RIN 2120–AA64

Airworthiness Directives; Lycoming Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2026–17–10, which applied to Lycoming Engines (Lycoming) Model O–235, O–540, and IO–540 engines with a certain piston pin installed. AD 2026–17–10 required replacement of the affected piston pin with a part eligible for installation and, for certain engines, oil change and visual inspection of the engine oil filter, oil pressure screen, and oil suction screen for metal particulates. AD 2026–17–10 also prohibited the installation of an affected piston pin on any engine. Since the FAA issued AD 2026–17–10, the manufacturer has identified additional Lycoming Model engines that are subject to the unsafe condition, and the FAA determined the need to clarify the definition for an ''affected piston pin,'' and include corrective action for engine models that were not listed in the manufacturer's service material. This AD requires replacement of the affected piston pin with a part eligible for installation and, for certain engines, oil change and visual inspection of the engine oil filter, oil pressure screen, and oil suction screen for metal particulates. This AD also prohibits the installation of an affected piston pin on any engine. This AD also expands the applicability to include additional affected engines with a certain piston pin installed. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 24, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 24, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of September 14, 2026 (91 FR 55451, August 28, 2026).

The FAA must receive comments on this AD by December 24, 2026.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–13797; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Lycoming material identified in this AD, contact Lycoming Engines, 652 Oliver Street, Williamsport, PA 17701; phone: (800) 258–3279; website: *lycoming.com/contact/knowledge-base/publications.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at *regulations.gov* under Docket No. FAA–2026–13797.

FOR FURTHER INFORMATION CONTACT: Ramanpreet Singh, Aviation Safety Engineer, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (516) 228–7300; email: *ECB-COS@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments using a method listed under the **ADDRESSES** section. Include ''Docket No. FAA–2026–13797; Project Identifier AD–2026–01052–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI

should be sent to Ramanpreet Singh, Aviation Safety Engineer, FAA, 1701 Columbia Avenue, College Park, GA 30337. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2026–17–10, Amendment 39–23454 (91 FR 55451, August 28, 2026) (AD 2026–17–10), for Lycoming Model O–235, O–540, and IO–540 engines with a certain piston pin installed. AD 2026–17–10 required replacement of the affected piston pin with a part eligible for installation and, for certain engines, oil change and visual inspection of the engine oil filter, oil pressure screen, and oil suction screen for metal particulates. AD 2026–17–10 was prompted by several reports of piston pin failure that resulted in metal particulate contamination in the engine oil and engine failure. The FAA issued AD 2026–17–10 to prevent failure of the piston pin.

Actions Since AD 2026–17–10 Was Issued

Since the FAA issued AD 2026–17–10, the manufacturer has identified additional Lycoming Model engines that are subject to the unsafe condition and identified Lycoming Model engines that were included in the applicability of AD 2026–17–10 that are not subject to the unsafe condition. Additionally, the FAA determined the need to clarify the applicability, the definition for an ''affected piston pin,'' and corrective actions. The FAA is issuing this AD to address the unsafe condition on these products.

FAA's Determination

The FAA is issuing this AD because the agency determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Material Incorporated by Reference Under 1 CFR part 51

The FAA reviewed Lycoming Service Instruction No. 1009BF, dated July 20, 2026, which identifies the compliance times between overhauls for certain Lycoming Model engines.

This AD also requires the following material, which the Director of the Federal Register approved for incorporation by reference as of September 14, 2026 (91 FR 55451, August 28, 2026).

- Lycoming Mandatory Service Bulletin No. (MSB) 667A, dated March 12, 2026 (Lycoming MSB 667A).

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

AD Requirements

This AD requires replacement of the affected piston pin with a part eligible for installation and, for certain engines, oil change and visual inspection of the engine oil filter, oil pressure screen, and oil suction screen for metal particulates. This AD also prohibits the installation of an affected piston pin on any engine. This AD also expands the applicability to include additional affected engines with a certain piston pin installed.

Differences Between This AD and the Referenced Material

This AD requires oil change and visual inspection of the engine oil filter, oil pressure screen, and oil suction screen for metal particulates within 5 hours time-in-service (TIS), while Lycoming MSB 667A does not have this requirement.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies forgoing notice and comment prior to adoption of this rule because piston pin microcracks and inclusions are difficult to detect prior to failure, and can result in internal damage to the engine, in-flight shutdown, and loss of control of the airplane. The FAA has determined that affected engines will need to be inspected and have affected piston pins replaced within 25 hours TIS or earlier after the effective date of this AD depending on the engine model. Additionally, the compliance time in this AD is shorter than the time necessary for the public to comment and for publication of the final rule. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 957 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Piston pin replacement, oil change, and oil inspection.	25 work-hours × $85 per hour = $2,125	$2,200	$4,325	$4,139,025

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue

rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2026–17–10, Amendment 39–23454 (91 FR 55451, August 28, 2026); and

■ b. Adding the following new airworthiness directive:

2026–22–13 Lycoming Engines: Amendment 39–23515; Docket No. FAA–2026–13797; Project Identifier AD–2026–01052–E.

(a) Effective Date

This airworthiness directive (AD) is effective November 24, 2026.

(b) Affected ADs

This AD replaces AD 2026–17–10, Amendment 39–23454 (91 FR 55451, August 28, 2026).

(c) Applicability

This AD applies to Lycoming Engines (Lycoming) Model engines identified in table 1 to paragraph (c) of this AD with an installed piston pin having part number (P/N) LW–13445 that was manufactured between January 7, 2021 to December 15, 2025. If the date of manufacture for the piston pin cannot be determined, this AD is applicable. If the current piston pins (P/N LW–13445) were installed prior to January 7, 2021, this AD is not applicable.

TABLE 1 TO PARAGRAPH (c)—LYCOMING MODEL ENGINES

Engine series	Engine model
O–235	–C1, –C1A, –C1B, –C1C, –C2A, –C2B, –C2C, –E1, –E1B, –E2A, –E2B, –F1, –F1B, –F2A, –F2B, –G1, –G1B, –G2A, –G2B, –H2C, –J2A, –J2B, –K2A, –K2B, –K2C, –L2A, –L2C, –M1, –M2C, –M3C, –N2A, –N2C, –P1, –P2A, –P2C, –P3C.
O–320	–A1A, –A1B, –A2A, –A2B, –A2C, –A2D, –A3A, –A3B, –A3C, –B1A, –B1B, –B2A, –B2B, –B2C, –B2D, –B2E, –B3A, –B3B, –B3C, –D1A, –D1B, –D1C, –D1D, –D1F, –D2A, –D2B, –D2C, –D2F, –D2J, –D3G, –E1A, –E1B, –E1C, –E1F, –E1J, –E2A, –E2B, –E2C, –E2D, –E2F, –E2G, –E2H, –E3D, –E3H.
IO–320	–B1A, –B1C, –B1D, –B1E, –B2A, –C1A,–C1B, –D1A, –D1B, –D1C, –E1A, –E1B, –E2A,–E2B.
AIO–320	–A1B, –B1B, –C1B.
LIO–320	–B1A, –C1A.
AEIO–320	–D1B, –D2B, –E1A, –E1B, –E2A, –E2B.
VO–435	–A1A (O–435–21), –A1B (O–435–6), –A1C (O–435–23, –23A, –23B, –23C), –A1D (O–435–6A), –A1E, –A1F, –B1A.
TVO–435	–A1A, –B1A (O–435–25A), –B1B, –C1A, –D1A, –D1B, –E1A, –F1A, –G1A, –G1B.
O–540	–J1A5D, –J1B5D, –J1C5D, –J1D5D, –J2A5D, –J2B5D, –J2C5D, –J2D5D, –J3A5, –J3A5D, –J3C5D, –L3C5D.
IO–540	–AB1A5, –J4A5, –W1A5, –W1A5D, –W3A5D.

(d) Subject

Joint Aircraft System Component (JASC) Code 8530, Reciprocating Engine Cylinder Section.

(e) Unsafe Condition

This AD was prompted by reports from Lycoming of metal particulates found in the engine oil during oil change and two non-detectable engine failures. The FAA is issuing this AD to prevent failure of the piston pin. The unsafe condition, if not addressed, could result in engine failure, loss of thrust control, in-flight shutdown, damage to the airplane, and loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Definitions

(1) For the purpose of this AD, a ''part eligible for installation'' is one of the following:

(i) A piston pin that does not have P/N LW–13445.

(ii) A piston pin having P/N LW–13445 that was not manufactured between January 7, 2021 to December 15, 2025.

(2) For the purpose of this AD, an ''affected piston pin'' is a piston pin having P/N LW–13445 and one of the following:

(i) A date of manufacture between January 7, 2021 to December 15, 2025.

(ii) A date of manufacture that is unknown.

(3) For the purpose of this AD, Group 1 engines are all affected engines, except engines with an installed piston pin having P/N LW–13445 with a manufacture date between March 23, 2023 to December 15, 2025, or an installed piston pin having P/N LW–13445 with a manufacture date that is unknown.

(4) For the purpose of this AD, Group 2 engines are engines with an installed piston pin having P/N LW–13445 with a manufacture date between March 23, 2023 to December 15, 2025, or an installed piston pin having P/N LW–13445 with a manufacture date that is unknown.

(h) Required Actions

(1) For Group 1 and Group 2 engines, except for Group 2 engines with greater than or equal to 150 hours time in service (TIS)

as of the effective date of this AD, within 5 hours TIS after the effective date of this AD, perform an oil change and visual inspection of the engine oil filter, oil pressure screen, and oil suction screen for metal particulates.

Note 1 to paragraph (h)(1): Guidance for engine oil filter, oil pressure screen, and oil suction screen inspection instructions and identification of metallic solids may be found in Lycoming Mandatory Service Bulletin No. (MSB) No. 480F, dated May 25, 2017.

(2) If any metal particulates are found during the oil change and inspection required by paragraph (h)(1) of this AD, before further flight, replace any affected piston pin with a part eligible for installation in accordance with the Required Action of Lycoming MSB 667A, dated March 12, 2026 (Lycoming MSB 667A), as applicable to engine model.

(3) For Group 1 engines with an installed piston pin with a manufacture date between January 07, 2021, to March 22, 2023, where metal particulates were not found during the oil change and inspection required by paragraph (h)(1) of this AD, at the next maintenance event requiring the removal of a cylinder assembly with an affected piston pin, or at the next engine overhaul not to exceed the time between overhaul specified in Lycoming Service Instruction No. 1009BF, dated July 20, 2026, whichever occurs first after the effective date of this AD, replace any affected piston pin with a part eligible for installation in accordance with the Required Action of Lycoming MSB 667A, as applicable to engine model.

(4) For Group 2 engines with greater than or equal to 150 hours TIS as of the effective date of this AD, before further flight, replace any affected piston pin with a part eligible for installation in accordance with the Required Action of Lycoming MSB 667A, as applicable to engine model.

(5) For Group 2 engines with less than 150 hours TIS as of the effective date of this AD, within 25 hours TIS after the effective date of this AD but before or upon reaching 150 total hours TIS since installation of the affected piston pins, whichever comes first after the effective date of this AD, replace any affected piston pin with a part eligible for installation in accordance with the Required Action of Lycoming MSB 667A, as applicable to engine model.

(i) Installation Prohibition

After the effective date of this AD, do not install an affected piston pin as defined in paragraph (g)(2) of this AD on any engine.

(j) No Return of Parts

Although the service material specifies returning certain parts to the manufacturer, this AD does not include those requirements.

(k) Special Flight Permits

(1) Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199199 for the replacement requirements of this AD provided no metal particulates are found during the inspection required by this AD. For Group 2 engines that are not affected by paragraph (h)(1) of this AD, an oil change showing that no metal particulates are present would be required prior to issuing a special flight permit.

(2) Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed for the visual inspection of the engine oil filter, oil pressure screen, and oil suction screen for metal particulates requirement of this AD.

(l) Alternative Methods of Compliance (AMOCs)

The Manager, East Certification Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the East Certification Branch, send it to the attention of the person identified in paragraph (m)(1) of this AD and email to: *AMOC@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(m) Additional Information

(1) For more information about this AD, contact Ramanpreet Singh, Aviation Safety Engineer, FAA, Ramanpreet Singh, Aviation Safety Engineer, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (516) 228–7300; email: *ECB-COS@faa.gov.*

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (n)(4) of this AD.

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following material was approved for IBR November 24, 2026.

(i) Lycoming Service Instruction No. 1009BF, dated July 20, 2026.

(ii) [Reserved]

(4) The following material was approved for IBR on September 14, 2026. (91 FR 55451, August 28, 2026).

(i) Lycoming Mandatory Service Bulletin No. (MSB) 667A, dated March 12, 2026.

(ii) [Reserved]

(5) For Lycoming material identified in this AD, contact Lycoming Engines, 652 Oliver Street, Williamsport, PA 17701; phone: (800) 258–3279; website: *lycoming.com/contact/knowledge-base/publications*.

(6) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(7) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*.

Issued on October 30, 2026.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2026–22785 Filed 11–5–26; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2025–5571; Airspace Docket No. 25–AWP–172]

RIN 2120–AA66

Amendment of Class D and Establishment of Class E Airspace; Chandler and Phoenix, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published by the FAA in the **Federal Register** on October 30, 2026, amending the Class D airspace and establishing Class E airspace at Chandler and Phoenix, AZ. Specifically, this action corrects a statement in the preamble of the rule for greater clarity.

DATES: The effective date of the final rule published in the **Federal Register** on October 30, 2026, remains 0901 UTC, February 18, 2027. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11M, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Airspace Regulation Group, Operational Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** (91 FR 68449; October 30, 2026), amending the Class D airspace and establishing Class E airspace at Chandler and Phoenix, AZ. After publication, the FAA determined

that a statement in the preamble discussion requires a correction for greater clarity and alignment with the scope of the action. The final rule stated, ''There are no new instrument procedures in development, and the airspace change does not require new, complex procedures to be developed or implemented at Mesa Gateway Airport.'' While separate instrument flight procedures are planned through normal airport modernization channels, they are entirely independent of this Class D and Class E action. This correction does not make substantive changes or alter the text of the airspace legal descriptions.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the final rule for Docket No. FAA–2025–5571, as published in the **Federal Register** on October 30, 2026 (91 FR 68449; FR Doc. 2026–22197), is corrected as follows:

On page 68452, column 1, within the History section, remove, ''There are no new instrument procedures in development, and the airspace change does not require new, complex procedures to be developed or implemented at Mesa Gateway Airport.'' And replace it with, ''This airspace change does not require new, complex procedures to be developed or implemented at Mesa Gateway Airport.''

Issued in Fort Worth, Texas, on November 5, 2026.

Courtney E. Johns,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2026–22830 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 413, 414, 450, and 460

[Docket No.: FAA–2026–7035; Amdt. Nos. 413–15, 414–5, 450–4, 460–5]

RIN 2120–AM32

Technical Corrections of Commercial Space Transportation Regulations

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; technical amendment.

SUMMARY: This final rule contains technical corrections in FAA regulations.

DATES: Effective November 9, 2026.

ADDRESSES: For further information on where to obtain copies of rulemaking document and other information related to this final rule, see ''Additional Information'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lisa Cacciatore, Office of Commercial Space Transportation, Federal Aviation Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 880–1489; email *Lisa.E.Cacciatore@faa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Overview of the Final Rule

FAA is amending the authority citations in parts 413, 414, and 450 to include 51 U.S.C. 50924. In addition, FAA has identified six technical corrections to parts 413, 414, 450, and 460. These technical corrections are non-substantive in nature and are intended to correct typographical errors, clarify regulatory text, and ensure consistency. The changes correct mistakes and omissions and clarify the regulations published in the part 450 final rule.[1]

B. Summary of the Costs and Benefits

This final rule makes non-substantive technical corrections to correct typographical errors, clarify regulatory text, and ensure consistency. FAA expects no additional costs for the public or FAA because these changes do not affect existing regulatory requirements.

II. Authority for This Rulemaking and 5 U.S.C. 553 Implementation Exceptions

A. Authority for This Rulemaking

The Commercial Space Launch Act of 1984, as amended and codified at 51 U.S.C. 50901–50924 (the Act), authorizes the Secretary of Transportation (Secretary) to oversee, license, and regulate commercial launch and reentry activities, and the operation of launch and reentry sites within the United States (U.S.) or as carried out by U.S. citizens. Section 50905 directs the Secretary to exercise this responsibility consistent with public health and safety, safety of property, and the national security and foreign policy interests of the United States. In addition, section 50903 requires the Secretary to encourage, facilitate, and promote commercial space launches and reentries by the private sector. As codified in 49 CFR 1.83(b), the Secretary has delegated authority to the FAA Administrator to carry out these functions.

B. Good Cause Exemption per 5 U.S.C. 553(b)(B)

Section 553(b)(B) of the Administrative Procedure Act (APA) (5 U.S.C.) authorizes agencies to dispense with notice and comment procedures for rulemakings when the agency for ''good cause'' finds those procedures to be ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking. FAA has concluded that notice and comment is unnecessary for this rulemaking.

Courts have consistently recognized that notice and comment are unnecessary where a rule makes only technical, clerical, or nonsubstantive changes that do not alter the rights or obligations of regulated entities and are unlikely to generate meaningful public input.[2] For example, in *Utility Solid Waste Activities Group* v. *EPA,* the D.C. Circuit explained that the ''unnecessary'' prong applies where the regulated community has ''little or nothing to say'' regarding the agency's action because the rule does not implicate substantive policy choices.[3] In *Mack Trucks, Inc* v. *EPA,* the D.C. Circuit cautioned that the unnecessary exception must be narrowly construed, but made clear that its application is appropriate where notice and comment would serve no practical purpose.[4]

The technical amendments in this final rule correct incorrect words, remove unnecessary references, and clarify the purpose of the text to conform to the statutory requirements. These amendments do not reflect a change in policy judgment, nor do they affect how regulated parties comply with FAA requirements.

Thus, FAA has determined that this rule is suitable for a final rulemaking because these changes are noncontroversial and a notice and comment period is unnecessary.

[1] Streamlined Launch and Reentry License Requirements, 85 FR 79566 (December 10, 2020) (hereby referred to as ''SLR2'').

[2] *Utility Solid Waste Activities Group* v. *EPA,* 236 F.3d 749, 754 (D.C. Cir. 2001); *Mack Trucks, Inc.* v. *EPA,* 682 F. 3d 87, 93 (D.C. Cir. 2012).

[3] 236 F.3d 749, 754 (D.C. Cir. 2001).

[4] Courts have held that the unnecessary prong of good cause must be ''confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.'' *Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012) (quoting Util. Solid Waste Activities Grp., 236 F.3d at 755).

C. Effective Upon Publication per 5 U.S.C. 553(d)(3)

The APA generally requires that a substantive rule be published at least 30 days before its effective date. However, 5 U.S.C. 553(d)(3) permits an agency to make a rule effective less than 30 days after publication for good cause. As discussed in the previous section, FAA has found good cause for forgoing notice and comment under 5 U.S.C. 553(b)(B). For these same reasons, FAA finds good cause under 5 U.S.C. 553(d)(3) to make this rule effective immediately upon publication in the **Federal Register**.

III. Background

A. History

In 2018, Space Policy Directive-2 (SPD–2) directed FAA to streamline and modernize commercial space launch and reentry licensing. As a result, in 2020, FAA published Streamlined Launch and Reentry License Requirements, 85 FR 79566 (the SLR2 final rule). The SLR2 final rule, codified as part 450, streamlined and increased flexibility in FAA commercial space launch and reentry regulations and removed obsolete requirements. It consolidated and revised multiple regulatory parts and applied a single set of licensing and safety regulations across several types of operations and vehicles. Part 450 provides the requirements to obtain a vehicle operator license, the safety requirements, and the terms and conditions of a vehicle operator license.

On August 13, 2025, the President issued Executive Order (E.O.) 14335, ''Enabling Competition in the Commercial Space Industry,'' which requires the Secretary of Transportation to ''reevaluate, amend, or rescind'' the regulations in part 450 for the purpose of further streamlining the commercial licensing process. As part of FAA's response to this directive, FAA is making non-substantive, technical revisions to its regulations to correct errors and improve clarity. These changes do not modify existing compliance obligations or impose new requirements; rather, they are intended to ensure that FAA regulations remain accurate, clear, and effective.

IV. Discussion of the Final Rule

A. Correction to Part 413, License Application Procedures

FAA is amending 14 CFR 413.7(d)(1) through (3) by replacing the term ''safety approval'' with ''safety element approval'' in each instance that it occurs. In the SLR2 final rule, FAA replaced the term ''safety approval'' with ''safety element approval'' in a number of instances to distinguish between two types of approvals falling under the term ''safety approval.'' Prior to the SLR2 final rule, ''safety approval'' could refer to either (1) an FAA determination that an applicant is capable of launching a launch or reentry vehicle and its payload without jeopardizing public health and safety and safety of property or (2) the approval of a ''safety element,'' as that term is defined in § 414.3. The SLR2 final rule differentiated these usages by using the term ''safety approval'' to capture the former meaning, and ''safety element approval'' to capture the latter meaning. However, the SLR2 final rule inadvertently omitted this terminology change in § 413.7(d), which discusses how an applicant may incorporate a safety element approval into a license application.

This rule corrects that omission by replacing the term ''safety approval'' in § 413.7(d) with ''safety element approval'' in each instance that it occurs. The correction does not represent a substantive change in the rule because the other language in § 413.7(d) clearly indicates that the paragraph only relates to safety element approvals.

B. Correction to § 414.43(c), Submissions; Oral Presentations in Safety Element Approval Applications

The procedures by which applicants may obtain a safety element approval and renew and transfer an existing safety element approval are set forth in 14 CFR part 414. Subpart D of part 414 describes the procedures for appealing a decision by FAA regarding safety element approval. Section 414.41(a) states that FAA will give a safety element approval applicant or holder notice of its decision to deny, modify, suspend, or revoke a safety element approval. Section 414.41(b) states that the applicant or holder is entitled to a determination on the record after opportunity for a hearing. Section 414.43 describes the process by which the determination on the record will be handled, including paragraph (c) of that section, which states that ''[p]etitions [for a determination by an administrative law judge] must be filed as soon as practicable, but in no event more than 30 days after issuance of decision or finding under § 414.37.''

FAA is replacing the reference to § 414.37 in § 414.43(c) with a reference to § 414.41. In the SLR2 final rule, FAA renumbered part 414, including renumbering previous § 414.37 as current § 414.41. However, the cross-reference to § 414.37 in § 414.43(c) was inadvertently not updated to match the renumbering. The change is nonsubstantive because FAA has consistently maintained that retention of the cross-reference to § 414.37 was unintentional and the result of a drafting oversight in the SLR2 rulemaking.

C. Correction to § 450.101, Safety Criteria

Section 450.101 provides the safety criteria for launch and reentry vehicles, with launch vehicles addressed in § 450.101(a) and reentry vehicles in § 450.101(b). When the SLR2 final rule was published, it inadvertently included a reference to ''launch vehicle'' in § 450.101(b)(2). Given that § 450.101(b) addresses risk criteria for reentry vehicles, it is incorrect for this section to reference the proposed flight of a launch vehicle. This rule changes the phrase ''flight of a launch vehicle'' to ''deorbit of a reentry vehicle'' in § 450.101(b)(2). FAA intended for ''reentry vehicle'' to be used in § 450.101(b)(2) but inadvertently used the term ''launch vehicle'' instead. Since the adoption of § 450.101(b)(2), FAA has applied the regulation to reentry vehicles as originally intended. This correction will formally remedy the error and reduce the risk of confusion.

D. Correction to § 450.173(f), Mishap Plan—Reporting, Response, and Investigation Requirements

Section 450.173(f) outlines the requirements for an applicant's mishap plan, including reporting, response, and investigation requirements. When the SLR2 final rule was published, FAA used the word ''preventative'' in the title of § 450.173(f), but the word ''preventive'' in the text of § 450.173(f). While both words can be used interchangeably, FAA wants to ensure consistency and clarity in its regulations. This change provides consistent usage by changing the word ''preventive'' in the text of § 450.173(f) to ''preventative,'' so that it matches the title of the subsection.

E. Correction to § 450.207, Human Space Flight Requirements

Section 450.207 requires an applicant be in compliance with part 460 for licensees conducting launches or reentries with humans on board. The regulation is currently written with ''spaceflight'' as one word both in the title and in the text of § 450.207. However, ''space flight'' is two words throughout the rest of part 450. In order to be consistent throughout part 450, this rule changes ''spaceflight'' to

''space flight'' in both the title and text of § 450.207.

F. Corrections to Part 460, Human Space Flight Requirements

Section 460.45 requires that an operator inform each space flight participant in writing about the risks of the launch and reentry, including the safety record of the launch or reentry vehicle type. In the SLR2 final rule, FAA adopted a new definition of ''mishap'' for the purposes of part 450. As part of this, FAA incorporated the prior definitions of accident and incident into the new ''mishap'' definition. In addition, FAA updated the broader part 400 regulations to remove the terms ''accident'' and ''incident'' from regulations that applied to part 450 operations, because those terms were no longer defined. However, FAA inadvertently failed to update § 460.45(e) in the SLR2 final rule. This rule corrects § 460.45(e) by replacing the phrase ''accidents and human space flight incidents'' with the phrase ''events that meet any of paragraph (1), (4), (5), or (8) of the definition of 'mishap' in § 401.7 of this chapter.'' This amendment aligns the language of § 460.45(e) with the defined terms applicable to part 450.

G. Amendments to Authority Citations

Lastly, FAA is revising the authority citations for parts 413, 414, 450, and 460 from ''51 U.S.C. 50901–50923'' to 51 U.S.C. 509.'' The Commercial Space Launch Act of 1984 (''CSLA''), Public Law 98–575, authorizes the Secretary of Transportation to oversee, license, and regulate commercial launch and reentry activities, and the operation of launch and reentry sites. In 1994, the CSLA was codified at 49 U.S.C. ch. 701 (*see* Pub. L. 103–272), which was subsequently transferred to 51 U.S.C. 509 in 2010 (*see* Pub. L. 111–314). At that time, Chapter 509 contained sections 50901 through 50923. In 2025, a new section 50924 was added to Chapter 509 by Public Law 119–21, commonly known as the One Big Beautiful Bill Act.

FAA is amending the authority citations to account for this new section. However, rather than updating the authority citations to state the number of this new section (*i.e.,* 51 U.S.C. 50901–50924), FAA has determined that the authority citations should instead point to 51 U.S.C. 509. This change will prevent FAA from needing to update the authority citations each time a new section is added to 51 U.S.C. 509.

V. Regulatory Notices and Analyses

A. Regulatory Impact Analysis

E.O. 12866 (''Regulatory Planning and Review'') and E.O. 13563 (''Improving Regulation and Regulatory Review'') require agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' The Office of Management and Budget has determined that this rule is not a significant regulatory action as defined in section (3)(f) of E.O. 12866. This final rule is considered an E.O. 14192 deregulatory action.

Table 1 lists the changes to each provision along with their respective impacts. Because these are technical corrections addressing typographical errors, clarifying regulatory text, and ensuring consistency, there are no additional costs to industry and FAA.

TABLE 1—REGULATORY CHANGES AND IMPACT

Provision	Change	Impact
14 CFR 413.7(d)—Correct Safety Element Approval name.	Amends § 413.7(d)(1) through (d)(3), by adding the word ''element'' to the phrase ''safety approval''.	No impact.
14 CFR 414.43—Correction to reference	Amends the reference to § 414.37 in § 414.43(c) by changing it to § 414.41.	No impact.
14 CFR 450.101—Correct error in Reentry Risk Criteria.	Amends § 450.101(b)(2) by changing the phrase ''flight of a launch vehicle'' to ''deorbit of a reentry vehicle''.	Small administrative cost savings because it provides clarity to regulated entities. FAA will not have to provide guidance to clarify any confusion from regulated entities.
14 CFR 450.173(f)—Correct terminology in Mishap Plan.	Corrects § 450.173(f) by changing the word ''preventive'' in the sentence to ''preventative''.	No impact.
14 CFR 450.207—Correct terminology for consistency in Human Space Flight Regulations.	Corrects § 450.207 by changing the word ''spaceflight'' to the phrase ''space flight'' to be consistent with the rest of the final rule.	No impact.
14 CFR 460—Correct Mishap terminology in Human Space Flight Regulations.	Corrects § 460.45(e) by replacing the phrase ''accidents and human space flight incidents'' with the phrase ''events that meet any of paragraph (1), (4), (5), or (8) of the definition of 'mishap' in § 401.7 of this chapter''.	No impact.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), in 5 U.S.C. 603, requires an agency to prepare an initial regulatory flexibility analysis describing impacts on small entities whenever 5 U.S.C. 553 or any other law requires an agency to publish a general notice of proposed rulemaking for any proposed rule. Similarly, 5 U.S.C. 604 requires an agency to prepare a final regulatory flexibility analysis when an agency issues a final rule under 5 U.S.C. 553 after that section or any other law requires publication of a general notice of proposed rulemaking. FAA concludes good cause exists to forgo notice and comment and to not delay the effective date for this rule. As 5 U.S.C. 553 does not require notice and comment in this situation, 5 U.S.C. 603 and 604 similarly do not require regulatory flexibility analyses.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of

international standards and, where appropriate, that they be the basis for U.S. standards.

FAA has assessed the potential effect of this rule and determined it ensures the safety of the American public and does not exclude imports that meet this objective. As a result, FAA does not consider this rule as creating an unnecessary obstacle to foreign commerce.

D. Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or Tribal government or the private sector to incur direct costs without the Federal Government having first provided the funds to pay those costs. FAA determined the rule will not result in the expenditure of $193,000,000 or more ($100,000,000 adjusted for inflation using the most current Implicit Price Deflator for the Gross Domestic Product) by State, local, or Tribal governments, in the aggregate, or the private sector, in any one year.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires FAA consider the impact of paperwork and other information collection burdens imposed on the public. FAA has determined there is no new requirement for information collection associated with this final rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. FAA has determined there are no ICAO Standards and Recommended Practices that correspond to these regulations.

G. Environmental Analysis

The Department has analyzed the environmental impacts of this final rule pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*). FAA has determined this rule is categorically excluded pursuant to FAA Order 1050.1G. Categorical exclusions are categories of actions FAA has determined normally do not significantly affect the quality of the human environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS).1 In analyzing the applicability of a categorical exclusion, FAA must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS.2 This rulemaking, which makes minor nonsubstantive technical edits to FAA's commercial space regulations, is categorically excluded pursuant to FAA Order 1050.1G, Appendix B, Paragraph B–2.6(f), which categorically excludes issuance of regulatory documents. FAA does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

VI. E.O. Determinations

A. E.O. 13132, Federalism

FAA has analyzed this final rule under the principles and criteria of E.O. 13132, Federalism. FAA has determined this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, will not have federalism implications.

B. E.O. 13175, Consultation and Coordination With Indian Tribal Governments

Consistent with E.O. 13175, Consultation and Coordination with Indian Tribal Governments,[5] and FAA Order 1210.20, American Indian and Alaska Native Tribal Consultation Policy and Procedures,[6] FAA ensures that Federally Recognized Tribes (Tribes) are given the opportunity to provide meaningful and timely input regarding proposed Federal actions that have the potential to have substantial direct effects on one or more Tribes, on the relationship between the Federal Government and Tribes, or on the distribution of power and responsibilities between the Federal Government and Tribes; or to affect uniquely or significantly their respective Tribes. At this point, FAA has not identified any unique or significant effects, environmental or otherwise, on Tribes resulting from this final rule.

C. E.O. 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

FAA analyzed this final rule under E.O. 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). FAA has determined it is not a ''significant energy action'' under the E.O. and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

D. E.O. 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. FAA has analyzed this action under the policies and agency responsibilities of E.O. 13609 and has determined this action will have no effect on international regulatory cooperation.

VII. Additional Information

A. Electronic Access and Filing

A copy of this final rule and all background material may be viewed online at *www.regulations.gov* using the docket number listed above. A copy of this final rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.federalregister.gov* and the Government Publishing Office's website at *www.govinfo.gov.* A copy may also be found on FAA's Regulations and Policies website at *www.faa.gov/regulations_policies.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Requesters must identify the docket or amendment number of this rulemaking.

All documents FAA considered in developing this final rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857, Mar. 29, 1996) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official or the person listed under

[5] 65 FR 67249 (Nov. 6, 2000).

[6] FAA Order No. 1210.20 (Jan. 28, 2004), available at *www.faa.gov/documentLibrary/media/1210.pdf.*

the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects

14 CFR Part 413

Confidential business information, Space transportation and exploration.

14 CFR Part 414

Airspace, Aviation safety, Space transportation and exploration.

14 CFR Part 450

Aircraft, Aviation safety, Environmental protection, Investigations, Reporting and recordkeeping requirements, Space transportation and exploration.

14 CFR Part 460

Aircraft, Reporting and recordkeeping requirements, Space transportation and exploration.

The Amendments

For the reasons discussed in the preamble, the Federal Aviation Administration amends chapter III of title 14, Code of Federal Regulations as follows:

PART 413—LICENSE APPLICATION PROCEDURES

■ 1. The authority citation for part 413 is revised to read as follows:

Authority: 51 U.S.C. chapter 509.

■ 2. Amend § 413.7 by revising paragraph (d) to read as follows:

§ 413.7 Application submission.

* * * * *

(d) *Safety element approval.* If the applicant proposes to include a safety element for which the FAA issued a safety element approval under part 414 of this chapter in the proposed license activity, the applicant must—

(1) Identify the safety element approval in the application and explain the proposed use of the approved safety element.

(2) Show that the proposed use of the approved safety element is consistent with the designated scope specified in the safety element approval.

(3) Certify that the safety element will be used according to any terms and conditions of the issued safety element approval.

* * * * *

PART 414—SAFETY ELEMENT APPROVALS

■ 3. The authority citation for part 414 is revised to read as follows:

Authority: 51 U.S.C. chapter 509.

■ 4. Amend § 414.43 by revising paragraph (c) to read as follows:

§ 414.43 Submissions; oral presentations in safety element approval actions.

* * * * *

(c) Petitions must be filed as soon as practicable, but in no event more than 30 days after issuance of decision or finding under § 414.41.

PART 450—LAUNCH AND REENTRY LICENSE REQUIREMENTS

■ 5. The authority citation for part 450 is revised to read as follows:

Authority: 51 U.S.C. chapter 509.

■ 6. Amend § 450.101 by revising the second sentence of paragraph (b)(2) introductory text to read as follows:

§ 450.101 Safety criteria.

* * * * *

(b) * * *

(2) * * * Public risk due to any other hazard associated with the proposed deorbit of a reentry vehicle will be determined on a case-by-case basis.

* * * * *

■ 7. Amend § 450.173 by revising paragraph (f) to read as follows:

§ 450.173 Mishap plan—reporting, response, and investigation requirements.

* * * * *

(f) *Preventative measures.* An operator must identify and implement preventative measures for avoiding recurrence of the mishap prior to the next flight, unless otherwise approved by the Administrator.

* * * * *

■ 8. Revise § 450.207 to read as follows:

§ 450.207 Human space flight requirements.

A licensee conducting a launch or reentry with a human being on board the vehicle must comply with human space flight requirements of part 460 of this chapter as specified in a license or license order.

PART 460—HUMAN SPACE FLIGHT REQUIREMENTS

■ 9. The authority citation for part 460 is revised to read as follows:

Authority: 51 U.S.C. chapter 509.

■ 10. Amend § 460.45 by revising paragraph (e) to read as follows:

§ 460.45 Operator informing space flight participant of risk.

* * * * *

(e) An operator must inform a space flight participant that he or she may request additional information regarding any events that meet any of paragraph (1), (4), (5), or (8) of the definition of ''mishap'' in § 401.7 of this chapter.

* * * * *

Issued under authority provided by 49 U.S.C. 106(f), and 51 U.S.C. 50903–50924 in Washington, DC.

Bryan K. Bedford,

Administrator.

[FR Doc. 2026–22781 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 732, 734, 736, 744, and 748

[Docket No. 261027–0002]

RIN 0694–AK34

Extension of the Suspension of Expansion of End-User Controls for Affiliates of Certain Listed Entities

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule; stay.

SUMMARY: The Bureau of Industry and Security (BIS) is extending the suspension of the interim final rule (IFR), ''Expansion of End-User Controls to Cover Affiliates of Certain Listed Entities.'' The suspension was set to end November 9, 2026. This final rule extends the suspension through January 10, 2027.

DATES: Effective November 9, 2026, the amendments to 15 CFR parts 732, 734, 736, 744, and 748 in the interim final rule published at 90 FR 47201, on September 30, 2025, and stayed on November 10, 2025, at 90 FR 50857, are further stayed until January 10, 2027.

FOR FURTHER INFORMATION CONTACT: Noah Jaffe at *noah.jaffe@bis.doc.gov,* Bureau of Industry and Security, Department of Commerce.

SUPPLEMENTARY INFORMATION:

Background

On September 20, 2025, BIS published the IFR, ''Expansion of End-User Controls to Cover Affiliates of Certain Listed Entities,'' (90 FR 47201) (Affiliates Rule). On November 12, 2025, BIS published a final rule titled, ''One Year Suspension of Expansion of End-User Controls for Affiliates of Certain

Listed Entities,'' (90 FR 50857) (Stay of Affiliates Rule), imposing a one-year suspension of the Affiliates Rule, which was set to end November 9, 2026.

BIS is extending the suspension until January 10, 2027.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801–4852). ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. In particular, Section 1753 of ECRA (50 U.S.C. 4812) authorizes the regulation of exports, reexports, and transfers (in-country) of items subject to U.S. jurisdiction. Further, Section 1754(a)(1)–(16) of ECRA (50 U.S.C. 4813(a)(1)–(16)) authorizes, inter alia, establishing and maintaining a list of foreign persons and end uses that are determined to be a threat to the national security and foreign policy of the United States pursuant to the policy set forth in Section 1752(2)(A), and restricting exports, reexports, and in-country transfers of any controlled items to any foreign person or end use so listed; apprising the public of changes in policy, regulations, and procedures; and any other action necessary to carry out ECRA that is not otherwise prohibited by law. Pursuant to Section 1762(a) of ECRA (50 U.S.C. 4821(a)), these changes can be imposed in a final rule without prior notice and comment.

Rulemaking Requirements

1. This rule has been determined to be not significant for purposes of Executive Order (E.O.) 12866. This final rule is not a regulatory action pursuant to E.O. 14192 because it is not a significant rule under E.O. 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves the following OMB-approved collections of information subject to the PRA:

- 0694–0088, ''Simple Network Application Process and Multipurpose Application Form,'' which carries a burden hour estimate of 29.7 minutes for a manual or electronic submission;
- 0694–0096 ''Five Year Records Retention Period,'' which carries a burden hour estimate of less than 1 minute;
- 0607–0152 ''Automated Export System (AES) Program,'' which carries a burden hour estimate of 3 minutes per electronic submission; and
- 0694–0134 ''Procedure for parties on the Entity List or the Unverified List to Request Removal or Modification of their Listing,'' which carries a burden hour estimate of 15 hours per electronic submission.

BIS estimates no changes to these information collections based on the continued suspension of the license requirements and related provisions. Additional information regarding these collections of information—including all background materials—can be found at: *https://www.reginfo.gov/public/do/PRAMain* by using the search function to enter either the title of the collection or the OMB Control Number.

3. This rule does not contain policies with federalism implications as that term is defined in E.O. 13132.

4. Pursuant to Section 1762 of the Export Control Reform Act of 2018, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date. This final rule did not consider public comments received on the Affiliates Rule. Public comments received on the Affiliates Rule will be considered for future, subsequent rulemakings.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) are not applicable. Accordingly, no final regulatory flexibility analysis is required, and none has been prepared.

Jeffrey I. Kessler,

Under Secretary for Industry and Security.

[FR Doc. 2026–22793 Filed 11–5–26; 4:15 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 18

RIN 1290–AA36

Rules of Practice and Procedure for Administrative Hearings Before the Office of Administrative Law Judges

AGENCY: Office of the Secretary, Department of Labor.

ACTION: Final rule.

SUMMARY: This action finalizes the Department of Labor's (DOL or Department) proposal to require electronic filing (e-filing) in proceedings before the Office of Administrative Law Judges (OALJ), published on January 11, 2021. The Department has reviewed the comments received in response to the proposal and is now implementing the rule as described in the proposed rule of January 11, 2021, with appropriate exceptions for good cause shown and self-represented parties.

DATES: This final rule is effective on December 9, 2026.

FOR FURTHER INFORMATION CONTACT: Alyssa Kaercher, General Counsel of the Office of Administrative Law Judges, at *Kaercher.Alyssa.J@dol.gov* or 202–693–7347.

SUPPLEMENTARY INFORMATION: This preamble is divided into three sections: Section I provides an overview of this rulemaking and describes its procedural background; Section II provides a summary of the public comments received; and Section III covers the administrative requirements for this rulemaking.

I. Background

On January 11, 2021, the Department published a direct final rule (DFR) (86 FR 1800) and companion notice of proposed rulemaking (NPRM) (86 FR 1862) to require e-filing and make acceptance of electronic service (e-service) automatic by attorneys and lay representatives representing parties in proceedings before the OALJ, and to provide an option for self-represented parties to utilize these electronic capabilities. The rule also would have required advance notice to the parties of the manner of a hearing or prehearing conference, whether in person in the same physical location, by telephone, by videoconference, or by other means. The Department invited written comments from the public for 30 days on the proposed rule. The Department received significant adverse public comments from stakeholders on the direct final

rule. Therefore, the OALJ withdrew the direct final rule on February 25, 2021. The Department has reviewed the comments received in response to the proposal and is now implementing the rule as described in the proposed rule of January 11, 2021, with appropriate exceptions for good cause shown and self-represented parties.

A. Overview

This action finalizes the corresponding NPRM published in the January 11, 2021 issue of the **Federal Register** (86 FR 1862). The e-filing amendments are revising 29 CFR part 18 in order to require e-filing and allow for automatic e-service system for OALJ, as well as require advance notice to the parties of the manner of a hearing or prehearing conference, whether in person, by telephone, by videoconference, or by other means.

A general overview of the legal framework, statements explaining the necessity of this e-filing rule, as well as further background on the rulemaking is available in the Department's NPRM, as published in the **Federal Register** on January 11, 2021, and will not be restated in full herein.

In brief, this final rule requires persons represented by attorney and non-attorney representatives to use the Department's system to file all papers electronically and to receive electronic service of documents unless another form of filing or service is allowed by the presiding judge for good cause or is required by standing order; gives self-represented persons the option to use conventional means of filing, or to use the Department's system to file all papers electronically and to receive electronic service of documents; and provides that a filing made through a person's eFile/eServe system account and authorized by that person, together with that person's name on a signature block, constitutes that person's signature. It also requires advance notice to the parties of the manner of a hearing or prehearing conference, whether in person in the same physical location, by telephone, by videoconference, or by other means, to account for the increase in the use of telephonic and video hearings as a result of the COVID–19 national emergency. See 5 U.S.C. 554(b)(1) (requiring timely notice of the time, place, and nature of the hearing).

The Department notes that, as with all OALJ rules of practice and procedure, the e-filing provisions will not apply if they are ''inconsistent with a governing statute, regulation, or executive order. . . . If a specific Department of Labor regulation governs a proceeding, the provisions of that regulation apply[.]'' 29 CFR 18.10(a). For instance, OALJ will continue to serve decisions via certified mail where required by the governing statute or regulation, including on persons participating in the Department's eFile/eServe system.

B. Procedural History

On January 11, 2021, the Department initially published the e-filing amendments as a DFR (86 FR 1800) without a prior proposal because the Department viewed such amendments as noncontroversial at that time and anticipated no adverse comment. The Department also published a companion NPRM in the ''Proposed Rules'' section of the January 11, 2021 (86 FR 1862) issue to expedite notice-and-comment rulemaking in case significant adverse comments were received from stakeholders. A significant adverse comment for the purposes of these notices is one that explains (1) why the rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. The proposed and direct final rules were substantively identical, and their respective comment periods ran concurrently. The Department is treating comments received on the companion direct final rule as comments regarding the proposed rule, and vice versa.

On February 25, 2021, the Department withdrew the January 11, 2021 DFR due to the receipt of significant adverse comment (86 FR 11426). Accordingly, on March 17, 2021, the Department re-opened the comment period on the January 11, 2021 NPRM for 15 days in order to give the public an additional opportunity to voice concerns regarding the proposed e-filing rule (86 FR 14559). The Department also scheduled listening sessions in order to better understand and address concerns from practitioners and the regulated community.

II. Public Comments Received

The Department invited written comment in its January 11, 2021 DFR and concurrently published NPRM. The proposed and direct final rules were substantively identical, and their comment periods ran contemporaneously from January 11, 2021 to February 10, 2021. On March 17, 2021, each comment period was reopened for fifteen days. Comments were submitted electronically at *http://www.regulations.gov* using docket number DOL–2020–0015. The Department requested comments on all issues related to the rule, including economic or other regulatory impacts of the rule on the regulated community.

In issuing this final action, the Department considered comments received on the DFR and NPRM during both the initial and subsequent comment periods. The Department also considered comments received on the conforming Benefits Review Board (Board) rulemaking because commenters noted that they also practiced before the OALJ. Comments to the conforming Board rulemaking were submitted electronically at *http://www.regulations.gov* using docket number DOL–2020–0013.

The Department received thirty-six unique comments on its OALJ and Board e-filing rules. Of the thirty-six comments received, twelve were determined to be out of scope either because they were comments exclusively on the technical aspects of the Electronic Filing System and did not address the substance of the e-filing rule, addressed issues wholly unrelated to this rulemaking, or were general statements. Of the remaining twenty-four comments, one commenter supported the e-filing rule and twenty-three raised concerns that are discussed below.

A. Comment Supporting the E-Filing Rule

The Department received one comment in support of the rule's e-filing requirement and automation of e-service, and the rule's extension of the provisions to self-represented parties. The commenter attested to the ''overall greater convenience for both parties to use e-filing and e-service, as well as the costs saved by going paperless.'' They observed that ''it is in the public interest for the DOL to create a streamlined procedure'' because ''[a] disarray of inconsistent filing methods is not only burdensome to those processing at DOL, but also to those who would like to track their submitted applications.'' Additionally, the commenter cited to both *Forbes* and the New York City Bar Environmental Law Committee in addressing the range of significant environmental benefits that e-filing provides.

This comment reflects the Department's belief that e-filing will benefit all participants in OALJ matters. The greater utilization of e-filing and e-service will reduce case processing times by eliminating the timeframes required to allow for the delivery of traditional mailings. These time savings will allow the OALJ to more efficiently process appeals without any sacrifice to the quality of their work. It will also

greatly reduce mailing and copying costs for both OALJ and the parties. The Department agrees that the cost, convenience, and efficiency benefits merit this final rule.

B. Comments Raising Concerns About the E-Filing Rule

Nearly all commenters raising concerns about the rule identified themselves as practitioners before OALJ or the Board. These commenters predominately objected to the rule's e-filing mandate at § 18.30, but many expressed support for the Department's efforts to move to e-filing and e-service. Three opposing commenters addressed concerns with other rule provisions.

1. Comments Regarding the Portion of the Rule That Makes E-Filing Mandatory at § 18.30

Twenty-two commenters recommended that the rule's e-filing mandate be delayed or abandoned. Several commenters expressed general support for the efficiency and modernization that e-filing provides. However, commenters expressed frustration with the OALJ and Board e-filing systems, which they found to be time-consuming, resource intensive, and difficult to navigate. Accordingly, commenters asked that the e-filing mandate be abandoned or delayed to allow for the eFile/eServe system's redesign.

Three of the commenters encouraged the continued use of paper filings to accommodate unreliable technology. One practitioner identified the particular technological barriers faced by black lung practitioners, who ''likely have some of the worst internet service in the United States'' and ''[o]ften experience the loss of internet access.'' Another noted, ''[i]f internet service is disrupted, we currently have backup: 'snail mail', wherein dropping a document in the mail constitutes proper service.'' Practitioners also expressed concern that pro se (self-represented) applicants may be disadvantaged if they cannot use the e-filing system successfully.

The Department has acknowledged the commenters' concerns with the e-filing system and has taken initiatives to improve the user experience of the system. All twenty-two comments requesting that the rule be delayed due to concerns about the eFile/eServe system were made during the initial comment period that closed on February 10, 2021. After receiving these comments, the Department held listening sessions for users to provide feedback on the e-filing systems. The Department relied on the information obtained at these listening sessions to make improvements to the eFile/eServe system. The Department is confident that the issues identified have been addressed sufficiently to merit effectuating the e-filing mandate without additional delay.

Additionally, the final rule sufficiently responds to the commenters' technology concerns. First, § 18.30(b)(3) allows attorneys and lay representatives to request an exemption from the e-filing mandate for good cause. Individuals who anticipate technological barriers to e-filing may use this provision to request an exception to the mandate. Second, § 18.30(b)(3)(i)(B) exempts self-represented petitioners from the e-filing mandate, allowing those who cannot navigate the e-filing system to continue submitting paper filings. The Department notes that these concerns were largely Board specific, and that the corresponding Board e-filing rule contains an additional provision addressing technological failures. Overall, the OALJ framework is largely consistent with Federal district court and U.S. Courts of Appeals practice, which generally mandate e-filings for attorneys unless an exception is granted, and provide self-represented parties the option of filing pleadings in paper form.

2. Comments Regarding Portions of the Rule Addressing Filing Deadlines, Public Access, and Service

One commenter asked that the rule's requirement at § 18.32 be changed to allow e-filings to be considered timely if they are filed by 11:59 p.m. based on the time in which the filer is located. Section 18.32 requires that filing deadlines be computed ''using the time zone of the presiding judge's office—or, for cases not yet assigned to an OALJ national or district office—at 11:59:59 p.m. in the time zone of the office of the Chief Judge of OALJ [Eastern Time].'' The commenter supported the rule's definition of the end of the filing day at 11:59 p.m. However, the commenter observed that ''[w]hether the filing is made at 11:59 p.m. East Coast, or 11:59 p.m. West Coast, the Agency personnel who receive the filing will find it the next morning when they report to the office.'' Accordingly, there is ''no harm'' in allowing all filers to file at the end of their local day.

The Department has considered this request and finds that maintaining the rulemaking's filing deadline computation better effectuates its goal of efficiently processing case appeals. Computing filing deadlines by the time zone of the presiding judge's office allows OALJ to expeditiously determine whether a filing is timely. In contrast, a filing deadline based on the filer's location creates an administrative burden because it requires an individualized assessment of the filer's location, which may not be readily apparent in firms with multiple office locations. Using the presiding judge's office, or Eastern Time for unassigned cases, mirrors the approach of Federal courts. *See, e.g.,* Fed. R. App. P. 26(a)(4); Fed. R. Civ. P. 6(a)(4). Further, the preamble to the DFR explained that the Department initially considered standardizing the time for electronic filing at midnight Eastern Time on the last day of the filing period, because the Department's eFile/eServe system is administered in Washington, DC. *Rules of Practice and Procedure for Administrative Hearings Before the Office of Administrative Law Judges,* 86 FR 1800, 1803 (Jan. 11, 2021). However, the Department opted to set the time based on local time ''at the presiding judge's location in order not to reduce hours available for e-filing for persons outside the Eastern Time zone,'' satisfying this commenter's concern. *Id.*

One commenter asserted that requiring separate e-service was inefficient and requested that the Electronic Case Filing System be changed so that service was automatically made on all parties. Section 18.30 allows for e-service to be completed sending a filing to a user registered with the Department's eFile/eServe system. The eFile/eServe system is designed to function similarly to the Case Management/Electronic Case Files (CM/ECF) system used by the Federal district courts and Courts of Appeals. This allows for automatic e-service with minimal exceptions for individuals exempted from e-filing and documents containing sensitive information that must be served through an alternative, secure method. Accordingly, the Department has taken measures to establish automatic service through the eFile/eServe system.

One commenter expressed concern that e-filing would impede public access to OALJ and Board case files because the rule does not allow for general access by non-parties. The Department appreciates this comment. However, the Department believes that public policy concerns merit the level of public access provided, which balances the public's right to know about proceedings and the parties' privacy interests. Here, broad, public access is inappropriate because of the significant personal information contained within OALJ and Board case files. OALJ adjudicates immigrant and non-immigrant employment-related cases, which often contain extensive

information about job applicants, wage documents, personally identifiable information, and similar information of a private, business or financial nature. Black lung and longshore claims also often contain extensive information of a private nature, where general public interest is limited.

Restricting general access by non-parties is consistent with the approach of the federal courts in similar cases. Fed. R. Civ. P. 5.2(c) limits remote public access to electronic files in Social Security and immigration cases due to the significant amount of personal information these files contain. Fed. R. Civ. P. 5.2(c) does not completely bar public access because it permits non-parties to obtain the full case file at the courthouse. Likewise, this rulemaking limits non-parties' remote access to electronic files, while allowing access through an alternative means. The Freedom of Information Act (FOIA) governs public access to agency rules, opinions, orders, records, and proceedings. *See* 5 U.S.C. 552; 29 CFR 70.1 through 70.54. Under FOIA, non-parties may submit a request to obtain OALJ and Board case files subject to the applicable FOIA exceptions. Accordingly, this final rule's restrictions on non-parties' access to electronic records in agency proceedings are consistent with FOIA's public access provisions, the federal court process, and the policy considerations inherent in Fed. R. Civ. P. 5.2(c).

C. Out of Scope Comments

Twelve comments were beyond the scope of this action. Five comments related only to specific concerns about using the Electronic Filing System, rather than the rule's specific e-filing mandate or other procedural amendments. To the extent that these comments refer to the e-filing mandate, these comments do not alter the Department's conclusion for the reasons noted above. One comment appears to pose questions to employers about their ''coronavirus response plan,'' and is therefore out of scope. Finally, six comments made general and vague statements that did not address specific provisions of the OALJ or Board rules, or about e-filing or e-service, and were therefore also out of scope.

D. Removal of Delayed Applicability Date

This final rule will take effect December 9, 2026. Although this is a rule of agency procedure, the Department is using the minimum period provided under section 553(d) of the APA for substantive rules that do not meet a statutory exception. *See* 5 U.S.C. 553(d)(3). The Department is removing the 45-day delayed applicability date included in the initial DFR and NPRM. *See Rules of Practice and Procedure for Administrative Hearings Before the Office of Administrative Law Judges,* 86 FR 1803, 1805; *Rules of Practice and Procedure for Administrative Hearings Before the Office of Administrative Law Judges,* 86 FR 1862, 1865, 1867 (proposed Jan. 11, 2021). The 30-day period between publication and the effective date of this final rule is reasonable and practical because the eFile/eServe system is currently operational. Accordingly, the Department no longer needs additional time to update communications about e-filing or to allow parties time to adjust to the e-filing system. The Department determines that both it and the public are prepared to adhere to the e-filing mandate within 30 days of this rule's publication, obviating the need for a delayed applicability date.

III. Administrative Requirements of the Rulemaking

A. Executive Orders 12866, Regulatory Planning and Review; and 13563, Improving Regulation and Regulatory Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This final rule has been drafted and reviewed in accordance with Executive Order 12866. The Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) determined that this final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 because the rule will not have an annual effect on the economy of $100 million or more; will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; and will not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof. Furthermore, the rule does not raise a novel legal or policy issue arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Accordingly, OMB has waived review.

B. Regulatory Flexibility Act of 1980

Because no notice of proposed rulemaking is required for this rule under section 553(b) of the Administrative Procedure Act, the regulatory flexibility requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, do not apply to this rule. *See* 5 U.S.C. 601(2), 604(a).

C. Paperwork Reduction Act

The Department has determined that this final rule is not subject to the requirements of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* as this rulemaking involves administrative actions to which the federal government is a party or that occur after an administrative case file has been opened regarding a particular individual. *See* 5 CFR 1320.4(a)(2), (c).

D. Unfunded Mandates Reform Act of 1995 and Executive Order 13132, Federalism

The Department has reviewed this rule in accordance with the requirements of Executive Order 13132 and the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.,* and has found no potential or substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. As there is no federal mandate contained herein that could result in increased expenditures by state, local, and tribal governments, or by the private sector, the Department has not prepared a budgetary impact statement.

E. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

The Department has reviewed this rule in accordance with Executive Order 13175 and has determined that it does not have ''tribal implications.'' The final rule does not ''have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

List of Subjects in 29 CFR Part 18

Administrative practice and procedure, Labor.

For the reasons set out in the Preamble, the Department of Labor amends 29 CFR part 18 as set forth below.

PART 18—RULES OF PRACTICE AND PROCEDURE FOR ADMINISTRATIVE HEARINGS BEFORE THE OFFICE OF ADMINISTRATIVE LAW JUDGES

■ 1. The authority citation for part 18 continues to read as follows:

Authority: 5 U.S.C. 301; 5 U.S.C. 551–553; 5 U.S.C. 571 note; E.O. 12778; 57 FR 7292.

■ 2. Amend § 18.11 by adding definitions in alphabetical order for ''eFile/eServe system'', ''Registered user'', and ''Standing order'' to read as follows:

§ 18.11 Definitions.

* * * * *

eFile/eServe system means the Department of Labor's electronic filing and electronic service system for adjudications.

* * * * *

Registered user means any person registered to file papers using the Department's eFile/eServe system.

* * * * *

Standing order means an order issued by the Chief Judge or District Chief Judge addressing court administration that applies to all cases pending before the Office of Administrative Law Judges (OALJ) or an OALJ district office, and which is in force until changed or withdrawn by a subsequent order.

■ 3. Amend § 18.30 by:

■ a. Revising paragraph (a)(2)(ii)(E);

■ b. Adding paragraph (a)(2)(iii);

■ c. Revising the first sentence in paragraph (b)(1) introductory text and paragraphs (b)(2) and (3); and

■ d. Removing paragraph (b)(4).

The revisions and addition read as follows:

§ 18.30 Service and filing.

(a) * * *

(2) * * *

(ii) * * *

(E) Sending it to a registered user by filing it with the Department's eFile/eServe system or sending it by other electronic means that the person consented to in writing—in either of which events service is complete upon filing or sending, but is not effective if the filer or sender learns that it did not reach the person to be served; or

* * * * *

(iii) *Consent to electronic service.* Any person required to file electronically pursuant to paragraph (b)(3)(i)(A) of this section and any person who opts to file electronically pursuant to paragraph (b)(3)(i)(B) of this section is deemed to have consented to electronic service of documents issued by the judge and papers filed by a registered user of the Department's eFile/eServe system.

* * * * *

(b) * * *

(1) * * * Any paper that is required to be served must be filed no later than a reasonable time after service with a certificate of service. * * *

(2) *Filing: when made—in general.* A paper submitted electronically in the Department's eFile/eServe system is filed when received by the system. Papers submitted by other means are filed when received by the docket clerk or by the judge during a hearing.

(3) *Filing: how made*—(i) *Electronic filing and signing*—(A) *By a represented person—generally required; exceptions.* A person represented by an attorney or non-attorney representative must file using the Department's eFile/eServe system following the instructions on the system's website, unless another form of electronic or non-electronic filing is allowed by the judge for good cause or is allowed or required by standing order.

(B) *By a self-represented person—when allowed or required.* A person not represented by an attorney or non-attorney representative may file using the Department's eFile/eServe system following the instructions on the system's website.

(C) *Signing.* A filing made through a person's eFile/eServe system account and authorized by that person, together with that person's name on a signature block, constitutes the person's signature.

(D) *Same as a written paper.* A paper filed electronically is a written paper for purposes of this section.

(ii) *Other forms of filing.* Persons who are excepted from e-filing under paragraph (b)(3)(i)(A) of this section, or who have opted not to use e-filing as permitted by paragraph (b)(3)(i)(B) of this section, may file papers by mail, courier service, hand delivery, facsimile, or alternative means of electronic delivery. The mailing addresses for OALJ's National and District offices are found at *https://www.dol.gov/agencies/oalj/contacts.*

(A) *Filing by facsimile—cover sheet.* Filings by facsimile must include a cover sheet that identifies the sender, the total number of pages transmitted, the matter's docket number, and the document's title.

(B) *Filing by facsimile—retention of the original document.* The original signed document will not be substituted into the record unless required by law or the judge. Any party filing a facsimile of a document must maintain the original document and transmission record until the case is final. A transmission record is a paper printed by the transmitting facsimile machine that states the telephone number of the receiving machine, the number of pages sent, the transmission time, and an indication that no error in transmission occurred. Upon a party's request or judge's order, the filing party must provide for review the original transmitted document from which the facsimile was produced.

■ 4. Amend § 18.32 by revising paragraph (a)(2) to read as follows:

§ 18.32 Computing and extending time.

(a) * * *

(2) ''*Last day*'' *defined.* Unless a different time is set by a statute, regulation, Executive order, or judge's order, the ''last day'' ends:

(i) For electronic filing, at 11:59:59 p.m. in the time zone of the presiding judge's office—or, for cases not yet assigned to an OALJ national or district office—at 11:59:59 p.m. in the time zone of the office of the Chief Judge of OALJ; and

(ii) For filing by other means, when the clerk's office is scheduled to close.

* * * * *

■ 5. Amend § 18.34 by revising the introductory text to read as follows:

§ 18.34 Format of papers filed.

Papers submitted electronically in the Department's eFile/eServe system must be in a format accepted by the Department's eFile/eServe system. Papers not filed electronically must be printed in black ink on 8.5 x 11-inch opaque white paper. All papers must be legible, and begin with a caption that includes:

* * * * *

■ 6. Revise § 18.40 to read as follows:

§ 18.40 Notice of hearing.

(a) *In general.* Except when the hearing is scheduled by calendar call, the judge must, at least 14 days before the hearing, notify the parties of the hearing's date, time, and place, and of the manner of the hearing, whether in person in the same physical location, by telephone, by videoconference, or by other means. The notice is sent by the means provided for at § 18.30(a), unless the judge determines that circumstances require service by certified mail or other means. The parties may agree to waive the 14-day notice for the hearing.

(b) *Date, time, place, and manner.* The judge must consider the convenience and necessity of the parties and the witnesses in selecting the date, time, place, and manner of the hearing.

■ 7. Amend § 18.41 by revising the section heading and paragraphs (a), (b)

introductory text, and (b)(2) to read as follows:

§ 18.41 Continuances and changes in place or manner of hearing.

(a) *By the judge.* Upon reasonable notice to the parties, the judge may change the time, date, place, and manner of the hearing.

(b) *By a party's motion.* A request by a party to continue a hearing or to change the place or manner of the hearing must be made by motion.

* * * * *

(2) *Change in place or manner of hearing.* A motion to change the place or manner of a hearing must be filed promptly.

■ 8. Amend § 18.44 by revising paragraph (b) to read as follows:

§ 18.44 Prehearing conference.

* * * * *

(b) *Scheduling.* Prehearing conferences may be conducted in person in the same physical location, by telephone, by videoconference, or by other means after reasonable notice of time, place, and manner of conference has been given.

* * * * *

■ 9. Revise § 18.82 to read as follows:

§ 18.82 Exhibits.

(a) *Filing of exhibits to be offered into evidence.* Persons who are required to file electronically pursuant to § 18.30(b)(3)(i)(A)—or who have opted to use e-filing as permitted by § 18.30(b)(3)(i)(B)—must electronically file in the Department's eFile/eServe system any exhibits to be offered in evidence at a hearing, unless that exhibit is not susceptive to filing in electronic form.

(b) *Identification.* All exhibits offered in evidence must be marked with a designation identifying the party offering the exhibit and must be numbered and paginated as the judge orders.

(c) *Electronic data.* By order, the judge may prescribe the format for the submission of data that is in electronic form.

(d) *Exchange of exhibits.* When written exhibits are offered in evidence, one copy must be furnished to the judge and to each of the parties. If the exhibit being offered was previously filed with the judge, either electronically pursuant to paragraph (a) of this section or otherwise, and furnished to the other parties prior to hearing, the exhibit need not be produced at the hearing unless the judge directs otherwise. If the exhibit being offered at the hearing was not furnished to each party or filed with the judge prior to the hearing, a paper copy of that exhibit for the judge and each party must be produced at the hearing unless the judge directs otherwise. If the judge does not fix a date for the exchange of exhibits, the parties must exchange copies of exhibits at the earliest practicable time before the hearing begins.

(e) *Authenticity.* The authenticity of a document identified in a pre-hearing exhibit list is admitted unless a party files a written objection to authenticity at least seven days before the hearing. The judge may permit a party to challenge a document's authenticity if the party establishes good cause for its failure to file a timely written objection.

(f) *Substitution of copies for original exhibits.* The judge may permit a party to withdraw original documents offered in evidence and substitute accurate copies of the originals.

(g) *Designation of parts of documents.* When only a portion of a document contains relevant matter, the offering party must exclude the irrelevant parts to the greatest extent practicable.

(h) *Records in other proceedings.* Portions of the record of other administrative proceedings, civil actions, or criminal prosecutions may be received in evidence, when the offering party shows the copies are accurate.

Keith Sonderling,

Secretary of Labor.

[FR Doc. 2026–22761 Filed 11–6–26; 8:45 am]

BILLING CODE 4510–HW–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2026–1405]

Security Zones; Protection of Military Cargo, Captain of the Port Zone Puget Sound, WA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce security zones for the Protection of Military Cargo from November 8 through November 12, 2026, to provide for the security of life and vessels on navigable waterways during this event. Our regulation for Protection of Military Cargo within the Captain of the Port Zone Puget Sound, WA identifies the security zones for this event in the Blair Waterway and Sitcum Waterway in Commencement Bay, WA. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Captain of the Port or a designated representative.

DATES: The regulations in 33 CFR 165.1321 will be enforced for the security zones identified in the **SUPPLEMENTARY INFORMATION** section below for the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LT Anthony Pinto, Sector Puget Sound Waterways Management Division, U.S. Coast Guard; telephone 206–217–6051, email *sectorpugetsoundWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce security zones in 33 CFR 165.1321 for the Blair Waterway Security Zone (33 CFR 165.1321(c)(1)) and the Sitcum Waterway Security Zone ((c)(2)), for military outloads from 12:01 a.m. on November 8, 2026, through 11:59 p.m. on November 12, 2026. This action is being taken to provide for the security of life and vessels on navigable waterways during this 5-day event. Our regulation for Protection of Military Cargo within the Captain of the Port Zone Puget Sound, WA, § 165.1321, specifies the location of the regulated area for the Military Outloads which encompasses portions of the Blair Waterway and Sitcum Waterway in Commencement Bay, WA. During the enforcement periods, as reflected in § 165.1321(d), if you are the operator of a vessel in the regulated area, you must comply with directions from the Captain of the Port or any Designated Representative to enter, move within, or exit the security zones. Vessels 20 meters or greater in length should seek permission from the COTP or a Designated Representative at least 4 hours in advance. Vessels less than 20 meters in length should seek permission at least 1 hour in advance. VTS Puget Sound may be reached on VHF channel 14.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners.

Michael J. Hunt,

Captain, U.S. Coast Guard, Captain of the Port, Sector Puget Sound.

[FR Doc. 2026–22831 Filed 11–6–26; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2002–0037; FRL–5678–03–OAR]

RIN 2060–AR73

National Emission Standards for Hazardous Air Pollutants: Polyvinyl Chloride and Copolymer Production Reconsideration; New Major Source Process Wastewater Standards

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is finalizing amendments to the national emission standards for hazardous air pollutants (NESHAP) for the Polyvinyl Chloride (PVC) and Copolymer Production source category (''PVC NESHAP'') under Clean Air Act (CAA) section 112. For new major sources, the EPA is finalizing the removal of the total non-vinyl chloride organic hazardous air pollutant (HAP) process wastewater emission limit and the associated testing, monitoring, recordkeeping, and reporting requirements. The EPA is also finalizing that the new major source vinyl chloride emission limit acts as a surrogate for non-vinyl chloride organic HAP emissions from process wastewater. The EPA is not taking final action on other aspects of the reconsideration proposal at this time.

DATES: This final rule is effective on November 9, 2026.

ADDRESSES: The EPA established a docket for this action under Docket ID No. EPA–HQ–OAR–2002–0037. The docket lists all documents at *https://www.regulations.gov.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The EPA does not place certain other material, such as copyrighted material, on the internet; this material is publicly available only as portable document format versions accessible only on EPA computers in the docket office reading room. The public cannot download certain databases and physical items from the docket but may request these items by contacting the docket office at (202) 566–1744. The docket office has 10 business days to respond to such requests. With the exception of such material, publicly available docket materials are available electronically at *https://www.regulations.gov* or on EPA computers in the docket office reading room at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time (ET), Monday through Friday (except Federal holidays). The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For information about this final rule, contact U.S. EPA, Attn: William Gallagher, Mail Drop: Industrial Processing and Power Division (E140C), 109 T.W. Alexander Drive, P.O. Box 12055, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2336; and email address: *gallagher.william@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. Throughout this preamble the use of ''we,'' ''us,'' or ''our'' refers to the EPA. The EPA uses multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CAA Clean Air Act
CFR Code of Federal Regulations
CRA Congressional Review Act
EPA Environmental Protection Agency
Fe fraction emitted
Fr fraction removed
FR Federal Register
GACT generally available control technology
HAP hazardous air pollutant
HON Hazardous Organic NESHAP
ICR information collection request
MACT maximum achievable control technology
MON Miscellaneous Organic Chemical Manufacturing NESHAP
NAICS North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NTTAA National Technology Transfer and Advancement Act
OMB Office of Management and Budget
ppmw part per million by weight
PRA Paperwork Reduction Act
PRD Pressure relief device
PM particulate matter
PVC polyvinyl chloride
PVCPU PVC and copolymer production process unit
RDL representative detection level
RFA Regulatory Flexibility Act
RIN Regulatory Information Number
tpy ton per year
UMRA Unfunded Mandates Reform Act
U.S.C. United States Code

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I. General Information

A. Executive Summary

On April 17, 2012, the EPA codified standards for the PVC and Copolymer Production source category at 40 Code of Federal Regulations (CFR) part 63, subpart HHHHHHH (''2012 Final Rule'').[1] Subsequently, industry

[1] The EPA also finalized revisions to the area source NESHAP, codified at 40 CFR part 63, subpart DDDDDD, in the 2012 Final Rule. 77 FR 22848 (April 17, 2012).

stakeholders notified the EPA that the Agency used data from outside the PVC and Copolymer Production source category to set the total non-vinyl chloride organic HAP process wastewater emission limits for new major sources and new and existing area sources. The EPA agreed with stakeholders, and in February 2015, the Agency issued a direct final rule to rescind the total non-vinyl chloride organic HAP process wastewater emission limits for new and existing PVC and copolymer production area sources (''2015 Final Rule'').[2]

On November 9, 2020, the EPA proposed reconsideration (''2020 Proposal'') of several aspects of the PVC NESHAP in response to petitions for reconsideration on the 2012 Final Rule.[3] As part of that action, the EPA proposed to remove the new and existing major source total non-vinyl chloride organic HAP process wastewater emission limits and the associated testing, monitoring, recordkeeping, and reporting requirements. In addition, the EPA proposed that vinyl chloride can act as a surrogate for non-vinyl chloride organic HAP in PVC and copolymer production process wastewater. This action finalizes the removal of the total non-vinyl chloride organic HAP process wastewater emission limit for new major PVC and copolymer production sources and associated testing, monitoring, recordkeeping, and reporting requirements and finalizes the proposed surrogacy.

This action will have no immediate cost or emissions impacts as it does not affect existing sources, and the EPA is unaware of any new sources currently subject to the rule. If a new major source PVC and copolymer production facility becomes operational in the future, the EPA estimates that this action will save the facility approximately $2,900 in capital/startup costs and $30,000 in annual costs (in 2025 dollars) due to the reduction in total non-vinyl chloride organic HAP testing, monitoring, recordkeeping, and reporting burdens.

B. Does this action apply to me?

Regulated entities. This final action addresses the PVC and Copolymer Production source category regulated under 40 CFR part 63, subpart HHHHHHH. Table 1 of this preamble lists the NESHAP and the associated regulated industrial source category that this action may affect.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORY AFFECTED BY THIS FINAL ACTION

NESHAP	Source category	NAICS[a] code
40 CFR part 63, subpart HHHHHHH	PVC and Copolymer Production	325211

[a] North American Industry Classification System (NAICS).

The EPA provides table 1 of this preamble as a guide, not an exhaustive list, of entities that this final rule likely affects for the listed source category. This final rule does not affect Federal, State, local, or Tribal government entities.

To determine whether this action affects your facility, examine the applicability criteria of this NESHAP. If you have any questions regarding the applicability of this NESHAP, contact the appropriate person listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

C. What is the statutory authority for this action?

CAA section 112, as amended, provides the statutory authority for this action.[4] CAA section 112 establishes a multi-stage regulatory process to develop standards for emissions of HAP from stationary sources. Generally, the first stage involves establishing technology-based standards that reflect application of the maximum achievable control technology (MACT) or appropriate alternative.[5] The second stage involves evaluating those standards within 8 years under CAA section 112(f)(2) to determine whether the EPA needs to promulgate standards to address any remaining risk associated with HAP emissions.[6] This second stage is commonly referred to as the ''residual risk review.'' In addition to conducting the residual risk review, pursuant to CAA section 112(d)(6), the EPA must review the standards every 8 years and to ''revise [them] as necessary,'' taking into account any ''developments in practices, processes, and control technologies.'' [7] This review is commonly referred to as the ''technology review.''

In the first stage of the CAA section 112 standard-setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). The CAA refers to sources of HAP emissions as either major sources or area sources. ''Major sources'' are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP.[8] All other sources are ''area sources.'' CAA section 112 establishes different requirements for major source standards and area source standards. For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of reduction in emissions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to, those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

CAA section 112(d)(3) establishes a minimum control level for MACT standards, known as the MACT ''floor,'' based on emission controls achieved in practice by the best performing sources. For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. For existing sources, the MACT standards can be less stringent than floors for new sources, but the standards cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer

[2] 40 FR 5938 (February 4, 2015).
[3] 85 FR 71490 (November 9, 2020).
[4] 42 U.S.C. 7412.
[5] *Id.* 7412(d)(1)–(3).
[6] *Id.* 7412(f)(2).
[7] *Id.* 7412(d)(6).
[8] *Id.* 7412(a)(1).

than 30 sources).[9] In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards in lieu of numerical emission standards. The EPA must also consider control options that are more stringent than the floor, often referred to as ''beyond-the-floor'' standards, and may establish standards more stringent than the floor taking into consideration the cost of achieving the emission reductions, and any non-air quality health and environmental impacts and energy requirements.[10]

In the second stage of the regulatory process, for categories of major sources and any area source categories subject to MACT standards, CAA section 112 requires the EPA to identify and address any remaining (*i.e.,* ''residual'') risk within 8 years pursuant to CAA section 112(f)(2) and to conduct a technology review pursuant to CAA section 112(d)(6). This latter provision requires the EPA to review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years. In conducting the technology review, the EPA is not required to recalculate the MACT floors that the Agency established in earlier rulemakings.[11] The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6).[12] Finally, the EPA reviews available data to determine if there are certain unregulated emissions of HAP within the major source category and evaluates these data for use in developing new emission standards.[13]

For the residual risk review required by CAA section 112(f), within 8 years of promulgating the technology-based standards for a source category, the EPA must evaluate the risk to public health remaining after the application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect, taking into consideration costs, energy, safety, and other relevant factors. For categories of area sources subject to generally available control technologies or management practices (GACT) standards, the CAA does not require the EPA to address residual risk. However, CAA section 112(d)(6) requires the EPA to conduct a technology review for all standards established under CAA section 112(d), including GACT standards that apply to area sources. For categories of area sources subject to GACT standards, CAA section 112(d)(5) and (f)(5) provide that the EPA is not required to conduct a residual risk review under CAA section 112(f)(2).

The EPA first set MACT standards for the PVC and Copolymer Production major source category in 2002 (''2002 Final Rule'').[14] Upon vacatur and remand by the United States Court of Appeals for the District of Columbia Circuit (''D.C. Circuit''),[15] the EPA promulgated new MACT standards for the PVC and Copolymer Production source category for major sources and revised the area source NESHAP in the 2012 Final Rule.[16] After receiving petitions for reconsideration of the 2012 Final Rule, the EPA proposed reconsideration of several aspects of that rule in the 2020 Proposal.[17] This final action addresses only the proposed reconsideration of the new major source total non-vinyl chloride organic HAP process wastewater emission limit. The EPA intends to address the remaining issues presented in the 2020 Proposal in a separate action.

D. Where can I get a copy of this document and other related information?

In addition to placing this action in the docket, the EPA provides an electronic copy on the internet. Following signature by the EPA Administrator, the Agency will post a copy of this action at *https://www.epa.gov/stationary-sources-air-pollution/polyvinyl-chloride-and-copolymers-production-national-emission.* Following publication in the **Federal Register** (FR), the EPA will post the **Federal Register** version of the final rule and key technical documents at this same website. The EPA has placed in the docket a memorandum showing the ''track changes'' version of the regulatory language that incorporates the changes in this action.[18]

E. Judicial Review and Administrative Reconsideration

Under CAA section 307(b)(1), a party may obtain judicial review of this action only by filing a petition for review in the D.C. Circuit by January 8, 2027. CAA section 307(b)(2) prohibits a party from separately challenging this final rule in any civil or criminal enforcement proceedings that the EPA brings.

CAA section 307(d)(7)(B) provides that, during judicial review, a party may raise only an objection to a rule or procedure that the party raised with reasonable specificity during the period for public comment (including any public hearing). This section also requires the EPA to reconsider the rule if the person raising an objection demonstrates to the Administrator that either it was impracticable to raise the objection during the period for public comment or that the grounds for the objection arose after the period for public comment (but within the time specified for judicial review) and if the objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a petition for reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460. The person should also send a copy to both the person(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the PVC and Copolymer Production source category, and how does the NESHAP regulate HAP emissions from the source category?

The EPA first promulgated the PVC and Copolymer Production source category NESHAP with the 2002 Final Rule and codified the NESHAP at 40 CFR part 63, subpart J.[19] Following judicial review, the D.C. Circuit vacated and remanded the 2002 Final Rule to the EPA after determining that the Agency failed to adequately explain the basis for the decision to use vinyl chloride as a surrogate for other HAP.[20] The EPA separately promulgated an area source NESHAP for the PVC and Copolymer Production source category on January 23, 2007, and codified it at 40 CFR part 63, subpart DDDDDD.[21] With the 2012 Final Rule, the EPA promulgated new major source standards for the PVC and Copolymer Production source category at 40 CFR part 63, subpart HHHHHHH and aligned

[9] *Id.* 7412(d)(3)(A)–(B).

[10] *Id.* 7412(d)(2).

[11] *See Ass'n of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013); *Nat. Resources Defense Council* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008).

[12] 42 U.S.C. 7412(d)(2), (6); *see Ass'n of Battery Recyclers,* 716 F.3d at 673–74.

[13] *See La. Env't Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020).

[14] 67 FR 45886 (July 10, 2002).

[15] *See Mossville Env't Action Now* v. *EPA,* 370 F.3d 1243 (D.C. Cir. 2004).

[16] 77 FR 22848 (April 17, 2012).

[17] 85 FR 71490 (November 9, 2020).

[18] Docket ID No. EPA–HQ–OAR–2002–0037.

[19] 67 FR 45886 (July 10, 2002).

[20] *See Mossville Env't Action Now,* 370 F.3d 1232.

[21] 72 FR 2930 (January 23, 2007).

the major and area source NESHAP by revising 40 CFR part 63, subpart DDDDDD.

The EPA received multiple petitions for reconsideration of the 2012 Final Rule.[22] To better assess the issues raised for reconsideration, the EPA issued CAA section 114 information collection requests (ICRs) to gather additional information on PVC and copolymer production process vents and wastewater. Additionally, industry stakeholders identified that the EPA used data from outside the PVC and Copolymer Production source category to establish the major and area source total non-vinyl chloride organic HAP process wastewater emission limits. The EPA agreed with industry stakeholders and promulgated the 2015 Final Rule to rescind the total non-vinyl chloride organic HAP process wastewater emission limits for new and existing area sources.[23] In addition, the D.C. Circuit resolved certain contested issues via *Mexichem Specialty Resins, Inc.* v. *EPA* [24] and *U.S. Sugar Corporation* v. *EPA,*[25] thus mooting the need for the EPA to act on requests to reconsider those aspects of the rule. To further address the remaining reconsideration issues and other technical and editorial corrections, the EPA issued the 2020 Proposal to reconsider certain aspects of the major source PVC NESHAP, including the major source total non-vinyl chloride organic HAP process wastewater emission limits.[26] This final action addresses the proposed reconsideration of the new major source total non-vinyl chloride organic HAP process wastewater emission limit. The EPA intends to address the remaining issues presented in the 2020 Proposal in a separate action.

The 2012 Final Rule regulates HAP emissions from PVC and copolymer production process units (PVCPU) that produce PVC and copolymers as their primary product(s). A PVCPU is the collection of process components assembled and connected by hard-piping or duct work used to process raw materials to manufacture PVC and/or PVC copolymers and includes, but is not limited to, polymerization reactors, resin stripping operations, resin blend tanks, resin centrifuges, resin dryers, resin product separators, recovery devices, reactant and raw material charge vessels and tanks, holding tanks, mixing and weighing tanks; finished resin product storage tanks or storage silos; finished resin product loading operations; and connected duct and piping. A PVCPU also includes pumps, compressors, agitators, PRDs, sampling connection systems, open-ended valves or lines, valves and connectors, and instrumentation systems.

PVC is the third most widely produced synthetic polymer in the world and comes in a variety of rigid and flexible forms depending on the application. Vinyl chloride monomer is the primary raw material in PVC and copolymer production, and manufacturers add other components to the polymerization reaction as necessary to modify the properties of the resulting resin to meet product specifications. As such, there are a wide variety of PVC and copolymer resin recipes, and each recipe will result in different HAP present in the PVCPU. There are multiple ways to produce PVC and copolymer resins including bulk polymerization, dispersion polymerization, and suspension polymerization.[27]

The HAP emission sources at PVC and copolymer production facilities include process vents, storage vessels, equipment leaks, heat exchange systems, wastewater, and stripped resin. While all PVC and copolymer production sources emit vinyl chloride, a PVCPU may also emit other HAP such as benzene, formaldehyde, and toluene depending on the specific resin recipes. The PVC NESHAP includes numeric emission limits for process vents, stripped resin, and wastewater; a mixture of numeric emission limits and work practices for storage vessels depending on the volume and pressure; and work practices for equipment leaks and heat exchange systems.

The EPA identified that this action may affect one potential new major source upon construction and startup. However, this potential new source has not yet commenced construction. While existing sources may reconstruct their PVCPU(s) and become subject to the new source standards, the EPA is unaware of any ongoing reconstruction efforts. As such, the EPA does not anticipate that this action will have any immediate cost or emissions impacts (see section IV of this preamble for additional details).

B. What changes did we propose for the PVC and Copolymer Production source category in our 2020 Proposal?

In 2020, the EPA proposed reconsideration of several aspects of the 2012 Final Rule to resolve reconsideration issues that the D.C. Circuit had not addressed.[28] These items included reconsideration of the process vent, stripped resin, and process wastewater emission limits; the process vent emission profile requirements; the pressure vessel provisions; the use of vapor balancing as a method of compliance; and the definition of the affected source. In addition, the EPA proposed technical corrections and clarifications to the alternative emission limit format for compliance with the stripped resin standards, the initial and continuous monitoring requirements for total non-vinyl chloride organic HAP emissions from stripped resin, the fixed and floating roof storage vessel provisions, the equipment leaks practices, and the closed vent system requirements.[29] The EPA also proposed to remove the affirmative defense provisions and to make certain editorial changes to correct errors within the major and area source PVC NESHAP.[30]

This action only addresses the proposed reconsideration of the new major source total non-vinyl chloride organic HAP process wastewater emission limit. On this issue, the EPA proposed to remove the major source total non-vinyl chloride organic HAP process wastewater emission limits and the associated testing, monitoring, recordkeeping, and reporting requirements. Relatedly, the EPA also proposed that vinyl chloride can serve as and is a reasonable surrogate for non-vinyl chloride organic HAP in PVC and copolymer production process wastewater because (1) vinyl chloride is the predominant HAP present in all PVC and copolymer production process wastewater streams, and (2) the best performing steam strippers with respect to vinyl chloride are also the most effective at removing non-vinyl chloride organic HAP. The EPA proposed that focusing the emission limit on vinyl chloride via surrogacy rather than on total non-vinyl chloride organic HAP ensured the Agency could identify the best performing wastewater strippers while still controlling non-vinyl chloride organic HAP air emissions. To that end, the EPA proposed that resin recipes determine the presence of other

[22] For the petitions for reconsideration, see Document ID Nos. EPA–HQ–OAR–2002–0037–0544, EPA–HQ–OAR–2002–0037–0568, EPA–HQ–OAR–2002–0037–0217, and EPA–HQ–OAR–2002–0037–0569.

[23] 40 FR 5938 (February 4, 2015).

[24] *See Mexichem Specialty Resins, Inc.* v. *EPA,* 787 F.3d 544 (D.C. Cir. 2015).

[25] *See U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 639 (D.C. Cir. 2016).

[26] 85 FR 71490 (November 9, 2020).

[27] The EPA defines ''bulk process,'' ''dispersion process,'' and ''suspension process'' at 40 CFR 63.12005.

[28] For additional details on the petitions for reconsideration and the reconsideration issues proposed, see 85 FR 71490 (November 9, 2020).

[29] 85 FR at 71499–505.

[30] 85 FR at 71505–508.

non-vinyl chloride organic HAP in the liquid phase exiting the steam stripper (*i.e.,* the stripper bottoms). The EPA proposed that the makeup of the stripper bottoms does not necessarily define the overall effectiveness of the steam stripper and stated that wastewater is more likely to retain the non-vinyl chloride organic HAP that steam stripping does not effectively treat. The EPA further proposed that biological treatment will effectively target and reduce those remaining HAP.

C. What stakeholder engagement took place following the 2020 Proposal?

In January 2026, Olin Corporation contacted the EPA to express concern with the new major source total non-vinyl chloride organic HAP process wastewater emission limit in the PVC NESHAP. A summary of this meeting and subsequent calls is in the docket for this action in the memorandum titled *Meetings and Calls Between U.S. EPA and the Olin Corporation.*

III. What is included in this final rule, and what is our rationale for our final decisions and amendments for the PVC and Copolymer Production source category?

A. What final rule amendments are we finalizing based on our reconsideration?

In this action, the EPA is finalizing aspects of the 2020 Proposal concerning the new major source total non-vinyl chloride organic HAP process wastewater emission limit. The EPA is still considering the relevant information and commenter feedback on other portions of the 2020 Proposal and intends to take action on those other portions at a later date.

B. New Major Source Total Non-Vinyl Chloride Organic HAP Process Wastewater Emission Limit

This section describes what the EPA proposed and what the Agency is finalizing, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. The EPA intends to address the remaining comments on the proposed rulemaking when the Agency takes final action on the other aspects of the reconsideration proposal at a later date.

1. What did we propose affecting the new major source wastewater emission limits for the PVC and Copolymer Production source category?

The EPA proposed to revise the approach to regulating new major source total non-vinyl chloride organic HAP process wastewater emissions. Specifically, the EPA proposed to eliminate the new major source total non-vinyl chloride organic HAP process wastewater emission limit; remove the associated testing, monitoring, recordkeeping, and reporting requirements; and establish vinyl chloride as a surrogate for non-vinyl chloride organic HAP in PVC and copolymer production process wastewater. This would mean that new major PVC and copolymer production sources would only have to meet the current new major source vinyl chloride process wastewater emission limit (*i.e.,* process wastewater streams must contain less than 0.28 parts per million by weight (ppmw) vinyl chloride). Refer to section II.B of this preamble, to section III.B of the 2020 Proposal,[31] and to the documents titled *Technical Analysis and Documentation to support EPA's Reconsideration of 40 CFR part 63 Subpart HHHHHHH National Emission Standards for the Polyvinyl Chloride and Copolymers (PVC) Production Source Category*[32] and *Analysis of HAP in PVC Process Wastewater*[33] in the docket for additional information on the proposed changes to the PVC and copolymer production process wastewater standards. At this time, the EPA is not taking final action on the proposal to eliminate the existing major source total non-vinyl chloride organic HAP process wastewater emission limit (110 ppmw total non-vinyl chloride organic HAP); to remove the associated testing, monitoring, recordkeeping, and reporting requirements; and to revise the vinyl chloride emission limits for both new and existing sources (0.28 ppmw and 6.8 ppmw vinyl chloride, respectively) (see section III.B.4 of this preamble for additional details).

How did the approach to the new major source process wastewater emission limit change for the PVC and Copolymer Production source category?

The EPA is finalizing the proposed removal of the total non-vinyl chloride organic HAP process wastewater emission limit and the associated testing, monitoring, recordkeeping, and reporting requirements for new major sources without change. In addition, the EPA is finalizing the proposed vinyl chloride surrogacy without changes.

3. What key comments did we receive on the new major source wastewater emission limits, and what are our responses?

This section provides summaries of and responses to key stakeholder comments regarding the EPA's proposed removal of the major source total non-vinyl chloride organic HAP process wastewater emission limits and the proposed vinyl chloride surrogacy determination.

Comment: Commenters both supported and opposed the EPA's proposal to remove the major source total non-vinyl chloride organic HAP process wastewater emission limits and establish vinyl chloride as a surrogate for non-vinyl chloride organic HAP for major and area sources.

At least two commenters said that vinyl chloride is a reasonable surrogate for non-vinyl chloride organic HAP because: (1) vinyl chloride and individual organic HAP are invariably present in process wastewater, (2) the wastewater strippers used to control vinyl chloride also control other HAP, and (3) wastewater strippers are the only means that PVC affected sources can use to control organic HAP from process wastewater. Other commenters said that they agree with the EPA's analysis of the other organic HAP being treated in the steam strippers.

A commenter cited *Mossville Environmental Action Now* v. *EPA* and said the EPA's proposal (and the accompanying preamble discussion) is responsive to the D.C. Circuit's request that the Agency ''properly explain its methodology for regulating [HAP] emitted in PVC production other than vinyl chloride by use of a surrogate.''[34] Another commenter cited *U.S. Sugar Corporation* v. *EPA*[35] and *National Lime Association* v. *EPA*[36] and said that the D.C. Circuit has held that the EPA may use a surrogate to regulate HAP under CAA section 112 where ''reasonable.'' The commenter added that the variety of resin recipes and products manufactured by PVC MACT affected sources, which require significant variations in ingredients, as well as process parameters, make the use of vinyl chloride as a surrogate the only workable solution. The commenter contended that different resin recipes use widely varying ingredients, with corresponding changes in the HAP profile. The commenter said that individual resin recipes normally

[31] 85 FR 71490 (November 9, 2020).

[32] Document ID No. EPA–HQ–OAR–2002–0037–0693.

[33] Document ID No. EPA–HQ–OAR–2002–0037–0681.

[34] *See Mossville Env't Action Now,* 370 F.3d at 1232.

[35] *See U.S. Sugar Corp.,* 830 F.3d 579.

[36] *See Nat'l Lime Ass'n* v. *EPA,* 233 F.3d at 637 (D.C. Cir. 2000).

include different reactor temperature profiles, reactor pressure, and other process changes, which impact the HAP emissions. The commenter further noted that the slurry stripper operating parameters are also usually different for different products, including residence time/slurry feed rate, steam feed rate, temperature at various column locations, pressure/vacuum, *etc.*

Commenters confirmed that effluent wastewater from virtually all PVCPUs is eventually routed to secondary treatment facilities with biological destruction capabilities for HAP. The commenters said steam stripping PVC process wastewater for vinyl chloride effectively reduces or removes all organic HAP according to the Fraction Removed (Fr) values in the Hazardous Organic NESHAP (HON).[37] However, a commenter noted an error in the memorandum titled *Analysis of HAP in PVC Process Wastewater* that they claimed could be used to undermine the effectiveness of using vinyl chloride as a surrogate.[38] The commenter said that the average concentration of ethylene glycol in stripped wastewater across the industry as specified in the memorandum (*i.e.,* 9,150 ppmw) is skewed by data from a single facility that is no longer in operation. The commenter said that of 642 samples analyzed, ethylene glycol was found in only 48, and that the concentration of 46 samples ranged from 0.6 to 19.7 ppmw yielding an average ethylene glycol concentration of 3.7 ppm. The commenter added that the high average ethylene glycol concentration is due to the inclusion of two samples, measuring 50,400 ppmw on March 25, 2013, and 64,000 ppmw on April 7, 2013, which were provided by the CertainTeed facility (Westlake, Louisiana) as part of its response to the EPA's November 8, 2012, ICR for wastewater. The commenter said that CertainTeed was the last facility to produce PVC resin using a bulk process, which uses significant amounts of ethylene glycol as a coating agent to concentrate the bulk resins and prevent buildup inside the resin autoclave. The commenter said that ethylene glycol was steam stripped out of the resin in situ in the autoclave and eventually collected in the facility's wastewater. However, the commenter was unsure whether CertainTeed used steam stripping to control its wastewater. The commenter contended that these levels of ethylene glycol are unlikely to reoccur because concentrators and autoclaves are not used by suspension, dispersion, or copolymer resin producers.

Another commenter said that variations in non-vinyl chloride monomer HAP concentrations in the ICR wastewater data that were used to develop emission limitations are attributable to varying resin formulations among producers. Thus, some producer formulations may include a HAP that another producer does not use and vice versa. The commenter also said that various starting concentrations of the same HAP will affect final concentrations. The commenter said that using vinyl chloride monomer as a common HAP (*i.e.,* as a surrogate) allows the EPA to identify the most efficient stripping operations providing the greatest pollutant reductions for all HAP present, and that the surrogacy greatly simplifies sample collection and analysis requirements, data collection, and reporting burdens while still requiring emission reductions equivalent to the best performers.

Another commenter argued that the EPA's failure to set emission limits for HAP other than vinyl chloride is unlawful and that the Agency's claim that vinyl chloride is a surrogate for the other HAP emitted from PVC plants' process wastewater is unlawful. The commenter cited *National Lime Association* v. *EPA* [39] and *Mossville Environmental Action Now* v. *EPA* [40] and argued that the CAA unambiguously requires the EPA's emission standards for a source category to include limits for each HAP that the source category emits. The commenter asserted that under binding D.C. Circuit precedent, the EPA may use standards for surrogates to meet this obligation only if the Agency's limits for the surrogate reflect ''the average level achieved by the best performers with regard to [the target] HAPs.'' [41] The commenter quoted *Sierra Club* v. *EPA,* stating ''if EPA looks only to [the surrogate], but HAPs are reduced [in another] way that does not reduce [the surrogate], the best achieving sources, and what they can achieve with respect to HAPs, might not be properly identified.'' [42]

The commenter contended that, considering this D.C. Circuit precedent, a valid surrogacy relationship between vinyl chloride and total non-vinyl chloride organic HAP does not exist.

The commenter asserted that the EPA does not even attempt to show that its vinyl chloride standards will reduce emissions of such other HAP to ''the average level achieved by the best performers with regard to those HAP.'' The commenter said that the D.C. Circuit has made plain that the best performers are the sources with the lowest emissions.[43] The commenter said that if the EPA could designate the sources that reduce their emissions most through the use of a control technology, the Agency could ignore the many other factors—specifically identified in CAA section 112(d)(2)—that affect sources' actual emission levels, such as the use of cleaner raw materials and fuels and cleaner processes. The commenter said that the D.C. Circuit has explained repeatedly that it is not sufficient for the EPA to only consider sources using MACT controls if factors other than MACT technology influence a source's performance.[44] The commenter said that the D.C. Circuit has stated that the EPA is not required to use the MACT approach and, if it is insufficient to adequately consider the factors influencing source performance, the Agency must devise a different approach.[45]

The commenter said that the EPA made clear in the proposal preamble that emission levels of the other HAP (for which the Agency claims vinyl chloride is a surrogate) are actually determined by at least one factor that is not correlated to vinyl chloride emissions: the various ''resin recipe slates'' that different plants use. The commenter asserted that the record shows that 33 non-vinyl chloride organic HAP are emitted from PVC plants' wastewater, that the top performers ''with regard to'' some of these HAP are achieving emission levels of zero, and that the EPA admits that the effect of different plants' resin recipes on the emissions of HAP other than vinyl chloride is so significant that the sources the Agency has identified as best performers for vinyl chloride—the ones with the best performing steam

[37] *See* table 9 to 40 CFR part 63, subpart G.

[38] *See* Document ID No. EPA–HQ–OAR–2002–0037–0681.

[39] *See Nat'l Lime Ass'n,* 233 F.3d at 633–634.

[40] *See Mossville Environmental Action Now,* 370 F.3d at 1243.

[41] The commenter cited *U.S. Sugar Corp.,* 830 F.3d 579, 628.

[42] *See Sierra Club* v. *EPA,* 353 F.3d 976, 985 (D.C. Cir. 2004).

[43] The commenter cited *Sierra Club* v. *EPA,* 479 F.3d 875, 880 (D.C. Cir. 2007) (section ''7412(d)(3) requires floors based on the emission level actually achieved by the best performers (those with the lowest emission levels)'' (citing *Cement Kiln Recycling Coalition* v. *EPA,* 255 F.3d 855, 861 (D.C. Cir. 2001))).

[44] *Sierra Club,* 479 F.3d at 882 (quoting *Cement Kiln Recycling Coalition,* 255 F.3d at 864–65 (D.C. Cir. 2001)).

[45] *Sierra Club,* 479 F.3d at 882.

strippers—are not the best performers for other organic HAP.[46]

Response: The EPA acknowledges the comments submitted in support of and in opposition to the Agency's proposal to remove the total non-vinyl chloride organic HAP process wastewater emission limits from the major source PVC NESHAP by establishing vinyl chloride as a surrogate for non-vinyl chloride organic HAP. After considering these comments, the EPA is finalizing the removal of the new major source total non-vinyl chloride organic HAP process wastewater emission limit and the proposed surrogacy without changes.

In response to the commenter's concern regarding the average ethylene glycol concentration identified in table 2 of the document titled *Analysis of HAP in PVC Process Wastewater,* the EPA agrees that the two ethylene glycol data points (*i.e.,* concentrations of 50,400 ppm and 64,000 ppm) from the CertainTeed facility skew the average concentration.[47] However, this does not change the EPA's conclusions regarding vinyl chloride's ability to act as a surrogate for non-vinyl chloride organic HAP in PVC and copolymer production process wastewater. The data in table 2 in the document titled *Analysis of HAP in PVC Process Wastewater* demonstrate that steam stripping reduces emissions of the majority of organic HAP in PVC and copolymer production to levels similar to or below that of vinyl chloride. However, it is not necessary to reduce the ethylene glycol concentration below that of vinyl chloride for vinyl chloride to be a valid surrogate, as the EPA explains later in this comment response.

Responding to the commenter's arguments regarding the lawfulness and validity of the proposed (and final) surrogacy, the EPA disagrees that it is unlawful for the Agency to use vinyl chloride as a surrogate for non-vinyl chloride organic HAP in PVC and copolymer production process wastewater.

When considering the surrogacy relationship between particulate matter (PM) and metal HAP, the D.C. Circuit applied three general criteria that clearly demonstrate that a surrogate is reasonable: (1) ''HAP metals are invariably present in . . . PM;'' (2) ''PM control technology indiscriminately captures HAP metals along with other particulates;'' and (3) ''PM control is the only means by which facilities 'achieve' reductions in HAP metal emissions.'' [48] In that situation, PM is the surrogate for metal HAP. Applying these criteria to PVC and copolymer production process wastewater, the EPA interprets similar criteria to be: (1) both non-vinyl chloride organic HAP and vinyl chloride must be present in the wastewater streams; (2) the vinyl chloride control technology must indiscriminately capture both non-vinyl chloride organic HAP and vinyl chloride; and (3) steam stripping is the only means by which affected sources achieve reductions in non-vinyl chloride organic HAP emissions. The EPA notes that other commenters who expressed support for the proposed (and final) surrogacy identified the same criteria.

With respect to the first criterion, the EPA explained in the 2020 Proposal that both vinyl chloride and non-vinyl chloride HAP are invariably present in PVC and copolymer production process wastewater streams.[49] Additionally, the wastewater analyses show that vinyl chloride is present in all of the analyzed wastewater streams (as are acetaldehyde and formaldehyde), yet many other non-vinyl chloride organic HAP (*e.g.,* methanol, chloroform, benzene, hexane) are not.[50] [51] As other commenters noted, vinyl chloride monomer is the primary feedstock for PVC and copolymer resin manufacturing, and the resin recipes dictate the presence of other non-vinyl chloride organic HAP in the resulting process wastewater. When a source does not identify the presence of a particular organic HAP in a wastewater stream, it does not necessarily indicate that the source achieved complete control of the given organic HAP. Instead, it more likely indicates that the resin recipe did not call for that specific HAP, and it was never present in the process. This is particularly relevant considering that steam stripping will remove a similar fraction of HAP from the wastewater for 26 of the 33 HAP identified in table 1 of the wastewater analysis, as the EPA explains later in this comment response.[52] In addition, the EPA notes that while the Agency has the authority to subcategorize process wastewater based on resin type to establish total non-vinyl chloride organic HAP emission limits to address these differences in HAP composition (as the EPA has done for the stripped resin emission limits for the various PVC production types), a single facility may have up to 100 different resin recipes, all of which may require different HAP in different concentrations.[53] The EPA does not have sufficient information to subcategorize by resin type, nor would it be practical to do so given the burden of monitoring for dozens of different emission limits, all applying at different times depending on the batch. Using vinyl chloride as a surrogate will address those concerns by allowing facilities to monitor for a single representative HAP to demonstrate adequate control.

The EPA also notes that it is common for chemical sector rulemakings to have more general standards for streams potentially containing a wide variety of HAP (*e.g.,* the process vent and process wastewater standards in the HON and in the Miscellaneous Organic Chemical Manufacturing NESHAP (MON)).[54] The EPA uses total organic carbon as a surrogate for individual organic HAP in those rules because there is no guarantee that any one HAP will be present in all affected process streams as those rules affect many different manufacturing processes. A similar situation applies for the PVC NESHAP; however, vinyl chloride is the primary feedstock common to all PVC and copolymer production operations, and all process wastewater streams contain vinyl chloride. Thus, while the presence of other organic HAP may vary between sources, measuring control via vinyl chloride provides the best indication of the level of control despite the potential differences in HAP composition between sources.

Addressing the second criterion, regardless of which non-vinyl chloride organic HAP are in a process wastewater stream, steam stripping (the MACT control technology) will control the emissions. The EPA has long held that steam stripping will indiscriminately control all organic HAP, as stated in the 2000 proposal [55] and the 2012 Final Rule [56] with respect to the stripped resin and wastewater standards, respectively, and in the document titled *Analysis of HAP in PVC Process Wastewater,*[57] which is in the docket. The EPA has considered steam stripping as a primary control option for many different chemical sector rulemakings including the HON, the MON, the Polyether

[46] The commenter cited EPA Document ID No. EPA–HQ–OAR–2002–0037–0681 and *U.S. Sugar,* 830 F.3d 628.

[47] *See* Document ID No. EPA–HQ–OAR–2002–0037–0681.

[48] *See Sierra Club,* 353 F.3d at 985 (quoting *Nat'l Lime Ass'n,* 233 F.3d at 639).

[49] 85 FR 71490 (November 9, 2020).

[50] *See* Document ID No. EPA–HQ–OAR–2002–0037–0693.

[51] *See* table 1 in Document ID No. EPA–HQ–OAR–2002–0037–0681.

[52] *Id.*

[53] *See* 77 FR 22848, 22867 (April 17, 2012).

[54] 40 CFR 63.113 and 63.138 in the HON; 40 CFR 63.2455 and 63.2485 in the MON.

[55] 65 FR 76958, 76961 (December 8, 2000).

[56] 77 FR 22848, 22867 (April 17, 2012).

[57] Document ID No. EPA–HQ–OAR–2002–0037–0681.

Polyols Productions NESHAP, the Ethylene Production NESHAP, and the Benzene Waste Operations NESHAP, all of which affect sources with differing emission profiles.[58] As such, the EPA has clearly demonstrated that steam stripping will indiscriminately control both vinyl chloride and non-vinyl chloride organic HAP emissions.

Addressing the third criterion, the EPA is unaware of any other technology that will control organic HAP emissions from PVC and copolymer production process wastewater to the same extent as steam stripping. While many, if not all, PVC and copolymer production sources send their stripped wastewater to a secondary biological treatment unit (as confirmed by two commenters), biological treatment does not effectively reduce all organic HAP in PVC and copolymer production process wastewater. Table 3 of the document titled *Analysis of HAP in PVC Process Wastewater* shows the F_r and Fraction Emitted (F_e) values for the HAP in PVC and copolymer production wastewater. The EPA expects that a design steam stripper will remove a fraction of HAP equal to the F_r value from process wastewater streams while the Agency also expects that a wastewater process will emit a fraction of HAP equal to the F_e value as a result of downstream treatment (*i.e.,* biotreatment) and collection processes.[59] The F_e values vary significantly and include two HAP (2,2,4-trimethylpentane and hexane) with F_e values of 1.00. F_e values of 1.00 mean that all of the 2,2,4-trimethylpentane and hexane in the process will be emitted from the biotreatment and collection processes if the source does not control those emissions another way. Therefore, it is not possible for PVC and copolymer production sources to rely solely on biotreatment to control all HAP emissions from process wastewater.

By comparison, 26 of the 33 non-vinyl chloride organic HAP have F_r values and of those, 23 have the same F_r value as vinyl chloride, 0.99, and none have F_r values of zero. For the remaining seven HAP without F_r values, the D.C. Circuit in *National Lime Association* v. *EPA* established that if ''HAP metals are invariably present in cement kiln PM, then even if the ratio of metals to PM is small and variable, or simply unknown, PM is a reasonable surrogate for metals—assuming . . . that PM control technology indiscriminately captures HAP metals along with other particulates.'' [60] In context of the present rulemaking, the EPA applies this rationale to find that vinyl chloride is a reasonable surrogate, even though steam stripping will not control all of the non-vinyl chloride HAP equally as well as vinyl chloride (potentially including those HAP for which the EPA does not have an F_r value), because the control technology (*i.e.,* steam stripping) indiscriminately targets all organic HAP. The EPA notes that non-vinyl chloride organic HAP that are not as well controlled by steam stripping also tend to have low F_e values, indicating that those organic HAP are more likely to remain in the wastewater than volatilize into air emissions.

In addition, the EPA notes that PVC and copolymer production process wastewater enters the biotreatment unit after a steam stripper removes the majority of HAP. By the time the wastewater reaches the biotreatment units, a design steam stripper will have controlled 99 percent of emissions from 24 of the 34 organic HAP in table 1 of the document titled *Analysis of HAP in PVC Process Wastewater.* Although the EPA acknowledges that biotreatment will reduce emissions for certain non-vinyl chloride organic HAP, the Agency maintains that steam stripping is the only technology achieving emission reductions of all organic HAP emitted by PVC and copolymer production wastewater.

Lastly, addressing the commenter's assertion that the EPA failed to demonstrate that the finalized surrogacy will achieve emission reductions reflective of the best performing sources with respect to non-vinyl chloride organic HAP, the F_r and F_e values do not depend on the quantities of the treated HAP. As described in the document titled *Analysis of HAP in PVC Process Wastewater* in the docket for this action, a design steam stripper will reduce organic HAP in the wastewater by an amount equal to the F_r values.[61] So, as sources remove vinyl chloride with a control efficiency equal to the F_r value, they will also be reducing other non-vinyl chloride organic HAP in the wastewater by an amount equal to the F_r values for those HAP (as steam stripping indiscriminately controls all organic HAP). This means that the effectiveness of stream stripping for 23 of the 33 non-vinyl chloride HAP will match the effectiveness of the control technology for vinyl chloride. For the remaining non-vinyl chloride organic HAP, while steam stripping will continue to remove the HAP in quantities approaching the F_r value, the amount of HAP remaining in the wastewater will be greater than if a similar amount of vinyl chloride entered the steam stripper. As such, an elevated concentration of hard-to-strip HAP in a wastewater stream does not necessarily imply the overall performance of the steam stripper is worse than the performance of a steam stripper controlling streams containing similar levels of vinyl chloride (or any of the other 23 HAP with F_r values equal to vinyl chloride's F_r value) but not containing those hard-to-strip HAP. This is especially true because the resin recipes do not include all HAP in each batch of polymer, as discussed previously. Nonetheless, all PVC and copolymer production process wastewater streams will contain vinyl chloride. As such, sources that demonstrate the greatest reductions in vinyl chloride represent those sources with the most effective steam stripping systems. Thus, the standards demonstrate total non-vinyl chloride emission reductions reflective of the best performing sources, so long as the EPA bases the vinyl chloride emission limits on the best performing sources, as the CAA requires.

The EPA notes that while the Agency is not finalizing the proposed changes to the major source vinyl chloride emission limits for PVC and copolymer production process wastewater at this time, the current vinyl chloride emission limits (which have been in place for over a decade) consider the best performing sources with respect to the 2012 final rule. The EPA intends to review the proposed vinyl chloride limits and relevant comments in taking final action on the other reconsideration issues. The EPA will review and determine at that time if it is necessary to revise the standards.

4. What is the rationale for our final approach and final decisions for the new source wastewater emission limits?

The EPA is finalizing the revisions to the approach to regulating new major source total non-vinyl chloride organic HAP process wastewater emissions without change. Specifically, the EPA is finalizing the removal of the total non-vinyl chloride organic HAP process wastewater emission limit for new major PVC and copolymer production sources; the associated testing, monitoring, recordkeeping, and

[58] 40 CFR part 63, subparts F, G, and H; FFFF; PPP; and YY and 40 CFR part 61, subpart FF, respectively.

[59] The EPA developed a ''design steam stripper'' with certain operational and design criteria to assess the efficiency of steam stripping (*i.e.,* the F_r value) as a control option for process wastewater from SOCMI operations subject to the HON. 40 CFR 63.138(d) details the criteria. See document ID Nos. EPA–HQ–OAR–2002–0037–0666 and EPA–HQ–OAR–2002–0037–0664.

[60] *See Nat'l Lime Ass'n,* 233 F.3d at 639.

[61] *See* Document ID No. EPA–HQ–OAR–2002–0037–0681.

reporting requirements; and that vinyl chloride can serve as a surrogate for non-vinyl chloride organic HAP in PVC and copolymer production process wastewater, without change.

This action focuses on the removal of a regulatory barrier for new major source PVC and copolymer production manufacturers. The EPA is not taking final action on the proposed removal of the existing major source total non-vinyl chloride organic HAP process wastewater emission limit at this time. Although the EPA believes that the current new major source vinyl chloride wastewater emission limit ensures sufficient control of non-vinyl chloride organic HAP emissions, the current existing major source vinyl chloride emission limit for PVC and copolymer production process wastewater is 24 times larger than the equivalent emission limit for new major sources (6.8 ppmw vinyl chloride for existing major sources versus 0.28 ppmw vinyl chloride for new major sources). With vinyl chloride acting as a surrogate, this corresponds to potentially 24 times more non-vinyl chloride organic HAP emissions from existing major sources than from new major sources. Although the total existing source non-vinyl chloride organic HAP concentration in the process wastewater must remain below 110 ppmw, the non-vinyl chloride organic HAP emission limit is 16 times greater than the vinyl chloride emission limit. Given that steam stripping removes a similar fraction of HAP for 26 of the 33 non-vinyl chloride organic HAP in PVC process wastewater, if sources are controlling vinyl chloride to just below the existing source emission limit (*i.e.,* 6.8 ppmw), and there are similar amounts of vinyl chloride as other organic HAP in the process wastewater, then wastewater streams at existing major sources could contain 16 organic HAP with concentrations up to 24 times greater than equivalent wastewater streams at new major sources. As such, it is appropriate for existing major sources to continue to test, monitor, and report total non-vinyl chloride organic HAP concentrations in process wastewater and to comply with the associated emission limit at this time. The EPA notes that existing sources have complied with the current existing source vinyl chloride and total non-vinyl chloride organic HAP process wastewater emission limits for over a decade.

Similarly, the EPA is not taking final action on removing the non-vinyl chloride organic HAP process wastewater monitoring requirements for area source PVC and copolymer production manufacturers. The area source vinyl chloride process wastewater emission limits are 7.5 times greater than the new major source vinyl chloride process wastewater emission limit (2.1 ppmw vinyl chloride for new and existing area sources versus 0.28 ppmw for a new major source). This corresponds to potentially 7.5 times more emissions per HAP from area source process wastewater as compared to similar streams at a new major source. In addition, although the EPA rescinded the total non-vinyl chloride organic HAP process wastewater emission limits with the 2015 Final Rule, the NESHAP has required area sources to monitor and report total non-vinyl chloride organic HAP concentrations in process wastewater for more than a decade.[62] As sources have continued the monitoring without major adverse effect, the EPA anticipates continuing to test, monitor, and report total non-vinyl chloride organic HAP concentrations will not be burdensome. Therefore, the EPA believes it is appropriate for area PVC and copolymer production sources to continue monitoring and reporting total non-vinyl chloride organic HAP concentrations at this time.

The EPA is also not taking final action on the proposed revisions to the major source vinyl chloride process wastewater emission limits at this time. The EPA continues to evaluate the comments on the 2020 Proposal and the Agency's identification of the best performing sources with respect to process wastewater. The EPA intends to make final determinations on whether it is appropriate to remove the total non-vinyl chloride organic HAP process wastewater emission limit for existing major sources, revise the vinyl chloride emission limits for new and existing major sources, and remove the associated total non-vinyl chloride organic HAP testing and monitoring requirements in addressing the other aspects of the proposed reconsideration at a later date.

C. What are the effective and compliance dates of the standards?

CAA section 112(i) and 5 United States Code (U.S.C.) 801(3) provide that for the finalized requirements, all new affected sources that commenced construction after May 20, 2011, must comply with all requirements under CAA section 112(d)(2), (3), (6), and 112(h) by November 9, 2026, or upon startup, whichever is later.

[62] 80 FR 5938 (February 4, 2015).

IV. Summary of Environmental and Economic Impacts

A. What are the affected sources?

While no new PVC sources have become operational since the 2012 Final Rule, the EPA is aware that an industry stakeholder has expressed interest in potentially developing, constructing, and operating a new PVC manufacturing facility within the next decade. If constructed, this final rule could impact such a new facility. The EPA approximated the impacts of reducing the testing, monitoring, recordkeeping, and reporting requirements in the rule to provide a conservative estimate of this action's cost-savings on a per facility basis (see section IV.C of this preamble for additional details).

B. What are the air quality impacts?

The EPA does not expect any air quality impacts as a result of this rule, as there will be no change to the total emissions from the PVC and Copolymer Production source category. This action does not affect existing major PVC and copolymer production sources, and so there will be no emission changes from currently operating facilities. While this action will affect new major sources (*i.e.,* sources that commenced construction after May 20, 2011), vinyl chloride will act as a surrogate for non-vinyl chloride organic HAP, and the EPA is not revising the new major source vinyl chloride emission limit. In addition, the EPA is unaware of any new sources currently subject to the rule. As such, there will be no changes to the potential vinyl chloride and non-vinyl chloride organic HAP emissions if a new source becomes operational.

The EPA notes that if stakeholders construct a new PVC and copolymer production facility and it becomes operational, the sector's HAP emissions will increase. However, the EPA cannot speculate on the potential impacts of emissions that may never occur. As such, the EPA does not anticipate any immediate impacts to human health as a consequence of this final rule. If stakeholders construct a new facility and it becomes operational, the EPA will consider the associated emissions when conducting future rulemakings.

C. What are the costs?

The EPA does not anticipate any operational changes for existing PVC and copolymer manufacturing facilities to accommodate the revisions in this final action. As such, existing sources will incur no costs as a result of this final action. In addition, as the EPA is unaware of any new sources currently subject to the rule, new sources will also

incur no cost as a result of this final action. Thus, this action will have no immediate cost impacts.

However, if a new PVC and copolymer production facility becomes operational, the EPA estimates owners and operators would save approximately $2,900 in initial capital/startup costs as well as an estimated $30,000 in annual costs (both in 2025 dollars) compared to the facility's costs if it became operational after May 20, 2011, but prior to this final action due to the reductions in the non-vinyl chloride organic HAP testing, monitoring, recordkeeping, and reporting requirements the Agency is finalizing with this action.

The EPA calculated these cost savings using information from the ICR supporting statement, assuming one respondent (see section V.C of this preamble for additional details).[63] The EPA estimates that the costs for initial total non-vinyl chloride organic HAP testing for stripped wastewater and uncontrolled wastewater are $820 and $2,100, respectively. A new major source subject to the requirements in this final rule would no longer incur those costs. In addition, a new major source would no longer need to conduct monthly total non-vinyl chloride organic HAP monitoring for treated wastewater streams (resulting in $9,800 saved annually) or annual monitoring for untreated wastewater streams ($2,100 saved annually).

Also, new major sources subject to the requirements in this final rule would save on labor costs. The EPA estimated that sampling would require approximately 4 hours per sample and two samples per wastewater stream. Using labor rates from the United States Department of Labor, Bureau of Labor Statistics and inflating them by 110 percent to account for varying industry wage rates and the additional overhead business costs, the EPA estimated that new major sources would save approximately $18,000 in labor costs per year while incurring a one-time cost of $2,000 to read and understand this final action.[64] Finally, the EPA estimated that new major sources would save approximately $1,900 per year in recordkeeping costs due to no longer having to keep, retain, or report total non-vinyl chloride organic HAP concentrations in process wastewater.

D. What are the benefits?

This action removes a regulatory barrier affecting the potential construction of new major source PVC and copolymer production manufacturing facilities. By removing this barrier, the EPA is addressing feasibility concerns and reducing overall regulatory burden by simplifying the NESHAP without increasing the potential total non-vinyl chloride organic HAP emissions from process wastewater from a newly constructed PVC and copolymer production plant.

E. What are the economic impacts?

The EPA anticipates no emission or air quality impacts and no qualitative or quantitative changes in health benefits. Therefore, there are no estimated monetized health or emissions impacts, and the potential costs detailed in section IV.C of this preamble are the only potential economic impacts of this final action.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders is available at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is considered an Executive Order 14192 deregulatory action. For regulatory accounting purposes, this action will have no immediate cost impacts as it affects no currently operating sources. However, if a new source becomes operational, the EPA anticipates this action will save the source approximately $2,900 in capital/startup costs and $30,000 in annual costs. Details on the potential cost savings of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action (see section IV of this preamble).

C. Paperwork Reduction Act (PRA)

The EPA submitted the information collection activities in this rule to OMB for approval under the Paperwork Reduction Act (PRA). OMB has assigned EPA ICR number 2432.08 to the ICR document that the EPA prepared. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The EPA is finalizing amendments to the PVC NESHAP to remove the new major source total non-vinyl chloride organic HAP process wastewater emission limit and the associated testing and monitoring requirements from the PVC NESHAP. The EPA is also finalizing that vinyl chloride can act as a surrogate for non-vinyl chloride organic HAP in PVC and copolymer production process wastewater. The EPA is no longer collecting this information as it is no longer necessary to ensure compliance with the PVC NESHAP. The EPA notes that the Agency does not anticipate that any new sources will become operational in the next 3 years. As such, there will be no respondents impacted by this ICR, resulting in no cost savings at this time.

Respondents/affected entities: Owners or operators of PVC and PVC copolymer production facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart HHHHHHH).

Estimated number of respondents: 0.

Frequency of response: Initially and semiannually.

Total estimated burden: 0 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: Average annual cost is $0 per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities in this final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA). This action will not impose any requirements on small entities, as this is a deregulatory action affecting only new major sources.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million (adjusted annually for inflation) or more (in 1995 dollars) as described in the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The EPA estimates that

[63] *See* Docket ID No. EPA–HQ–OAR–2002–0037.

[64] *https://www.bls.gov/oes/2025/may/oessrci.htm.*

costs involved in this action will not exceed $191 million in 2025 dollars ($100 million in 1995 dollars adjusted for inflation using the GDP implicit price deflator) or more in any one year.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. None of the facilities that the EPA has identified as being affected by this action are owned or operated by Tribal governments or located within Tribal lands. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action does not affect existing sources. While this action does affect new sources as defined in the 2012 Final Rule (sources that commenced construction after May 20, 2011), the EPA is not aware of any such currently operating source. If a new source were to come online, this action would not affect the process wastewater emissions, as the new source would still need to meet the vinyl chloride emission limit and the control technology (*i.e.,* steam stripping) controls all HAP indiscriminately. With no immediate emissions impacts, this action will not disproportionately affect children's health.

The EPA's Policy on Children's Health applies to this action. The EPA did not conduct an analysis of children's environmental health for this final action as there are no immediate emissions impacts. Thus, the EPA expects no changes in HAP exposure to infants and children as a result of this action.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Congressional Review Act (CRA)

This action is subject to the Congressional Review Act (CRA), and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Lee Zeldin,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency amends part 63 of title 40, chapter I, of the Code of Federal Regulations as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart HHHHHHH—National Emission Standards for Hazardous Air Pollutant Emissions for Polyvinyl Chloride and Copolymers Production

■ 2. Amend § 63.11875 by revising paragraphs (b) and (c) and adding paragraph (e) to read as follows:

§ 63.11875 When must I comply with this subpart?

* * * * *

(b) Except as specified in paragraph (e) of this section, if you start up a new affected source on or before April 17, 2012, you must achieve compliance with the provisions of this subpart no later than April 17, 2012. On or after April 17, 2012, any such new affected source is not subject to the provisions of 40 CFR part 61, subpart F.

(c) Except as specified in paragraph (e) of this section, if you start up a new affected source after April 17, 2012, you must achieve compliance with the provisions of this subpart upon startup of your affected source. Upon startup, any such new affected source is not subject to the provisions of 40 CFR part 61, subpart F.

* * * * *

(e) All new affected sources that commenced construction or reconstruction after May 20, 2011, are subject to the provisions in § 63.11880(d) beginning on November 9, 2026, or initial startup, whichever is later.

■ 3. Amend § 63.11880 by adding paragraph (d) to read as follows:

§ 63.11880 What emission limits, operating limits and standards must I meet?

* * * * *

(d) Beginning no later than the compliance dates specified in § 63.11875(e), new affected sources, as defined in § 63.11870, are no longer required to comply with item 4.b of table 2 to this subpart for process wastewater and the associated total non-vinyl chloride organic HAP testing, monitoring, recordkeeping, and reporting requirements specified in §§ 63.11965(a) through (d), 63.11970(a) and (b), and 63.11975(b) and (c).

■ 4. Amend § 63.11900 by revising paragraphs (c) and (d) to read as follows:

§ 63.11900 By what date must I conduct initial performance testing and monitoring, establish any applicable operating limits and demonstrate initial compliance with my emission limits and work practice standards?

* * * * *

(c) For new or reconstructed affected sources, you must establish any applicable operating limits required in § 63.11880, and demonstrate initial compliance with the emission limits and standards specified in tables 2 and 3 to this subpart, as applicable, no later than 180 days after the compliance date specified in § 63.11875 or within 180 days after startup of the source, whichever is later, according to § 63.7(a)(2)(ix).

(d) For new and reconstructed affected sources, you must demonstrate initial compliance with any applicable work practice standards required in § 63.11880 no later than the compliance date specified in § 63.11875 and according to the applicable provisions in § 63.7(a)(2).

* * * * *

■ 5. Revise § 63.11965 to read as follows:

§ 63.11965 What are my general compliance requirements for wastewater?

(a) *General requirements for process wastewater.* Except as specified in § 63.11880(d), the concentration of vinyl chloride and total non-vinyl chloride organic HAP in each process wastewater stream containing greater than the limits specified in table 1 or 2 to this subpart, measured immediately as it leaves a piece of process equipment and before being mixed with any other process wastewater stream, must be reduced to the limits specified in table 1 or 2 to this subpart. The applicable limits in table 1 or 2 to this subpart must be met before the process wastewater stream is mixed with any other process wastewater stream containing vinyl chloride or total non-vinyl chloride organic HAP concentrations less than the applicable limits specified in table 1 or 2 to this subpart, before being exposed to the atmosphere, and before being discharged from the affected source.

(b) *Initial determination of process wastewater streams that need to be treated.* Except as specified in § 63.11880(d), you must determine which process wastewater streams require treatment as specified in paragraphs (b)(1) and (2) of this section and meet the requirements of paragraphs (c) and (d) of this section.

(1) You must collect process wastewater samples as specified in paragraphs (b)(1)(i) and (ii) of this section.

(i) For treated process wastewater streams, you must collect process wastewater samples at the outlet of the treatment process and before the process wastewater stream is mixed with any other process wastewater stream containing vinyl chloride or total non-vinyl chloride organic HAP concentrations less than the applicable limits specified in table 1 or 2 to this subpart, before being exposed to the atmosphere, and before being discharged from the affected source.

(ii) For untreated process wastewater streams, you must collect process wastewater samples at the location immediately as the stream leaves a piece of process equipment, before being mixed with any other process stream or process wastewater stream, before being exposed to the atmosphere, and before being discharged from the affected source.

(2) You must measure the concentration of vinyl chloride and total non-vinyl chloride organic HAP using the test methods and procedures specified in § 63.11980.

(c) *Requirements for process wastewater streams that must be treated.* Except as specified in § 63.11880(d), you must treat each process wastewater stream that has a vinyl chloride or total non-vinyl chloride organic HAP concentration equal to or greater than the applicable emission limits specified in table 1 or 2 to this subpart as determined pursuant to paragraph (b) of this section, to reduce the concentration below the applicable emission limits specified in table 1 or 2 to this subpart. You must route wastewater streams through hard-piping to the treatment process and route the vent stream from the treatment process to a closed vent system and control device meeting the requirements of §§ 63.11925 through 63.11950. You must also meet the initial and continuous compliance requirements specified in §§ 63.11970(a) and 63.11975(a) and (b).

(d) *Requirements for process wastewater streams that do not need to be treated.* Except as specified in § 63.11880(d), for each process wastewater stream that has a vinyl chloride or total non-vinyl chloride organic HAP concentration less than the applicable emission limits specified in table 1 or 2 to this subpart as determined pursuant to paragraph (b) of this section, you must meet the initial and continuous compliance requirements specified in §§ 63.11970(b) and 63.11975(c).

(e) *Maintenance wastewater.* You must comply with the requirements specified in § 63.105.

(f) *Determination of total non-vinyl chloride organic HAP.* If you are subject to the emission limits specified in table 1 or 2 to this subpart, then you must develop a facility-specific list of HAP that are expected to be present in each process wastewater stream at your PVCPU and comply with paragraph (f)(1) of this section. This list must be continuously updated and must be available for inspection by the Administrator. This list must include the identification of each HAP expected to be present in each process wastewater stream, and the CAS number for each HAP.

(1) For the purposes of demonstrating initial and continuous compliance as required in §§ 63.11970 and 63.11975, you must meet the requirements specified in paragraphs (f)(1)(i) and (ii) of this section.

(i) You must analyze each process wastewater sample for all table 10 HAP using the test methods specified in § 63.11980(a)(2) and (3).

(ii) You must also analyze each process wastewater sample for any HAP that are not table 10 HAP but are expected to be present in that sample based on your facility-specific list of HAP using the appropriate test method specified in § 63.11980(a)(2).

(2) [Reserved]

■ 6. Revise § 63.11970 to read as follows:

§ 63.11970 What are my initial compliance requirements for process wastewater?

(a) *Demonstration of initial compliance for process wastewater streams that must be treated.* Except as specified in § 63.11880(d), for each process wastewater stream that must be treated as specified in § 63.11965(b) and (c), you must conduct an initial performance test for the wastewater treatment process, measuring the concentration of vinyl chloride and total non-vinyl chloride organic HAP in the wastewater stream at the outlet of the wastewater treatment process before the wastewater is exposed to the atmosphere, mixed with any other process stream, and before being discharged from the affected facility, using the test method and procedures specified in § 63.11980(a).

(b) *Demonstration of initial compliance for process wastewater streams that are not required to be treated.* Except as specified in § 63.11880(d), for each process wastewater stream that has a vinyl chloride or total non-vinyl chloride organic HAP concentration less than the applicable emission limits specified in table 1 or 2 to this subpart, you must use the collection and measurement procedures specified in § 63.11965(b)(1)(ii) and (b)(2) to demonstrate initial compliance.

■ 7. Revise § 63.11975 to read as follows:

§ 63.11975 What are my continuous compliance requirements for process wastewater?

(a) For each process wastewater stream that must be treated as specified in § 63.11965(b) and (c), you must demonstrate continuous compliance as specified in paragraph (b) of this section. For each process wastewater stream for which you initially determine in § 63.11970(b) that treatment is not required, you must demonstrate continuous compliance as specified in paragraph (c) of this section.

(b) Except as specified in § 63.11880(d), for each process wastewater stream that must be treated according to § 63.11965(b) and (c), you must demonstrate continuous compliance with the emission limits specified in table 1 or 2 to this subpart

by following the procedures specified in paragraphs (b)(1) and (2) of this section.

(1) Following your demonstration of initial compliance in § 63.11970(a), make monthly measurements of the vinyl chloride and total non-vinyl chloride organic HAP concentrations using the procedures and methods specified in § 63.11965(b)(1)(i) and (b)(2).

(2) You must demonstrate continuous compliance with the emission limits in table 1 or 2 to this subpart on a monthly basis, using the monthly concentration measurement specified in paragraph (b)(1) of this section.

(c) Except as specified in § 63.11880(d), for each wastewater stream for which you initially determine in § 63.11970(b) that treatment is not required, you must demonstrate continuous compliance as specified in paragraphs (c)(1) and (2) of this section.

(1) Conduct annual performance tests, measuring the vinyl chloride and total non-vinyl chloride organic HAP concentrations using the procedures and methods specified in § 63.11965(b)(1)(ii) and (b)(2).

(2) If any annual performance test conducted as specified in paragraph (c)(1) of this section results in a concentration of vinyl chloride or total non-vinyl chloride organic HAP in the process wastewater stream that is greater than or equal to the applicable emission limits in table 1 or 2 to this subpart, then you must meet the requirements of § 63.11965(c).

■ 8. Amend § 63.11980 by revising paragraphs (a)(1) and (b) to read as follows:

§ 63.11980 What are the test methods and calculation procedures for process wastewater?

(a) * * *

(1) You must conduct performance tests during worst-case operating conditions for the PVCPU when the process wastewater treatment process is operating as close as possible to maximum representative operating conditions. If the wastewater treatment process will be operating at several different sets of operating conditions, you must supplement the testing with additional testing, modeling or engineering assessments to demonstrate compliance with the emission limits.

* * * * *

(b) *Method for calculating total non-vinyl chloride organic HAP concentration.* If you are subject to the emission limits specified in table 1 or 2 to this subpart, then for each process wastewater stream analyzed using the methods specified in paragraph (a) of this section, calculate the sum of the measured concentrations of each HAP analyzed as required in § 63.11965(f)(1) by using the following equation:

Equation 1 to Paragraph (b)

$$C_{TNVCH} = \sum_{i=1}^{n} C_i$$

Where:

C_{TNVCH} = Concentration of total non-vinyl chloride organic HAP, in parts per million by weight (ppmw).

C_i = Concentration of individual HAP present in the sample analyzed pursuant to § 63.11965(f)(1) excluding vinyl chloride, in ppmw, where a value of zero should be used for any HAP concentration that is below the detection limit.

■ 9. Amend § 63.11985 by revising paragraphs (a)(8)(ii) and (b)(8) to read as follows:

§ 63.11985 What notifications and reports must I submit and when?

* * * * *

(a) * * *

(8) * * *

(ii) You must include results of the initial sampling used to determine initial compliance with the vinyl chloride and, if applicable, total non-vinyl chloride organic HAP limits in table 1 or 2 to this subpart.

* * * * *

(b) * * *

(8) For wastewater operations, you must include the results of monthly vinyl chloride and, if applicable, monthly total non-vinyl chloride organic HAP concentration results for each process wastewater stream discharged from the affected source that did not meet the process wastewater emission limits in table 1 or 2 to this subpart.

* * * * *

■ 10. Amend § 63.11990 by:

■ a. Revising paragraph (i) introductory text and paragraph (i)(4); and

■ b. Removing paragraph (i)(5).

The revisions read as follows:

§ 63.11990 What records must I keep?

* * * * *

(i) *Process wastewater.* For treatment processes, you must maintain the records specified in paragraphs (i)(1) through (4) of this section.

* * * * *

(4) All testing data, including monthly measurements of the concentrations of vinyl chloride, and if applicable, the concentration of total non-vinyl chloride organic HAP in each process wastewater stream required to be measured, as specified in § 63.11975.

* * * * *

■ 11. Amend table 2 to subpart HHHHHHH of part 63 by revising the entry ''4. Process Wastewater'' and adding footnote c to read as follows:

TABLE 2 TO SUBPART HHHHHHH OF PART 63—EMISSION LIMITS AND STANDARDS FOR NEW AFFECTED SOURCES

For this type of emission point . . .	And for this air pollutant . . .	And for an affected source producing this type of PVC resin . . .	You must meet this emission limit . . .
* *	* *	* *	*
4. Process Wastewater	a. Vinyl chloride	All resin types	0.28 ppmw.
	b. Total non-vinyl chloride organic HAP [c].	All resin types	0.018 ppmw.
* *	* *	* *	*

[c] For new affected sources, as defined in § 63.11870, the total non-vinyl chloride organic HAP emission limit does not apply as specified in § 63.11880(d).

[FR Doc. 2026–22788 Filed 11–6–26; 8:45 am]

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Proposed Rules

Federal Register
Vol. 91, No. 215
Monday, November 9, 2026

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 986

[Doc. No. AMS–SC–25–0881]

Pecans Grown in the States of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas; Changes to Membership and Handling Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement recommendations from the American Pecan Council (Council) to eliminate regional and size designations for sheller members, modify the nomination process for sheller members, adjust the requirements of the inter-handler transfer report form, and establish a late fee and interest charges for unpaid assessments. The rule will also propose two technical corrections.

DATES: Comments must be received by December 9, 2026.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments can be sent to the Docket Clerk, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237. Comments can also be sent to the Docket Clerk electronically by email: *MarketingOrderComment@usda.gov* or via the internet at: *https://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register**. Comments submitted in response to this proposed rule will be included in the record, will be made available to the public, and can be viewed at: *https://www.regulations.gov.* Please be advised that comments are posted to *regulations.gov* without change.

FOR FURTHER INFORMATION CONTACT: Jennie M. Varela, Marketing Specialist, or Christian D. Nissen, Chief, Southeast Region Branch, Market Development Division, Specialty Crops Program, AMS, USDA; telephone: (863) 324–3375; or email: *Jennie.Varela@usda.gov* or *Christian.Nissen@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes to amend regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674) (the Act), amending Marketing Order No. 986 (7 CFR part 986) (the Order), which regulates the handling of pecans grown in Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas. The Council locally administers the Order and is comprised of growers and handlers of pecans operating within the production area, as well as one accumulator member and one public member.

This proposed action is exempt from the Office of Management and Budget (OMB) review process required by Executive Order 12866. This proposed rule would amend existing Marketing Order No. 986, as amended (7 CFR part 986), ''Pecans Grown in the States of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas,'' and is necessary for the continued operation of the Order. Additionally, this proposed action is exempt from the requirements of Executive Order 14192, ''Unleashing Prosperity Through Deregulation,'' pursuant to section 5(c).

This proposed rule has been reviewed under Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' which requires Federal agencies to consider whether their rulemaking actions would have Tribal implications. The Agricultural Marketing Service (AMS) has determined this proposed rule is unlikely to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

This proposed rule has been reviewed under Executive Order 12988, ''Civil Justice Reform.'' This proposed rule is not intended to have a retroactive effect.

This proposed rule would eliminate regional and size designations for sheller members, modify the nomination process for sheller members, adjust the requirements of the inter-handler transfer report form, and establish a late fee and interest charges for unpaid assessments. In addition, this proposed rule would make administrative corrections to § 986.178 to remove an inadvertently duplicated paragraph and a paragraph that was previously incorporated under § 986.177(b).

Section 986.45 of the Order establishes Council membership, with two sheller seats currently allocated to each of the three regions as defined in § 986.33: Eastern, Central, and Western. Section 986.45(b)(2) provides that each region is represented by two sheller seats, with one seat allocated to a sheller who handles more than 12.5 million pounds of pecans per year, and one seat allocated to a sheller handling 12.5 million pounds or less of pecans per year. Each member has an alternate. Section 986.45(c) also authorizes the Council to recommend, with the approval of the Secretary, changes to the requirements for grower and sheller seats to accommodate changes within the industry.

Section 986.46 of the Order outlines the nomination procedures for the Council and § 986.46(b)(8) authorizes the Council to recommend, subject to the approval of the Secretary, changes to the member nomination process. Section 986.58 authorizes the Council to recommend, with the approval of the Secretary, reapportionment and reestablishment of the regions specified in § 986.33.

The Council and Order's activities are funded through handler assessments as authorized in § 986.61. Each handler in the production area pays a pro rata share based on their weight of inshell pecans handled. Section 986.61(g) authorizes the Council, with the approval of the Secretary, to establish a late payment and/or interest charge when assessments are not paid on time. The current assessment rates and due

dates are codified in §§ 986.161 and 986.177, respectively, of the Order's rules and regulations. Assessments are due at the time of reporting and monthly reports are due on the 10th day of the month following the month the pecans were handled.

Section 986.62 provides for the inter-handler transfers of pecans and allows for the transferring handler to shift the reporting and payment of assessments for these pecans to the receiving handler. Under § 986.162, handlers are required to file reports the month following the first transfer between two handlers to indicate a transfer was completed during the season, regardless of the frequency of transfers or weight transferred.

Pursuant to the authorities listed above, the Council recommended revising the rules and regulations under the Order. The Council met on August 14, 2025, and unanimously recommended, with a vote of 14 in favor and none opposed, to eliminate the regional and size designation requirements for sheller seats and modify the nomination process to reflect these changes; to revise the inter-handler transfer report from an annual to monthly submission and include information on the weight and type of inshell of pecans transferred; and to establish a five percent one-time late fee for unpaid assessments and a one percent monthly interest charge on any outstanding balances. The Council recommended these changes to increase sheller representation on the Council, improve data collection accuracy, and encourage timely payment of assessments.

During the original promulgation of the Order in 2016 (81 FR 51298, August 4, 2016), representative membership was a principal issue. As a result, Council membership structure was established to represent distinctive production areas as well as maintain a balance between grower and handler interests. To represent handlers, the Order included six regional seats for shellers and one at-large seat for accumulators. Understanding the dynamic nature of the industry, the Order included provisions for reapportionment and reestablishment if needed in the future.

Since the current membership requirements were established in 2016, the pecan industry has experienced consolidation and change, particularly among shelling operations. As of August 2025, fewer than 30 shellers remain in business, down from 50 in 2016. Due to the decline in the number of shellers, the Council has experienced challenges filling sheller member positions during its nomination cycles, resulting in several vacancies on the Council over the last few years.

When sheller seat vacancies occur, the Council believes it lacks the benefit of additional perspectives in its deliberations. The Council considered solutions to resolve the issue of sheller vacancies, including reducing the weight of inshell pecans required to be considered a large sheller. However, after reviewing the breakdown of active shellers, the Council determined this adjustment would not fully address the problem and that there would still be a shortage of eligible shellers to fill available seats.

At the August 14, 2025, meeting, the Council indicated that many of the remaining shellers now source pecans from multiple regions, operating multiple facilities with some in multiple regions. These changes make the regional affiliations for sheller members required under the Order less applicable. Further, the distribution of shellers throughout the regions is not uniform, making filling seats in some regions more challenging.

During its discussions, the Council also determined that the large and small designations on the sheller seats reduced the number of candidates available for nomination. Because there are fewer large shellers than small, the Council reported that it was difficult finding enough large shellers to fill all the available large sheller member and alternate seats. Consequently, the Council determined that the three regions and size distinctions are no longer representative of the sheller portion of the industry and impede the Council's nominations process.

Accordingly, this proposal would combine the three sheller regions into one sheller region, which would consist of all states within the production area, and remove the large and small sheller seat allocations. All six sheller seats would be open to any qualified sheller, regardless of location or size. This is similar to the accumulator seat on the Council, which is an at-large position that is not limited by location or size. The Council believes these proposed changes would help increase participation on the Council and ensure full sheller representation. During Council discussions on August 14, 2025, it was noted the National Pecan Shellers Association had also expressed support for the proposal.

Implementing these changes would require changes to the sheller member nomination process. Therefore, this proposal would adjust the nomination process to reflect one region with six sheller member seats and six alternate seats. All shellers would be able to nominate and vote on all seats regardless of their size or location. To implement this proposed change, the Council also recommended staggering the initial terms of the new sheller seats, with half serving two-year terms of office and the other half serving the full four-year term of office, so that half of the sheller seats will be up for nomination every two years. Accordingly, this proposed rule would add §§ 986.145 and 986.146 to the administrative provisions under the Order's rules and regulations to establish a single region for sheller seats and a modified nomination process, respectively.

Because the grower segment of industry has not experienced the same level of changes that the sheller segment has, these changes would pertain solely to the sheller seats and nomination process. Thus, the proposal would not redefine the existing regions for growers or modify the grower nomination qualifications and process.

The Order also authorizes specific reporting requirements, with handlers reporting pecans received, shipped, and in inventory to the Council to provide valuable aggregated data to the industry. Assessments are paid according to the reports of pecans received by handlers. The Order's inter-handler transfer provisions allow handlers to shift responsibility for reporting and payment of assessments to another handler when transferring loads of pecans. Having this flexibility has been particularly useful for small entities selling to larger handlers.

The inter-handler transfer provides a way to document the transfer of pecans, ensure transferred pecans are reported as received, and that the associated assessments are paid. Council members agreed these provisions are useful to handlers of all sizes, particularly when lots of pecans need to be redistributed to meet customer needs. Without this record, it would be difficult for the Council to verify which pecans have already been reported and assessed.

Currently, the Order requires the inter-handler transfer form, APC Form #4, to be submitted once during the season, in the month following the initial transfer between the handlers involved. In practice, however, the Council reported the submission of this report is frequently delayed. This creates difficulty for the Council when verifying assessments due and completing handler compliance audits, as there may have been transfers that have not yet been reported. Further, because the current reporting requirement does not include the weight

or type of inshell pecans transferred, the Council must conduct additional follow-up with handlers to determine if the proper assessments are being paid and to ensure the transferred pecans are not being overreported when tracking industry inventory.

During discussions on the issue, the Council reflected on the original intent of the inter-handler transfer report and determined that a monthly report documenting the handler parties involved, as well as the weight and type of inshell pecans transferred, would ensure proper and more accurate accounting of pecans handled and assessments paid. The Council anticipates this proposed change to § 986.162 would enable handlers to better maintain complete records, as required under the Order, as well as assist Council staff in identifying reporting discrepancies. Additionally, because transfers typically occur from November to February, for many handlers, this monthly reporting requirement would only apply to about four months of the year. The Council also noted that the proposed change would not be overly burdensome for handlers and their operations, as the report is completed using readily available information. Accordingly, on August 14, 2025, the Council unanimously recommended making the inter-handler transfer report due monthly and requiring that the weight and type of inshell pecans transferred be reported.

Regarding the timely payment of assessments, the Council reported that some handlers are repeatedly late in paying assessments. Chronic late payments increase administrative burden, disrupt cash flow, and force the Council to devote additional staff resources to collections. Currently, there are no consequences for late payments unless a full compliance case is filed with USDA for consideration of civil penalties, as would be warranted and appropriate under the Act. Although it does not wish to create a financial burden on the industry, the Council believes it is unfair to handlers paying on time to allow handlers who are late submitting their payments to incur no penalty.

To address this, the Council discussed adding a five percent one-time late fee for each occurrence of unpaid assessments that are 30 days past due, as well as a one percent monthly interest charge on the outstanding balance until paid. While late payment penalties and interest fees might be more burdensome on small handlers that are already experiencing cash flow problems, just as assessments are based on a pro rata share of the program's cost, the Council believes the proposed penalties should also apply proportionally. While it is an additional cost, the Council agreed this type of penalty would ensure fairness for all handlers, promote on-time assessment payments, and reduce Council resources spent managing delinquent handlers. The proposed late fee and interest charge would also be consistent with those in place for the industry's Federal research and promotion program. After discussing various options, including extending the allowable payment period, the Council unanimously recommended on August 14, 2025, implementing a five percent one-time late fee for each occurrence of assessments that are 30 days past due and a one percent monthly interest charge on the outstanding balance until paid. These requirements would be codified in a new § 986.163 of the Order's administrative provisions.

Additionally, this rule would also make administrative corrections to § 986.178. A final rule published in the **Federal Register** on April 8, 2020 (85 FR 19651, 19654), made changes to several reporting requirements prescribed under the Order, and inadvertently duplicated a paragraph in § 986.178 and failed to remove language from this section that was incorporated under § 986.177(b). This rule would remove paragraph (b) from § 986.178, which was inadvertently duplicated from paragraph (a) in the section, as well as remove paragraph (c), which was previously consolidated under § 986.177(b). These corrections are administrative in nature and would not have an effect on the other changes proposed in this rulemaking and would not alter reporting requirements.

Therefore, this proposed rule would revise the rules and regulations under the Order by eliminating the regional and size designation requirements for sheller seats and modifying the nomination process to reflect these changes; revising the inter-handler transfer report from an annual to monthly submission and to include information on the weight and type of inshell pecans transferred; and establishing a five percent one-time late fee for unpaid assessments and a one percent monthly interest charge on any outstanding balances. The proposal would also include administrative corrections to § 986.178 to remove an inadvertently duplicated paragraph and a paragraph that was previously incorporated under § 986.177(b).

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act are unique regulations in that they are brought about through group action of typically small entities acting on their own behalf.

There are approximately 4,500 growers of pecans in the production area and approximately 110 handlers subject to regulation under the Order. At the time this analysis was prepared, the Small Business Administration (SBA) defined small agricultural growers as those having annual receipts equal to or less than $3,750,000 (North American Industry Classification System (NAICS) code 111335, Tree Nut Farming) (13 CFR 121.201). Small agricultural service firms a were defined by the SBA as those having annual receipts equal to or less than $34,000,000 (NAICS code 115114, Postharvest Crop Activities).

Based on data from the National Agricultural Statistics Service (NASS), the average annual grower price for pecans utilized for processing during the 2023–2024 season was approximately $1.77 per pound. With a total utilization of 264,980,000 pounds for the 2023–2024 fiscal year, the total 2023–2024 value of the crop utilized for processing is estimated at $469,014,600 ($1.77 per pound multiplied by $264,980,000 pounds). Dividing the crop value by the estimated number of pecan growers yields an estimated average receipt per grower of $104,225 ($469,014,600 divided by 4,500 pecan growers). Thus, the majority of growers would be classified as small entities.

Based on AMS Market News shipping point and terminal market data for 2024 and 2025, AMS has determined a grower to handler price markup estimate of 25 percent. Adding this margin to the average grower price of $1.77 for in-shell pecans yields an estimated handler price of $2.21 per pound ($1.77 per pound multiplied by 0.25 equals $0.44, added to $1.77). With a total 2023–2024 utilization of 264,980,000 pounds, the total value of handled pecans for the fiscal year was $585,605,800 ($2.21 per pound multiplied by 264,980,000 pounds). Dividing this figure by the number of

handlers yields an estimated average annual handler receipt of $5,323,689 ($585,605,800 divided by 110 pecan handlers). Thus, the majority of handlers would be classified as small entities.

This proposed rule would eliminate regional and size designations for sheller members, modify the nomination process for sheller members, adjust the requirements of the inter-handler transfer report form, and establish a late fee and interest charges for unpaid assessments. In addition, this proposed rule would include administrative corrections to § 986.178 to remove an inadvertently duplicated paragraph and a paragraph that was previously incorporated under § 986.177(b). At its August 14, 2025, meeting, the Council unanimously voted 14 in favor, and none opposed to recommend the proposed changes.

Apart from imposing late fees and interest charges for unpaid assessments, it is not anticipated that this proposed rule would result in any additional cost for the industry. This proposed rule would combine the three sheller regions into one region and remove the designated seats for small and large shellers. While this proposal would modify the nomination process for sheller seats, it would not prohibit any qualified sheller, regardless of size or location, from seeking nomination on the Council. The Council believes this change would help increase sheller representation and participation and create opportunities for more shellers to serve on the Council. Grower seats and regions would remain unchanged.

The proposed rule would also modify the reporting requirements for inter-handler transfers. Rather than be submitted annually, the report would instead be submitted monthly and would include the weight and type of inshell pecans transferred. While this could increase the reporting burden for some handlers, this change would contribute to ensuring the Council's monthly industry reports are accurate and assist with program compliance, which would be beneficial to the industry. Additionally, because transfers typically occur from November to February, the monthly reporting requirement for handlers would apply to about four months of the year. The Council also noted that the proposed change would not be overly burdensome for handlers and their operations, as the report is completed using readily available information. The Council anticipates this change would enable handlers to better maintain complete records, as required under the Order, as well as assist Council staff in identifying reporting discrepancies.

Finally, the proposed rule would add a five percent one-time late fee on assessments that are more than 30 days past due and a one percent monthly interest charge on the outstanding balance until paid. However, these additional costs would only apply to those handlers who are not timely complying with the Order's assessment requirements. Handler assessments represent a pro rata share of the costs of operating the Order and are applied based on the weight of inshell pecans handled. Similarly, the penalties for delinquent assessments would be proportional to the weight of inshell of pecans handled and assessments due. The Council anticipates that establishing these penalties would help deter nonpayment of assessments.

The Council considered alternatives to the recommended changes made at its August 14, 2025, meeting. Regarding sheller membership, the Council previously recommended removing the regional distinctions but leaving the large and small seat designations. However, Council records indicated such a change would not solve the issue of repeated vacancies, as few remaining shellers meet the large sheller definition.

In reviewing the inter-handler transfer provisions, the Council considered removing the inter-handler transfer reporting requirement altogether but determined that small handlers may have difficulty complying with the additional reporting and tracking of assessments due on their own. The Council also considered leaving the report unchanged but found with more frequent reporting and the inclusion of the weight and type of inshell pecans transferred, the Council could improve its compliance processes and industry reports.

When discussing penalties for delinquent assessments, the Council considered changing the due dates for assessments, applying a longer period before assessing penalties, or not taking any additional action. However, the Council determined that these alternatives would not encourage timely payments or resolve the issue of unpaid assessments. For these reasons, the Council rejected all other alternatives.

Council meetings are widely publicized throughout the pecan industry. All interested persons are invited to attend meetings and participate in Council deliberations. Like all Council meetings, the August 14, 2025, meeting was a public meeting and all entities, both large and small, were able to express their views on these issues. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0291, ''Federal Marketing Order for Pecans.'' This proposed rule would require changes to the Council's existing forms. Specifically, the proposed rule would make nominal adjustments to two sheller nomination forms, Forms SC–308 and SC–310, and the inter-handler transfer form, APC Form #4. The proposed changes to the sheller nomination forms would not increase the reporting burden. For the inter-handler transfer report, the changes would be minor and the currently approved burden for the form would be minimally increased by the proposed changes. The revised forms have been submitted to OMB for approval.

This proposed rule, if finalized, may impose some additional reporting or recordkeeping requirements on either small or large pecan handlers. However, the Council anticipates the changes to APC Form #4 and the inter-handler transfer reporting requirements would help ensure the Council's monthly industry reports are accurate and assist with program compliance, which would be beneficial to the industry. Additionally, because transfers typically occur from November to February, for many handlers, this monthly reporting requirement would only apply to about four months of the year. The Council also noted that the proposed change would not be overly burdensome for handlers and their operations, as the report is completed using readily available information. The Council anticipates this change would enable handlers to better maintain complete records, as required under the Order, as well as assist Council staff in identifying reporting discrepancies. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services and for other purposes.

AMS has not identified any relevant Federal rules that duplicate, overlap, or conflict with this proposed rule.

After consideration of all relevant material presented, including the information and recommendations submitted by the Council and other available information, AMS has determined that this proposed rule would be consistent with and would effectuate the purposes of the Act.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. All written comments timely received will be considered before a final determination is made on this action.

List of Subjects in 7 CFR Part 986

Marketing agreements, Nuts, Pecans, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, AMS proposes to amend 7 CFR part 986 as follows:

PART 986—PECANS GROWN IN THE STATES OF ALABAMA, ARKANSAS, ARIZONA, CALIFORNIA, FLORIDA, GEORGIA, KANSAS, LOUISIANA, MISSOURI, MISSISSIPPI, NORTH CAROLINA, NEW MEXICO, OKLAHOMA, SOUTH CAROLINA, AND TEXAS

■ 1. The authority citation for part 986 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Add § 986.145 to subpart B to read as follows:

§ 986.145 Reapportionment and reestablishment of sheller regions.

Pursuant to § 986.58, beginning with the first nomination cycle following the effective date of this section, the sheller region shall include all states in the production area. This region shall have six at-large sheller members and alternates.

■ 3. Add § 986.146 to subpart B to read as follows:

§ 986.146 Nomination procedure for sheller seats.

Beginning with the first nomination cycle following the effective date of this section, nomination of sheller members and alternates shall follow the procedure set forth in this section. All nominees must meet the requirements set forth in § 986.48.

(a) After nominations have been submitted to the Council using the provisions of § 986.46(b)(1), the Council shall mail to all known shellers within the production area a sheller ballot indicating the nominees for the sheller seats, along with voting instructions. Shellers may cast ballots on approved ballot forms either at meetings of shellers, by mail, or by email as designated by the Council. For ballots to be considered, they must be submitted on the approved forms with all required information, including signatures.

(b) Sheller Seats 1, 2, and 3 and their alternates will be selected for an initial two-year term, and Seats 4, 5, and 6 and their alternates will be selected for a four-year term of office. Following the initial selection, sheller member and alternate seats will continue the rotation with half of the sheller member and alternate seats expiring every two years, with members and alternates serving a four-year term of office.

■ 4. Revise § 986.162 to read as follows:

§ 986.162 Inter-handler transfers.

Pursuant to § 986.62, handlers shall submit to the Council, by the tenth day of the month following the month of transfer, a report of inter-handler transfer. Should the tenth day of the month fall on a weekend or holiday, reports are due by the first business day following the tenth day of the month. The transfer shall be reported to the Council on APC Form 4 and contain the following information:

(a) Month of transfer;

(b) Weight and type of inshell pecans transferred;

(c) The names and signatures for both the transferring and receiving handler; and

(d) Handler assuming the reporting and assessment obligations on the pecans transferred.

■ 5. Add § 986.163 to read as follows:

§ 986.163 Delinquent assessments.

(a) Each handler shall submit assessments to the American Pecan Council monthly as required in § 986.177.

(b) A late payment charge will be imposed on any handler who fails to make timely remittance to the Council of the total assessments for which they are liable. The late payment will be imposed on any assessments not received within 30 calendar days of the date when assessments are due. This one-time late payment charge will be five percent of the assessments due before interest charges have accrued.

(c) In addition to the late payment charge, a one percent per month interest charge on the outstanding balance, including any late payment and accrued interest, will be added to any accounts for which payment has not been received within 30 calendar days of the date when assessments are due. Interest will continue to accrue monthly until the outstanding balance is paid to the Council.

■ 6. Revise § 986.178 to read as follows:

§ 986.178 Other reports.

Exports by country of destination. Handlers shall submit to the Council, by the tenth day of the month following the month of shipment, a report of exports. Should the tenth day of the month fall on a weekend or holiday, reports are due by the first business day following the tenth day of the month. The report shall be reported to the Council on APC Form 3 and contain the following information:

(a) The name and address of the handler;

(b) The month covered by the report;

(c) The total weight of pecans shipped for export, whether inshell, shelled, or substandard during the reporting period;

(d) The total weight of pecans shipped for export, whether inshell, shelled, or substandard during the previous period and year to date; and

(e) The destination(s) of such exports.

Erin Morris,

Administrator, Agricultural Marketing Service.

[FR Doc. 2026–22826 Filed 11–6–26; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 401 and 450

[Docket No.: FAA–2026–9942; Notice No. 26–20]

RIN 2120–AM33

Conditional Expected Casualty Exception for Failures Resulting in an Uncontrolled Atmospheric Return

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: FAA proposes to amend its commercial space launch and reentry licensing regulations to streamline the licensing process and reduce regulatory burden for license applicants. Specifically, FAA proposes to allow a launch and reentry vehicle operator to protect against high consequence events during an uncontrolled atmospheric return by showing that there would be sufficient breakup of the vehicle to ensure protection against a single event expected to produce multiple casualties.

DATES: Send comments on or before December 9, 2026.

ADDRESSES: Send comments identified by docket number FAA–2026–9942 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, 5th Floor (W58–213), Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W58–213 of the West Building 5th Floor at 1200 New Jersey Avenue SE, Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lisa E. Cacciatore, Office of Commercial Space Transportation, Federal Aviation Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 880–1489; email *Lisa.E.Cacciatore@faa.gov*.

SUPPLEMENTARY INFORMATION:

I. Overview

In accordance with Executive Order (E.O.) 14335 ''Enabling Competition in the Commercial Space Industry,'' FAA proposes to amend its commercial space launch and reentry regulations at 14 CFR part 450 to further streamline the commercial licensing process. Specifically, FAA proposes to add an option by which applicants may comply with the high consequence event protection requirements in § 450.101(c). The proposed rule would allow an applicant to meet the requirement for an uncontrolled atmospheric return (UAR), commonly called a ''random reentry,'' by showing that the UAR would result in sufficient breakup of the vehicle, including all vehicle components and undeployed payloads, to ensure protection against a single event expected to produce multiple casualties.

II. Authority for This Rulemaking

The Commercial Space Launch Act of 1984, as amended and codified at 51 U.S.C. 50901–50924, authorizes the Secretary of Transportation to oversee, license, and regulate commercial launch and reentry activities, and the operation of launch and reentry sites within the United States (U.S.) or as carried out by U.S. citizens. Section 50905 directs the Secretary to exercise this responsibility consistent with public health and safety, safety of property, and the national security and foreign policy interests of the United States. In addition, section 50903 requires the Secretary to encourage, facilitate, and promote commercial space launches and reentries by the private sector. As codified in 49 CFR 1.83(b), the Secretary has delegated authority to the FAA Administrator to carry out these functions.

III. Background

FAAhasestablishedcommercial space regulations governing licensing of launch and reentry in 14 CFR chapter III. On December 10, 2020, FAA issued a final ruleconsolidatingall substantive launch and reentry licensing regulations into a new part 450 (85 FR 79566) that went into effect on March 10, 2021.

On August 13, 2025,the President issued E.O. 14335, ''Enabling Competition in the Commercial Space Industry,'' requiring the Secretary of Transportation to ''reevaluate, amend, or rescind'' the part 450 regulations for the purpose of further streamlining the commercial licensing process. This proposed rule is being published in furtherance of this executive order.

In accordance with current FAA guidance, high consequence events include incidents that could involve multiple casualties, massive toxic exposures, extensive property or environmental damage, or events that jeopardize the national security or foreign policy interests of the United States.[1] The term ''high consequence events'' does not generally include incidents that result in only one casualty. The potential for any casualties remains covered by the individual and collective risk criteria in § 450.101(a) and (b). The objective of high consequence protection is to provide additional constraints beyond the individual and collective risk criteria.

Currently, in accordance with § 450.101(c), an operator must protect against a high consequence event by one of three methods: flight abort, ensuring that conditional expected casualties (CE_C) would fall below a specified threshold, or demonstrated reliability. However, these three methods are not well-attuned for protection against high consequence events during a UAR. A UAR, commonly called a ''random reentry,'' occurs when a vehicle makes an uncontrolled descent from orbit as a result of natural orbital decay, rather than as a result of action by the operator.

Currently, no UARs are close to attaining the demonstrated reliability necessary to protect against high consequence events, which makes compliance with § 450.101(c)(3) improbable at this time. Likewise, any vehicle flight that could be aborted in accordance with § 450.101(c)(1) is not a UAR because the operator is able to accomplish a controlled end to the flight; a UAR is always an uncontrolled end to flight. Thus, operators currently must comply with the CE_C requirement in § 450.101(c)(2), which can be a labor-intensive calculation.

IV. Discussion of the Proposal

The proposed rule would amend § 450.101(c)(2) to allow an operator to demonstrate protection against a high consequence event resulting from a UAR by showing that the UAR would result in sufficient breakup of the vehicle, including all vehicle components and payloads, to ensure protection against a single event expected to produce multiple casualties. The proposed method of demonstrating compliance to high consequence events for UARs provides an equivalent level of safety to the current requirements.

An uncontrolled atmospheric return is fundamentally a return in which the operator has no control over the eventual impact site of the vehicle. Accordingly, the proposal would define ''uncontrolled atmospheric return'' in § 401.7 to include two characteristics that limit the definition to cover only those returns over which the operator exercises no control. The first proposed defining characteristic of a UAR would be that only natural forces cause the orbit of an object to decay and eventually impact the Earth or burn up in the atmosphere. Natural forces that cause orbital decay include aerodynamic drag, gravitational variations, solar radiation, and third-body gravitational effects. A perigee of

[1] See Advisory Circular 450.101–1B, ''High Consequence Event Protection,'' dated May 03, 2024, available at: *www.faa.gov/documentLibrary/media/Advisory_Circular/AC_450.101–1B.pdf;* see also Footnote 65 in final rule titled ''Streamlined Launch and Reentry Requirements'' (85 FR 79566).

70 nautical miles (nm) or greater is considered the threshold of being in orbit (see definition of ''Deorbit'' in § 401.7). Thus, a scenario in which propulsion (which is not a natural force) reduces the perigee below the 70 nm threshold would not be considered a UAR. However, a propulsion system that fails before the perigee reaches the threshold could result in a UAR. The second proposed defining characteristic of a UAR would be that the operator lacks control over the trajectory. Thus, a flight that uses orientation to control aerodynamic forces to reduce the perigee below the 70 nm threshold would not be considered a UAR. Likewise, a vehicle that falls out of orbit due to natural forces, but which an operator may abort or otherwise guide, would not be considered a UAR.

The proposed method of demonstrating compliance to high consequence events at proposed § 450.101(c)(2)(ii) would only be available for UARs (as opposed to controlled returns) because UARs have unique properties. First, the impact probability distributions from a UAR, which are the subject of § 450.123(b), are extremely large. It is most likely that debris would impact in areas with relatively low population density because high-density populations are concentrated in small areas. In addition, when multiple fragments survive deorbit during a UAR, they are generally dispersed over a large geographical area, so it is unlikely that separate fragments would injure multiple people from the same UAR as long as the collective risk safety criterion in § 450.101(a) or (b) is satisfied.

The proposed requirement for operators to demonstrate sufficient breakup of the vehicle acts as an added layer of protection against multiple casualty events. Typically, deorbit produces extreme aerothermal and inertial forces that cause extensive breakup of vehicles that were not designed to survive substantially intact. However, extensive break-up is not always a guaranteed outcome. Therefore, an operator would be required to demonstrate that each piece of resulting debris from a UAR has a small enough effective casualty area to make multiple casualties an unlikely outcome. This demonstration would use the information already required by the debris analysis in accordance with § 450.121 and consequence analysis in § 450.135(b), so no additional analysis or application requirements would be needed.

V. Regulatory Notices and Analyses

A. Regulatory Impact Analysis

E.O. 12866 (''Regulatory Planning and Review'') and E.O. 13563 (''Improving Regulation and Regulatory Review'') require agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' The Office of Management and Budget has determined this proposed rule is not a significant regulatory action as defined in Section 3(f) of E.O. 12866. FAA is seeking comments on the following analysis.

Currently, most applicants meet the requirement in § 450.101(c) to protect against high consequence events by ensuring that the consequence of any reasonably foreseeable failure mode, in any significant period of flight, is no greater than 1×10^{-3} CE_C. The proposed rule would allow an applicant to forgo this demonstration for a UAR if the applicant shows that there is sufficient breakup of the launch or reentry vehicle, including all vehicle components and undeployed payloads.

The applicant would make the showing using the information already required by the debris analysis in accordance with § 450.121 and consequence analysis in § 450.135(b). Consequently, no additional analysis or application requirements would be needed.

FAA estimates that forgoing the CE_C demonstration for a UAR would save each applicant around 60 hours of labor. An aerospace engineer would complete this work. The base 2024 wage rate of a private industry worker working full-time as an aerospace engineer is $67.88 per hour.[2] When including benefits, the total compensation for an aerospace engineer[3] is $96.28 per hour. Therefore, the total cost savings for industry would be $5,777 per application.

For FAA, an aerospace engineer would take about 30 hours to provide guidance and review the data. The aerospace engineer is on the FAA Core Compensation Plan at a J band[4] with a base hourly rate of $95.33. FAA uses a factor of 1.3625 for benefits[5] which results in a total loaded hourly wage of $129.88. This results in total cost savings of $3,897 per application for FAA. Therefore, the total cost savings between FAA and an applicant would be $9,674 per application. Any cost savings would only impact new applicants, and FAA expects about 40 new applications in the next 5 years. However, not all applicants would apply to conduct operations where UARs are possible. Therefore, the total number of applications impacted would be less than 40.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), agencies must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rulemaking on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). No regulatory flexibility analysis is required, however, if the head of an agency certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. FAA has concluded and hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities; therefore, an analysis is not included.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as

[2] ''Employer Costs for Employee Compensation—May 2024,'' Bureau of Labor Statistics, Employee costs for private industry workers in Series: 17–2011 Aerospace Engineers, available at: *data.bls.gov/oes/#/industry/000000.*

[3] The total compensation includes Bureau of Labor Statistics (BLS) compensation data. For 2024, BLS estimates that wages make up 70.5 percent of total compensation while benefits make up 29.5 percent. Employer Costs for Employee Compensation—December 2024, available at: *www.bls.gov/news.release/archives/ecec_03142025.htm.* To calculate total compensation, FAA multiplies the base wage by a factor of 1.42 (rounded from 100/70.5). Therefore, the total compensation for an aerospace engineers is 96.28 per hour ($67.88 per hour × 1.42).

[4] FAA Engineering Pay Band J with Washington DC locality; effective Jan. 2026, maximum salary $198,281, available at: *www.faa.gov/jobs/working_here/benefits/pay/core_salary_with_conversion.xlsx.*

[5] Update to Civilian Position Full Fringe Benefit Cost Factor, Federal Pay Raise Assumptions, and Inflation Factors used in OMB Circular No. A–76, ''Performance of Commercial Activities'', Office of Management and Budget, March 11, 2008, available at: *www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2008/m08-13.pdf.*

the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, they be the basis for U.S. standards.

FAA has assessed the potential effect of this proposed rule and determined that it would not create unnecessary obstacles to the foreign commerce of the United States.

D. Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or Tribal government or the private sector to incur direct costs without the Federal Government having first provided the funds to pay those costs. FAA determined the proposed rule would not result in the expenditure of $193,000,000 or more ($100,000,000 adjusted for inflation using the most current Implicit Price Deflator for the Gross Domestic Product) by State, local, or Tribal governments, in the aggregate, or the private sector, in any one year.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires FAA consider the impact of paperwork and other information collection burdens imposed on the public. FAA has determined there would be no new requirement for information collection associated with this proposed rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. FAA has determined there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

G. Environmental Analysis

The Department has analyzed the environmental impacts of this notice of proposed rulemaking pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321, *et seq.*). FAA has determined this proposed rule is categorically excluded pursuant to FAA Order 1050.1G. Categorical exclusions are categories of actions FAA has determined normally do not significantly affect the quality of the human environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). In analyzing the applicability of a categorical exclusion, FAA must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. This rulemaking, which would allow a launch and reentry vehicle operator to protect against high consequence events during an uncontrolled atmospheric return by showing that there would be sufficient breakup of the vehicle to ensure protection against a single event expected to produce multiple casualties, is categorically excluded pursuant to FAA Order 1050.1G, Appendix B, Paragraph B–2.6(f), which categorically excludes issuance of regulatory documents. FAA does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

VI. E.O. Determinations

A. E.O. 13132, Federalism

FAA has analyzed this proposed rule under the principles and criteria of E.O. 13132, Federalism. FAA has determined this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have federalism implications.

B. E.O. 13175, Consultation and Coordination With Indian Tribal Governments

Consistent with E.O. 13175, Consultation and Coordination with Indian Tribal Governments,[6] and FAA Order 1210.20, American Indian and Alaska Native Tribal Consultation Policy and Procedures,[7] FAA ensures Federally Recognized Tribes (Tribes) are given the opportunity to provide meaningful and timely input regarding proposed Federal actions that have the potential to affect uniquely or significantly their respective Tribes. At this point, FAA has not identified any unique or significant effects, environmental or otherwise, on Tribes resulting from this proposed rule.

C. E.O. 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

FAA analyzed this proposed rule under E.O. 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). FAA has determined it would not be a ''significant energy action'' under the E.O. and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

D. E.O. 13609, Promoting International Regulatory Cooperation

E.O. 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to (1) meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or (2) prevent unnecessary differences in regulatory requirements. FAA has analyzed this action under the policies and agency responsibilities of E.O. 13609 and has determined this action would have no effect on international regulatory cooperation.

E. E.O. 14192, Unleashing Prosperity Through Deregulation

This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action because it has total costs less than zero as it streamlines the licensing process and reduces regulatory burden for license applicants.

VII. Additional Information

A. Comments Invited

FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. FAA also invites comments relating to the economic, environmental, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rule. Before acting on this proposal, FAA will consider all

[6] 65 FR 67249 (November 6, 2000).

[7] FAA Order No. 1210.20 (January 28, 2004), available at: *www.faa.gov/documentLibrary/media/1210.pdf.*

comments it receives on or before the closing date for comments. FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. FAA may change this proposal in light of the comments it receives.

B. Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and is relevant or responsive to this NPRM, it is important you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person in the **FOR FURTHER INFORMATION CONTACT** section of this document. Any commentary FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

C. Electronic Access and Filing

A copy of this NPRM, all comments received, any final rule, and all background material may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.federalregister.gov* and the Government Publishing Office's website at *www.govinfo.gov.* A copy may also be found at FAA's Regulations and Policies website at *www.faa.gov/regulations_policies.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Requesters must identify the docket or notice number of this rulemaking.

All documents FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

D. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857, Mar. 29, 1996) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects

14 CFR Part 401

Organization and functions (Government agencies), Space transportation and exploration.

14 CFR Part 450

Aircraft, Aviation safety, Environmental protection, Investigations, Reporting and recordkeeping requirements, Space transportation and exploration.

The Proposed Amendments

For the reasons discussed in the preamble, the Federal Aviation Administration proposes to amend chapter III of title 14, Code of Federal Regulations, as follows:

PART 401—ORGANIZATION AND DEFINITIONS

■ 1. The authority citation for part 401 is revised to read as follows:

Authority: 51 U.S.C. Chapter 509.

■ 2. Amend § 401.7 by adding the definition for ''Uncontrolled atmospheric return'' in alphabetical order to read as follows:

§ 401.7 Definitions.

* * * * *

Uncontrolled atmospheric return means the passive descent of a launch or reentry vehicle from orbit that occurs as a result of natural orbital decay and where there is no ability to control the vehicle's trajectory.

* * * * *

PART 450—LAUNCH AND REENTRY LICENSE REQUIREMENTS

■ 3. The authority citation for part 450 is revised to read as follows:

Authority: 51 U.S.C. Chapter 509.

■ 4. Amend § 450.101 by revising paragraph (c) to read as follows:

§ 450.101 Safety criteria.

* * * * *

(c) *High consequence event protection.* An operator must protect against a high consequence event in uncontrolled areas for each phase of flight by:

(1) Using flight abort as a hazard control strategy in accordance with the requirements of § 450.108;

(2) Ensuring the consequence of any reasonably foreseeable failure mode, in any significant period of flight:

(i) Is no greater than 1×10^{-3} conditional expected casualties; or

(ii) Results in sufficient breakup of the launch or reentry vehicle, including all vehicle components and undeployed payloads, during an uncontrolled atmospheric return; or

(3) Establishing the launch or reentry vehicle has sufficient demonstrated reliability as agreed to by the Administrator based on conditional expected casualties criteria during that phase of flight.

* * * * *

Issued under authority provided by 49 U.S.C. 106(f) and 51 U.S.C. chapter 509 in Washington, DC.

Anh Minh Ngoc Nguyen,

Deputy Associate Administrator, Office of Commercial Space Transportation.

[FR Doc. 2026–22784 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 450

[Docket No.: FAA–2026–9943; Notice No. 26–21]

RIN 2120–AM37

Flight Abort Burden Reducing Clarification on End of Flight Safety Limits

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: FAA proposes to amend its commercial space launch and reentry licensing regulations to streamline the licensing process and reduce regulatory burden for license applicants. Specifically, FAA proposes to clarify the conditions under which a vehicle operator is not required to abort a flight.

DATES: Send comments on or before December 9, 2026.

ADDRESSES: Send comments identified by docket number FAA–2026–9943 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, 5th Floor (W58–213), Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W58–213 of the West Building 5th Floor at 1200 New Jersey Avenue SE, Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lisa E. Cacciatore, Office of Commercial Space Transportation, Federal Aviation Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 880–1489; email *Lisa.E.Cacciatore@faa.gov*.

SUPPLEMENTARY INFORMATION:

I. Overview

In accordance with Executive Order (E.O.) 14335 ''Enabling Competition in the Commercial Space Industry,'' FAA proposes to amend its commercial space launch and reentry regulations at 14 CFR part 450 to further streamline the commercial licensing process. Currently, 14 CFR 450.108(e) provides that a vehicle operator using flight abort as a hazard control strategy is not required to initiate flight abort to protect against high consequence events once certain conditions are met. The proposed rule would clarify that the exception in paragraph (e) applies only to a phase of flight in which the conditions are present.

II. Authority for This Rulemaking

The Commercial Space Launch Act of 1984, as amended and codified at 51 U.S.C. 50901–50924, authorizes the Secretary of Transportation to oversee, license, and regulate commercial launch and reentry activities, and the operation of launch and reentry sites within the United States (U.S.) or as carried out by U.S. citizens. Section 50905 directs the Secretary to exercise this responsibility consistent with public health and safety, safety of property, and the national security and foreign policy interests of the United States. In addition, section 50903 requires the Secretary to encourage, facilitate, and promote commercial space launches and reentries by the private sector. As codified in 49 CFR 1.83(b), the Secretary has delegated authority to the FAA Administrator to carry out these functions.

III. Background

FAA has established commercial space regulations governing licensing of launch and reentry in 14 CFR chapter III. On December 10, 2020, FAA issued a final rule consolidating all substantive launch and reentry licensing regulations into a new part 450 (85 FR 79566) that went into effect on March 10, 2021.

On August 13, 2025, the President issued E.O. 14335, ''Enabling Competition in the Commercial Space Industry,'' requiring the Secretary of Transportation to ''reevaluate, amend, or rescind'' the part 450 regulations for the purpose of further streamlining the commercial licensing process. This proposed rule is being published in furtherance of this E.O.

Section 450.101(c) provides that an operator may use flight abort as a hazard control strategy to protect against a high consequence event in uncontrolled areas. Flight abort accomplishes a controlled ending to vehicle flight, such as through explosive destruct. Section 450.108 provides requirements for flight abort, including requirements for flight safety limits. Flight safety limits, in this context, define the criteria under which a vehicle operator must initiate flight abort.

For some mission scenarios, at some point in flight, flight abort can no longer mitigate risk, and applicants may wish to turn off the flight abort system to prevent accidental initiation of the abort system. This possibility is addressed by § 450.108(e), which states that a flight does not need to be aborted to protect against high consequence events beginning immediately after critical vehicle parameters are validated, if the vehicle is able to achieve a useful mission, and if, for the remainder of flight: (1) flight abort would not materially decrease the risk from a high consequence event; and (2) there are no key flight safety events.

To meet the first condition that flight abort would not materially decrease the risk of a high consequence event for the remainder of flight, an operator should perform a comparison of the risk (*i.e.,* expected casualties (E_C)) with and without flight abort from failure modes that produce conditional expected casualties (CE_C) greater than 0.01. If flight abort would not reduce E_C associated with each failure mode materially, then this condition is met. To meet the second condition, an operator must demonstrate that the remainder of flight does not include any ''key flight safety event,'' which is defined in 14 CFR 401.7 to mean ''a flight activity that has an increased likelihood of causing a failure compared with other portions of flight.'' However, even if these conditions are satisfied for the remainder of flight, an operator is only permitted to switch off the flight abort system if, during flight, the operator is able to validate ''critical vehicle parameters,'' meaning parameters that demonstrate the vehicle is capable of completing safe flight through the upcoming phase of flight where population is exposed to hazardous debris effects from reasonably foreseeable failure modes.

IV. Discussion of the Proposal

The proposed rule maintains the essential requirements and structure of § 450.108(e), with two minor revisions. First, the proposed rule would change the title of § 450.108(e) from ''End of flight abort'' to ''End of flight safety limits'' to match the intention of the paragraph more closely. Paragraph (e) does not require an operator to turn off flight abort capability or eliminate flight abort as a hazard control strategy, as unintentionally suggested by the current title, but rather describes conditions under which an operator is not required to set flight safety limits to protect against high consequence events in uncontrolled areas during some subsequent phases of flight.

Second, the proposed rule would also scope paragraph (e) to apply only to a phase of flight rather than ''the remainder of flight,'' as the paragraph currently states. Current paragraph (e) was drafted with the understanding that most operators would only turn off the flight abort capability at the end of a

flight, such as the phase immediately before orbital insertion. However, FAA anticipates that operators may seek to turn off flight abort capability during one phase of flight and turn it back on during a subsequent phase. As such, this revision would provide additional flexibility to operators while preserving public safety by explicitly accommodating this practice. This proposal, therefore, would amend paragraph (e) to say that a flight does not need to be aborted for the remainder of a phase of flight if the specified conditions are present during that phase.

V. Regulatory Notices and Analyses

A. Regulatory Impact Analysis

E.O. 12866 (''Regulatory Planning and Review'') and E.O. 13563 (''Improving Regulation and Regulatory Review'') require agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' The Office of Management and Budget has determined this proposed rule is not a significant regulatory action as defined in Section 3(f) of E.O. 12866.

The proposed rule would change the title of § 450.108(e) from ''End of flight abort'' to ''End of flight safety limits'' to match the intention of the paragraph more closely. Paragraph (e) does not require an operator to turn off flight abort capability or eliminate flight abort as an option during any subsequent phase of flight, as suggested by the current title, but rather describes conditions under which an operator is not required to set flight safety limits to protect against high consequence events in uncontrolled areas during a specified phase of flight. In addition, the proposed rule would amend § 450.108(e) so that the section only applies to a phase of flight rather than ''the remainder of flight,'' as the paragraph currently states. This proposed rule would not impose incremental costs. However, there may be minimal cost savings. FAA estimates that the change would save FAA time in providing guidance per licensee. The proposed rule would provide operators the additional flexibility to turn off flight abort capability during one phase of flight and turn it back on during a subsequent phase of flight. In addition, FAA estimates that the change would also save licensees time in seeking and receiving guidance. FAA requests public comments on these assumptions.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), agencies must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rulemaking on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). No regulatory flexibility analysis is required, however, if the head of an agency certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. FAA has concluded and hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities; therefore, an analysis is not included.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, they be the basis for U.S. standards.

FAA has assessed the potential effect of this proposed rule and determined that it would not create unnecessary obstacles to the foreign commerce of the United States.

D. Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or Tribal government or the private sector to incur direct costs without the Federal Government having first provided the funds to pay those costs. FAA determined the proposed rule would not result in the expenditure of $193,000,000 or more ($100,000,000 adjusted for inflation using the most current Implicit Price Deflator for the Gross Domestic Product) by State, local, or Tribal governments, in the aggregate, or the private sector, in any one year.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires FAA consider the impact of paperwork and other information collection burdens imposed on the public. FAA has determined there would be no new requirement for information collection associated with this proposed rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. FAA has determined there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

G. Environmental Analysis

The Department has analyzed the environmental impacts of this notice of proposed rulemaking pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321, *et seq.*). FAA has determined this rule is categorically excluded pursuant to FAA Order 1050.1G. Categorical exclusions are categories of actions FAA has determined normally do not significantly affect the quality of the human environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). In analyzing the applicability of a categorical exclusion, FAA must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. This proposed rulemaking, which would clarify the conditions under which a vehicle operator is not required to abort a flight, is categorically excluded pursuant to FAA Order 1050.1G, Appendix B, Paragraph B–2.6(f), which categorically excludes issuance of regulatory documents. FAA does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

VI. E.O. Determinations

A. E.O. 13132, Federalism

FAA has analyzed this proposed rule under the principles and criteria of E.O. 13132, Federalism. FAA has determined this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the

distribution of power and responsibilities among the various levels of government, and, therefore, would not have federalism implications.

B. E.O. 13175, Consultation and Coordination With Indian Tribal Governments

Consistent with E.O. 13175, Consultation and Coordination with Indian Tribal Governments,[1] and FAA Order 1210.20, American Indian and Alaska Native Tribal Consultation Policy and Procedures,[2] FAA ensures Federally Recognized Tribes (Tribes) are given the opportunity to provide meaningful and timely input regarding proposed Federal actions that have the potential to affect uniquely or significantly their respective Tribes. At this point, FAA has not identified any unique or significant effects, environmental or otherwise, on Tribes resulting from this proposed rule.

C. E.O. 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

FAA analyzed this proposed rule under E.O. 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). FAA has determined it would not be a ''significant energy action'' under the E.O. and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

D. E.O. 13609, Promoting International Regulatory Cooperation

E.O. 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to (1) meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or (2) prevent unnecessary differences in regulatory requirements. FAA has analyzed this action under the policies and agency responsibilities of E.O. 13609 and has determined this action would have no effect on international regulatory cooperation.

E. E.O. 14192, Unleashing Prosperity Through Deregulation

This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action.

[1] 65 FR 67249 (November 6, 2000).

[2] FAA Order No. 1210.20 (January 28, 2004), available at: *www.faa.gov/documentLibrary/media/1210.pdf.*

VII. Additional Information

A. Comments Invited

FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. FAA also invites comments relating to the economic, environmental, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rule. Before acting on this proposal, FAA will consider all comments it receives on or before the closing date for comments. FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. FAA may change this proposal in light of the comments it receives.

B. Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and is relevant or responsive to this NPRM, it is important you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person in the **FOR FURTHER INFORMATION CONTACT** section of this document. Any commentary FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

C. Electronic Access and Filing

A copy of this NPRM, all comments received, any final rule, and all background material may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.federalregister.gov* and the Government Publishing Office's website at *www.govinfo.gov.* A copy may also be found at FAA's Regulations and Policies website at *www.faa.gov/regulations_policies.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Requesters must identify the docket or notice number of this rulemaking.

All documents FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

D. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857, Mar. 29, 1996) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 450

Aircraft, Aviation safety, Environmental protection, Investigations, Reporting and recordkeeping requirements, Space transportation and exploration.

The Proposed Amendments

For the reasons discussed in the preamble, the Federal Aviation Administration proposes to amend chapter III of title 14, Code of Federal Regulations, as follows:

PART 450—LAUNCH AND REENTRY LICENSE REQUIREMENTS

■ 1. The authority citation for part 450 is revised to read as follows:

Authority: 51 U.S.C. Chapter 509.

■ 2. Revise § 450.108(e) to read as follows:

§ 450.108 Flight abort.

* * * * *

(e) *End of flight safety limits.* A flight does not need to be aborted to protect against high consequence events in uncontrolled areas for the remainder of a phase of flight beginning immediately after critical vehicle parameters are validated, if the vehicle is able to achieve a useful mission and the following conditions are met for the remainder of the phase:

* * * * *

Issued under authority provided by 49 U.S.C. 106(f) and 51 U.S.C. chapter 509 in Washington, DC.

Anh Minh Ngoc Nguyen,

Deputy Associate Administrator, Office of Commercial Space Transportation.

[FR Doc. 2026–22782 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 450

[Docket No.: FAA–2026- 9937; Notice No. 26–24]

RIN 2120–AM43

Flight Safety Limits Objectives Burden Reducing Clarification

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: FAA proposes to amend its commercial space launch and reentry licensing regulations to streamline the licensing process and reduce regulatory burden for license applicants. Specifically, FAA proposes to clarify the requirements for establishing flight safety limits that define when a vehicle operator must initiate flight abort.

DATES: Send comments on or before December 9, 2026.

ADDRESSES: Send comments identified by docket number FAA–2026–9937 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, 5th Floor (W58–213), Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W58–213 of the West Building, 5th Floor at 1200 New Jersey Avenue SE, Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process better. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W58–213 of the West Building 5th Floor at 1200 New Jersey Avenue SE, Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lisa E. Cacciatore, Office of Commercial Space Transportation, Federal Aviation Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 880–1489; email *Lisa.E.Cacciatore@faa.gov*.

SUPPLEMENTARY INFORMATION:

I. Overview

In accordance with Executive Order (E.O.) 14335, ''Enabling Competition in the Commercial Space Industry,'' FAA proposes to amend its commercial space launch and reentry regulations at 14 CFR part 450 to further streamline the commercial licensing process. The regulations at 14 CFR 450.108(c) require a vehicle operator to determine flight safety limits that define when the operator must initiate flight abort. To address applicant confusion about the meaning of 14 CFR 450.108(c)(4), FAA proposes to reword the paragraph to clarify which inputs are necessary for establishing flight safety limits to prevent high consequence events.

II. Authority for This Rulemaking

The Commercial Space Launch Act of 1984, as amended and codified at 51 U.S.C. 50901–50924, authorizes the Secretary of Transportation to oversee, license, and regulate commercial launch and reentry activities, and the operation of launch and reentry sites within the United States or as carried out by U.S. citizens. Section 50905 directs the Secretary to exercise this responsibility consistent with public health and safety, safety of property, and the national security and foreign policy interests of the United States. In addition, section 50903 requires the Secretary to encourage, facilitate, and promote commercial space launches and reentries by the private sector. As codified in 49 CFR 1.83(b), the Secretary has delegated authority to the FAA Administrator to carry out these functions.

III. Background

FAA has established commercial space regulations governing licensing of launch and reentry in 14 CFR chapter III. On December 10, 2020, FAA issued a final rule consolidating all substantive launch and reentry licensing regulations into a new part 450 (85 FR 79566) that went into effect on March 10, 2021.

On August 13, 2025, the President issued E.O. 14335, ''Enabling Competition in the Commercial Space Industry,'' requiring the Secretary of Transportation to ''reevaluate, amend, or rescind'' the part 450 regulations for the purpose of further streamlining the commercial licensing process. This proposed rule is being published in furtherance of this E.O.

Section 450.101(c) provides that an operator may use flight abort as a hazard control strategy to protect against a high consequence event in uncontrolled areas.[1] Flight abort accomplishes a controlled ending to vehicle flight, such as through explosive destruct. Section 450.108 provides requirements for flight abort, including requirements for flight safety limits. Flight safety limits, in this context, define the criteria under which a vehicle operator must initiate flight abort.

One of the requirements for flight abort, located at § 450.108(c)(4), provides that an operator must determine and use flight safety limits defining when the operator must initiate flight abort ''to prevent conditional expected casualties (CE_C) greater than 1×10^{-2} in uncontrolled areas due to flight abort or due to flight outside the limits of a useful mission from any reasonably foreseeable off-trajectory failure mode in any significant period of flight . . . .'' The purpose of § 450.108(c)(4) is to ensure that, when an operator cannot develop flight safety limits that prevent hazards from affecting uncontrolled areas, the flight safety limits nonetheless protect against

[1] As defined by 14 CFR 401.7, an ''uncontrolled area'' is ''an area of land not controlled by a launch or reentry operator, a launch or reentry site operator, an adjacent site operator, or other entity by agreement.''

high consequence events in uncontrolled areas. The paragraph asks operators to compute the CE_C in each significant period of flight [2] where flight abort or flight outside the limits of a useful mission [3] may be an outcome for each reasonably foreseeable off-trajectory failure mode.[4] If the maximum CE_C developed through this method is not greater than 1×10^{-2}, an operator can demonstrate high consequence event protection. If this analysis does not demonstrate compliance with high consequence event protection, an operator may modify the limits of a useful mission or flight safety limits, and an operator should update the flight safety limits analysis accordingly until compliance with § 450.108(c)(4) can be demonstrated.

However, the phrasing of paragraph (c)(4) has led some applicants to misinterpret the paragraph as requiring two separate CE_C calculations: one for outcomes resulting in flight abort and one for outcomes that result in flight outside the limits of a useful mission. Meanwhile, other applicants have interpreted the paragraph to mean that an applicant may select only one of these two outcomes and ignore the other in CE_C calculations. In AC 450.108–1, *Flight Abort Rule Development,* FAA attempted to clarify the requirement, writing that ''[t]he CE_C results from various end states, such as break-up due to aerodynamic loads or FSS activation, from flight abort and flight outside the limits of a useful mission should be averaged together to compute the mean CE_C for each significant period of flight.'' However, misinterpretations of the rule have persisted and led to repeated exchanges with the applicants, requiring additional time and effort to develop an acceptable application.

IV. Discussion of the Proposal

The proposed rule would reword § 450.108(c)(4) to reduce confusion among applicants regarding how to comply with the requirement. The proposed rule would clarify that the CE_C should be calculated as an average that accounts for both breakup states due to flight abort and any outcomes involving flight outside the limits of a useful mission—but not breakups within the limits of a useful mission—and evaluated against the threshold for each failure mode within each significant period of flight. This clarification would ensure that both outcomes are combined and accounted for as a single CE_C for each failure mode within each significant period of flight.

V. Regulatory Notices and Analyses

A. Regulatory Impact Analysis

E.O. 12866 (''Regulatory Planning and Review'') and E.O. 13563 (''Improving Regulation and Regulatory Review'') require agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' The Office of Management and Budget has determined this proposed rule is not a significant regulatory action as defined in Section 3(f) of E.O. 12866. FAA is seeking comments on the following analysis.

Currently, 14 CFR 450.108(c) requires a vehicle operator to determine flight safety limits that define when the operator must initiate flight abort. The proposed rule would reword 14 CFR 450.108(c)(4) to clarify which inputs are necessary for establishing flight safety limits to prevent high consequence events. The current wording has caused confusion among vehicle operators, which has prompted operators to seek guidance from FAA.

The analysis first provides an estimate of the cost savings per operator. This is a one-time cost savings per operator because they would only seek this guidance once. FAA estimates the labor time, per operator, to provide this guidance is eight hours for FAA and operators each. For FAA, an analyst at a G-Band would complete this work at an hourly wage with benefits of $72.80.[5] This amounts to $582 per operator. For an operator, an aerospace engineer would seek this guidance from FAA. At an hourly wage rate [6] with benefits [7] of $96.28, the aerospace engineer cost is $770 per applicant.[8] Thus, the cost savings per operator would be $1,347.

The cost savings would be minimal because FAA expects there to be 40 new license applications over the next 5 years. Assuming eight applications per year, the total undiscounted cost savings would be $53,880. At a seven percent discount rate, the total cost savings would be $50,355, and $48,888 at a three percent discount rate.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), agencies must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rulemaking on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). No regulatory flexibility analysis is required, however, if the head of an agency certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. FAA has concluded and hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities; therefore, an analysis is not included.

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[2] As discussed in the final rule establishing part 450 ''Streamlined Launch and Reentry Requirements'' (85 FR 79566), a period of flight is considered significant if it is long enough for a mitigation, such as flight abort, to decrease the public risks or consequences materially from any reasonably foreseeable failure mode (85 FR 79566, 79604).

[3] As defined by 14 CFR 401.7, a ''useful mission'' means ''a mission that can attain one or more objectives.'' The ''limits of a useful mission,'' as defined by that section, means ''the trajectory data or other parameters that bound the performance of a useful mission, including flight azimuth limits.'' The limits of a useful mission are developed as part of the flight safety analysis under 14 CFR 450.119.

[4] As discussed in the final rule establishing part 450 ''Streamlined Launch and Reentry Requirements'' (85 FR 79566), an off-trajectory failure is a failure ''for which a vehicle deviates from its intended flight path—for example, due to failures of the guidance, navigation, or control systems'' (85 FR 79566, 79620). Failure modes are categories of hazardous events that share significant similarity in cause and system response, prior to consideration of mitigations or hazard control strategies. Therefore an ''off-trajectory failure mode'' is a failure mode where a vehicle deviates from its intended flight path. AC 450.101–1, *High Consequence Event Protection,* provides additional background on ''failure modes'' and how applicants may identify ''reasonably foreseeable'' failure modes.

[5] FAA Technical Pay Band, G Band with Washington DC locality; effective Jan. 2026, maximum salary of $111,138. The government overhead rate is 36.25 percent. This results in the loaded salary of $151,426 ($111,138 * 1.3625 = $151,426). The total loaded salary of $151,426 is divided by 2,080 hours to get the $72.80 hourly wage. 2026 FAA Core Compensation Plan Pay Bands, available at: *www.faa.gov/jobs/working_here/benefits/pay/core_salary_with_conversion.xlsx;* Office of Management and Budget, *Update to Civilian Position Full Fringe Benefit Cost Factor, Federal Pay Raise Assumptions, and Inflation Factors Used in OMB Circular No. A–76, ''Performance of Commercial Activities''* (Mar. 11, 2008), available at: *www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2008/m08-13.pdf.*

[6] Bureau of Labor Statistics (BLS), *Occupational Employment and Wage Statistics—May 2024, Industry: Cross-industry, Private, Federal, State, and Local Government, Aerospace Engineers (17–2011),* available at: *data.bls.gov/oes/#/industry/000000.*

[7] The total wage includes BLS compensation data. For 2024, BLS has wages at 70.5 percent of total compensation, while benefits are 29.5 percent. See BLS, *Employer Costs for Employee Compensation—December 2024,* available at: *www.bls.gov/news.release/archives/ecec_03142025.htm* (Mar. 14, 2025).

[8] The hourly salary is $67.88. The total loaded factor is 1.42 (1/0.705 = 1.42). Therefore, the total overhead wage is $96.28 (1.42 * $67.88 = $96.28).

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, they be the basis for U.S. standards.

FAA has assessed the potential effect of this proposed rule and determined that it would not create unnecessary obstacles to the foreign commerce of the United States.

D. Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or Tribal government or the private sector to incur direct costs without the Federal Government having first provided the funds to pay those costs. FAA determined the proposed rule would not result in the expenditure of $193,000,000 or more ($100,000,000 adjusted for inflation using the most current Implicit Price Deflator for the Gross Domestic Product) by State, local, or Tribal governments, in the aggregate, or the private sector, in any one year.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires FAA consider the impact of paperwork and other information collection burdens imposed on the public. FAA has determined there would be no new requirement for information collection associated with this proposed rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. FAA has determined there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

G. Environmental Analysis

The Department has analyzed the environmental impacts of this notice of proposed rulemaking pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321, *et seq.*). FAA has determined this proposed rule is categorically excluded pursuant to FAA Order 1050.1G. Categorical exclusions are categories of actions FAA has determined normally do not significantly affect the quality of the human environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). In analyzing the applicability of a categorical exclusion, FAA must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. This rulemaking, which would clarify the requirements for establishing flight safety limits that define when a vehicle operator must initiate flight abort, is categorically excluded pursuant to FAA Order 1050.1G, Appendix B, Paragraph B–2.6(f), which categorically excludes issuance of regulatory documents. FAA does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

VI. E.O. Determinations

A. E.O. 13132, Federalism

FAA has analyzed this proposed rule under the principles and criteria of E.O. 13132, Federalism. FAA has determined this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have federalism implications.

B. E.O. 13175, Consultation and Coordination With Indian Tribal Governments

Consistent with E.O. 13175, Consultation and Coordination with Indian Tribal Governments,[9] and FAA Order 1210.20, American Indian and Alaska Native Tribal Consultation Policy and Procedures,[10] FAA ensures Federally Recognized Tribes (Tribes) are given the opportunity to provide meaningful and timely input regarding proposed Federal actions that have the potential to affect uniquely or significantly their respective Tribes. At this point, FAA has not identified any unique or significant effects, environmental or otherwise, on Tribes resulting from this proposed rule.

C. E.O. 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

FAA analyzed this proposed rule under E.O. 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). FAA has determined it would not be a ''significant energy action'' under the E.O. and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

D. E.O. 13609, Promoting International Regulatory Cooperation

E.O. 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to (1) meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or (2) prevent unnecessary differences in regulatory requirements. FAA has analyzed this action under the policies and agency responsibilities of E.O.13609 and has determined this action would have no effect on international regulatory cooperation.

E. E.O. 14192, Unleashing Prosperity Through Deregulation

This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action.

VII. Additional Information

A. Comments Invited

FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. FAA also invites comments relating to the economic, environmental, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning

[9] 65 FR 67249 (November 6, 2000).

[10] FAA Order No. 1210.20 (January 28, 2004), available at *www.faa.gov/documentLibrary/media/1210.pdf.*

this proposed rule. Before acting on this proposal, FAA will consider all comments it receives on or before the closing date for comments. FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. FAA may change this proposal in light of the comments it receives.

B. Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and is relevant or responsive to this NPRM, it is important you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person in the **FOR FURTHER INFORMATION CONTACT** section of this document. Any commentary FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

C. Electronic Access and Filing

A copy of this NPRM, all comments received, any final rule, and all background material may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.federalregister.gov* and the Government Publishing Office's website at *www.govinfo.gov.* A copy may also be found at FAA's Regulations and Policies website at *www.faa.gov/regulations_policies.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Requesters must identify the docket or notice number of this rulemaking.

All documents FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

D. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857, Mar. 29, 1996) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 450

Aircraft, Aviation safety, Environmental protection, Investigations, Reporting and recordkeeping requirements, Space transportation and exploration.

The Proposed Amendments

For the reasons discussed in the preamble, the Federal Aviation Administration proposes to amend chapter III of title 14, Code of Federal Regulations, as follows:

PART 450—LAUNCH AND REENTRY LICENSE REQUIREMENTS

■ 1. The authority citation for part 450 is revised to read as follows:

Authority: 51 U.S.C. Chapter 509.

■ 2. Revise § 450.108(c)(4) to read as follows:

§ 450.108 Flight abort.

* * * * *

(c) * * *

(4) To prevent conditional expected casualties in uncontrolled areas, averaged over outcomes that result in either flight abort or flight outside the limits of a useful mission, greater than 1×10^{-2} from any reasonably foreseeable off-trajectory failure mode in any significant period of flight; and

* * * * *

Issued under authority provided by 49 U.S.C. 106(f) and 51 U.S.C. chapter 509 in Washington, DC.

Anh Minh Ngoc Nguyen,

Deputy Associate Administrator, Office of Commercial Space Transportation.

[FR Doc. 2026–22783 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Parts 1010 and 1020

RIN 1506–AB41

Threshold for the Requirement To Collect, Retain, and Transmit Information on Funds Transfers and Transmittals of Funds That Begin or End Outside the United States, and Clarification of the Requirement To Collect, Retain, and Transmit Information on Transactions Involving Convertible Virtual Currencies and Digital Assets With Legal Tender Status; Withdrawal

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury; Board of Governors of the Federal Reserve System (Board).

ACTION: Proposed rule; withdrawal.

SUMMARY: FinCEN and the Board (collectively, the ''Agencies'') are withdrawing the joint notice of proposed rulemaking (NPRM) published on October 27, 2020, that proposed modifying the threshold in the Agencies' rules implementing the Bank Secrecy Act (BSA) requiring financial institutions to collect and retain information on certain funds transfers and transmittals of funds. The NPRM would have reduced this threshold from $3,000 to $250 for funds transfers and transmittals of funds that begin or end outside the United States. FinCEN additionally proposed reducing from $3,000 to $250 the threshold in FinCEN's rule requiring financial institutions to transmit to other financial institutions in the payment chain information on funds transfers and transmittals of funds that begin or end outside the United States. The NPRM also would have clarified the meaning of ''money'' as used in the Agencies' rules to specify that the rules apply to domestic and cross-border transactions involving convertible virtual currency (CVC) and digital assets that have legal tender status to a recipient. The Agencies will not take further action on this NPRM.

DATES: FinCEN and the Board are withdrawing the NPRM published at 85 FR 68005 (October 27, 2020), as of November 9, 2026.

FOR FURTHER INFORMATION CONTACT:

FinCEN: The FinCEN Regulatory Support Section by submitting an inquiry at *www.fincen.gov/contact.*

Board: Evan Winerman, Deputy Associate General Counsel, (202) 872–7578, Legal Division, Board of

Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551. Users of Telecommunication Device for Deaf (TDD) only, call (202) 263–4869.

SUPPLEMENTARY INFORMATION:

I. Background

Certain Federal regulations—often referred to as the ''Recordkeeping Rule'' and ''Travel Rule''—collectively require banks and nonbank financial institutions to collect, retain, and transmit information on funds transfers and transmittals of funds in amounts of $3,000 or more.[1] The Recordkeeping Rule, which requires banks and nonbank financial institutions to collect and retain information related to funds transfers and transmittals of funds that begin or end outside the United States, is jointly issued by both the Board and FinCEN. The Travel Rule, which requires banks and nonbank financial institutions to transmit information on funds transfers and transmittals of funds that begin or end outside the United States, is issued by FinCEN.

On October 27, 2020, FinCEN and the Board published a joint NPRM that proposed modifying the Recordkeeping Rule to reduce the threshold at which banks and nonbank financial institutions must collect and retain certain information from $3,000 to $250.[2] FinCEN additionally proposed to modify the Travel Rule to change the threshold at which banks and nonbank financial institutions must transmit information from $3,000 to $250.[3] The Agencies also proposed clarifying the meaning of ''money'' in these rules by revising the definitions of ''payment order'' and ''transmittal order'' to specify that the Recordkeeping Rule and Travel Rule apply to domestic and cross-border transactions involving CVC or any digital asset having legal tender status to a recipient.[4]

II. Summary of Public Comments

The Agencies received nearly 3,000 comments on the proposal from depository institutions, money services businesses, trade associations, individuals, and others.[5]

Commenters generally opposed the proposal to reduce the thresholds applicable to the Recordkeeping Rule and Travel Rule for international transactions. Many comments argued that a threshold of $250 would impose a significant regulatory burden on financial institutions, particularly smaller financial institutions; would disrupt the ability of consumers to send remittances overseas (and could potentially drive consumers into less regulated marketplaces); would significantly increase the number of transactions subject to the provisions of the Recordkeeping Rule and Travel Rule; and would increase the liability exposure of financial institutions required to maintain personally identifiable information. Many comments also noted that some potentially illicit transactions under the $3,000 threshold were already being reported to FinCEN through Suspicious Activity Reports (SARs). A number of commenters asserted that the Agencies did not provide sufficient analysis or data to justify the proposed reduction in the threshold. Several commenters stated that, rather than decrease the threshold, the Agencies should adopt a higher threshold due to the effects of inflation since the original threshold was adopted in 1995.

Commenter sentiment was mixed with respect to the proposal to specify that the Recordkeeping Rule and Travel Rule apply to CVC transactions. In general, companies that provide CVC-related services (and related trade associations) opposed this aspect of the proposal, while some depository institutions, money services businesses, and related trade associations supported this aspect of the proposal. Commenters opposed to this aspect of the proposal stated that implementing the proposal would be challenging (*e.g.,* due to technological limitations and the lack of an international messaging standard for CVC transactions), that the proposal would inhibit CVC innovation, and that the Agencies should improve coordination with other regulators who were, at that time, simultaneously developing rules affecting the CVC industry.

Many commenters offered more general comments on the proposal, including that the proposal would constitute an unwarranted invasion of privacy or an unreasonable search and seizure in violation of the Fourth Amendment. Many commenters also stated that the comment period on the proposal was insufficient, and that, if the Agencies finalize the proposal, the proposed implementation period should be extended.

III. Withdrawal of NPRM

The Agencies have reconsidered the proposal in light of the public comments received and have determined to withdraw the joint NPRM for two primary reasons. First, more than five years have passed since the issuance of the NPRM, and the Agencies believe that additional feedback from the public would be useful before the Agencies adopted any amendments to the Recordkeeping Rule or Travel Rule that are similar to the proposed amendments. The proposal is being withdrawn to provide certainty to the public that no final rule will be issued without an additional opportunity for public comment.

Second, and relatedly, the Agencies believe that there have been significant recent developments in the CVC industry since the proposal was issued. For example, CVC markets have continued to mature, and new legal frameworks are emerging.[6] The Agencies believe that any future, potential amendments to the Recordkeeping Rule and Travel Rule related to CVC should be considered in light of these recent developments to ensure that such amendments are fit for purpose.[7]

Because the Agencies no longer intend to issue a final rule with respect to this proposal, the NPRM published at 85 FR 68005 is hereby withdrawn.

Jimmy L. Kirby,

Deputy Director, Financial Crimes Enforcement Network.

Jointly issued by:

By order of the Board of Governors of the Federal Reserve System.

Benjamin McDonough,

Secretary of the Board.

[FR Doc. 2026–22809 Filed 11–6–26; 8:45 am]

BILLING CODE 4810–02–P

[1] *See* 31 CFR 1020.410(a), 1010.410(e) (Recordkeeping Rule); 31 CFR 1010.410(f) (Travel Rule). The Board's Regulation S incorporates the substantive requirements of the Recordkeeping Rule. *See* 12 CFR 219.23. For additional background on the Recordkeeping Rule and Travel Rule, see generally *Board and FinCEN, Threshold for the Requirement To Collect, Retain, and Transmit Information on Funds Transfers and Transmittals of Funds That Begin or End Outside the United States, and Clarification of the Requirement To Collect, Retain, and Transmit Information on Transactions Involving Convertible Virtual Currencies and Digital Assets With Legal Tender Status,* 85 FR 68005, 68006–07 (Oct. 27, 2020).

[2] *See* 85 FR 68007–10.

[3] *See id.*

[4] *See* 85 FR 68010–11.

[5] A significant majority of these comment letters were substantially similar form letters.

[6] For example, on July 18, 2025, a Federal statute establishing a regulatory framework for payment stablecoins was enacted. Guiding and Establishing National Innovation for U.S. Stablecoins (GENIUS) Act, Public Law 119–27; 12 U.S.C. 5901 *et seq.*

[7] *See* White House, *Strengthening American Leadership in Digital Financial Technology,* p. 100 (July 2025), *https://www.whitehouse.gov/wp-content/uploads/2025/07/Digital-Assets-Report-EO14178.pdf; see also* E.O. 14178, 90 FR 8647 (Jan. 31, 2025).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4214–CN]

RIN 0938–AV88

Medicare Program; Implementation of Sections 6219, 6220, and 6224 of the Consolidated Appropriations Act, 2026; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule; correction.

SUMMARY: This document corrects a typographical error in the proposed rule that appeared in the October 20, 2026 **Federal Register** titled ''Medicare Program; Implementation of Sections 6219, 6220, and 6224 of the Consolidated Appropriations Act, 2026''.

FOR FURTHER INFORMATION CONTACT: Kristy Nishimoto, (206) 615–2367.

I. Background and Summary of Errors

In FR Doc. 2026–21420 of October 20, 2026 (91 FR 66408), we are correcting a typographical error in the docket number that may be used for submitting public comments on the proposed rule.

III. Correction of Errors

In FR Doc. 2026–21420 of October 20, 2026 (91 FR 66408), we are making the following correction:

1. On page 66408, first column, 13th full paragraph (**ADDRESSES** section), line 4, the number ''CMS–2026–2533'' is corrected to read ''CMS–2026–3533''.

Liesl I. Fowler,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2026–22807 Filed 11–6–26; 8:45 am]

BILLING CODE 4169–69–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 26–302; RM–12034; DA 26–1169; FR ID 375916]

Television Broadcasting Services Odessa, Texas

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Table of TV Allotments (Table) of the Federal Communications Commission's (Commission) rules in response to a petition for rulemaking filed by Gray Television Licensee, LLC (Gray), the licensee of KOSA–TV (KOSA–TV), Odessa, Texas (Odessa). Gray held a construction permit to construct a facility on UHF channel 31 at Odessa, and now requests that the Bureau substitute VHF channel 7 for UHF channel 31 in the Table, with the technical parameters as set forth in KOSA–TV's current license. The Media Bureau previously granted a petition for rulemaking submitted by Gray to substitute UHF channel 31 for VHF channel 7 at Odessa. Gray states that it is unable to complete construction of its new channel within the time specified on the construction permit, and therefore requests amendment of the Table to allow it to continue to operate on VHF channel 7 at its currently licensed technical parameters to provide uninterrupted service to viewers. Given that the Licensee proposes to utilize its currently licensed parameters, we believe VHF channel 7 can be substituted for UHF channel 31 at Odessa as proposed, in compliance with the principal community coverage requirements of the Commission's rules. In addition, we find that this channel change meets the technical requirements set forth in the Commission's rules.

DATES: Comments must be filed on or before December 9, 2026 and reply comments on or before December 24, 2026.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Petitioner as follows: Joan Stewart, Wiley Rein LLP, 2050 M Street NW, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Emily Harrison at *Emily.Harrison@fcc.gov,* (202) 418–1665 or Mark Colombo at *Mark.Colombo@fcc.gov,* (202) 418–7611.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 26–302; RM–12034; DA 26–1169, adopted October 28, 2026, and released October 28, 2026. The full text of this document is available online at *https://www.fcc.gov/edocs.*

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a notice of proposed rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in § 1.1204(a) of the Commission's rules, 47 CFR 1.1204(a).

See §§ 1.415 and 1.420 of the Commission's rules for information regarding the proper filing procedures for comments, 47 CFR 1.415 and 1.420.

Providing Accountability Through Transparency Act: The Providing Accountability Through Transparency Act, Public Law 118–9, requires each agency, in providing notice of a rulemaking, to post online a brief plain-language summary of the proposed rule. The required summary of this notice of proposed rulemaking is available at *https://www.fcc.gov/proposed-rulemakings.*

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622, in the table in paragraph (j), under Texas, revise the entry for ''Odessa'' to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(j) * * *

Community	Channel No.
* * * * *	
Texas	
* * * * *	
Odessa	7, 9, 15, 23, *28, 30

Community	Channel No.
* * * * *	

* * * * *

[FR Doc. 2026–22833 Filed 11–6–26; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 261104–0005]

RIN 0648–BN99

Pacific Island Fisheries; Commercial Fishing in the Pacific Remote Islands Marine National Monument Expansion

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule, request for comments.

SUMMARY: NMFS proposes to amend regulations that prohibit commercial fishing in the Pacific Remote Islands Marine National Monument Expansion (PRIMNM Expansion), which comprises waters of the U.S. exclusive economic zone (EEZ) between 50 to 200 nautical miles (nmi; 93 to 370 kilometers (km)) around Johnston Atoll and Wake and Jarvis Islands. This action is necessary to conform fishing regulations with Presidential Proclamation 10918 of April 17, 2025—Unleashing American Commercial Fishing in the Pacific, as amended by Presidential Proclamation 11035 of June 11, 2026—Restoring American Commercial Fishing in the Pacific, and in light of a court order. Fisheries in the PRIMNM Expansion would be regulated pursuant to existing fishing regulations under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the Western and Central Pacific Fisheries Convention Implementation Act (WCPFCIA), the South Pacific Tuna Act (SPTA), and other applicable laws, that apply to all U.S. commercial fishing vessels but were superseded and made inapplicable when the commercial fishing prohibition for the PRIMNM Expansion was established. The proposed rule supports the long-term sustainability of U.S. fisheries and provides for the proper care and management of the PRIMNM and PRIMNM Expansion and the objects of historic or scientific interest therein, as directed by Proclamation 10918, as amended by Proclamation 11035.

DATES: NMFS must receive comments by December 9, 2026.

ADDRESSES: A plain language summary of this proposed rule is available at *https://www.regulations.gov/docket/NOAA-NMFS-2026-2410.* You may submit comments on this document, identified by NOAA–NMFS–2026–2410, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit *https://www.regulations.gov* and type NOAA–NMFS–2026–2410 in the Search box, Click the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Sarah Malloy, Regional Administrator, NMFS Pacific Islands Regional Office (PIRO), 1845 Wasp Blvd. Bldg. 176, Honolulu, HI 96818.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). NMFS has voluntarily prepared an environmental assessment (EA) that discusses the impact on the quality of the human environment as a result of this proposed rule and the resumption of commercial fishing under applicable regulations in PRIMNM Expansion. The EA, and other supporting documents referenced in this rule are available at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jarad Makaiau, NMFS PIRO Sustainable Fisheries, 808–725–5000.

SUPPLEMENTARY INFORMATION: Since the 1980s, NMFS and the Western Pacific Fishery Management Council (Council) have managed fisheries in the U.S. EEZ in the Western Pacific through five species-based fishery management plans (FMP) consistent with the provisions of the Magnuson-Stevens Act—the Bottomfish and Seamount Groundfish FMP, the Crustaceans FMP, the Precious Corals FMP, the Coral Reef Ecosystems FMP, and the Pelagic FMP. Pursuant to section 303(a) of the Magnuson-Stevens Act, an FMP, FMP amendment and the issuance of implementing regulations, or modification to regulations under section 303(c) are undertaken when necessary and appropriate for the conservation and management of the fishery to prevent overfishing and rebuild overfished stocks, and to protect, restore, and promote the long-term health and stability of the fishery, consistent with the Magnuson-Stevens Act's National Standards. NMFS, in cooperation with the Council, implements or amends FMP regulations that prevent overfishing while achieving on a continuing basis the optimum yield from each fishery for the U.S. fishing industry when the best scientific information available indicate it is necessary or appropriate.

In 2009, the Council recommended, and NMFS approved the restructuring of the five species-based FMPs by incorporating the conservation and management measures of the species-based FMPs into five place-based fishery ecosystem plans (FEP)—the American Samoa FEP, the Hawaii FEP, the Marianas FEP, the Pacific Remote Islands Area FEP (PRIA FEP) and the Pelagics FEP (75 FR 2198, January 14, 2010). In developing these FEPs, NMFS also prepared an environmental impact statement that evaluated the potential environmental effects of fishing under the five place-based FEPs.

The PRIA FEP governs fishing in the U.S. EEZ (0 to 200 nmi; 0 to 370 km) around the Pacific Remote Island Areas (PRIA) of Baker, Jarvis, Wake and Howland Islands, Kingman Reef, and Johnston and Palmyra Atolls and establishes conservation and management measures for coral reef fish, bottomfish, crustacean, and precious coral fisheries, including permit and reporting requirements, marine protected areas, gear restrictions, at-sea observer requirements and other measures to ensure sustainable fishing. Since 2010, the PRIA FEP has been amended three times and NMFS has evaluated the potential environmental effects of fishing under the amended FEP consistent with the Magnuson-Stevens Act, the National Environmental Policy Act (NEPA), the Endangered Species Act (ESA) and other applicable laws.

Similarly, the Pelagics FEP establishes conservation and management measures for pelagic fisheries and includes limited access programs, gear restrictions, protected species mitigation measures, prohibited area management and other measures to ensure sustainable fishing. Since 2010, the Pelagics FEP has been amended 12 times and NMFS has evaluated the potential environmental effects of

fishing under the amended FEP consistent with the Magnuson-Stevens Act, NEPA, ESA and other applicable laws. Regulations implementing the PRIA FEP and Pelagics FEP are found at 50 CFR part 665 subparts E and F, respectively. General Magnuson-Steven Act regulations prohibiting the use of any gear or participation in a fishery not on the list of authorized fisheries and gear under a fishery management plan are also found at 50 CFR 600.725.

In addition, U.S. fisheries for highly migratory species (HMS), including tunas and billfish in the U.S. EEZ around the PRIA, and on the adjacent high seas are also subject to regulations implementing the WCPFCIA, the SPTA and other applicable laws. Regulations implementing conservation and management measures pursuant to these Acts are found in 50 CFR 300 subparts D and O, respectively. When these regulations were codified, NMFS likewise evaluated the potential environmental effects of fishing for HMS consistent with the WCPFCIA, the SPTA, NEPA, ESA and other applicable laws.

On January 6, 2009, Presidential Proclamation 8336 established the PRIMNM for the purpose of protecting objects of historic or scientific interest identified in the proclamation, including corals, fish, shellfish, marine mammals, seabirds, water birds, land birds, insects, and vegetation not found elsewhere (74 FR 1565, January 12, 2009). At that time, the PRIMNM comprised the waters and submerged and emergent lands of Wake Island, Baker Island, Howland Island, Jarvis Island, Johnston Atoll, Kingman Reef, and Palmyra Atoll seaward to a distance approximately 50 nmi (93 km) from the mean low water line around each island, reef, and atoll. Proclamation 8336 directed the Secretaries of Commerce and the Interior to prohibit commercial fishing within the boundaries of the PRIMNM and authorized the Secretaries to permit non-commercial fishing, including recreational fishing in the PRIMNM. The proclamation also directed the Secretaries to take appropriate action pursuant to their respective authorities under the Antiquities Act and the Magnuson-Stevens Act, and such other authorities as may be available to implement this proclamation, to regulate fisheries, and to provide for the proper care and management of the monument. Proclamation 8336 had the effect of making the existing regulations authorizing and regulating sustainable commercial fishing in the U.S. EEZ in the PRIMNM inapplicable (50 CFR 665 subparts E and F). The Council did not, however, recommend nor did NMFS take action to amend those regulations, and they remain codified in the Code of Federal Regulations.

On June 3, 2013, NMFS published a final rule establishing requirements for fishing in the PRIMNM (78 FR 32996). Specifically, the final rule added regulatory provisions to codify the non-discretionary prohibition on commercial fishing and established new management measures for non-commercial fishing, including recreational fishing, including permit and reporting requirements and other discretionary measures NMFS, with input from the Council, deemed necessary and appropriate to regulate non-commercial fishing in the PRIMNM (78 FR 32996, June 3, 2013; 78 FR 39583, July 2, 2013).

On September 25, 2014, Presidential Proclamation 9173 expanded the boundaries of the PRIMNM around Wake Island, Johnston Atoll, and Jarvis Island to the seaward limit of the U.S. EEZ to establish the PRIMNM Expansion (79 FR 58645, September 29, 2014). The purpose of the PRIMNM Expansion was to provide an expanded area for the protection of objects of scientific interest identified in the proclamation, including seamounts, deep sea corals, sea turtles, seabirds, and other migratory species. Proclamation 9173 directed the Secretaries of Commerce and the Interior to prohibit commercial fishing within the boundaries of the PRIMNM Expansion and authorized the Secretaries to permit non-commercial fishing and provide a process to ensure recreational fishing continues to be managed as a sustainable activity in the PRIMNM and PRIMNM Expansion. The proclamation also directed the Secretaries to take appropriate action pursuant to their respective authorities under the Antiquities Act and the Magnuson-Stevens Act, and such other authorities as may be available to implement the proclamation, to regulate fisheries, and to provide for the proper care and management of the monument. Proclamation 9173 had the effect of making the existing regulations authorizing and regulating sustainable commercial fishing in the U.S. EEZ in the PRIMNM Expansion inapplicable (50 CFR 665 subparts E and F). The Council did not, however, recommend nor did NMFS take action to amend those regulations, and they also remain codified in the Code of Federal Regulations.

On March 25, 2015, NMFS published a final rule establishing requirements for fishing in the PRIMNM Expansion (80 FR 15694). Specifically, the final rule added regulatory provisions to codify the non-discretionary prohibition on commercial fishing in the PRIMNM Expansion and established new management measures for non-commercial fishing, including recreational fishing in the PRIMNM Expansion, including permit and reporting requirements among other discretionary measures NMFS, with input from the Council, deemed necessary and appropriate to regulate non-commercial fishing in the PRIMNM Expansion.

On April 17, 2025, Presidential Proclamation 10918—Unleashing American Commercial Fishing in the Pacific (90 FR 16987, April 22, 2025) provided that a prohibition on commercial fishing in the PRIMNM Expansion ''is not, at this time, necessary for the proper care and management of the Monument or the objects of historic or scientific interest therein'' and declared the ''section entitled 'Management of the Marine National Monument' in Proclamation 9173 is deleted and replaced'' with a provision that includes direction that the Secretary of Commerce not prohibit commercial fishing. Specifically, Proclamation 10918 provides: ''Between 50 to 200 nautical miles from the landward boundaries of the Monument, the Secretary of Commerce shall not prohibit commercial fishing within the boundaries of the Monument and the Monument Expansion in those areas where the Monument and Monument Expansion is coterminous with the Exclusive Economic Zone of the United States.'' Proclamation 10918 also directed the Secretaries of Commerce and the Interior to take appropriate action pursuant to their respective authorities under the Antiquities Act, the Magnuson-Stevens Act, and such other authorities as may be available to implement the proclamation, to regulate fisheries, and to provide for the proper care and management of the PRIMNM Expansion.

On April 25, 2025, due to inquiries from the regulated fishing industry on whether fishermen could fish in the PRIMNM Expansion given Proclamation 10918, NMFS issued a letter to the regulated community notifying fishermen that regulations implementing the prohibition on commercial fishing in Proclamation 9173 are no longer effective. NMFS further indicated it planned to expeditiously initiate rulemaking to bring fishing regulations into compliance with Proclamation 9173 as amended by Proclamation 10918. NMFS's letter was subsequently challenged in court by various

individuals and environmental groups in *Kapa'a* v. *Trump,* 794 F. Supp. 3d 793 (D. Haw. 2025). The U.S. District Court for the District of Hawaii found the plaintiffs were ''entitled to participate in a notice and comment'' process on whether commercial fishing in the PRIMNM Expansion would be appropriately managed to provide for the proper care and management of monument resources (*Kapa'a,* 794 F. Supp. 3d at 823).

At its 206th meeting held March 24–26, 2026, in Honolulu, the Council considered management alternatives to amend fisheries regulations at 50 CFR part 665 to restore commercial fishing in the PRIMNM Expansion consistent with Presidential Proclamation 10918. Before making final recommendations, the Council provided opportunity for public testimony and comment (91 FR 11046, March 6, 2026). The public comments received reflected both support and opposition to the resumption of commercial fishing in the PRIMNM Expansion.

After considering public comments, the Council recommended revising commercial fishing prohibitions to authorize commercial fishing in the PRIMNM Expansion subject to the regulatory requirements that had been superseded and made inapplicable by commercial fishing prohibitions established in Presidential Proclamation 9173.

Before the Council transmitted its proposed regulations for Secretarial review pursuant to Section 303(c) of the Magnuson-Stevens Act, on June 11, 2026, the President issued Proclamation 11035, ''Restoring American Commercial Fishing in the Pacific,'' (91 FR 36741, June 17, 2026). Proclamation 11035 amended Proclamation 10918 ''to clarify that the proclamation itself removes monument-based prohibitions on commercial fishing and agency rulemaking is intended to amend or repeal inconsistent regulations.'' Accordingly, NMFS has no discretion and must ''amend or repeal existing regulations that are inconsistent with this proclamation's removal of monument-based prohibitions on commercial fishing'' (91 FR 36742, June 17, 2026). Thus, notice and comment rulemaking to amend monument-based prohibitions on commercial fishing would not be necessary. However, out of an abundance of caution and in light of an Order by the U.S. District Court for the District of Hawaii in *Kapa'a* v. *Trump,* NMFS is providing the public with prior notice and an opportunity to comment on this proposed rule. NMFS is also requesting public comment on whether the resumption of commercial fishing under the Council and NMFS's existing regulations and restrictions provide for the proper care and management of the PRIMNM and monument resources, consistent with Proclamation 10918.

Consistent with the directives in Proclamations 10918, as amended by Proclamation 11035, this proposed rule would amend Magnuson-Stevens Act regulations at 50 CFR 665 subpart H (§§ 665.930–665.936) that prohibit commercial fishing in the PRIMNM Expansion. When finalized, commercial fisheries operating in the PRIMNM Expansion will be subject to existing fishing regulations and restrictions at 50 CFR 665 subpart A (§§ 665.1–665.20), implementing general requirements for fisheries in the Western Pacific; 50 CFR 665 subpart E (§§ 665.598–665.669) and 50 CFR subpart F (§§ 665.798–665.819), implementing the PRIA FEP and Pelagics FEP, respectively; 50 CFR 600.725, implementing Magnuson-Stevens Act general prohibitions; 50 CFR 300 subpart D (§§ 300.30–300.46), implementing the SPTA and subpart O (§§ 300.210–300.230), implementing WCPFCIA.

Under the proposed action, commercial fishing shoreward of 50 nmi (93 km) around Wake Island, Johnston Atoll and Jarvis Island in the PRIMNM will continue to be prohibited by regulations at 50 CFR 665 subpart H (§§ 665.933–665.934) implementing the PRIMNM, consistent with Presidential Proclamation 10918, as amended by Presidential Proclamation 11035. For this reason, NMFS anticipates only longline and purse seine fishing for highly migratory species such as tunas and billfish would resume in the PRIMNM Expansion because the habitat to support non-pelagic species managed under the PRIA FEP, including bottomfish, crustacean, coral reef and precious corals are found entirely within 50 nmi (93 km) from shore, which will remain closed to commercial fishing.

NMFS anticipates the resumption of commercial fishing by pelagic longline and purse seine vessels in the PRIMNM Expansion under the proposed action would have no effect on terrestrial resources, coral reefs, shallow water coral reef ecosystem resources, reef fish, shellfish, and outer reef slope communities because these monument resources are found entirely within 12 nmi (22 km) from the shoreline, well within the 50 nmi (93 km) boundary where commercial fishing will remain prohibited and are spatially separated from commercial fishing activities. Similarly, NMFS does not anticipate the resumption of commercial fishing in the PRIMNM Expansion would result in adverse impacts to seamounts, deep sea coral communities and demersal habitats because pelagic fishing gear is deployed in the water column within 985 ft (300 m) of the surface and does not come into contact with the ocean floor. As such, commercial fishing activities are spatially separated from these resources and unlikely to affect them.

In addition, reverting to existing management measures for resuming commercial fishing in the PRIMNM Expansion is in accordance with the Magnuson-Stevens Act, ESA of 1973, and Marine Mammal Protection Act of 1972 (MMPA). NMFS evaluates the impacts of fishing activity on the population of target stocks and protected species throughout the entirety of their range. Under the proposed action, NMFS expects the combined amount of catch of target stocks and other marketable fishery resources by longline and purse seine fisheries within the PRIMNM Expansion would remain within historical levels and would not cause a change in the sustainability of fish populations throughout their range as currently assessed in accordance with the Magnuson-Stevens Act and other domestic and international requirements.

Similarly, NMFS expects the shift of fishing effort by longline and purse seine fishing vessels from the high seas into the PRIMNM Expansion would result in a negligible change in the amount of fishery interactions over the range of ESA-listed species, including sea turtles, sharks and rays, marine mammals, and seabirds. And we anticipate interactions would remain within the levels that do not exceed thresholds established under ESA consultations. Based on ESA consultations and analyses, the overall effects on protected species are expected to be negligible.

NMFS expects a likely minor, beneficial impact to fisheries operations and management. For longline and purse seine vessels, the proposed action would restore 2.04 percent and 1.55 percent of historical fishing areas, respectively. The longline and purse seine fisheries will also experience minor beneficial impacts due to reduced competition with foreign fleets, which are prohibited from fishing in U.S. waters of the PRIMNM Expansion and access to fishing areas closer to home ports, reducing transit times and overall fuel and operational costs.

NMFS estimates up to a maximum of 6 percent of the total effort of the purse seine fishery to shift to the Jarvis Island

EEZ and up to a maximum of 6 percent of the total effort of longline fisheries to shift to the Johnston Atoll from areas currently accessible to the fisheries. Because the functional restraints, including catch and effort limits and limited entry permits on the fisheries will not change as a result of this action, NMFS expects negligible impacts on fisheries catch and effort and target fish populations.

Thus, NMFS expects the resumption of commercial fishing in the PRIMNM Expansion would not result in a substantial increase in vessel traffic or fishing gear entering the PRIMNM Expansion and is expected to have negligible effects on monument resources, given the limited increase in fishing activity expected, and spatial protective boundary within 50 nmi (93 km). Additionally, Federal protections under current laws governing vessel operations, marine pollution, refuge management, and gear management and disposal would limit impacts by vessels operating in the PRIMNM Expansion.

NMFS also expects resumption of commercial fishing in the PRIMNM Expansion would have negligible effects on activities managed under authorities other than the Magnuson-Stevens Act, as directed by Proclamation 10918. This is because within the PRIMNM Expansion, transiting of maritime vessels, including innocent passage is the primary non-fishing activity that occurs in this area, and NMFS anticipates transiting vessels would avoid vessels actively engaged in fishing so as to avoid collisions.

To the extent that other non-fishing activities may occur, they would be subject to management by the U.S. Fish and Wildlife Service. NMFS believes that the commercial fishing that would resume under the proposed action would not interfere with other non-fishing activities managed by the U.S. Fish and Wildlife Service.

NMFS further expects impacts on cultural resources would be negligible due to the geographic separation from fishing activities and land-based practices and the low likelihood of encounters between cultural practitioners and voyagers and fishing vessels in the PRIMNM Expansion. Since the establishment of the PRIMNM Expansion, zero cultural practitioners have sought Special Use Permits for cultural activities.

Finally, NMFS expects the resumption of commercial fishing in the PRIMNM Expansion under the proposed action would result in minor beneficial impacts on fishery economics, as vessels could save cost on fuel by fishing closer to home ports instead of on the high seas and purse seine vessels may avoid daily access fees required for fishing in foreign EEZs adjacent to the PRIMNM Expansion.

As discussed above, regulations at 50 CFR 665 subpart A (§§ 665.1–665.20), 50 CFR 665 subpart E (§§ 665.598–665.669); 50 CFR subpart F (§§ 665.798–665.819); 50 CFR 600.725; 50 CFR 300 subpart D (§§ 300.30–300.46); and 50 CFR 300 subpart O (§§ 300.210–300.230) provide the conservation and management measures developed and evaluated under the Magnuson-Stevens Act and other applicable law, including NEPA, the ESA, and MMPA. Under these existing regulations and restrictions, NMFS believes that commercial fisheries operating in the PRIMNM and PRIMNM Expansion would be appropriately managed and that monument resources would receive proper care and management, consistent with the direction in Proclamation 10918.

NMFS invites public comment on whether these existing regulations and restrictions appropriately manage commercial fishing and would provide for the proper care and management of monument resources in the PRIMNM and PRIMNM Expansion, consistent with the proclamation.

NMFS will consider public comments on this proposed rule and will announce the final rule in the **Federal Register**. NMFS must receive any comments by the date provided in the **DATES**.

Classification

Magnuson-Stevens Act

NMFS is proposing this rule pursuant to 305(d) of the Magnuson-Stevens Act to carry out section 303(a)(1)(C). This action is necessary to ensure that MSA regulations implementing the PRIA FEP and Pelagics FEP are carried out consistent with Presidential Proclamation 10918, as amended by Proclamation 11035, directing the removal of monument-based prohibitions on commercial fishing in the PRIMNM Expansion. Accordingly, this proposed rule would amend those regulations that are inconsistent with Proclamation 10918, as amended by Proclamation 11035. The Assistant Administrator for Fisheries, NOAA has determined that this rule is consistent with, and conforms to Presidential Proclamation 10918, as amended by Proclamation 11035, the Antiquities Act, the PRIA and Pelagics FEPs, other provisions of the Magnuson-Stevens Act, and other applicable laws.

NEPA

This proposed action is to bring Magnuson-Stevens Act implementing regulations in conformity with applicable law—specifically Presidential Proclamation 10918—as amended by Proclamation 11035, which removed prohibitions on commercial fishing described in Presidential Proclamation 9173, and specified that agency rulemaking is intended to amend inconsistent regulations. NMFS has voluntarily prepared an EA that discusses the impact on the quality of the human environment as a result of this rule and the resumption of commercial fishing under applicable regulations in the PRIMNM Expansion. NMFS considered two alternatives: the proposed action to amend regulations that restrict commercial fishing in the PRIMNM Expansion, which would restore commercial fishing under existing regulations and taking no action which would maintain existing commercial fishing prohibitions in the PRIMNM Expansion.

A copy of the EA is available from NMFS (See **ADDRESSES**).

Executive Order 12866

This proposed rule has been determined to be significant for purposes of Executive Order 12866 section 3(f). However, it has not been found to be economically significant under section 3(f)(1) because it would not likely result in an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

Executive Order 14192

This proposed rule is considered an Executive Order 14192 deregulatory action because it would amend regulations that prohibit commercial fishing between 50 to 200 nautical miles (nmi; 93 to 370 kilometers (km)) around Johnston Atoll and Wake and Jarvis Islands and restore access to these areas for U.S. commercial fishermen.

Regulatory Flexibility Act

The Senior Lead Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

The proposed rule would amend regulations under the Magnuson-Stevens Act that prohibit commercial

fishing between 50 to 200 nmi (93 to 370 km) around Wake Island, Johnston Atoll and Jarvis Island in the PRIMNM Expansion. This action, which would expand areas open to commercial fishing by over 300,000 square nmi (1,030,000 square km), is necessary to conform U.S. fishing regulations with Presidential Proclamation 10918 of April 17, 2025—Unleashing American Commercial Fishing in the Pacific, and Presidential Proclamation 11035 of June 11, 2026—Restoring American Commercial Fishing in the Pacific, and in light of the U.S. District Court of Hawaii's Order in *Kapa'a* v. *Trump,* 794 F. Supp. 3d 793 (D. Haw. 2025), which found the plaintiffs were entitled to participate in a notice and comment process on whether commercial fishing in the PRIMNM Expansion would be appropriately managed to provide for the proper care and management of monument resources.

The proposed action would apply to all fisheries managed under the PRIA FEP and Pelagics FEP, as well as the U.S. purse seine and longline vessels operating under the SPTA and the WCPFCIA. However, given the remote location of the monument and considerable distance from U.S. ports, the fisheries affected are essentially limited to longline and purse seine fisheries; the areas between 50 to 200 nmi (93 to 370 km) around Wake Island, Johnston Atoll and Jarvis Island that would be reopened by this action (hereafter the PRIMNM Expansion) are generally inaccessible to small boat fisheries managed under the Pelagics FEP. While the proposed action would apply to as many as 224 longline vessels and 40 purse seine vessels, given recent fishing activities, it would likely affect only the 163 permitted and active longline vessels and 13 licensed and active purse seine vessels. The Hawaii and American Samoa longline fisheries are limited entry fisheries. The Hawaii longline fishery is capped at 164 vessels with 149 currently permitted. The American Samoa longline fishery is capped at 60 vessels with 20 currently permitted. Six of those 20 current permit holders are dual permitted so they also possess current Hawaii longline vessel permits. The purse seine fleet is limited to a total of 40 licenses under the SPTA, with 13 active licensed vessels. There has historically been only very limited fishing by the Pelagics FEP small boat fisheries and none by the PRIA FEP fisheries within the PRIMNM Expansion. This is because habitat to support species managed under the PRIA FEP, including bottomfish, crustacean, coral reef fish and precious corals are found entirely within 50 nmi (93 km) from shore, which will remain closed to commercial fishing.

NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (North American Industry Classification System code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. Based on available information, NMFS believes that most of the affected fish harvesting businesses are small entities under the NMFS standard, as they are engaged in the business of fish harvesting, independently owned or operated, are not dominant in their field of operation, and have annual gross receipts not in excess of $11 million. In 2025, the Hawaii longline fishery earned $109 million fleetwide ($731,543 per vessel on average) while the American Samoa longline fishery earned approximately $3 million ($150,000 per vessel on average). With regard to the purse seine fleet, the majority, but not all vessels, could be considered small entities. For the 11 vessels that operated between 2022 and 2024 and were still active in 2025, the average per vessel revenue was almost $10 million. Seven of those 11 vessels could be considered small entities with estimated revenues of less than $11 million. Even though this proposed action may apply to a substantial number of entities, based on our analysis the implementation of this action would not result in significant adverse economic impacts on individual entities.

The primary benefit for fishermen under the proposed action is a modest increase in the available U.S. EEZ waters where U.S. fishing vessels do not have to compete with foreign fleets for access to fish. This benefit primarily applies to longline fleets based in Hawaii, where the majority of U.S. EEZ waters are closed due to the longline exclusion zone around the main Hawaiian Islands (50 CFR 665.806(a)(2)) and prohibitions on commercial fishing in the PRIMNM (50 CFR 665.933), Papahānaumokuākea Marine National Monument (50 CFR 404) and Papahānaumokuākea National Marine Sanctuary (15 CFR 922 subpart W—Papahānaumokuākea National Marine Sanctuary). From the purse seine fishery perspective, the major benefit is related to avoiding costs associated with fishing in the EEZs of foreign nations that, under the SPTA, charge daily access fees for fishing activity. These access fees range from $10,000 to $13,000 per day, depending on the EEZ or groups of EEZs that are fished. Considered relative to daily average revenue for purse seine vessels ($68,000), these fees are about 14 to 19 percent of daily revenue, on days that these vessels fish in the EEZs of foreign nations that charge daily access fees.

The amount of annual effort shifted to the action area from current fishing locations under the proposed action is expected to range from 0 to about 6 percent of overall fleetwide effort in both the longline and purse seine fisheries given past fishing in the action area prior to the initial commercial fishery prohibitions in 2009 and further expansion of fishing restrictions in 2014. In longline fisheries, deep- and shallow-set fisheries combined averaged 22,020 sets over the last 5 years (2020–2024). This suggests that the number of sets that could shift to areas that open as a result of implementing the proposed action could range from 0 to 1,321 longline sets fleetwide. For purse seine fisheries, the number of sets has averaged 1,753 in the last 5 years (2020–2024). Implementing the proposed action could shift the number of purse seine sets in these waters ranging from 0 to 105 sets fleetwide.

With regard to longline vessels, there could potentially be some savings in fuel costs associated with this anticipated switched effort; however, both Johnston Atoll and Jarvis Island are far from Honolulu relative to where the majority of longline effort is concentrated. The anticipated fuel cost differences for shifted effort under the proposed action are difficult to estimate, but fuel represents about 50 percent of the total costs of a fishing trip and therefore does represent a substantial portion of operating costs.

For purse seine vessels, a similar magnitude minor shift in effort under the proposed action may affect fuel costs. In general, purse seine fishing is concentrated in the productive skipjack tuna fishing waters to the west and south of the PRIMNM Expansion; inside the EEZs of countries party to the South Pacific Tuna Treaty. Transit distances to Jarvis Island from the center of purse seine effort would be significant, but the lack of daily access fees in the PRIMNM Expansion may increase the economic value of reopened areas around Jarvis Island. If we assume that all effort shifted to the PRIMNM Expansion under the proposed action moved from areas where a daily access fee was required, the total savings fleetwide could be as high as $1,367,340. Based

on 13 currently licensed and active purse seine vessels, each vessel could save up to $105,180 per year in access fees, or roughly 1 percent of a vessel's average annual revenue of $10 million. Revenue gains would be on the higher end of the potential range if purse seine vessels decide to fully transition away from foreign EEZs upon reopening commercial fishing in the PRIMNM Expansion, and closer to zero if they do not. Because fishing location choice is based on many factors, and fishermen are unlikely to fully transition away from foreign EEZs, the fleet-wide revenue gain as a result of the expanded locations available for commercial fishing as a result of this proposed action, would likely be less than $1,367,340, and individual vessel revenue gains would be lower than $105,180 (*i.e.,* lower than 1 percent).

The proposed action does not duplicate, overlap, or conflict with other Federal rules and is not expected to have a significant impact on small entities, organizations or government jurisdictions. The proposed action also will not place a substantial number of small entities at a significant competitive disadvantage nor disproportionately flow to large entities because the expansion of fishing areas would provide minor benefits to all entities without regard to the size of each individual entity.

For the reasons above, NMFS does not expect the proposed action to have a significant economic impact on a substantial number of small entities.

As a result, an initial regulatory flexibility analysis is not required, and none has been prepared.

Paperwork Reduction Act

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

Coastal Zone Management Act

Because this proposed rule affects fisheries that occur outside the coastal zone of any State and will not have reasonably foreseeable effects on any coastal use or resource, NMFS is not required to coordinate with State agencies under section 307 of the Coastal Zone Management Act.

ESA

Fishing activities conducted pursuant to this rule will not affect endangered and/or threatened species or critical habitat under the ESA in a manner that would result in effects that have not previously been considered in current ESA section 7 consultations.

Under the proposed rule, NMFS anticipates only longline and purse seine fishing for HMS such as tunas and billfish would be resumed in the PRIMNM Expansion because the habitat to support non-pelagic species such as bottomfish, crustacean, coral reef and precious corals are found entirely within 50 nmi (93 km) from shore, which will remain closed to commercial fishing.

NMFS previously evaluated the potential impact of longline and purse seine fisheries on ESA-listed species and designated critical habitat in areas of the Pacific Ocean where fishing vessels fish and transit on their way to fishing grounds. NMFS determined these fisheries are not likely to jeopardize the continued existence of ESA-listed species or result in adverse modification of designated critical habitat.

NMFS does not expect that resuming commercial longline and purse seine fishing under existing fishing regulations in the PRIMNM Expansion would cause an effect on endangered and/or threatened species or critical habitat beyond that considered in applicable consultations for these fisheries. This conclusion is reached in part because there is no designated critical habitat for ESA-listed species in the PRIMNM Expansion for pelagic longline and purse seine fisheries to affect. Additionally, some ESA-listed species such as corals are only found in shallow nearshore waters around the islands and well within 50 nmi (93 km) of shore where commercial fishing remains prohibited. This buffer provides spatial separation that prevents their exposure to fishing activities occurring 50 to 200 nmi (93 to 370 km) offshore.

Many of the ESA-listed species, such as sea turtles, sharks and manta rays are highly migratory, and the PRIMNM Expansion represents just a small fraction of their range. For this reason, existing ESA consultations account for the potential population level impacts of fishing activities on ESA-listed species that may visit the PRIMNM Expansion but are exposed to fishing activities throughout their range.

Historically, annual fishing effort in the PRIMNM waters prior to monument designation represented up to a maximum of 6 percent of total fishing effort for longline and purse seine fisheries. As both longline and purse seine fisheries are limited entry fisheries with maximum caps on the number of vessels that can fish, we expect that fishing in the restored areas of the PRIMNM Expansion will reflect effort by existing vessels shifting from currently open fishing areas into the PRIMNM, as opposed to additional increased fishing effort.

Therefore, the shift in some fishing effort from outside the PRIMNM Expansion into the PRIMNM Expansion is expected to result in a negligible change in the amount of fishery interactions over the range of ESA-listed species and would remain within the levels considered and analyzed in the current ESA section 7 consultations for these fisheries. The results of the ESA consultations for Pacific Island longline and purse seine fisheries are detailed in the EA developed for this action (see **ADDRESSES**).

Executive Order 13175

NMFS has determined that this action would not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes; therefore, consultation with Tribal officials under E.O. 13175 is not required, and the requirements of sections (5)(b) and (5)(c) of E.O. 13175 also do not apply. A Tribal summary impact statement under section (5)(b)(2)(B) and section (5)(c)(2) of E.O. 13175 is not required and has not been prepared.

List of Subjects in 50 CFR Part 665

Administrative practice and procedure, Commercial fishing, Fisheries, Monuments and memorials, Pacific Remote Islands.

Dated: November 5, 2026.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS proposes to amend 50 CFR part 665 as follows:

PART 665—FISHERIES IN THE WESTERN PACIFIC

■ 1. The authority citation for 50 CFR Part 665 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. Amend § 665.932 by revising the definition of ''Proclamations'' to read as follows:

§ 665.932 Definitions.

* * * * *

Proclamations means Presidential Proclamation 8336 of January 6, 2009, ''Establishment of the Pacific Remote Islands Marine National Monument,'' Presidential Proclamation 9173 of September 29, 2014, ''Pacific Remote Islands Marine National Monument

Expansion,'' Presidential Proclamation 10918 of April 17, 2025 ''Unleashing American Commercial Fishing in the Pacific,'' and Presidential Proclamation 11035 of June 11, 2026, ''Restoring American Commercial Fishing in the Pacific.''

■ 3. Amend § 665.933 by revising paragraph (a) to read as follows:

§ 665.933 Prohibitions.

* * * * *

(a) Commercial fishing in prohibited areas. Commercial fishing is prohibited in the areas of the Monument as defined in paragraphs (a)(1) through (a)(5) of this paragraph.

(1) *Wake Island.* Commercial fishing is prohibited in the Wake Island unit of the Monument within an area defined by straight lines connecting the following coordinates in the order listed:

ID	Longitude—east	Latitude—north
1	165°42′56″	20°9′27″
2	167°32′23″	20°9′27″
3	167°32′23″	18°25′51″
4	165°42′56″	18°25′51″
1	165°42′56″	20°9′27″

(2) *Howland and Baker Islands.* Commercial fishing is prohibited in the Howland and Baker units of the Monument as defined in 50 CFR 931(b).

(3) *Jarvis Island.* Commercial fishing is prohibited in the Jarvis Island unit of the Monument within an area defined by straight lines connecting the following coordinates in the order listed:

ID	Longitude—west	Latitude
1	160°50′52″	0°28′39″ N
2	159°8′53″	0°28′39″ N
3	159°8′53″	1°13′15″ S
4	160°50′52″	1°13′15″ S
1	160°50′52″	0°28′39″ N

(4) *Johnston Atoll.* Commercial fishing is prohibited in the Johnston Atoll unit of the Monument within an area defined by straight lines connecting the following coordinates in the order listed:

ID	Longitude—west	Latitude—north
1	170°24′37″	17°35′39″
2	168°37′32″	17°35′39″
3	168°37′32″	15°53′26″
4	170°24′37″	15°53′26″
1	170°24′37″	17°35′39″

(5) *Kingman and Palmyra Atoll.* Commercial fishing is prohibited in the Kingman Reef and Palmyra Atoll unit of the Monument as defined in 50 CFR 931(e).

* * * * *

■ 4. Amend § 665.934 by revising paragraph (a) to read as follows:

§ 665.934 Regulated activities.

(a) Commercial fishing in the Monument is prohibited in certain areas, as defined in § 665.933.

* * * * *

■ 5. Amend § 665.935 by revising introductory paragraph (a) and paragraph (a)(1) to read as follows:

§ 665.935 Fishing permit procedures and criteria.

(a) *Non-commercial and commercial fishing—*

(1) *Applicability.* Except as provided in section 665.934(d), a vessel that is used to non-commercially or commercially fish for, take, retain, or possess MUS in the Monument must be registered for use with a permit issued pursuant to §§ 665.603, 665.624, 665.642, 665.662, and 665.801.

* * * * *

[FR Doc. 2026–22815 Filed 11–6–26; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 91, No. 215
Monday, November 9, 2026

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2026–1288]

Pioneer Hi-Bred International, Inc.: Availability of a Petition for a Determination of Nonregulated Status and Draft Plant Pest Risk Assessment for Insect Resistant COR-ØØ121–4 Maize (Zea mays)

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has received a petition from Pioneer Hi-Bred International, Inc. seeking a determination of nonregulated status for COR-ØØ121–4 maize (corn), which has been developed using genetic engineering to express the IPD083Cb protein for protection against certain susceptible lepidopteran pests and the phosphomannose isomerase protein that was used as a selectable marker. We are making the petition and draft plant pest risk assessment available for public review and comment.

DATES: We will consider all comments that we receive on or before January 8, 2027.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2026–1288 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2026–1288, Regulatory Analysis and Development, PPD, APHIS, 5601 Sunnyside Avenue #AP760, Beltsville, MD 20705.

The petition, draft plant pest risk assessment, and any comments we receive on this docket may be viewed at *www.regulations.gov,* or in our reading room, which is located in 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. Alan Pearson, Biotechnology Regulatory Services, APHIS, USDA, 5601 Sunnyside Avenue, AP100–3–WS–1151, Beltsville, MD 20705; (301) 851–3944; email: *alan.pearson@usda.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,'' regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such organisms and products are considered ''regulated articles.''

Section 340.6(a) of the regulations provides that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 26–084–01p) from Pioneer Hi-Bred International, Inc. seeking a determination of nonregulated status for COR-ØØ121–4 maize (corn), referred to as COR121 maize, which has been developed using genetic engineering to express the IPD083Cb protein for protection against certain susceptible lepidopteran pests and the phosphomannose isomerase protein that was used as a selectable marker. The petition states that the information provided indicates that COR121 maize is unlikely to pose a plant pest risk and therefore should not be regulated under APHIS' regulations in 7 CFR part 340.

As part of our decision-making process regarding the organism's regulatory status, APHIS prepared a draft plant pest risk assessment (PPRA) to assess the plant pest risk of the organism. APHIS' draft PPRA compared the pest risk posed by COR121 maize with that of the unmodified variety from which it was derived. The draft PPRA concluded that COR121 maize is unlikely to pose an increased plant pest risk compared to the unmodified corn.

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the **Federal Register** providing 60 days for public comment on petitions for a determination of nonregulated status. In accordance with § 340.6(d), we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition and draft PPRA from interested or affected persons for a period of 60 days from the date of this notice. The petition and draft PPRA are available for public review and comment, and copies are available as indicated under **ADDRESSES** and from the individual listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. We are particularly interested in receiving comments regarding biological or ecological issues, and we encourage the submission of scientific data, studies, or research to support your comments.

After the comment period closes, APHIS will review and evaluate any information received during the comment period and any other relevant information. Based upon available information, APHIS will respond to the petitioner either approving or denying the petition. APHIS will post its regulatory determination on its website and publish a notice of availability in the **Federal Register**.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 26th day of October 2026.

Kelly Moore,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2026–22810 Filed 11–6–26; 8:45 am]

BILLING CODE 3410–34–P

CIVIL RIGHTS COLD CASE RECORDS REVIEW BOARD

[Agency Docket Number: CRCCRRB–2027–0003–N]

Notice of Formal Determination on Records Release

AGENCY: Civil Rights Cold Case Records Review Board.

ACTION: Notice.

SUMMARY: The Civil Rights Cold Case Records Review Board received 11,428 pages of records and one video recording from the National Archives and Records Administration (NARA) related to two civil rights cold case incidents to which the Review Board assigned the unique identifiers 2024–003–008 and 2024–003–060. NARA proposed 1,864 postponements including postponements of sealed federal grand jury information in the records. After consultation with the Review Board, NARA withdrew 64 postponements. On October 23, 2026, the Review Board approved 1,772 postponements and portions of 2 additional postponements. It determined that 9,696 pages in full and 27 pages and one video recording in part should be publicly disclosed in the Civil Rights Cold Case Records Collection. The Review Board will request that the Attorney General petition the relevant court to unseal federal grand jury information in the records for incident 2024–003–008. By issuing this notice, the Review Board complies with the Civil Rights Cold Case Records Collection Act of 2018 that requires the Review Board to publish in the **Federal Register** its determinations on the disclosure or postponement of records in the Collection no more than 14 days after the date of its decision.

FOR FURTHER INFORMATION CONTACT: Stephannie Oriabure, Chief of Staff, Civil Rights Cold Case Records Review Board, 1800 F Street NW, Washington, DC 20405, (771) 221–0014, *info@coldcaserecords.gov.*

SUPPLEMENTARY INFORMATION:

Incident identifier	Postponement identifier	Review board decision
2024–003–008	2026–NARA–03–0001 through 2026–NARA–03–0003.	Approve.
2024–003–008	2026–NARA–03–0004 through 2026–NARA–03–0006.	Withdrawn by agency.
2024–003–008	2026–NARA–03–0007 and 2026–NARA–03–0008.	Reject.
2024–003–008	2026–NARA–03–0009 through 2026–NARA–03–0015.	Withdrawn by agency.
2024–003–008	2026–NARA–03–0016 through 2026–NARA–03–0022.	Reject.
2024–003–008	2026–NARA–03–0023 and 2026–NARA–03–0024.	Withdrawn by agency.
2024–003–008	2026–NARA–03–0025	Reject.
2024–003–008	2026–NARA–03–0026	Withdrawn by agency.
2024–003–008	2026–NARA–03–0027 through 2026–NARA–03–0029.	Reject.
2024–003–008	2026–NARA–03–0030 through 2026–NARA–03–0035.	Approve.
2024–003–008	2026–NARA–03–0036 through 2026–NARA–03–0051.	Withdrawn by agency.
2024–003–008	2026–NARA–03–0052 through 2026–NARA–03–0090.	Approve.
2024–003–008	2026–NARA–03–0091	Approve with changes.
2024–003–008	2026–NARA–03–0092 through 2026–NARA–03–0095.	Approve.
2024–003–008	2026–NARA–03–0096	Approve with changes.
2024–003–008	2026–NARA–03–0097	Approve.
2024–003–008	2026–NARA–03–0098 through 2026–NARA–03–0101.	Reject.
2024–003–008	2026–NARA–03–0102 through 2026–NARA–03–1545.	Approve.
2024–003–008	2026–NARA–03–1546 through 2026–NARA–03–1549.	Reject.
2024–003–008	2026–NARA–03–1550 through 2026–NARA–03–1555.	Approve.
2024–003–008	2026–NARA–03–1556	Reject.
2024–003–060	2025–NARA–03–0634 through 2025–NARA–03–0872.	Approve.
2024–003–060	2025–NARA–03–0873	Withdrawn by agency.
2024–003–060	2025–NARA–03–0874 through 2025–NARA–03–0881.	Approve.
2024–003–060	2025–NARA–03–0882 through 2025–NARA–03–0893.	Withdrawn by agency.
2024–003–060	2025–NARA–03–0894 through 2025–NARA–03–0896.	Approve.
2024–003–060	2025–NARA–03–0897 and 2025–NARA–03–0898.	Reject.
2024–003–060	2025–NARA–03–0899 through 2025–NARA–03–0904.	Approve.
2024–003–060	2025–NARA–03–0905	Reject.
2024–003–060	2025–NARA–03–0906	Withdrawn by agency.

Incident identifier	Postponement identifier	Review board decision
2024–003–060	2025–NARA–03–0907 through 2025–NARA–03–0907c.	Approve.
2024–003–060	2025–NARA–03–0908 through 2025–NARA–03–0921.	Withdrawn by agency.
2024–003–060	2025–NARA–03–0922 through 2025–NARA–03–0929.	Approve.
2024–003–060	2025–NARA–03–0930 through 2025–NARA–03–0936.	Withdrawn by agency.
2024–003–060	2025–NARA–03–0937	Approve.
2024–003–060	2025–NARA–03–0937a	Reject.

*Authority:*Pub. L. 115–426, 132 Stat. 5489 (44 U.S.C. 2107).

Dated: November 4, 2026.

Stephannie Oriabure,

Chief of Staff.

[FR Doc. 2026–22767 Filed 11–6–26; 8:45 am]

BILLING CODE 6820–SY–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Maryland Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Maryland Advisory Committee (Committee) to the Commission will hold public meetings via Zoom. The purpose is for the committee to begin hearing expert testimony and continue briefing planning on the committee's chosen topic of artificial intelligence and its application in voting administration.

DATES:

Monday, November 9, 2026; 2:00 p.m.

Registration Link (Audio/Visual): https://www.zoomgov.com/webinar/register/WN_aUz6unNTRl6IHLKot7u__w.

• *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Webinar ID: 165 799 0113 #.

Tuesday, December 1, 2026; 10:00 a.m.–12:00 p.m.: Panel 2

Registration Link (Audio/Visual): https://www.zoomgov.com/webinar/register/WN_5LdD85bSraH84Hn3Wd8Qw.

• *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Webinar ID: 165 301 2797 #.

Tuesday, December 8, 2026; 10:00 a.m.–12:00 p.m.: Panel 3

Registration Link (Audio/Visual): https://www.zoomgov.com/webinar/register/WN_eobL-aFoQ0K2RvXgjGuIow.

• *Join by Phone (Audio Only):* 1–833–435–1820 USA Toll Free; Webinar ID: 165 732 8304 #.

Agendas: https://usccr.box.com/s/apmfnfyjmh2i44huqf8354o23sbh88hn (note: final meeting agendas will be available prior to the meeting dates).

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer, at *bpeery@usccr.gov* or 1–202–701–1376.

SUPPLEMENTARY INFORMATION: Virtual committee meetings are available to the public through the registration links above. Any interested member of the public may join at the links to listen to meetings. Open comment periods for each date will be provided to allow members of the public to make statements as time allows. Pursuant to the Federal Advisory Committee Act, public minutes of the meetings will include a list of persons who are present at the meetings. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting ''CC'' in the Zoom meeting platform. To request additional accommodations, please email *ebohor@usccr.gov* at least 10 business days prior to each meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the scheduled meeting. Written comments may be emailed to Evelyn Bohor at *ebohor@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (202) 809–9618.

Records generated from these meetings may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after meetings. Records of meetings will be available via the file sharing website: *https://tinyurl.com/mnshz8n9* as well as at: *www.facadatabase.gov* under the Commission on Civil Rights, selecting the Advisory Committee of interest. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *ebohor@usccr.gov.*

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for the November meeting is given fewer than 7 calendar days prior to the meeting because of the exceptional circumstances of staffing shortage.

Dated: November 5, 2026

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2026–22799 Filed 11–6–26; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–425–2026]

Foreign-Trade Zone 27; Approval of Subzone Status; Persimmon Technologies Corporation; Bedford, Massachusetts

On August 28, 2026, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Massachusetts Port Authority, grantee of FTZ 27, requesting subzone status subject to the existing activation limit of FTZ 27, on behalf of Persimmon Technologies Corporation, in Bedford, Massachusetts.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (91 FR 56424, September 2, 2026). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant

to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to establish Subzone 27U was approved on November 2, 2026, subject to the FTZ Act and the Board's regulations, including section 400.13, and further subject to FTZ 27's 129-acre activation limit.

Dated: November 3, 2026.

Colin Agostisi,

Executive Secretary.

[FR Doc. 2026–22765 Filed 11–6–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

C–570–244]

Certain Wooden Fence Components From the People's Republic of China: Initiation of Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable November 3, 2026.

FOR FURTHER INFORMATION CONTACT: Suresh Maniam, Office I, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0176.

SUPPLEMENTARY INFORMATION:

The Petition

On September 24, 2026, the U.S. Department of Commerce (Commerce) received a countervailing duty (CVD) petition concerning imports of certain wooden fence components [1] from the People's Republic of China (China), filed in proper form on behalf of the American Alliance of Wooden Fence Producers (the petitioner),[2] the members of which are domestic producers of certain wooden fence components.[3] The CVD Petition was accompanied by an antidumping duty (AD) petition concerning imports of certain wooden fence components from China.[4]

On October 13, 2026, Commerce extended the initiation deadline by 20 days to further examine the issue of industry support, because it was not clear from the Petition whether the industry support criteria had been met.[5]

Between September 29 and October 29, 2026, Commerce requested supplemental information pertaining to certain aspects of the Petition in supplemental questionnaires.[6] Between October 4 and 30, 2026, the petitioner filed timely responses to these requests for additional information.[7]

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that the Government of China (GOC) is providing countervailable subsidies, within the meaning of sections 701 and 771(5) of the Act, to producers of certain wooden fence components from China, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing certain wooden fence components in the United States. Consistent with section 702(b)(1) of the Act and 19 CFR 351.202(b), for those alleged programs on which we are initiating a CVD investigation, the Petition was accompanied by information reasonably available to the petitioner supporting its allegations.

Commerce finds that the petitioner filed the Petition on behalf of the domestic industry, because the petitioner is an interested party, as defined in section 771(9)(F) of the Act.[8] Commerce also finds that the petitioner demonstrated sufficient industry support with respect to the initiation of the requested CVD investigation.[9]

Period of Investigation (POI)

Because the Petition was filed on September 24, 2026, the POI is January 1, 2025, through December 31, 2025.[10]

Scope of the Investigation

The products covered by this investigation are certain wooden fence components from China. For a full description of the scope of this investigation, *see* the appendix to this notice.

Comments on the Scope of the Investigation

Between September 29 and October 14, 2026, Commerce requested information and clarification from the petitioner regarding the proposed scope to ensure that the scope language in the Petition is an accurate reflection of the products for which the domestic industry is seeking relief.[11] Between October 4 and 19, 2026, the petitioner provided clarifications and/or revised the scope.[12] The description of merchandise covered by this investigation, as described in the appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (*i.e.,* scope).[13] Commerce will consider all scope comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information, all such factual information should be limited to public information.[14] Commerce requests that interested parties provide at the beginning of their scope comments a public executive summary for each comment or issue raised in

[1] *See* Petitioner's Letter, ''Notice of Change in Case Name,'' dated November 2, 2026; *see also* Memorandum, ''Product Name Change,'' dated November 3, 2026.

[2] The individual members of the American Alliance of Wooden Fence Producers (Alliance) are Alta Forest Products, Sierra Pacific Industries, and Mendocino Forest Products.

[3] *See* Petitioner's Letter, ''Petition for the Imposition of Antidumping and Countervailing Duties,'' dated September 24, 2026 (Petition).

[4] *Id.*

[5] *See Notice of Extension of the Deadline for Determining the Adequacy of the Antidumping and Countervailing Duty Petitions: Certain Wooden Fence Pickets from China,* 91 FR 66106 (October 19, 2026) (*Initiation Extension Notice*).

[6] *See* Commerce's Letters, ''General Issues Supplemental Questions,'' dated September 29, 2026 (First General Issues Supplemental Questionnaire); ''Second General Issues Supplemental Questions,'' dated October 8, 2026 (Second General Issues Supplemental Questionnaire); ''Third Supplemental Questions,'' dated October 14, 2026 (Third General Issues Supplemental Questionnaire); ''CVD Supplemental Questions,'' dated October 5, 2026 (First CVD Supplemental Questionnaire); and ''Second CVD Supplemental Questions,'' dated October 29, 2026 (Second CVD Supplemental Questionnaire).

[7] *See* Petitioner's Letters, ''Petitioner Response to the 1st Supplemental Questionnaire Regarding Common Issues and Injury Volume I of the Petition,'' dated October 4, 2026 (First General Issues Supplement); ''Petitioner Response to the 2nd Supplemental Questionnaire Regarding Common Issues and Injury Volume I of the Petition,'' dated October 9, 2026 (Second General Issues Supplement); ''Petitioner Response to the 3rd Supplemental Questionnaire Regarding Common Issues and Injury Volume I of the Petition,'' dated October 19, 2026; ''Petitioner Response to the 1st Supplemental Questionnaire Regarding China CVD Volume III of the Petition,'' dated October 8, 2026 (First CVD Supplement); and ''Petitioner Response to the 1st Supplemental Questionnaire Regarding China CVD Volume III of the Petition,'' dated October 30, 2026 (Second CVD Supplement).

[8] The members of the Alliance are interested parties within the meaning of section 771(9)(C) of the Act.

[9] *See* section on ''Determination of Industry Support for the Petition,'' *infra.*

[10] *See* 19 CFR 351.204(b)(2).

[11] *See* First General Issues Supplemental Questionnaire; *see also* Second General Issues Supplemental Questionnaire.

[12] *See* First General Issues Supplement at 1–8 and Exhibits I–Supp–2 through I–Supp–6; *see also* Second General Issues Supplement at 1–2 and Third General Issues Supplement at 1.

[13] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*); *see also* 19 CFR 351.312.

[14] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

their submission. Commerce further requests that interested parties limit their public executive summary of each comment or issue to no more than 450 words, not including citations. Commerce intends to use the public executive summaries as the basis of the comment summaries included in the analysis of scope comments. To facilitate preparation of its questionnaires, Commerce requests that scope comments be submitted by 5:00 p.m. Eastern Time (ET) on November 23, 2026, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, and should also be limited to public information, must be filed by 5:00 p.m. ET on December 3, 2026, which is 10 calendar days from the initial comment deadline.

Commerce requests that any factual information that parties consider relevant to the scope of this investigation be submitted during that period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party must contact Commerce and request permission to submit the additional information. All scope comments must be filed simultaneously on the records of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically via Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS), unless an exception applies.[15] An electronically filed document must be received successfully in its entirety by the time and date it is due.

Consultations

Pursuant to sections 702(b)(4)(A)(i) and (ii) of the Act, Commerce notified the GOC of the receipt of the Petition and provided an opportunity for consultations with respect to the Petition.[16] The GOC filed consultation remarks in lieu of consultations on October 13, 2026.[17]

Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The U.S. International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC apply the same statutory definition regarding the domestic like product,[18] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[19]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the investigation.[20] Based on our analysis of the information submitted on the record, we have determined that certain wooden fence components, as defined in the scope, constitute a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[21]

As noted above, on October 13, 2026, Commerce extended the initiation deadline by 20 days to further examine the issue of industry support. In determining whether the petitioner has standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in the appendix to this notice. To establish industry support, the petitioner provided the 2025 production of the domestic like product for the U.S. producers that support the Petition and compared this to the estimated total production of the domestic like product by the U.S. certain wooden fence components industry.[22] We relied on data provided by the petitioner for purposes of measuring industry support.[23]

Our review of the data provided in the Petition, the First General Issues Supplement, and the Third General Issues Supplement, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petition.[24] First, the Petition established support from domestic producers (or

[15] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014), for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on using ACCESS can be found at *https://access.trade.gov/help* and a handbook can be found at *https://access.trade.gov/ACCESS%20Handbook%20on%20Electronic%20Filing%20Procedures_March2026.pdf.*

[16] *See* Commerce's Letter, ''Invitation for Consultations to Discuss the Countervailing Duty Petition,'' dated September 24, 2026.

[17] *See* GOC's Letter, ''Comments of the Government of the People's Republic of China on the Countervailing Duty Petition Concerning Certain Wooden Fence Pickets from China,'' dated October 13, 2026.

[18] *See* section 771(10) of the Act.

[19] *See USEC, Inc.* v. *United States,* 132 F.Supp.2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F.Supp.639, 644 (CIT 1988), *aff'd Algoma Steel Corp., Ltd.* v. *United States,* 865 F.2d 240 (Fed. Cir. 1989)).

[20] For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, *see* Checklist, ''Countervailing Duty Investigation Initiation Checklist: Certain Wooden Fence Components from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (China CVD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Certain Wooden Fence Components from the People's Republic of China (Attachment II). This checklist is on file electronically via ACCESS.

[21] For further discussion, *see* Attachment II of the China CVD Initiation Checklist.

[22] *Id.*

[23] *Id.*

[24] *Id.*

workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[25] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[26] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[27] Accordingly, Commerce determines that the Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.[28]

Injury Test

Because China is a ''Subsidies Agreement Country'' within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to this investigation. Accordingly, the ITC must determine whether imports of the subject merchandise from China materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that imports of the subject merchandise are benefiting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[29]

The petitioner contends that the industry's injured condition is illustrated by significant increase in the volume of subject imports; significant market share by subject imports and reduced market share for the domestic industry; underselling and price depression and suppression; negative impact on financial performance; lost sales and revenue; and decline in production, U.S. shipments, capacity utilization, and employment variables.[30] We assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[31]

Initiation of CVD Investigation

Based upon the examination of the Petition and supplemental responses, we find that they meet the requirements of section 702 of the Act. Therefore, we are initiating a CVD investigation to determine whether imports of certain wooden fence components from China benefit from countervailable subsidies conferred by the GOC. In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 65 days after the date of this initiation.

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation on 37 programs alleged by the petitioner. For a full discussion of the basis for our decision to initiate on each program, *see* the China CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

Respondent Selection

In the Petition, the petitioner identified 80 companies in China.[32] Commerce intends to follow its standard practice in CVD investigations and calculate company-specific subsidy rates in the investigation. In the event Commerce determines that the number of companies is large, and it cannot individually examine each company based upon Commerce's resources, Commerce intends to select mandatory respondents based on U.S. Customs and Border Protection (CBP) data for imports under the appropriate Harmonized tariff Schedule of the United States (HTSUS) subheading(s) listed in the ''Scope of the Investigation,'' in the appendix.

On November 3, 2026, Commerce released CBP data on imports of certain wooden fence components from China under administrative protective order (APO) to all parties with access to information protected by APO and indicated that interested parties wishing to comment on CBP data and/or respondent selection must do so within three days of the publication date of the notice of initiation of this investigation.[33] Comments must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety via ACCESS by 5:00 p.m. ET on the specified deadline. Commerce will not accept rebuttal comments regarding the CBP data or respondent selection.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on Commerce's website at *https://www.trade.gov/administrative-protective-orders.*

Distribution of a Copy of the Petition

In accordance with section 702(b)(4)(A) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the GOC via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to each exporter named in the Petition, as provided under 19 CFR 351.203(c)(2).

ITC Notification

Commerce will notify the ITC of its initiation, as required by section 702(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 25 days after the date on which it receives notice of initiation of this investigation, whether there is a reasonable indication that imports of certain wooden fence components from China are materially injuring, or threatening material injury to, a U.S. industry.[34] A negative ITC determination will result in the investigation being terminated.[35] Otherwise, this CVD investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors of production under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR

[25] *Id.; see also* section 702(c)(4)(D) of the Act.

[26] *See* Attachment II of the China CVD Initiation Checklist.

[27] *Id.*

[28] *Id.*

[29] For further discussion, *see* China CVD Initiation Checklist at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Certain Wooden Fence Components from the People's Republic of China.

[30] *Id.*

[31] *Id.*

[32] *See* Petition at Volume I (pages 9–10 and Exhibit I–8); *see also* First General Issues Supplement at 1 and Exhibit I–Supp–1.

[33] *See* Memorandum, ''Release of U.S. Customs and Border Protection Entry Data,'' dated November 3, 2026.

[34] *See* section 703(a)(1) of the Act.

[35] *Id.*

351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 351.301(b) of Commerce's regulations requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted [36] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[37] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in this investigation.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by Commerce. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301, or as otherwise specified by Commerce.[38] For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, standalone submission; under limited circumstances we will grant untimely filed requests for the extension of time limits, where we determine, based on 19 CFR 351.302, that extraordinary circumstances exist. Parties should review Commerce's regulations concerning the extension of time limits and the *Time Limits Final Rule* prior to submitting factual information in this investigation.[39]

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[40] Parties must use the certification formats provided in 19 CFR 351.303(g).[41] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. Parties wishing to participate in this investigation should ensure that they meet the requirements of 19 CFR 351.103(d) (*e.g.,* by filing the required letters of appearance). Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[42]

This notice is issued and published pursuant to sections 702 and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: November 3, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Investigation

The scope of this investigation includes certain wooden fence components (commonly referred to as wooden fence pickets), finished and unfinished, whether assembled or unassembled. Wooden fence pickets included in this scope are made of one or more wood species, typically from Cryptomeria japonica (Japanese Cedar or Sugi), but can also be made from other wood species, including but not limited to Western Red Cedar, Redwood, Incense Cedar, Douglas Fir, Western Hemlock, Sitka Spruce, and Cunninghamia lanceolata (Chinese Fir). Wooden fence pickets are included within the scope of this investigation regardless of form or shape, including, but not limited to flat top (also known as square or square top), pointed, dog ear, gothic (including but not limited to French gothic, French gothic blunt point) and stockade.

Generally, assembled wooden fence pickets contain at least one fence picket attached to one or more cross rails, framing lumber, or other fencing materials, and can include fully pre-assembled fence panels. Unassembled wooden fence pickets consist of one or more wooden fence pickets, not attached to any framing lumber, whether sold individually, bundled, or in a kit with framing lumber.

The finished products covered by the scope of this investigation have the following dimensions: a thickness of no more than 1 inch, a width of no more than 12 inches, and a length of at least 3 feet. The products covered by the scope are typically a length of 5 feet, 6 feet, or 8 feet when finished.

Wooden fence pickets are included within the scope of this investigation regardless of whether they have been painted, stained, pressure-treated, or otherwise coated or treated. Subject merchandise also includes wooden fence pickets that have been further processed in a third country, including but not limited to trimming, cutting, notching, sanding, planing or any other processing that would not otherwise remove the merchandise from the scope of this investigation if performed in the country of manufacture of the in-scope product.

Excluded from the scope of this investigation are wooden fence pickets made exclusively of bamboo (including, but not limited to, Phyllostachys edulis, Bambusa textilis, and Bambusa oldhamii), Brazilian Pine (Paraná pine), or Southern Yellow Pine (including Shortleaf Pine (Pinus echinata), Slash Pine (Pinus ellioti), Longleaf Pine (Pinus palustris), or Loblolly Pine (Pinus taeda)).

Also excluded from the scope of this investigation are wood mouldings and millwork products covered by the antidumping and countervailing duty orders on wood mouldings and millwork products from the People's Republic of China. *See Wood Mouldings and Millwork Products from the People's Republic of China: Amended Final Antidumping Duty Determination and Antidumping Duty Order,* 86FR 9486 (February 16, 2021) (amended final antidumping duty determination and antidumping duty order); *Wood Mouldings and Millwork Products from the People's Republic of China: Countervailing Duty Order,* 86 FR 9484 (February 16, 2021) (countervailing duty order).

Imports of subject merchandise are typically classified under Harmonized Tariff Schedule of the United States (HTSUS) statistical numbers 4404.10.0040, 4407.19.0092, 4421.99.7020, and 4421.99.7040. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[FR Doc. 2026–22764 Filed 11–6–26; 8:45 am]

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[36] *See* 19 CFR 351.301(b).

[37] *See* 19 CFR 351.301(b)(2).

[38] *See* 19 CFR 351.302.

[39] *See* 19 CFR 351.301; *see also Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013) (*Time Limits Final Rule*), available at *https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm.*

[40] *See* section 782(b) of the Act.

[41] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2023) (*Final Rule*). Additional information regarding the *Final Rule* is available at *https://www.trade.gov/sites/default/files/2026-08/FAQ%20for%20Certifications.pdf?v=1787683944756.*

[42] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069 (September 29, 2023).

DEPARTMENT OF COMMERCE

International Trade Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Domestic and International Client Global Trade Services and Customized Forms Revision

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on August 27, 2026, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: International Trade Administration, Commerce.

Title: Domestic and International Client Global Trade Services & Customized Forms.

OMB Control Number: 0625–0143.

Form Number(s): None.

Type of Request: Regular submission with revision to a currently approved collection.

Number of Respondents: 100,020.

Average Hours per Response: 10 minutes.

Burden Hours: 34,133 (annual).

Needs and Uses: The International Trade Administration's (ITA) is mandated by Congress to broaden and deepen the U.S. exporter base and to attract inward foreign direct investment. ITA accomplishes this by providing counseling, programs and services to help U.S. organizations conduct business globally and to be successful in overseas markets. This information collection package enables ITA to provide appropriate global trade services to U.S. businesses and international buyers.

ITA offers a variety of services to enable clients to begin exporting and trading globally or to expand existing export and global trade efforts. Clients may learn about available services from business related entities such as the National Association of Manufacturers, Federal Express, State Economic Development offices, the internet or word of mouth. ITA provides a standard set of services to assist clients with identifying potential overseas partners, establishing meeting programs with appropriate overseas business contacts and providing due diligence reports on potential overseas business partners. ITA also provides other global trade related services considered to be of a ''customized nature'' because they do not fit into the standard set of services but are driven by unique business needs of individual clients.

The dissemination of international market information and potential business opportunities for U.S. companies interested and actively conducting business globally are critical components of the ITA's global trade assistance programs and services. U.S. companies can conveniently access and indicate their interest in services by completing the appropriate forms through various methods, including via a website (*e.g.* trade.gov), web-based survey or form links, or paper-based forms.

Affected Public: Business or other for-profit organizations; Not-for-profit institutions; State, Local, or Tribal government.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

Legal Authority: Public Law 15 U.S.C. et seq and 15 U.S.C. 171 *et seq.*

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0625–0143.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2026–22744 Filed 11–6–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–555–001, A–557–818, A–801–002, A–549–841, A–489–841, A–552–827, C–570–128]

Mattresses From Cambodia, Malaysia, Serbia, Thailand, the Republic of Türkiye, the People's Republic of China, and the Socialist Republic of Vietnam: Continuation of Antidumping Duty and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC) that revocation of the antidumping duty (AD) orders on mattresses from Cambodia, Malaysia, Serbia, Thailand, the Republic of Türkiye, and the Socialist Republic of Vietnam and the countervailing duty (CVD) order on mattresses from the People's Republic of China would likely lead to the continuation or recurrence of dumping or countervailable subsidies, and material injury to an industry in the United States, Commerce is publishing a notice of continuation of these AD and CVD orders.

DATES: Applicable November 2, 2026.

FOR FURTHER INFORMATION CONTACT: Katerina Katsiadas, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4929.

SUPPLEMENTARY INFORMATION:

Background

On May 14, 2021, Commerce published in the **Federal Register** the AD orders on mattresses from Cambodia, Malaysia, Serbia, Thailand, the Republic of Türkiye, and the Socialist Republic of Vietnam, and the CVD order on mattresses from the People's Republic of China.[1] On April 1, 2026, the ITC instituted,[2] and

[1] *See Mattresses from Cambodia, Indonesia, Malaysia, Serbia, Thailand, the Republic of Turkey, and the Socialist Republic of Vietnam: Antidumping Duty Orders and Amended Final Affirmative Antidumping Determination for Cambodia,* 86 FR 26460 (May 14, 2021); *see also Mattresses from the People's Republic of China: Countervailing Duty Order,* 86 FR 26463 (May 14, 2021) (collectively, *Orders*).

[2] *See Mattresses from Cambodia, China, Malaysia, Serbia, Thailand, Turkey, and Vietnam; Institution of Five-Year Reviews,* 91 FR 16229 (April 1, 2026).

Commerce initiated,[3] the first sunset review of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). As a result of its reviews, Commerce determined that revocation of the *Orders* would likely lead to the continuation or recurrence of dumping and countervailable subsidies, and therefore, notified the ITC of the magnitude of the margins of dumping likely to prevail should the *Orders* be revoked.[4]

On October 27, 2026, the ITC published its determination, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Orders

The products covered by these *Orders* are all types of youth and adult mattresses. The term ''mattress'' denotes an assembly of materials that at a minimum includes a ''core,'' which provides the main support system of the mattress, and may consist of innersprings, foam, other resilient filling, or a combination of these materials. Mattresses may also contain: (1) ''upholstery,'' the material between the core and the top panel of the ticking on a single-sided mattress; or between the core and the top and bottom panel of the ticking on a double-sided mattress; and/or (2) ''ticking,'' the outermost layer of fabric or other material (*e.g.,* vinyl) that encloses the core and any upholstery, also known as a cover.

The scope of these *Orders* is restricted to only ''adult mattresses'' and ''youth mattresses.'' ''Adult mattresses'' are frequently described as ''twin,'' ''extra-long twin,'' ''full,'' ''queen,'' ''king,'' or ''California king'' mattresses. ''Youth mattresses'' are typically described as ''crib,'' ''toddler,'' or ''youth'' mattresses. All adult and youth mattresses are included regardless of size and size description.

The scope encompasses all types of ''innerspring mattresses,'' ''non-innerspring mattresses,'' and ''hybrid mattresses.'' ''Innerspring mattresses'' contain innersprings, a series of metal springs joined together in sizes that correspond to the dimensions of mattresses. Mattresses that contain innersprings are referred to as ''innerspring mattresses'' or ''hybrid mattresses.'' ''Hybrid mattresses'' contain two or more support systems as the core, such as layers of both memory foam and innerspring units.

''Non-innerspring mattresses'' are those that do not contain any innerspring units. They are generally produced from foams (*e.g.,* polyurethane, memory (viscoelastic), latex foam, gel-infused viscoelastic (gel foam), thermobonded polyester, polyethylene) or other resilient filling.

Mattresses covered by the scope of these *Orders* may be imported independently, as part of furniture or furniture mechanisms (*e.g.,* convertible sofa bed mattresses, sofa bed mattresses imported with sofa bed mechanisms, corner group mattresses, day-bed mattresses, roll-away bed mattresses, high risers, trundle bed mattresses, crib mattresses), or as part of a set in combination with a ''mattress foundation.'' ''Mattress foundations'' are any base or support for a mattress. Mattress foundations are commonly referred to as ''foundations,'' ''boxsprings,'' ''platforms,'' and/or ''bases.'' Bases can be static, foldable, or adjustable. Only the mattress is covered by the scope if imported as part of furniture, with furniture mechanisms, or as part of a set in combination with a mattress foundation.

Excluded from the scope of these *Orders* are ''futon'' mattresses. A ''futon'' is a bi-fold frame made of wood, metal, or plastic material, or any combination thereof, that functions as both seating furniture (such as a couch, love seat, or sofa) and a bed. A ''futon mattress'' is a tufted mattress, where the top covering is secured to the bottom with thread that goes completely through the mattress from the top through to the bottom, and it does not contain innersprings or foam. A futon mattress is both the bed and seating surface for the futon.

Also excluded from the scope are airbeds (including inflatable mattresses) and waterbeds, which consist of air- or liquid-filled bladders as the core or main support system of the mattress.

Also excluded is certain multifunctional furniture that is convertible from seating to sleeping, regardless of filler material or components, where that filler material or components are upholstered, integrated into the design and construction of, and inseparable from, the furniture framing, and the outermost layer of the multifunctional furniture converts into the sleeping surface. Such furniture may, and without limitation, be commonly referred to as ''convertible sofas,'' ''sofabeds,'' ''sofa chaise sleepers,'' ''futons,'' ''ottoman sleepers'' or a like description.

Also excluded from the scope of these *Orders* are any products covered by the existing antidumping duty orders on uncovered innerspring units from China or Vietnam. *See Uncovered Innerspring Units from the People's Republic of China: Notice of Antidumping Duty Order,* 74 FR 7661 (February 19, 2009); *Antidumping Duty Order: Uncovered Innerspring Units from the Socialist Republic of Vietnam,* 73 FR 75391 (December 11, 2008).

Also excluded from the scope of these *Orders* are bassinet pads with a nominal length of less than 39 inches, a nominal width less than 25 inches, and a nominal depth of less than 2 inches.

Additionally, also excluded from the scope of these *Orders* are ''mattress toppers.'' A ''mattress topper'' is a removable bedding accessory that supplements a mattress by providing an additional layer that is placed on top of a mattress. Excluded mattress toppers have a height of four inches or less.

The products subject to these *Orders* are currently properly classifiable under HTSUS subheadings: 9404.21.0010, 9404.21.0013, 9404.29.1005, 9404.29.1013, 9404.29.9085, and 9404.29.9087. Products subject to these *Orders* may also enter under HTSUS subheadings: 9404.21.0095, 9404.29.1095, 9404.29.9095, 9401.40.0000, and 9401.90.5081. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by these *Orders* is dispositive.

Continuation of the Orders

As a result of the determinations by Commerce and the ITC that revocation of the *Orders* would likely lead to continuation or recurrence of dumping, countervailable subsidies, and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, Commerce hereby orders the continuation of the *Orders.* U.S. Customs and Border Protection will continue to collect AD and CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

[3] *See Initiation of Five-Year (Sunset) Reviews,* 91 FR 16181 (April 1, 2026).

[4] *See Mattresses from Cambodia, Malaysia, Serbia, Thailand, the Republic of Türkiye, and the Socialist Republic of Vietnam: Final Results of the Expedited First Sunset Reviews of the Antidumping Duty Orders,* 91 FR 48370 (July 31, 2026), and accompanying Issues and Decision Memorandum (IDM); *see also Mattresses from the People's Republic of China: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order,* 91 FR 46769 (July 24, 2026) and accompanying IDM.

[5] *See Mattresses from Cambodia, China, Malaysia, Serbia, Thailand, Turkey, and Vietnam; Determinations,* 91 FR 67611 (October 27, 2026) (*ITC Final Determination*).

The effective date of the continuation of the *Orders* will be October 27, 2026.[6] Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year reviews of the *Orders* not later than 30 days prior to fifth anniversary of the date of the last determination by the ITC.

Administrative Protective Order (APO)

This notice also serves as a final reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

These five-year (sunset) reviews and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act and published in accordance with section 777(i) of the Act, and 19 CFR 351.218(f)(4).

Dated: November 4, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–22823 Filed 11–6–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–943, C–560–847, C–553–004]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules From India, Indonesia, and the Lao People's Democratic Republic: Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the U.S. Department of Commerce (Commerce) and U.S. International Trade Commission (ITC), Commerce is issuing countervailing duty (CVD) orders on crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells) from India, Indonesia, and the Lao People's Democratic Republic (Laos).

DATES: Applicable November 9, 2026.

FOR FURTHER INFORMATION CONTACT: Jinny Ahn or Amber Hodak (India), Office VI, telephone: (202) 482–0339 or (202) 482–8034, respectively; Ted Pearson (Indonesia), Office I, telephone: (202) 482–2631; and Shane Subler or Laurel Smalley (Laos), Office VIII, telephone: (202) 482–6241 or (202) 482–3456, respectively; AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 705(d) and 777(i) of the Tariff Act of 1930 as amended (the Act) on September 16, 2026, Commerce published in the **Federal Register** its affirmative final determinations in the CVD investigations of solar cells from India, Indonesia, and Laos.[1] On November 2, 2026, the ITC notified Commerce of its final determinations, pursuant to sections 705(d) of the Act, that an industry in the United States is materially injured within the meaning of section 705(b)(1)(A)(i) of the Act by reason of imports of solar cells from India, Indonesia, and Laos.[2]

Scope of the Orders

The products covered by these orders are solar cells from India, Indonesia, and Laos. For a full description of the scope of these orders, *see* the appendix to this notice.

Countervailing Duty Orders

Based on the affirmative final determinations by the ITC that an industry in the United States is materially injured by reason of subsidized imports of solar cells from India, Indonesia, and Laos,[3] in accordance with sections 705(c)(2) and 706(a) of the Act, Commerce is issuing these CVD orders. Because the ITC determined that imports of solar cells from India, Indonesia, and Laos are materially injuring a U.S. industry, unliquidated entries of such merchandise entered, or withdrawn from warehouse, for consumption, are subject to the assessment of countervailing duties.

Therefore, in accordance with section 706(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instructions by Commerce, countervailing duties on certain unliquidated entries of solar cells from India, Indonesia, and Laos, that were entered, or withdrawn from warehouse, for consumption on or after February 26, 2026,[4] the date of publication of the *Preliminary Determinations,*[5] but will not include entries occurring after the expiration of the provisional measures period and before the publication of the ITC's final injury determination under section 705(b) of the Act, as further described below.

Critical Circumstances

In the *Final Determinations,* Commerce found that critical circumstances exist with respect to: (1) Mundra Solar Energy Limited and Mundra Solar PV Limited;[6] (2) PT Blue Sky Solar Indonesia (Blue Sky) and all other producers and/or exporters of solar cells from Indonesia;[7] and (3)

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from India: Final Affirmative Countervailing Duty Determination and the Final Affirmative Critical Circumstances Determination, in Part,* 91 FR 58643 (September 16, 2026) (*India Final Determination*); *see also Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules from Indonesia: Final Affirmative Countervailing Duty Determination and Final Affirmative Determination of Critical Circumstances, in Part,* 91 FR 58647 (September 16, 2026) (*Indonesia Final Determination*); and *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules from the Lao People's Democratic Republic: Final Affirmative Countervailing Duty Determination and Final Affirmative Determination of Critical Circumstances, in Part,* 91 FR 58638 (September 16, 2026) (*Laos Final Determination*); and (collectively, *Final Determinations*).

[2] *See* ITC's Letter, ''Notification of ITC Final Determinations,'' dated November 2, 2026.

[3] *Id.*

[4] In addition, Commerce intends to apply retroactive duties for certain unliquidated entries of solar cells from Indonesia due to affirmative findings for critical circumstances. *See* ''Critical Circumstances,'' *infra.*

[5] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from India: Preliminary Affirmative Countervailing Duty Determination, Preliminary Affirmative Critical Circumstances Determination, in Part, and Alignment of Final Determination with Final Antidumping Duty Determination,* 91 FR 9555 (February 26, 2026) (*India Preliminary Determination*); *see also Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules from Indonesia: Preliminary Affirmative Countervailing Duty Determination, Preliminary Affirmative Critical Circumstances Determination, in Part, and Alignment of Final Determination with Antidumping Duty Determination,* 91 FR 9564 (February 26, 2026) (*Indonesia Preliminary Determination*); and *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules from the Lao People's Democratic Republic: Preliminary Affirmative Countervailing Duty Determination, Preliminary Negative Critical Circumstances Determination, and Alignment of Final Determination with Final Antidumping Duty Determination,* 91 FR 9568 (February 26, 2026) (*Laos Preliminary Determination*) (collectively, *Preliminary Determinations*).

[6] *See India Final Determination,* 91 FR at 58643–58644.

[7] *See Indonesia Final Determination,* 91 FR at 58648.

[6] *See ITC Final Determination.*

Vietnam Sunergy Joint Stock Company and all other producers and/or exporters of solar cells from Laos.[8]

The ITC found that critical circumstances do not exist with respect to imports of solar cells from India and Laos. As a result, for India and Laos, we intend to instruct CBP to lift the suspension of liquidation and to refund all cash deposits for estimated countervailing duties with respect to all suspended entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after November 28, 2025 (*i.e.,* 90 days prior to the date of publication of the *India Preliminary Determination* and *Laos Preliminary Determination*), but before February 26, 2026 (*i.e.,* the date of publication of the *India Preliminary Determination* and *Laos Preliminary Determination*).

In addition, the ITC found that critical circumstances do exist with respect to imports of solar cells from Indonesia. As a result of Commerce's affirmative critical circumstances determination under section 705(a)(2) of the Act and the ITC's affirmative critical circumstances determination under section 705(b)(4)(A) of the Act, retroactive duties will be applied with respect to suspended entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after November 28, 2025 (*i.e.,* 90 days prior to February 26, 2026, the date of the publication of *Indonesia Preliminary Determination*), for imports from Blue Sky and all other producers and/or exporters of solar cells from Indonesia.[9]

Suspension of Liquidation and Cash Deposits

In accordance with section 706 of the Act, Commerce intends to instruct CBP to reinstitute the suspension of liquidation of solar cells from India, Indonesia, and Laos, effective on the date of publication of the ITC's final affirmative injury determination in the **Federal Register**, and to assess, upon further instruction by Commerce, pursuant to section 706(a)(1) of the Act, countervailing duties on each entry of subject merchandise in an amount based on the net countervailable subsidy rates below. These instructions suspending liquidation will remain in effect until further notice.

Commerce also intends, pursuant to section 706(a)(1) of the Act, to instruct CBP to require cash deposits equal to the amounts as indicated below. Accordingly, effective on the date of publication of the ITC's final affirmative injury determination in the **Federal Register**, CBP will require, at the same time as importers would normally deposit estimated customs duties on the subject merchandise, a cash deposit for each entry of subject merchandise equal to the subsidy rates listed below.[10] The all-others rates apply to all producers or exporters not specifically listed below, as appropriate.

Estimated Countervailable Subsidy Rates

The estimated countervailable subsidy rates are as follows:

INDIA

Company	Subsidy rate (percent *ad valorem*)
Mundra Solar Energy Limited	126.09*
Mundra Solar PV Limited	126.09*
All Others	126.09*

* Rate based on facts available with adverse inferences.

INDONESIA

Company	Subsidy rate (percent *ad valorem*)
PT Blue Sky Solar Indonesia	173.70*
PT REC Solar Energy Indonesia	73.20
All Others	73.20

* Rate based on facts available with adverse inferences.

LAOS

Company	Subsidy rate (percent *ad valorem*)
Solarspace Technology (Laos) Sole Co. Ltd.	82.03
Vietnam Sunergy Joint Stock Company	153.67*
All Others	82.03

* Rate based on facts available with adverse inferences.

Provisional Measures

Section 703(d) of the Act states that the suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months. In the underlying investigations, Commerce published the *Preliminary Determinations* on February 26, 2026.[11] As such, the four-month period beginning on the date of the publication of the *Preliminary Determinations* ended on June 25, 2026. Therefore, entries of solar cells from India, Indonesia, and Laos made on or after June 26, 2026, and prior to the date of publication of the ITC's final

[8] *See Laos Final Determination,* 91 FR at 58639.

[9] *See* Statement of Administrative Action Accompanying the Uruguay Round Agreements Act, H.R. Doc. 103–316, Vol. 1 (1994) at 876 (''If both agencies make affirmative critical circumstances determinations in their final investigations, retroactive duties will be applied for a period ninety days prior to suspension of liquidation.'').

[10] *See* section 706(a)(3) of the Act.

[11] *See Preliminary Determinations.*

determinations in the **Federal Register**, are not subject to the assessment of countervailing duties due to Commerce's discontinuation of the suspension of liquidation

In accordance with section 703(d) of the Act, Commerce instructed CBP to terminate the suspension of liquidation and to liquidate, without regard to countervailing duties, certain unliquidated entries of solar cells from India, Indonesia, and Laos entered, or withdrawn from warehouse, for consumption on or after June 26, 2026, the date on which the provisional CVD measures expired, until and through the day preceding the date of publication of the ITC's final injury determinations in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC final injury determinations in the **Federal Register**.

Establishment of the Annual Inquiry Service List

On September 20, 2021, Commerce published the *Final Rule* in the **Federal Register**.[12] On September 27, 2021, Commerce also published the *Procedural Guidance* in the **Federal Register**.[13] The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.[14]

In accordance with the *Procedural Guidance,* for orders published in the **Federal Register** after November 4, 2021, Commerce will create an annual inquiry service list segment in Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), available at *https://access.trade.gov,* within five business days of publication of the order. Each annual inquiry service list will be saved in ACCESS, under each case number, and under a specific segment type called ''AISL-Annual Inquiry Service List.'' [15]

Interested parties who wish to be added to the annual inquiry service list for an order must submit an entry of appearance to the annual inquiry service list segment for the order in ACCESS within 30 days after the date of publication of the order. For ease of administration, Commerce requests that law firms with more than one attorney representing interested parties in an order designate a lead attorney to be included on the annual inquiry service list. Commerce will finalize the annual inquiry service list within five business days thereafter. As mentioned in the *Procedural Guidance,* the new annual inquiry service list will be in place until the following year, when the *Opportunity Notice* for the anniversary month of the order is published.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website.

Special Instructions for Petitioners and Foreign Governments

In the *Final Rule,* Commerce stated that, ''after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.'' [16] Accordingly, as stated above, the petitioners and foreign governments should submit their initial entry of appearance after publication of this notice in order to appear in the first annual inquiry service list. Pursuant to 19 CFR 351.225(n)(3), the petitioners and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and foreign governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Notification to Interested Parties

This notice constitutes the CVD orders with respect to solar cells from India, Indonesia, and Laos pursuant to section 706(a) of the Act. Interested parties can find a list of CVD orders currently in effect at *https://www.trade.gov/data-visualization/adcvd-proceedings.*

These CVD orders are published in accordance with section 706(a) of the Act and 19 CFR 351.211(b).

Dated: November 4, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Orders

The products covered by these orders are crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.

These orders cover crystalline silicon photovoltaic cells of thickness equal to or greater than 20 micrometers, having a p/n junction formed by any means, whether or not the cell has undergone other processing, including, but not limited to, cleaning, etching, coating, and/or addition of materials (including, but not limited to, metallization and conductor patterns) to collect and forward the electricity that is generated by the cell.

Merchandise under consideration may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited to, modules, laminates, panels, building-integrated modules, building integrated panels, or other finished goods kits. Such parts that otherwise meet the definition of merchandise under consideration are included in the scope of the orders.

Excluded from the scope of the orders are thin film photovoltaic products produced from amorphous silicon (a-Si), cadmium telluride (CdTe), or copper indium gallium selenide (CIGS).

Also excluded from the scope of the orders are crystalline silicon photovoltaic cells, not exceeding 10,000 mm^2 in surface area, that are permanently integrated into a consumer good whose function is other than power generation and that consumes the electricity generated by the integrated crystalline silicon photovoltaic cell. Where more than one cell is permanently integrated into a consumer good, the surface area for purposes of this exclusion shall be the total combined surface area of all cells that are integrated into the consumer good.

[12] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021) (*Final Rule*).

[13] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

[14] *Id.*

[15] This segment will be combined with the ACCESS Segment Specific Information (SSI) field which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A–000–000 that was published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as ''AISL-January Anniversary.'' Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

[16] *See Final Rule,* 86 FR at 52335.

Additionally, excluded from the scope of the orders are panels with surface area from 3,450 mm^2 to 33,782 mm^2 with one black wire and one red wire (each of type 22 AWG or 24 AWG not more than 206 mm in length when measured from panel extrusion), and not exceeding 2.9 volts, 1.1 amps, and 3.19 watts. For the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Also excluded from the scope of the orders are:

(1) Off grid CSPV panels in rigid form with a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include a permanently connected wire that terminates in either an 8 mm male barrel connector, or a two-port rectangular connector with two pins in square housings of different colors; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features, and foam for transport); and

(2) Off grid CSPV panels without a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (E) each panel is (1) permanently integrated into a consumer good; (2) encased in a laminated material without stitching, or (3) has all of the following characteristics: (i) the panel is encased in sewn fabric with visible stitching, (ii) includes a mesh zippered storage pocket, and (iii) includes a permanently attached wire that terminates in a female USB–A connector.

In addition, the following CSPV panels are excluded from the scope of the orders: off-grid CSPV panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 80 watts per panel; (B) a surface area of less than 5,000 square centimeters (cm^2) per panel; (C) do not include a built-in inverter; (D) do not have a frame around the edges of the panel; (E) include a clear glass back panel; and (F) must include a permanently connected wire that terminates in a twoport rectangular connector.

Additionally excluded from the scope of these orders are off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (1) a total power output of 200 watts or less per panel; (2) a maximum surface area of 16,000 cm^2 per panel; (3) no built-in inverter; (4) an integrated handle or a handle attached to the package for ease of carry; (5) one or more integrated kickstands for easy installation or angle adjustment; and (6) a wire of not less than 3 meters either permanently connected or attached to the package that terminates in an 8 mm diameter male barrel connector.

Also excluded from the scope of these orders are off-grid crystalline silicon photovoltaic panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 180 watts per panel at 155 degrees Celsius; (B) a surface area of less than 16,000 square centimeters (cm^2) per panel; (C) include a keep-out area of approximately 1,200 cm^2 around the edges of the panel that does not contain solar cells; (D) do not include a built-in inverter; (E) do not have a frame around the edges of the panel; (F) include a clear glass back panel; (G) must include a permanently connected wire that terminates in a two-port rounded rectangular, sealed connector; (H) include a thermistor installed into the permanently connected wire before the twoport connector; and (I) include exposed positive and negative terminals at opposite ends of the panel, not enclosed in a junction box.

Further excluded from the scope of the orders are:

(1) Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

(2) Off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) no built-in inverter, (D) an integrated handle or a handle attached to the package for ease of carry, (E) one or more integrated kickstands for easy installation or angle adjustment, and (F) a wire either permanently connected or attached to the package terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure.

Also excluded from the scope of the orders are:

(1) Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

(2) Small off-grid panels with glass cover, with the following characteristics: (A) surface area from 3,450 mm^2 to 33,782 mm^2, (B) with one black wire and one red wire (each of type 22AWG or 28 AWG not more than 350 mm in length when measured from panel extrusion), (C) not exceeding 10 volts, (D) not exceeding 1.1 amps, (E) not exceeding 6 watts, and (F) for the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Additionally excluded from the scope of the orders are:

(1) Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 175 watts or less per panel, (B) a maximum surface area of 9,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

(2) Off grid CSPV panels without a glass cover, with the following characteristics, (A) a total power output of 220 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) do not include a built-in inverter, (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (E) each panel is encased in a laminated material without stitching.

Also excluded from the scope of these orders are off-grid CSPV panels in rigid form, with or without a glass cover, permanently attached to an aluminum extrusion that is an integral component of an automation device that controls natural light, whether or not assembled into a fully completed automation device that controls natural light, with the following characteristics:

(1) a total power output of 20 watts or less per panel;

(2) a maximum surface area of 1,000 cm^2 per panel;

(3) does not include a built-in inverter for powering third party devices.

Modules, laminates, and panels produced in a third-country from cells produced in a subject country are covered by the orders; however, modules, laminates, and panels produced in a subject country from cells produced in a third-country are not covered by the orders.

Also excluded from the scope of this orders are all products covered by the scope of the antidumping and countervailing duty orders on *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules,*

from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Order, 77 FR 73018 (December 7, 2012); and *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Countervailing Duty Order,* 77 FR 73017 (December 7, 2012).

Also excluded from the scope of these orders are all products covered by the scope of the antidumping and countervailing duty orders on *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the Socialist Republic of Vietnam: Amended Final Antidumping Duty Determination; Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Antidumping duty Orders,* 90 FR 26786 (June 24, 2025); *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the Socialist Republic of Vietnam: Amended Final Antidumping Duty Determination; Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Antidumping Duty Orders; Correction,* 90 FR 29843 (July 7, 2025); and *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Malaysia and Thailand: Amended Final Countervailing Duty Determinations; Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Countervailing Duty Orders,* 90 FR 26791 (June 24, 2025).

Merchandise covered by the orders is currently classified in the Harmonized Tariff System of the United States (HTSUS) under subheadings 8541.42.0010 and 8541.43.0010. Imports of the subject merchandise may enter under HTSUS subheadings 8501.71.0000, 8501.72.1000, 8501.72.2000, 8501.72.3000, 8501.72.9000, 8501.80.1000, 8501.80.2000, 8501.80.3000, 8501.80.9000, 8507.20.8010, 8507.20.8031, 8507.20.8041, 8507.20.8061, and 8507.20.8091. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of the orders is dispositive.

[FR Doc. 2026–22824 Filed 11–6–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–957]

Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe From India: Initiation of Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable November 4, 2026.

FOR FURTHER INFORMATION CONTACT: Kayden Jenson, Office II, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0967.

SUPPLEMENTARY INFORMATION:

The Petition

On October 15, 2026, the U.S. Department of Commerce (Commerce) received a countervailing duty (CVD) petition concerning imports of seamless carbon and alloy steel standard, line, and pressure pipe (seamless standard, line, and pressure pipe) from India, filed in proper form on behalf of Tenaris USA (Tenaris), Vallourec Star LP (Vallourec), and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC (USW) (collectively, the petitioners), domestic producers of seamless standard, line, and pressure pipe and a certified union, which represents workers engaged in the production of seamless standard, line, and pressure pipe in the United States.[1] The CVD Petition was accompanied by antidumping duty (AD) petitions concerning imports of seamless standard, line, and pressure pipe from Georgia and India.[2]

Between October 20 and 26, 2026, Commerce requested supplemental information pertaining to certain aspects of the Petition in supplemental questionnaires.[3] Between October 22 and 28, 2026, the petitioners filed timely responses to these requests for additional information.[4]

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioners allege that the Government of India (GOI) is providing countervailable subsidies, within the meaning of sections 701 and 771(5) of the Act, to producers of seamless standard, line, and pressure pipe from India, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing seamless standard, line, and pressure pipe in the United States. Consistent with section 702(b)(1) of the Act and 19 CFR 351.202(b), for those alleged programs on which we are initiating a CVD investigation, the Petition was accompanied by information reasonably available to the petitioners supporting their allegations.

Commerce finds that the petitioners filed the Petition on behalf of the domestic industry, because the petitioners are interested parties, as defined in sections 771(9)(C) and (D) of the Act.[5] Commerce also finds that the petitioners demonstrated sufficient industry support with respect to the initiation of the requested CVD investigation.[6]

Period of Investigation (POI)

Because the Petition was filed on October 15, 2026, the POI is January 1, 2025, through December 31, 2025.[7]

Scope of the Investigation

The product covered by this investigation is seamless standard, line, and pressure pipe from India. For a full description of the scope of this investigation, *see* the appendix to this notice.

Comments on the Scope of the Investigation

On October 20 and 26, 2026, Commerce requested information and clarification from the petitioners regarding the proposed scope to ensure that the scope language in the Petition is an accurate reflection of the products for which the domestic industry is seeking relief.[8] On October 22 and 28, 2026, the petitioners provided clarifications and revised the scope.[9] The description of merchandise covered by this investigation, as described in the appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting

[1] *See* Petitioners' Letter, ''Petition for the Imposition of Antidumping and Countervailing Duties,'' dated October 15, 2026 (Petition).

[2] *Id.*

[3] *See* Commerce's Letters, ''Supplemental Questions,'' dated October 20, 2026 (First General Issues Supplemental Questionnaire); ''Supplemental Questions,'' dated October 21, 2026 (India CVD Supplemental Questionnaire); and ''Second Supplemental Questions,'' dated October 26, 2026 (Second General Issues Questionnaire).

[4] *See* Petitioners' Letters, ''Petitioners' Response to General Issues Supplemental Questions,'' dated October 22, 2026 (First General Issues Supplement); ''Responses to Volume IV Supplemental Questions,'' dated October 26, 2026 (India CVD Supplement); and ''Petitioners' Response to General Issues Second Supplemental Questions,'' dated October 28, 2026 (Second General Issues Supplement).

[5] Tenaris and Vallourec are interested parties under section 771(9)(C) of the Act. The USW is a certified union representing workers engaged in the production of seamless standard, line, and pressure pipe in the United States and therefore is an interested party under section 771(9)(D) of the Act.

[6] *See* section on ''Determination of Industry Support for the Petition,'' *infra.*

[7] *See* 19 CFR 351.204(b)(2).

[8] *See* First General Issues Questionnaire; *see also* Second General Issues Questionnaire.

[9] *See* First General Issues Supplement at 2–3 and Exhibit I–SUPP–9; *see also* Second General Issues Supplement at 1–3 and Exhibit I–SUPP2–9.

aside a period for interested parties to raise issues regarding product coverage (*i.e.,* scope).[10] Commerce will consider all scope comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information, all such factual information should be limited to public information.[11] Commerce requests that interested parties provide at the beginning of their scope comments a public executive summary for each comment or issue raised in their submission. Commerce further requests that interested parties limit their public executive summary of each comment or issue to no more than 450 words, not including citations. Commerce intends to use the public executive summaries as the basis of the comment summaries included in the analysis of scope comments. To facilitate preparation of its questionnaires, Commerce requests that scope comments be submitted by 5:00 p.m. Eastern Time (ET) on November 24, 2026, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, and should also be limited to public information, must be filed by 5:00 p.m. ET on December 4, 2026, which is 10 calendar days from the initial comment deadline.

Commerce requests that any factual information that parties consider relevant to the scope of this investigation be submitted during that period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party must contact Commerce and request permission to submit the additional information. All scope comments must be filed simultaneously on the records of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically via Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS), unless an exception applies.[12] An electronically filed document must be received successfully in its entirety by the time and date it is due.

Consultations

Pursuant to sections 702(b)(4)(A)(i) and (ii) of the Act, Commerce notified the GOI of the receipt of the Petition and provided an opportunity for consultations with respect to the Petition.[13] Commerce held consultations with the GOI on November 3, 2026.[14]

Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The U.S. International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC apply the same statutory definition regarding the domestic like product,[15] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[16]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioners do not offer a definition of the domestic like product distinct from the scope of the investigation.[17] Based on our analysis of the information submitted on the record, we have determined that seamless standard, line, and pressure pipe, as defined in the scope, constitutes a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[18]

In determining whether the petitioners have standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in the appendix to this notice. To establish industry support, the petitioners provided the 2025 shipments of the domestic like product for the U.S. producers that support the Petitions, and compared this to the estimated total 2025 shipments of the domestic like

[10] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*); *see also* 19 CFR 351.312.

[11] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[12] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014), for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on using ACCESS can be found at *https://access.trade.gov/help* and a handbook can be found at *https://access.trade.gov/ACCESS%20Handbook%20on%20Electronic%20Filing%20Procedures_March2026.pdf.*

[13] *See* Commerce's Letter, ''Invitation for Consultations to Discuss the Countervailing Duty Petition,'' dated October 16, 2026.

[14] *See* Memorandum, ''Consultations with the Government of India,'' dated November 3, 2026; *see also* GOI's Letter, ''Response to invitation for consultation,'' dated November 4, 2026.

[15] *See* section 771(10) of the Act.

[16] *See USEC, Inc.* v. *United States,* 132 F.Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F.Supp. 639, 644 (CIT 1988), *aff'd Algoma Steel Corp., Ltd.* v. *United States,* 865 F.2d 240 (Fed. Cir. 1989)).

[17] For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, *see* Checklist, ''Countervailing Duty Investigation Initiation Checklist: Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from India,'' dated concurrently with, and hereby adopted by, this notice (India CVD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from Georgia and India (Attachment II). This checklist is on file electronically via ACCESS.

[18] For further discussion, *see* Attachment II of the India CVD Initiation Checklist.

product for the entire domestic industry.[19] Because total production data for the domestic like product for 2025 are not reasonably available to the petitioners, and the petitioners have established that shipments are a reasonable proxy for production data,[20] we relied on data provided by the petitioners for purposes of measuring industry support.[21]

Our review of the data provided in the Petition, the First General Issues Supplement, and other information readily available to Commerce indicates that the petitioners have established industry support for the Petition.[22] First, the Petition established support from domestic producers and supporters accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[23] Second, the domestic producers and supporters have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers and supporters who support the Petition account for at least 25 percent of the total production of the domestic like product.[24] Finally, the domestic producers and supporters have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers and supporters who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[25] Accordingly, Commerce determines that the Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.[26]

Injury Test

Because India is a ''Subsidies Agreement Country'' within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to this investigation. Accordingly, the ITC must determine whether imports of the subject merchandise from India materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioners allege that imports of the subject merchandise are benefiting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, the petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[27]

The petitioners contend that the industry's injured condition is illustrated by a significant increase in the volume of subject imports; underselling and price depression and/or suppression; negative impact on financial performance; and declines in production, U.S. shipments, and employment variables.[28] We assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[29]

Initiation of CVD Investigation

Based upon the examination of the Petition and supplemental responses, we find that they meet the requirements of section 702 of the Act. Therefore, we are initiating a CVD investigation to determine whether imports of seamless standard, line, and pressure pipe from India benefit from countervailable subsidies conferred by the GOI. In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 65 days after the date of this initiation.

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation on 24 programs alleged by the petitioners. For a full discussion of the basis for our decision to initiate on each program, *see* the India CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

Respondent Selection

In the Petition, the petitioners identified 16 companies in India.[30] Commerce intends to follow its standard practice in CVD investigations and calculate company-specific subsidy rates in this investigation. In the event that Commerce determines that the number of companies is large and it cannot individually examine each company based on Commerce's resources, where appropriate, Commerce intends to select mandatory respondents based on quantity and value (Q&V) questionnaires issued to the potential respondents. Commerce normally selects mandatory respondents in CVD investigations using U.S. Customs and Border Protection (CBP) entry data for U.S. imports under the appropriate Harmonized Tariff Schedule of the United States (HTSUS) subheadings listed in the ''Scope of the Investigation,'' in the appendix. However, for this investigation, some of the main HTSUS subheadings under which the subject merchandise would enter (7304.19.1020, 7304.19.1030, 7304.19.1045, 7304.19.1060, 7304.19.5020, 7304.19.5050, 7304.31.6050, 7304.39.0016, 7304.39.0020, 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.51.5005, 7304.51.5060, 7304.59.6000) are basket categories under which non-subject merchandise may also enter. Therefore, instead of relying on CBP entry data in selecting respondents, we intend to issue Q&V questionnaires to each potential respondent for which there is complete address information on the record.

Commerce will post the Q&V questionnaire along with filing instructions on Commerce's website at *https://www.trade.gov/ec-adcvd-qv-questionnaire.* Producers/exporters of seamless standard, line, and pressure pipe from India that do not receive Q&V questionnaires may still submit a response to the Q&V questionnaire and can obtain a copy of the Q&V questionnaire from Commerce's website. Responses to the Q&V questionnaire must be submitted by the relevant Indian producers/exporters no later than 5:00 p.m. ET on November 18, 2026, which is two weeks from the signature date of this notice. All Q&V questionnaire responses must be filed electronically via ACCESS. An

[19] *Id.*

[20] *Id.; see also Tenaris Bay City, Inc.* v. *United States,* No. 2025–1382, 2026 LX 545375, at *19 n.5 (Fed. Cir. Sep. 18, 2026).

[21] *See* Attachment II of the India CVD Initiation Checklist.

[22] *Id.*

[23] *Id.; see also* section 702(c)(4)(D) of the Act.

[24] *See* Attachment II of the India CVD Initiation Checklist.

[25] *Id.*

[26] *Id.*

[27] For further discussion, *see* the India CVD Initiation Checklist at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from Georgia and India.

[28] *Id.*

[29] *See* Attachment III of India CVD Initiation Checklist.

[30] *See* Petition at Volume I (Exhibit I–14).

electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the deadline noted above.

Interested parties must submit applications for disclosure under administrative protective order (APO) in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on Commerce's website at *https://www.trade.gov/administrative-protective-orders.*

Distribution of a Copy of the Petition

In accordance with section 702(b)(4)(A) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the GOI via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to each exporter named in the Petition, as provided under 19 CFR 351.203(c)(2).

ITC Notification

Commerce will notify the ITC of its initiation, as required by section 702(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petition was filed, whether there is a reasonable indication that imports of seamless standard, line, and pressure pipe from India are materially injuring, or threatening material injury to, a U.S. industry.[31] A negative ITC determination will result in the investigation being terminated.[32] Otherwise, this CVD investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors of production under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 351.301(b) of Commerce's regulations requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted [33] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[34] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in this investigation.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by Commerce. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301, or as otherwise specified by Commerce.[35] For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, standalone submission; under limited circumstances we will grant untimely filed requests for the extension of time limits, where we determine, based on 19 CFR 351.302, that extraordinary circumstances exist. Parties should review Commerce's regulations concerning the extension of time limits and the *Time Limits Final Rule* prior to submitting factual information in this investigation.[36]

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[37] Parties must use the certification formats provided in 19 CFR 351.303(g).[38] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. Parties wishing to participate in this investigation should ensure that they meet the requirements of 19 CFR 351.103(d) (*e.g.,* by filing the required letters of appearance). Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[39]

This notice is issued and published pursuant to sections 702 and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: November 4, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Investigation

The merchandise covered by this investigation is seamless carbon and alloy steel (other than stainless steel) pipes and redraw hollows, less than or equal to 16 inches (406.4 mm) in nominal outside diameter, regardless of wall-thickness, manufacturing process (*e.g.,* hot finished or cold-drawn), end finish (*e.g.,* plain end, beveled end, upset end, threaded, or threaded and coupled), or surface finish (*e.g.,* bare, lacquered or coated). Redraw hollows are any unfinished carbon or alloy steel (other than stainless steel) pipe or ''hollow profiles'' suitable for cold finishing operations, such as cold drawing, to meet the American Society for Testing and Materials (ASTM) or American Petroleum Institute (API) specifications referenced below, or comparable specifications. Specifically included within the scope are seamless carbon and alloy steel (other than stainless steel) standard, line, and pressure pipes produced to the ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–589, ASTM A–795, ASTM A–1024, and the API 5L specifications, or comparable specifications, and meeting the physical parameters described above, regardless of application, with the exception of the exclusions discussed below.

Specifically excluded from the scope of this investigation are: (1) all pipes meeting

[31] *See* section 703(a)(1) of the Act.

[32] *Id.*

[33] *See* 19 CFR 351.301(b).

[34] *See* 19 CFR 351.301(b)(2).

[35] *See* 19 CFR 351.302.

[36] *See* 19 CFR 351.301; *see also Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013) (*Time Limits Final Rule*), available at *https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm.*

[37] *See* section 782(b) of the Act.

[38] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *https://www.trade.gov/sites/default/files/2026-08/FAQ%20for%20Certifications.pdf?v=1787683944756.*

[39] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069 (September 29, 2023).

aerospace, hydraulic, and bearing tubing specifications, including: (a) aerospace tubing produced to SAE Aerospace Material Specifications (AMS) 6360, 6361, and 6362; (b) hydraulic tubing produced to ASTM A–822, SAE J524, and EN 10305–4 specifications; and (c) bearing tubing produced to the SAE AMS 6440 specification, including bearing tubing manufactured from steel meeting the chemical and metallurgical requirements of ASTM A–295; (2) all pipes meeting the chemical requirements of ASTM A–335, whether finished or unfinished; (3) unattached couplings; (4) all mechanical, boiler, condenser and heat exchange tubing, except when such products conform to the dimensional requirements, *i.e.,* outside diameter and wall thickness, of ASTM A–53, ASTM A–106 or API 5L specifications; (5) oil country tubular goods consisting of drill pipe, casing, tubing, and coupling stock; and (6) all pipes meeting the chemical requirements of ASTM A–335 regardless of their conformity to the dimensional requirements of ASTM A–53, ASTM A–106 or API 5L.

Subject seamless standard, line, and pressure pipe are normally entered under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7304.19.1020, 7304.19.1030, 7304.19.1045, 7304.19.1060, 7304.19.5020, 7304.19.5050, 7304.31.6050, 7304.39.0016, 7304.39.0020, 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.51.5005, 7304.51.5060, 7304.59.6000, 7304.59.8010, 7304.59.8015, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, 7304.59.8055, 7304.59.8060, 7304.59.8065, and 7304.59.8070. Subject merchandise may also enter under HTSUS subheadings 7304.31.6010, 7304.39.0002, 7304.39.0004, 7304.39.0006, 7304.39.0008, 7304.51.5015, 7304.51.5045, 7304.59.2030, 7304.59.2040, 7304.59.2045, 7304.59.2055, and 7304.59.2060. The HTSUS subheadings and specifications are provided for convenience and customs purposes; the written description of the scope is dispositive.

[FR Doc. 2026–22836 Filed 11–6–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–243]

Certain Wooden Fence Components From the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable November 3, 2026.

FOR FURTHER INFORMATION CONTACT: Frank Schmitt, Office III, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4880.

SUPPLEMENTARY INFORMATION:

The Petition

On September 24, 2026, the U.S. Department of Commerce (Commerce) received an antidumping duty (AD) petition concerning imports of certain wooden fence components [1] from the People's Republic of China (China), filed in proper form on behalf of the American Alliance of Wooden Fence Producers (the petitioner),[2] the members of which are domestic producers of certain wooden fence components.[3] The AD Petition was accompanied by a countervailing duty (CVD) petition concerning imports of certain wooden fence components from China.[4]

On October 13, 2026, Commerce extended the initiation deadline by 20 days to further examine the issue of industry support, because it was not clear from the Petition whether the industry support criteria had been met.[5]

Between September 29 and October 14, 2026, Commerce requested supplemental information pertaining to certain aspects of the Petition in supplemental questionnaires.[6] Between October 4 and 21, 2026, the petitioner filed timely responses to these requests for additional information.[7]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that imports of certain wooden fence components from China are being, or are likely to be, sold in the United States at less than fair value (LTFV) within the meaning of section 731 of the Act, and that imports of such products are materially injuring, or threatening material injury to, the certain wooden fence components industry in the United States. Consistent with section 732(b)(1) of the Act, the Petition was accompanied by information reasonably available to the petitioner supporting its allegations.

Commerce finds that the petitioner filed the Petition on behalf of the domestic industry, because the petitioner is an interested party, as defined in section 771(9)(F) of the Act.[8] Commerce also finds that the petitioner demonstrated sufficient industry support for the initiation of the requested LTFV investigation.[9]

Period of Investigation (POI)

Because the Petition was filed on September 24, 2026, and because China is a non-market economy (NME) country pursuant to 19 CFR 351.204(b)(1), the POI for the LTFV investigation is January 1, 2026, through June 30, 2026.

Scope of the Investigation

The products covered by this investigation are certain wooden fence components from China. For a full description of the scope of this investigation, *see* the appendix to this notice.

Comments on the Scope of the Investigation

Between September 29 and October 14, 2026, Commerce requested information and clarification from the petitioner regarding the proposed scope to ensure that the scope language in the Petition is an accurate reflection of the products for which the domestic

[1] *See* Petitioner's Letter, ''Notice of Change in Case Name,'' dated November 2, 2026; *see also* Memorandum, ''Product Name Change,'' dated November 3, 2026.

[2] The individual members of the American Alliance of Wooden Fence Producers (Alliance) are Alta Forest Products, Sierra Pacific Industries, and Mendocino Forest Products.

[3] *See* Petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties,'' dated September 24, 2026 (Petition).

[4] *Id.*

[5] *See Notice of Extension of the Deadline for Determining the Adequacy of the Antidumping and Countervailing Duty Petitions: Certain Wooden Fence Pickets from the People's Republic of China,* 91 FR 66106 (October 19, 2026) (*Initiation Extension Notice*).

[6] *See* Commerce's Letters, ''General Issues Supplemental Questions,'' dated September 29, 2026 (First General Issues Supplemental Questionnaire); ''Second General Issues Supplemental Questions,'' dated October 8, 2026 (Second General Issues Supplemental Questionnaire); ''Third Supplemental Questions,'' dated October 14, 2026 (Third General Issues Supplemental Questionnaire); ''Supplemental Questions,'' dated October 1, 2026 (First China AD Supplemental Questionnaire); and ''Second Supplemental Questions,'' dated October 14, 2026 (Second China AD Supplemental Questionnaire).

[7] *See* Petitioner's Letters, ''Petitioner Response to the 1st Supplemental Questionnaire Regarding Common Issues and Injury Volume I of the Petition,'' dated October 4, 2026 (First General Issues Supplement); ''Petitioner Response to the 2nd Supplemental Questionnaire Regarding Common Issues and Injury Volume I of the Petition,'' dated October 9, 2026 (Second General Issues Supplement); ''Petitioner Response to the 3rd Supplemental Questionnaire Regarding Common Issues and Injury Volume I of the Petition,'' dated October 19, 2026; ''Petitioner's Response to the 1st Supplemental Questionnaire Regarding the People's Republic of China Volume II of the Petition,'' dated October 6, 2026 (First China AD Supplement); and ''Petitioner's Response to the 2nd Supplemental Questionnaire Regarding the People's Republic of China Volume II of the Petition,'' dated October 21, 2026 (Second China AD Supplement).

[8] The members of the Alliance are interested parties within the meaning of section 771(9)(C) of the Act.

[9] *See* section on ''Determination of Industry Support for the Petition,'' *infra.*

industry is seeking relief.[10] Between October 4 and 19, 2026, the petitioner provided clarifications and/or revised the scope.[11] The description of merchandise covered by this investigation, as described in the appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (*i.e.,* scope).[12] Commerce will consider all scope comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information, all such factual information should be limited to public information.[13] Commerce requests that interested parties provide at the beginning of their scope comments a public executive summary for each comment or issue raised in their submission. Commerce further requests that interested parties limit their public executive summary of each comment or issue to no more than 450 words, not including citations. Commerce intends to use the public executive summaries as the basis of the comment summaries included in the analysis of scope comments. To facilitate preparation of its questionnaires, Commerce requests that scope comments be submitted by 5:00 p.m. Eastern Time (ET) on November 23, 2026, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, and should also be limited to public information, must be filed by 5:00 p.m. ET on December 3, 2026, which is 10 calendar days from the initial comment deadline.

Commerce requests that any factual information that parties consider relevant to the scope of this investigation be submitted during that period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party must contact Commerce and request permission to submit the additional information. All scope comments must be filed simultaneously on the records of the concurrent LTFV and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically via Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS), unless an exception applies.[14] An electronically filed document must be received successfully in its entirety by the time and date it is due.

Comments on Product Characteristics

Commerce is providing interested parties an opportunity to comment on the appropriate physical characteristics of certain wooden fence components to be reported in response to Commerce's AD questionnaires. This information will be used to identify the key physical characteristics of the subject merchandise in order to report the relevant factors of production (FOP) accurately, as well as to develop appropriate product comparison criteria.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all product characteristics comments must be filed by 5:00 p.m. ET on November 23, 2026, which is 20 calendar days from the signature date of this notice. Any rebuttal comments must be filed by 5:00 p.m. ET on December 3, 2026, which is 10 calendar days from the initial comment deadline. All comments and submissions to Commerce must be filed electronically using ACCESS, as explained above, on the record of the LTFV investigation.

Determination of Industry Support for the Petition

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The U.S. International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC apply the same statutory definition regarding the domestic like product,[15] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[16]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the investigation.[17] Based on our analysis of

[10] *See* First General Issues Supplemental Questionnaire; *see also* Second General Issues Supplemental Questionnaire and Third General Issues Supplemental Questionnaire.

[11] *See* First General Issues Supplement at 1–8 and Exhibits I-Supp-2 through Exhibit I-Supp-6; *see also* Second General Issues Supplement at 1–2; and Third General Issues Supplemental Questionnaire at 1.

[12] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*); *see also* 19 CFR 351.312.

[13] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[14] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014), for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on using ACCESS can be found at *https://access.trade.gov/help* and a handbook can be found at *https://access.trade.gov/ACCESS%20Handbook%20on%20Electronic%20Filing%20Procedures_March2026.pdf.*

[15] *See* section 771(10) of the Act.

[16] *See USEC, Inc.* v. *United States,* 132 F.Supp.2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F.Supp.639, 644 (CIT 1988), *aff'd Algoma Steel Corp., Ltd.* v. *United States,* 865 F.2d 240 (Fed. Cir. 1989)).

[17] For a discussion of the domestic like product analysis as applied to this case and information regarding industry support, see Checklist,

the information submitted on the record, we have determined that certain wooden fence components, as defined in the scope, constitute a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[18]

As noted above, on October 13, 2026, Commerce extended the initiation deadline by 20 days to further examine the issue of industry support. In determining whether the petitioner has standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in the appendix to this notice. To establish industry support, the petitioner provided the 2025 production of the domestic like product for the U.S. producers that support the Petition and compared this to the estimated total production of the domestic like product by the U.S. certain wooden fence components industry.[19] We relied on data provided by the petitioner for purposes of measuring industry support.[20]

Our review of the data provided in the Petition, the First General Issues Supplement, Third General Issues Supplement, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petition.[21] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[22] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[23] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[24] Accordingly, Commerce determines that the Petition was filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.[25]

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at LTFV. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[26]

The petitioner contends that the industry's injured condition is illustrated by a significant increase in the volume of subject imports; significant market share by subject imports and reduced market share for the domestic industry; underselling and price depression and suppression; negative impact on financial performance; lost sales and revenue; declines in production, U.S. shipments, capacity utilization, and employment variables; and the magnitude of the alleged dumping margins.[27] We assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[28]

Allegations of Sales at LTFV

The following is a description of the allegations of sales at LTFV upon which Commerce based its decision to initiate LTFV investigation of imports of certain wooden fence components from China. The sources of data for the deductions and adjustments relating to U.S. price and normal value (NV) are discussed in greater detail in the China AD Initiation Checklist.

U.S. Price

The petitioner based export price (EP) on pricing information for certain wooden fence components produced in China and sold or offered for sale in the U.S. market.[29] The petitioner made certain adjustments to U.S. price to calculate a net ex-factory U.S. price, where applicable.[30]

Normal Value

Commerce considers China to be an NME country.[31] In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by Commerce. Therefore, we continue to treat China as an NME country for purposes of the initiation of the LTFV investigation. Accordingly, we base NV on FOPs valued in a surrogate market economy country in accordance with section 773(C) of the Act.

The petitioner claims that Brazil, Mexico, and the Republic of Türkiye (Türkiye) are appropriate surrogate countries for China because they are market economy countries that are at a level of economic development comparable to that of China and are significant producers of comparable merchandise.[32] The petitioner provided publicly available information from Brazil, Mexico, and Türkiye to value all FOPs.[33] Based on the information provided by the petitioner, we believe it is appropriate to use Brazil, Mexico, and Türkiye as surrogate countries for China to value all FOPs for initiation purposes.

Interested parties will have the opportunity to submit comments regarding surrogate country selection and, pursuant to 19 CFR 351.301(c)(3)(i), will be provided an opportunity to submit publicly available information to value FOPs within 30 days before the scheduled date of the preliminary determination.

''Antidumping Duty Investigation Initiation Checklist: Certain Wooden Fence Components from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (China AD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Certain Wooden Fence Components from the People's Republic of China (Attachment II). This checklist is on file electronically via ACCESS.

[18] For further discussion, *see* Attachment II of the China AD Initiation Checklist.

[19] *Id.*

[20] For further discussion, *see* Attachment II of the China AD Initiation Checklist.

[21] *Id.*

[22] *Id.; see also* section 732(c)(4)(D) of the Act.

[23] *See* Attachment II of the China AD Initiation Checklist.

[24] *Id.*

[25] *Id.*

[26] For further discussion, *see* China AD Initiation Checklist at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Certain Wooden Fence Components from the People's Republic of China.

[27] *Id.*

[28] *Id.*

[29] *See* China AD Initiation Checklist.

[30] *Id.*

[31] *See, e.g., Certain Freight Rail Couplers and Parts Thereof from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value and Preliminary Affirmative Determination of Critical Circumstances,* 88 FR 15372 (March 13, 2023), and accompanying Preliminary Decision Memorandum at 5, unchanged in *Certain Freight Rail Couplers and Parts Thereof from the People's Republic of China: Final Affirmative Determination of Sales at Less-Than-Fair Value and Final Affirmative Determination of Critical Circumstances,* 88 FR 34485 (May 30, 2023).

[32] *See* China AD Initiation Checklist.

[33] *Id.*

Factors of Production

Because information regarding the volume of inputs consumed by Brazilian, Mexican, and Turkish producers/exporters was not reasonably available, the petitioner used the production experience and product-specific consumption rates of a U.S. producer of certain wooden fence components as a surrogate to value Chinese manufacturers' FOPs.[34] Additionally, the petitioner calculated factory overhead, selling, general, and administrative (SG&A) expenses, and profit based on the experiences of Brazilian and Turkish producers of comparable merchandise.[35]

Fair Value Comparisons

Based on the data provided by the petitioner, there is reason to believe that imports of certain wooden fence components from China are being, or are likely to be, sold in the United States at LTFV. Based on comparisons of EP to NV in accordance with sections 772 and 773 of the Act, after accounting for certain revisions made by Commerce, the estimated dumping margins for certain wooden fence components from China covered by this initiation range from (1) China (Brazil surrogate) 217.40 to 232.23 percent; (2) China (Mexico surrogate) 122.64 to 131.81 percent; and (3) China (Türkiye surrogate) 109.01 to 117.41 percent.[36]

Initiation of LTFV Investigation

Based upon the examination of the Petition and supplemental responses, we find that they meet the requirements of section 732 of the Act. Therefore, we are initiating an LTFV investigation to determine whether imports of certain wooden fence components from China are being, or are likely to be, sold in the United States at LTFV. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 140 days after the date of this initiation.

Respondent Selection

In the Petition, the petitioner identified 80 companies in China as producers and/or exporters of certain wooden fence components.[37] Our standard practice for respondent selection in an AD investigation involving an NME country is to select respondents based on quantity and value (Q&V) questionnaires in cases where Commerce has determined that the number of companies is large, and it cannot individually examine each company based upon its resources. Therefore, considering the number of producers and/or exporters identified in the Petition, Commerce will solicit Q&V information that can serve as a basis for selecting exporters for individual examination in the event that Commerce determines that the number is large and decides to limit the number of respondents individually examined pursuant to section 777A(c)(2) of the Act. Given the number of producers and/or exporters identified in the Petition, Commerce has determined that it will issue Q&V questionnaires to the largest producers and/or exporters that are identified in the U.S. Customs and Border Protection entry data for which there is complete address information on the record.[38]

Commerce will post the Q&V questionnaires along with filing instructions on Commerce's website at *https://www.trade.gov/ec-adcvd-qv-questionnaire.* Producers/exporters of certain wooden fence components from China that do not receive Q&V questionnaires may still submit a response to the Q&V questionnaire and can obtain a copy of the Q&V questionnaire from Commerce's website. Responses to the Q&V questionnaire must be submitted by the relevant Chinese producers/exporters no later than 5:00 p.m. ET on November 17, 2026, which is two weeks from the signature date of this notice. All Q&V questionnaire responses must be filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by ACCESS no later than 5:00 p.m. ET on the deadline noted above.

Interested parties must submit applications for disclosure under administrative protective order (APO) in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on Commerce's website at *https://www.trade.gov/administrative-protective-orders.*

Separate Rates

In order to obtain separate rate status in an NME investigation, exporters and producers must submit a separate rate application. The specific requirements for submitting a separate rate application in an NME investigation are outlined in detail in the application itself, which is available on Commerce's website at *https://www.trade.gov/non-market-economy-separate-rate-applications-and-certifications.* Note that Commerce recently promulgated new regulations pertaining to separate rates, including the separate rate application deadline and eligibility for separate rate status, in 19 CFR 351.108.[39] Pursuant to 19 CFR 351.108(d)(1), the separate rate application will be due 21 days after publication of this initiation notice.[40] Exporters and producers must file a timely separate rate application if they want to be considered for individual examination. In addition, pursuant to 19 CFR 351.108(e), exporters and producers who submit a separate rate application and have been selected as mandatory respondents will be eligible for consideration for separate rate status only if they fully respond to all parts of Commerce's AD questionnaire and participate in the LTFV proceeding as mandatory respondents.[41] Commerce requires that companies from China submit a response both to the Q&V questionnaire and to the separate rate application by the respective deadlines to receive consideration for separate rate status. Companies not filing a timely Q&V questionnaire response will not receive separate rate consideration.

Use of Combination Rates

Commerce will calculate combination rates for certain respondents that are eligible for a separate rate in an NME investigation. The Separate Rates and Combination Rates Bulletin states:

> {w}hile continuing the practice of assigning separate rates only to exporters, all separate rates that {Commerce} will now assign in its NME investigation will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the {weighted average} of the individually calculated rates. This practice is referred to as the application of ''combination rates'' because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question and produced by a firm that supplied the exporter during the period of investigation.[42]

[34] *Id.*

[35] *Id.*

[36] *Id.*

[37] *See* Petition at Volume I (pages 9–10 and Exhibit I–8); *see also* First General Issues Supplement at 1 and Exhibit I-Supp-1.

[38] *See* Memorandum, ''Release of U.S. Customs and Border Protection Entry Data,'' dated November 3, 2026.

[39] *See Regulations Enhancing the Administration of the Antidumping and Countervailing Duty Trade Remedy Laws,* 89 FR 101694, 101759–60 (December 16, 2024).

[40] *See* 19 CFR 351.108(d)(1).

[41] *See* 19 CFR 351.108(e).

[42] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates

Distribution of Copies of the Petition

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the Government of China via ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to each exporter named in the Petition, as provided under 19 CFR 351.203(c)(2).

ITC Notification

Commerce will notify the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 25 days after the date on which the ITC receives notice from Commerce of initiation of the investigation, whether there is a reasonable indication that imports of certain wooden fence components from China are materially injuring, or threatening material injury to, a U.S. industry.[43] A negative ITC determination will result in the investigation being terminated.[44] Otherwise, this LTFV investigation will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 351.301(b) of Commerce's regulations requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted [45] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[46] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in this investigation.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by Commerce. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301, or as otherwise specified by Commerce.[47] For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, standalone submission; under limited circumstances we will grant untimely filed requests for the extension of time limits, where we determine, based on 19 CFR 351.302, that extraordinary circumstances exist. Parties should review Commerce's regulations concerning the extension of time limits and the *Time Limits Final Rule* prior to submitting factual information in this investigation.[48]

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[49] Parties must use the certification formats provided in 19 CFR 351.303(g).[50] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. Parties wishing to participate in this investigation should ensure that they meet the requirements of 19 CFR 351.103(d) (*e.g.,* by filing the required letter of appearance). Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[51]

This notice is issued and published pursuant to sections 732(c)(2) and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: November 3, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Investigation

The scope of this investigation includes certain wooden fence components (commonly referred to as pickets), finished and unfinished, whether assembled or unassembled. Wooden fence pickets included in this scope are made of one or more wood species, typically from Cryptomeria japonica (Japanese Cedar or Sugi), but can also be made from other wood species, including but not limited to Western Red Cedar, Redwood, Incense Cedar, Douglas Fir, Western Hemlock, Sitka Spruce, and Cunninghamia lanceolata (Chinese Fir). Wooden fence pickets are included within the scope of this investigation regardless of form or shape, including, but not limited to flat top (also known as square or square top), pointed, dog ear, gothic (including but not limited to French gothic, French gothic blunt point) and stockade.

Generally, assembled wooden fence pickets contain at least one fence picket attached to one or more cross rails, framing lumber, or other fencing materials, and can include fully pre-assembled fence panels. Unassembled wooden fence pickets consist of one or more wooden fence pickets, not attached to any framing lumber, whether sold individually, bundled, or in a kit with framing lumber.

The finished products covered by the scope of this investigation have the following dimensions: a thickness of no more than 1 inch, a width of no more than 12 inches, and a length of at least 3 feet. The products covered by the scope are typically a length of 5 feet, 6 feet, or 8 feet when finished.

Wooden fence pickets are included within the scope of this investigation regardless of whether they have been painted, stained, pressure-treated, or otherwise coated or

Practice and Application of Combination Rates in Antidumping Investigation involving NME Countries,'' (April 5, 2005), at 6 (emphasis added), available on Commerce's website at *https://www.trade.gov/enforcement-and-compliance-policy-bulletins-0.*

[43] *See* section 733(a) of the Act.

[44] *Id.*

[45] *See* 19 CFR 351.301(b).

[46] *See* 19 CFR 351.301(b)(2).

[47] *See* 19 CFR 351.301; *see also Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013) (*Time Limits Final Rule*), available at *https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm.*

[48] *See* 19 CFR 351.302; *see also, e.g., Time Limits Final Rule.*

[49] *See* section 782(b) of the Act.

[50] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2023) (*Final Rule*). Additional information regarding the *Final Rule* is available at *https://www.trade.gov/sites/default/files/2026-08/FAQ%20for%20Certifications.pdf?v=1787683944756.*

[51] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069 (September 29, 2023).

treated. Subject merchandise also includes wooden fence pickets that have been further processed in a third country, including but not limited to trimming, cutting, notching, sanding, planing or any other processing that would not otherwise remove the merchandise from the scope of this investigation if performed in the country of manufacture of the in-scope product.

Excluded from the scope of this investigation are wooden fence pickets made exclusively of bamboo (including, but not limited to, Phyllostachys edulis, Bambusa textilis, and Bambusa oldhamii), Brazilian Pine (Paraná pine), or Southern Yellow Pine (including Shortleaf Pine (Pinus echinata), Slash Pine (Pinus ellioti), Longleaf Pine (Pinus palustris), or Loblolly Pine (Pinus taeda)).

Also excluded from the scope of this investigation are wood mouldings and millwork products covered by the antidumping and countervailing duty orders on wood mouldings and millwork products from the People's Republic of China. *See Wood Mouldings and Millwork Products from the People's Republic of China: Amended Final Antidumping Duty Determination and Antidumping Duty Order,* 86FR 9486 (February 16, 2021) (amended final antidumping duty determination and antidumping duty order); *Wood Mouldings and Millwork Products from the People's Republic of China: Countervailing Duty Order,* 86 FR 9484 (February 16, 2021) (countervailing duty order).

Imports of subject merchandise are typically classified under Harmonized Tariff Schedule of the United States (HTSUS) statistical numbers 4404.10.0040, 4407.19.0092, 4421.99.7020, and 4421.99.7040. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[FR Doc. 2026–22763 Filed 11–6–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–833–001, A–533–956]

Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe From Georgia and India: Initiation of Less-Than-Fair-Value Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable November 4, 2026.

FOR FURTHER INFORMATION CONTACT: Rebecca Janz at (202) 482–2972 (Georgia) and Aislin Salassi at (202) 482–1882 (India), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On October 15, 2026, the U.S. Department of Commerce (Commerce) received antidumping duty (AD) petitions concerning imports of seamless carbon and alloy steel standard, line, and pressure pipe (seamless standard, line, and pressure pipe) from Georgia and India, filed in proper form on behalf of Tenaris USA (Tenaris), Vallourec Star LP (Vallourec), and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC (USW) (collectively, the petitioners), domestic producers of seamless standard, line, and pressure pipe and a certified union, which represents workers engaged in the production of seamless standard, line, and pressure pipe in the United States.[1] The Petitions were accompanied by a countervailing duty (CVD) petition concerning imports of seamless standard, line, and pressure pipe from India.[2]

Between October 20 and 26, 2026, Commerce requested supplemental information pertaining to certain aspects of the Petitions in supplemental questionnaires.[3] Between October 22 and 28, 2026, the petitioners filed timely responses to these requests for additional information.[4]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioners allege that imports of seamless standard, line, and pressure pipe from Georgia and India are being, or are likely to be, sold in the United States at less than fair value (LTFV) within the meaning of section 731 of the Act, and that imports of such products are materially injuring, or threatening material injury to, the seamless standard, line, and pressure pipe industry in the United States. Consistent with section 732(b)(1) of the Act, the Petitions were accompanied by information reasonably available to the petitioners supporting their allegations.

Commerce finds that the petitioners filed the Petitions on behalf of the domestic industry, because the petitioners are interested parties, as defined in sections 771(9)(C) and (D) of the Act.[5] Commerce also finds that the petitioners demonstrated sufficient industry support for the initiation of the requested LTFV investigations.[6]

Periods of Investigations (POI)

Because the Petitions were filed on October 15, 2026, pursuant to 19 CFR 351.204(b)(1), the POI for the India LTFV investigation is October 1, 2025, through September 30, 2026. Because Georgia is a non-market economy (NME) country, pursuant to 19 CFR 351.204(b)(1), the POI for the Georgia LTFV investigation is April 1, 2026, through September 30, 2026.

Scope of the Investigations

The product covered by these investigations is seamless standard, line, and pressure pipe from Georgia and India. For a full description of the scope of these investigations, *see* the appendix to this notice.

Comments on the Scope of the Investigations

On October 20 and 26, 2026, Commerce requested information and clarification from the petitioners regarding the proposed scope to ensure that the scope language in the Petitions is an accurate reflection of the products for which the domestic industry is seeking relief.[7] On October 22 and 28, 2026, the petitioners provided clarifications and revised the scope.[8] The description of merchandise covered by these investigations, as described in the appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage

[1] *See* Petitioners' Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties,'' dated October 15, 2026 (Petitions).

[2] *Id.*

[3] *See* Commerce's Letters, ''Supplemental Questions,'' dated October 20, 2026 (First General Issues Questionnaire); Georgia AD Supplemental Questionnaire, dated October 20, 2026 (Georgia AD Questionnaire), and India AD Supplemental Questionnaire, dated October 20, 2026 (India AD Questionnaire); and ''Second Supplemental Questions,'' dated October 26, 2026 (Second General Issues Questionnaire).

[4] *See* Petitioners' Letters, ''Petitioners' Response to General Issues Supplemental Questions,'' dated October 22, 2026 (First General Issues Supplement); ''Responses to Supplemental Questions,'' dated October 22, 2026 (Georgia AD Supplement); ''Responses to Supplemental Questions,'' dated October 22, 2026 (India AD Supplement); ''Petitioners' Response to General Issues Second Supplemental Questions,'' dated October 28, 2026 (Second General Issues Supplement).

[5] Tenaris and Vallourec are interested parties under section 771(9)(C) of the Act. The USW is a certified union representing workers engaged in the production of seamless standard, line, and pressure pipe in the United States and therefore is an interested party under section 771(9)(D) of the Act.

[6] *See* section on ''Determination of Industry Support for the Petitions,'' *infra.*

[7] *See* First General Issues Supplemental Questionnaire; *see also* Second General Issues Supplemental Questionnaire.

[8] *See* First General Issues Supplement at 2–3 and Exhibit I–SUPP–9; *see also* Second General Issues Supplement at 1–3 and Exhibit I–SUPP2–9.

(*i.e.,* scope).[9] Commerce will consider all scope comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determinations. If scope comments include factual information, all such factual information should be limited to public information.[10] Commerce requests that interested parties provide at the beginning of their scope comments a public executive summary for each comment or issue raised in their submission. Commerce further requests that interested parties limit their public executive summary of each comment or issue to no more than 450 words, not including citations. Commerce intends to use the public executive summaries as the basis of the comment summaries included in the analysis of scope comments. To facilitate preparation of its questionnaires, Commerce requests that scope comments be submitted by 5:00 p.m. Eastern Time (ET) on November 24, 2026, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, and should also be limited to public information, must be filed by 5:00 p.m. ET on December 4, 2026, which is 10 calendar days from the initial comment deadline.

Commerce requests that any factual information that parties consider relevant to the scope of these investigations be submitted during that period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party must contact Commerce and request permission to submit the additional information. All scope comments must be filed simultaneously on the records of the concurrent LTFV and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically via Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS), unless an exception applies.[11] An electronically filed document must be received successfully in its entirety by the time and date it is due.

Comments on Product Characteristics

Commerce is providing interested parties an opportunity to comment on the appropriate physical characteristics of seamless standard, line, and pressure pipe to be reported in response to Commerce's AD questionnaires. This information will be used to identify the key physical characteristics of the subject merchandise in order to report the relevant factors of production (FOP) or cost of production (COP) accurately, as well as to develop appropriate product comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) general product characteristics; and (2) product comparison criteria. We note that it is not always appropriate to use all product characteristics as product comparison criteria. We base product comparison criteria on meaningful commercial differences among products. In other words, although there may be some physical product characteristics utilized by manufacturers to describe seamless standard, line, and pressure pipe, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, Commerce attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all product characteristics comments must be filed by 5:00 p.m. ET on November 24, 2026, which is 20 calendar days from the signature date of this notice. Any rebuttal comments must be filed by 5:00 p.m. ET on December 4, 2026, which is 10 calendar days from the initial comment deadline. All comments and submissions to Commerce must be filed electronically using ACCESS, as explained above, on the record of the each of the LTFV investigations.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The U.S. International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC apply the same statutory definition regarding the domestic like product,[12] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[13]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is

[9] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997) (*Preamble*); *see also* 19 CFR 351.312.

[10] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[11] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014), for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on using ACCESS can be found at *https://access.trade.gov/help* and a handbook can be found at *https://access.trade.gov/ACCESS%20Handbook%20on%20Electronic%20Filing%20Procedures_March2026.pdf.*

[12] *See* section 771(10) of the Act.

[13] *See USEC, Inc.* v. *United States,* 132 F.Supp.2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F.Supp. 639, 644 (CIT 1988), *aff'd Algoma Steel Corp., Ltd.* v. *United States,* 865 F.2d 240 (Fed. Cir. 1989)).

''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioners do not offer a definition of the domestic like product distinct from the scope of the investigations.[14] Based on our analysis of the information submitted on the record, we have determined that corrugated die-cut boxes, as defined in the scope, constitute a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[15]

In determining whether the petitioners have standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the ''Scope of the Investigations,'' in the appendix to this notice. To establish industry support, the petitioners provided their own shipments of seamless standard, line, and pressure pipe in 2025 and compared this to the estimated total shipments of the domestic like product for the entire domestic industry.[16] Because total production data for the domestic like product for 2025 are not reasonably available to the petitioners, and the petitioners have established that shipments are a reasonable proxy for production data,[17] we relied on data provided by the petitioners for purposes of measuring industry support.[18]

Our review of the data provided in the Petitions, the First General Issues Supplement, and other information readily available to Commerce indicates that the petitioners have established industry support for the Petitions.[19] First, the Petitions established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[20] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petitions account for at least 25 percent of the total production of the domestic like product.[21] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions.[22] Accordingly, Commerce determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.[23]

Allegations and Evidence of Material Injury and Causation

The petitioners allege that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at LTFV. In addition, the petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[24]

The petitioners contend that the industry's injured condition is illustrated by a significant increase in the volume of subject imports; underselling and price depression and/or suppression; negative impact on financial performance; and declines in production, U.S. shipments, and employment variables.[25] We assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, cumulation, as well as negligibility, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[26]

Allegations of Sales at LTFV

The following is a description of the allegations of sales at LTFV upon which Commerce based its decision to initiate LTFV investigations of imports of seamless standard, line, and pressure pipe from Georgia and India. The sources of data for the deductions and adjustments relating to U.S. price and normal value (NV) are discussed in greater detail in the Georgia AD Initiation Checklist and India AD Initiation Checklist.

U.S. Price

For Georgia and India, the petitioners based export price (EP) on POI average unit values derived from official import statistics for imports of seamless standard, line, and pressure pipe from each of the respective countries.[27] For each country, the petitioners made certain adjustments to U.S. price to calculate a net ex-factory U.S. price, where applicable.

Normal Value [28]

For India, the petitioners based NV on home market pricing information they obtained for seamless standard, line, and pressure pipe produced in and sold, or offered for sale, in India during the POI.[29] The petitioners provided information indicating that the prices for seamless standard, line, and pressure pipe sold or offered for sale in India were below the COP. Therefore, for India, the petitioners calculated NV based on CV. For further discussion of CV, *see* the section ''Normal Value Based on Constructed Value.''

Commerce considers Georgia to be an NME country.[30] In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is

[14] For a discussion of the domestic like product analysis as applied to these cases and information regarding industry support, *see* Checklists, ''Antidumping Duty Investigation Initiation Checklists: Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from Georgia and India,'' dated concurrently with, and hereby adopted by, this notice (Country-Specific AD Initiation Checklists), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from Georgia and India (Attachment II). These checklists are on file electronically via ACCESS.

[15] For further discussion, *see* Attachment II of the Country-Specific AD Initiation Checklists.

[16] *Id.*

[17] *Id.; see also Tenaris Bay City, Inc.* v. *United States,* No. 2025–1382, 2026 LX 545375, at *19 n.5 (Fed. Cir. Sep. 18, 2026).

[18] *See* Attachment II of the Country-Specific AD Initiation Checklists.

[19] *Id.*

[20] *Id.; see also* section 732(c)(4)(D) of the Act.

[21] *See* Attachment II of the Country-Specific AD Initiation Checklists.

[22] *Id.*

[23] *Id.*

[24] For further discussion, *see* Country-Specific AD Initiation Checklists at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe from Georgia and India.

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] In accordance with section 773(b)(2) of the Act, for the India investigation, Commerce will request information necessary to calculate the constructed value (CV) and COP to determine whether there are reasonable grounds to believe or suspect that sales of the foreign like product have been made at prices that represent less than the COP of the product.

[29] *See* India AD Initiation Checklist.

[30] Georgia, formerly part of the Union of Soviet Socialist Republics (USSR), assumed the NME status of the USSR upon the dissolution of the USSR, and, at that time, Commerce explained that such status would remain in effect until revoked. *See Preliminary Determinations of Sales at less Than Fair Value: Uranium from Kazakhstan, Kyrgyzstan, Russia, Tajikistan, Ukraine and Uzbekistan; and Preliminary Determinations of Sales at Not Less Than Fair Value: Uranium from Armenia, Azerbaijan, Byelarus, Georgia, Moldova and Turkmenistan,* 57 FR 23380, 23383 (June 3, 1992). To date, Commerce has not revoked the NME status of Georgia.

an NME country shall remain in effect until revoked by Commerce. Therefore, we continue to treat Georgia as an NME country for purposes of the initiation of the LTFV investigation. Accordingly, we base NV in Georgia on FOPs valued in surrogate market economy countries in accordance with section 773(C) of the Act.

The petitioners claim that Brazil, Colombia, and Malaysia are appropriate surrogate countries for Georgia because they are market economy countries that are at a level of economic development comparable to that of Georgia and are significant producers of comparable merchandise.[31] The petitioners provided publicly available information from Brazil, Colombia, and Malaysia to value all FOPs. Based on the information provided by the petitioners, we believe it is appropriate to use Brazil, Colombia, and Malaysia as surrogate countries for Georgia to value all FOPs for initiation purposes.

Interested parties will have the opportunity to submit comments regarding surrogate country selection and, pursuant to 19 CFR 351.301(c)(3)(i), will be provided an opportunity to submit publicly available information to value FOPs within 30 days before the scheduled date of the preliminary determination.

Factors of Production

Because information regarding the volume of inputs consumed by Brazilian, Colombian, and Malaysian producers/exporters were not reasonably available, the petitioners used a U.S. producer's production experience and product-specific consumption rates as a surrogate to value the Georgia manufacturer's FOPs.[32] Additionally, for Georgia, the petitioners calculated factory overhead, selling, general, and administrative (SG&A) expenses, and profit based on the experiences of Brazilian, Colombian, and Malaysian producers of comparable merchandise.[33]

Normal Value Based on Constructed Value

As noted above, the petitioners provided information indicating that the prices for seamless standard, line, and pressure pipe sold or offered for sale in India were below the COP. Therefore, the petitioners calculated NV based on CV.[34]

Pursuant to section 773(e) of the Act, the petitioners calculated CV as the sum of the cost of manufacturing, SG&A expenses, financial expenses, and profit.[35] In calculating the cost of manufacturing, the petitioners relied on a U.S. producer's production experience and input consumption rates for seamless standard, line, and pressure pipe, valued using publicly available information applicable to India.[36] In calculating SG&A expenses, financial expenses, and profit ratios, the petitioners relied on the fiscal year 2025–26 financial statements of a producer of comparable merchandise domiciled in India.

Fair Value Comparisons

Based on the data provided by the petitioners, there is reason to believe that imports of seamless standard, line, and pressure pipe from Georgia and India, are being, or are likely to be, sold in the United States at LTFV. Based on comparisons of EP to NV in accordance with sections 772 and 773 of the Act, the estimated dumping margins for seamless standard, line, and pressure pipe for each of the countries covered by this initiation are as follows: (1) Georgia (Brazil Surrogate)—173.72 to 188.52 percent; Georgia (Colombia Surrogate)—113.87 to 133.00 percent; Georgia (Malaysia Surrogate)—277.69 to 286.29 percent; and (2) India—41.03 to 63.57 percent.[37]

Initiation of LTFV Investigations

Based upon the examination of the Petitions and supplemental responses, we find that they meet the requirements of section 732 of the Act. Therefore, we are initiating LTFV investigations to determine whether imports of seamless standard, line, and pressure pipe from Georgia and India are being, or are likely to be, sold in the United States at LTFV. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Respondent Selection

Georgia

In the Petitions, the petitioners identified three companies in Georgia as producers and/or exporters of seamless standard, line, and pressure pipe.[38] Our standard practice in an AD investigation involving an NME country is to select respondents based on quantity and value (Q&V) questionnaires in cases where Commerce has determined that the number of companies is large, and it cannot individually examine each company based upon its resources. Therefore, considering the number of producers and/or exporters identified in the Petitions, Commerce will solicit Q&V information that can serve as a basis for selecting exporters for individual examination in the event that Commerce determines that the number is large and decides to limit the number of respondents individually examined pursuant to section 777A(c)(2) of the Act. Given the number of producers and/or exporters identified in the Petitions, Commerce has determined that it will issue Q&V questionnaires to each potential respondent for which there is complete address information on the record.

Commerce will post the Q&V questionnaire along with filing instructions on Commerce's website at *https://www.trade.gov/ec-adcvd-qv-questionnaire.* Producers/exporters of seamless standard, line, and pressure pipe from Georgia that do not receive Q&V questionnaires may still submit a response to the Q&V questionnaire and can obtain a copy of the Q&V questionnaire from Commerce's website. Responses to the Q&V questionnaire must be submitted by the relevant Georgian producers/exporters no later than 5:00 p.m. ET on November 18, 2026, which is two weeks from the signature date of this notice. All Q&V questionnaire responses must be filed electronically via ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the deadline noted above.

Interested parties must submit applications for disclosure under administrative protective order (APO) in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on Commerce's website at *https://www.trade.gov/administrative-protective-orders.*

India

In the Petitions, the petitioners identified 16 companies in India as producers and/or exporters of seamless standard, line, and pressure pipe.[39] In the event Commerce determines that the number of companies is large, and it cannot individually examine each company based on Commerce's resources, where appropriate, Commerce intends to select mandatory respondents based on Q&V questionnaires issued to potential

[31] *See* Georgia AD Initiation Checklist.

[32] *Id.*

[33] *Id.*

[34] *See* India AD Initiation Checklist.

[35] *Id.*

[36] *Id.*

[37] *See* Country-Specific AD Initiation Checklists.

[38] *See* Petitions at Volume I (page 15 and Exhibit I–13).

[39] *See* Petitions at Volume I (page 15 and Exhibit I–14).

respondents. Following the standard practice in AD investigations involving market economy countries, Commerce would normally select respondents based on U.S. Customs and Border Protection (CBP) entry data for imports under the appropriate HTSUS subheadings listed in the scope of the investigations. However, for these investigations, some of the main HTSUS subheadings under which the subject merchandise would enter (7304.19.1020, 7304.19.1030, 7304.19.1045, 7304.19.1060, 7304.19.5020, 7304.19.5050, 7304.31.6050, 7304.39.0016, 7304.39.0020, 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.51.5005, 7304.51.5060, 7304.59.6000) are basket categories under which non-subject merchandise may also enter. Therefore, instead of relying on CBP entry data in selecting respondents, we intend to issue Q&V questionnaires to each potential respondent for which there is complete address information on the record.

Commerce will post the Q&V questionnaire along with filing instructions on Commerce's website at *https://www.trade.gov/ec-adcvd-qv-questionnaire.* Producers/exporters of seamless standard, line, and pressure pipe from India that do not receive Q&V questionnaires may still submit a response to the Q&V questionnaire and can obtain a copy of the Q&V questionnaire from Commerce's website. Responses to the Q&V questionnaire must be submitted by the relevant Indian producers/exporters no later than 5:00 p.m. ET on November 18, 2026, which is two weeks from the signature date of this notice. All Q&V questionnaire responses must be filed electronically via ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the deadline noted above.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on Commerce's website at *https://www.trade.gov/administrative-protective-orders.*

Separate Rates

In order to obtain separate rate status in an NME investigation, exporters and producers must submit a separate rate application. The specific requirements for submitting a separate rate application in an NME investigation are outlined in detail in the application itself, which is available on Commerce's website at *https://www.trade.gov/non-market-economy-separate-rate-applications-and-certifications.* Note that Commerce recently promulgated new regulations pertaining to separate rates, including the separate rate application deadline and eligibility for separate rate status, in 19 CFR 351.108.[40] Pursuant to 19 CFR 351.108(d)(1), the separate rate application will be due 21 days after publication of this initiation notice.[41] Exporters and producers must file a timely separate rate application if they want to be considered for individual examination. In addition, pursuant to 19 CFR 351.108(e), exporters and producers who submit a separate rate application and have been selected as mandatory respondents will be eligible for consideration for separate rate status only if they fully respond to all parts of Commerce's AD questionnaire and participate in the LTFV proceeding as mandatory respondents.[42] Commerce requires that companies from Georgia submit a response to the Q&V questionnaire and a separate rate application by the respective deadlines to receive consideration for separate rate status. Companies not filing a timely Q&V questionnaire response will not receive separate rate consideration.

Use of Combination Rates

Commerce will calculate combination rates for certain respondents that are eligible for a separate rate in an NME investigation. The Separate Rates and Combination Rates Bulletin states:

> {w}hile continuing the practice of assigning separate rates only to exporters, all separate rates that {Commerce} will now assign in its NME investigation will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the {weighted average} of the individually calculated rates. This practice is referred to as the application of ''combination rates'' because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question and produced by a firm that supplied the exporter during the period of investigation.[43]

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public versions of the Petitions have been provided to the Governments of Georgia and India via ACCESS. To the extent practicable, we will attempt to provide copies of the public versions of the Petitions to each exporter named in the Petitions, as provided under 19 CFR 351.203(c)(2).

ITC Notification

Commerce will notify the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of seamless standard, line, and pressure pipe from Georgia and/or India are materially injuring, or threatening material injury to, a U.S. industry.[44] A negative ITC determination for any country will result in the investigation being terminated with respect to that country.[45] Otherwise, these LTFV investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 351.301(b) of Commerce's regulations requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted [46] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual

[40] *See Regulations Enhancing the Administration of the Antidumping and Countervailing Duty Trade Remedy Laws,* 89 FR 101694, 101759–60 (December 16, 2024).

[41] *See* 19 CFR 351.108(d)(1).

[42] *See* 19 CFR 351.108(e).

[43] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigation involving NME Countries,'' (April 5, 2005), at 6 (emphasis added), available on Commerce's website at *https://www.trade.gov/enforcement-and-compliance-policy-bulletins-0.*

[44] *See* section 733(a) of the Act.

[45] *Id.*

[46] *See* 19 CFR 351.301(b).

information seeks to rebut, clarify, or correct.[47] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in these investigations.

Particular Market Situation Allegation

Section 773(e) of the Act addresses the concept of particular market situation (PMS) for purposes of CV, stating that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act (*i.e.,* a cost-based PMS allegation), the submission must be filed in accordance with the requirements of 19 CFR 351.416(b), and Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a cost-based PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act, nor 19 CFR 351.301(c)(2)(v), sets a deadline for the submission of cost-based PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a cost-based PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of a respondent's initial section D questionnaire response

We note that a PMS allegation filed pursuant to sections 773(a)(1)(B)(ii)(III) or 773(a)(1)(C)(iii) of the Act (*i.e.,* a sales-based PMS allegation) must be filed within 10 days of submission of a respondent's initial section B questionnaire response, in accordance with 19 CFR 351.301(c)(2)(i) and 19 CFR 351.404(c)(2).

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by Commerce. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301, or as otherwise specified by Commerce.[48] For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, standalone submission; under limited circumstances we will grant untimely filed requests for the extension of time limits, where we determine, based on 19 CFR 351.302, that extraordinary circumstances exist. Parties should review Commerce's regulations concerning the extension of time limits and the *Time Limits Final Rule* prior to submitting factual information in these investigations.[49]

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[50] Parties must use the certification formats provided in 19 CFR 351.303(g).[51] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. Parties wishing to participate in these investigations should ensure that they meet the requirements of 19 CFR 351.103(d) (*e.g.,* by filing the required letter of appearance). Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[52]

This notice is issued and published pursuant to sections 732(c)(2) and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: November 4, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Investigations

The merchandise covered by these investigations is seamless carbon and alloy steel (other than stainless steel) pipes and redraw hollows, less than or equal to 16 inches (406.4 mm) in nominal outside diameter, regardless of wall-thickness, manufacturing process (*e.g.,* hot finished or cold-drawn), end finish (*e.g.,* plain end, beveled end, upset end, threaded, or threaded and coupled), or surface finish (*e.g.,* bare, lacquered or coated). Redraw hollows are any unfinished carbon or alloy steel (other than stainless steel) pipe or ''hollow profiles'' suitable for cold finishing operations, such as cold drawing, to meet the American Society for Testing and Materials (ASTM) or American Petroleum Institute (API) specifications referenced below, or comparable specifications. Specifically included within the scope are seamless carbon and alloy steel (other than stainless steel) standard, line, and pressure pipes produced to the ASTM A–53, ASTM A–106, ASTM A–333, ASTM A–334, ASTM A–589, ASTM A–795, ASTM A–1024, and the API 5L specifications, or comparable specifications, and meeting the physical parameters described above, regardless of application, with the exception of the exclusions discussed below.

Specifically excluded from the scope of these investigations are: (1) all pipes meeting aerospace, hydraulic, and bearing tubing specifications, including: (a) aerospace tubing produced to SAE Aerospace Material Specifications (AMS) 6360, 6361, and 6362; (b) hydraulic tubing produced to ASTM A–822, SAE J524, and EN 10305–4 specifications; and (c) bearing tubing produced to the SAE AMS 6440 specification, including bearing tubing manufactured from steel meeting the chemical and metallurgical requirements of ASTM A–295; (2) all pipes meeting the chemical requirements of ASTM A–335, whether finished or unfinished; (3) unattached couplings; (4) all mechanical, boiler, condenser and heat exchange tubing, except when such products conform to the dimensional requirements, *i.e.,* outside diameter and wall thickness, of ASTM A–53, ASTM A–106 or API 5L specifications; (5) oil country tubular goods consisting of drill pipe, casing, tubing, and coupling stock; and

[47] *See* 19 CFR 351.301(b)(2).

[48] *See* 19 CFR 351.301; *see also Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013) (*Time Limits Final Rule*), available at *https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm.*

[49] *See* 19 CFR 351.302; *see also, e.g., Time Limits Final Rule.*

[50] *See* section 782(b) of the Act.

[51] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2023) (*Final Rule*). Additional information regarding the *Final Rule* is available at *https://www.trade.gov/sites/default/files/2026-08/FAQ%20for%20Certifications.pdf?v=1787683944756.*

[52] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069 (September 29, 2023).

(6) all pipes meeting the chemical requirements of ASTM A–335 regardless of their conformity to the dimensional requirements of ASTM A–53, ASTM A–106 or API 5L.

Subject seamless standard, line, and pressure pipe are normally entered under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7304.19.1020, 7304.19.1030, 7304.19.1045, 7304.19.1060, 7304.19.5020, 7304.19.5050, 7304.31.6050, 7304.39.0016, 7304.39.0020, 7304.39.0024, 7304.39.0028, 7304.39.0032, 7304.39.0036, 7304.39.0040, 7304.39.0044, 7304.39.0048, 7304.39.0052, 7304.39.0056, 7304.39.0062, 7304.39.0068, 7304.39.0072, 7304.51.5005, 7304.51.5060, 7304.59.6000, 7304.59.8010, 7304.59.8015, 7304.59.8020, 7304.59.8025, 7304.59.8030, 7304.59.8035, 7304.59.8040, 7304.59.8045, 7304.59.8050, 7304.59.8055, 7304.59.8060, 7304.59.8065, and 7304.59.8070. Subject merchandise may also enter under HTSUS subheadings 7304.31.6010, 7304.39.0002, 7304.39.0004, 7304.39.0006, 7304.39.0008, 7304.51.5015, 7304.51.5045, 7304.59.2030, 7304.59.2040, 7304.59.2045, 7304.59.2055, and 7304.59.2060. The HTSUS subheadings and specifications are provided for convenience and customs purposes; the written description of the scope is dispositive.

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–942, A–560–846, A–553–003]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the Lao People's Democratic Republic: Amended Final Determination of Sales at Less Than Fair Value; Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From India, Indonesia, and the Lao People's Democratic Republic: Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC), Commerce is issuing antidumping duty (AD) orders on crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from India, Indonesia, and the Lao People's Democratic Republic (Laos). In addition, Commerce is amending its final determination with respect to solar cells from Laos to correct a ministerial error.

DATES: Applicable November 9, 2026.

FOR FURTHER INFORMATION CONTACT: Myrna Lobo (202) 482–2371 (Indonesia), Jonathan Schueler (202) 482–9175 (India), and Lilit Astvatsatrian at (202) 482–6412 (Laos), AD/CVD Operations, Offices VII, VIII, and IX, respectively, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 735(d) and 777(i) of the Tariff Act of 1930, as amended (the Act), on September 16, 2026, Commerce published its affirmative final determinations in the less-than-fair-value (LTFV) investigations of solar cells from India, Indonesia, and Laos.[1] On September 16, 2026, the Alliance for American Solar Manufacturing and Trade (the petitioner) timely alleged that Commerce made ministerial errors in the *Laos Final Determination*.[2] Section 351.224(f) of Commerce's regulations define ministerial errors as errors in addition, subtraction, or other arithmetic function, clerical errors resulting from inaccurate copying, duplication, or the like, and any other type of unintentional error which Commerce considers ministerial. We reviewed the allegations and determined that we made a ministerial error in the *Laos Final Determination*. *See* ''Amendment to the Laos Final Determination'' section below for further discussion.

On November 2, 2026, pursuant to section 735(d) of the Act, the ITC notified Commerce of its final affirmative determinations that an industry in the United States is materially injured by reason of LTFV imports of solar cells from India, Indonesia, and Laos within the meaning of section 735(b)(1)(A)(i) of the Act.[3]

Scope of the Orders

The merchandise covered by these orders is solar cells from India, Indonesia, and Laos. For a complete description of the scope of the orders, *see* the appendix to this notice.

Amendment to the Laos Final Determination

On September 16, 2026, the petitioner timely submitted ministerial error allegations in the *Laos Final Determination*.[4] Commerce reviewed the record and, on October 13, 2026, agreed that one of the petitioner's alleged errors constituted a ministerial error within the meaning of section 735(e) of the Act and 19 CFR 351.224(f).[5] Specifically, Commerce determined that it had erred in removing section 201 duties from reported U.S. duties for all of Solarspace Technology (Laos) Sole Co., Ltd.'s (Solarspace) U.S. sales, instead of limiting the deduction to those U.S. sales which incurred these duties, as the petitioner alleged; however, Commerce also determined that, because the petitioner's allegation regarding the exclusion of Solarspace's U.S. sales through Trina Solar Science & Technology (Thailand) Company Limited and Trina Solar Energy Development Pte. Ltd. in the margin calculation pertained to a methodological decision, it was not a ministerial error.[6] Pursuant to 19 CFR 351.224(e), Commerce is amending the *Laos Final Determination* to reflect the correction of the ministerial error, as described in the Ministerial Error Memorandum.[7] Correcting this error changes Solarspace's final dumping margin. In addition, in the *Laos Final Determination,* because we based the rate for the non-examined separate rate respondents and the Laos-wide entity on the dumping margin calculated for Solarspace,[8] we have also revised the rate assigned to these entities. The amended weighted-average dumping margins for Laos are listed in the ''Estimated Weighted-Average Dumping Margins'' section, below.

Antidumping Duty Orders

As stated above, based on the ITC's affirmative final determinations that an

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules from India: Final Affirmative Determination of Sales at Less Than Fair Value, and Final Affirmative Determination of Critical Circumstances, In Part,* 91 FR 58658 (September 16, 2026); *see also Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from Indonesia: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances,* 91 FR 58651 (September 16, 2026); and *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the Lao People's Democratic Republic: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances, in Part,* 91 FR 58633 (September 16, 2026) (*Laos Final Determination*).

[2] *See* Petitioner's Letter, ''Ministerial Error Allegations for the Final Determination,'' dated September 16, 2026 (Ministerial Error Allegations).

[3] *See* ITC's Letter, Investigation Nos. 701–TA–772–774 and 731–TA–1756–1758 (Final), dated November 2, 2026 (ITC Notification Letter).

[4] *See* Ministerial Error Allegations.

[5] *See* Memorandum, ''Less-Than-Fair-Value Investigation of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the Lao People's Democratic Republic: Analysis of Ministerial Error Allegations,'' dated October 13, 2026 (Ministerial Error Memorandum).

[6] *Id.*

[7] *Id.*

[8] *See Laos Final Determination,* 91 FR at 58634–35.

industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act by reason of LTFV imports of solar cells from India, Indonesia, and Laos,[9] in accordance with section 735(c)(2) of the Act, Commerce is issuing these AD orders. Because the ITC determined that imports of solar cells from India, Indonesia, and Laos are materially injuring a U.S. industry, unliquidated entries of subject merchandise from India, Indonesia, and Laos entered, or withdrawn from warehouse, for consumption, are subject to the assessment of antidumping duties.

Therefore, in accordance with section 736(a)(1) of the Act, Commerce intends to direct U.S. Customs and Border Protection (CBP) to assess, upon further instructions by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, on all relevant entries of solar cells from India, Indonesia, and Laos, which are entered, or withdrawn from warehouse, for consumption, on or after April 28, 2026, the date of publication of the *Preliminary Determinations,*[10] but will not include entries after the expiration of the provisional measures period and before publication of the ITC's final injury determinations under section 735(d) of the Act, as further described in the ''Provisional Measures'' section of this notice.

Continuation of Suspension of Liquidation and Cash Deposits

Except as noted in the ''Provisional Measures'' section of this notice, in accordance with section 735(c)(1)(B) of the Act, Commerce intends to instruct CBP to continue to suspend liquidation on all relevant entries of solar cells from India, Indonesia, and Laos. These instructions suspending liquidation will remain in effect until further notice.

Commerce will also instruct CBP to require cash deposits equal to the estimated weighted-average dumping margins indicated in the tables below. Effective on the date of publication in the **Federal Register** of the notice of the ITC's final affirmative injury determinations, CBP will require, at the same time as importers would normally deposit estimated customs duties on subject merchandise, a cash deposit equal to the rates listed in the table below.

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins are as follows:

INDIA

Exporter/producer	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Mundra Solar PV Limited	123.04 *	107.17
Mundra Solar Energy Limited	123.04 *	107.17
Kowa Company Ltd	123.04 *	107.17
Premier Energies Photovoltaic Private Limited	123.04 *	107.17
All Others	123.04	107.17

* Rate based on facts available with adverse inferences.

INDONESIA

Exporter/producer	Weighted-average dumping margin (percent)
PT Blue Sky Solar Indonesia	94.36 *
PT REC Solar Energy Indonesia	94.36 *
All Others	94.36

* Rate based on facts available with adverse inferences.

LAOS

Producer	Exporter	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset) (percent)
Solarspace Technology (Laos) Sole Co., Ltd..	Solarspace Technology (Laos) Sole Co., Ltd./SolarSpace Technology (Hong Kong) Limited.	65.76	65.36
Solarspace Technology (Laos) Sole Co., Ltd..	JA Solar Vietnam Co. Ltd.	65.76	65.36
Solarspace Technology (Laos) Sole Co., Ltd..	Trina Solar Energy Development Pte. Ltd..	65.76	65.36

[9] *See* ITC Notification Letter.

[10] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, and Preliminary Affirmative Determination of Critical Circumstances, in Part,* 91 FR 22798 (April 28, 2026); *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, and Preliminary Affirmative Determination of Critical Circumstances, in Part,* 91 FR 22802 (April 28, 2026); and *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the Lao People's Democratic Republic: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances, in Part, and Postponement of Final Determination and Extension of Provisional Measures,* 91 FR 22794 (April 28, 2026) (collectively, *Preliminary Determinations*).

LAOS—Continued

Producer	Exporter	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset) (percent)
Solarspace Technology (Laos) Sole Co., Ltd..	Trina Solar Science & Technology (Thailand) Company Limited.	65.76	65.36
Laos-Wide Entity		65.76	65.36

Provisional Measures

Section 733(d) of the Act states that suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months, except where exporters representing a significant proportion of exports of the subject merchandise request that Commerce extend the four-month period to no more than six months. At the request of exporters that account for a significant proportion of exports of solar cells from India, Indonesia, and Laos, Commerce extended the four-month period to six months in each of these investigations.[11]

The extended provisional measures period, beginning on the date of publication of the *Preliminary Determinations* on April 28, 2026,[12] ended on October 24, 2026. Therefore, in accordance with section 736(a)(1) of the Act and our practice,[13] Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of solar cells from India, Indonesia, and Laos entered, or withdrawn from warehouse, for consumption on or after October 25, 2026, the date on which the provisional measures expired, until and through the day preceding the date of publication of the ITC's final affirmative injury determinations in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's final determinations in the **Federal Register**.

Establishment of the Annual Inquiry Service Lists

On September 20, 2021, Commerce published the *Final Rule* in the **Federal Register**.[14] On September 27, 2021, Commerce also published the *Procedural Guidance* in the **Federal Register**.[15] The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.

In accordance with the *Procedural Guidance,* for orders published in the **Federal Register** after November 4, 2021, Commerce will create an annual inquiry service list segment in Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), available at *https://access.trade.gov,* within five business days of publication of the notice of the order. Each annual inquiry service list will be saved in ACCESS, under each case number, and under a specific segment type called ''AISL-Annual Inquiry Service List.'' [16]

Interested parties who wish to be added to the annual inquiry service list for an order must submit an entry of appearance to the annual inquiry service list segment for the order in ACCESS within 30 days after the date of publication of the order. For ease of administration, Commerce requests that law firms with more than one attorney representing interested parties in an order designate a lead attorney to be included on the annual inquiry service list. Commerce will finalize the annual inquiry service list within five business days thereafter. As mentioned in the *Procedural Guidance,*[17] the new annual inquiry service list will be in place until the following year, when the *Opportunity Notice* for the anniversary month of the order is published.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Changes or announcements pertaining to these procedures will be posted to the ACCESS website at *https://access.trade.gov.*

Special Instructions for the Petitioner and Foreign Governments

In the *Final Rule,* Commerce stated that, ''after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.''[18] Accordingly, as stated above, the petitioner and foreign governments should submit their initial entry of appearance after publication of this notice in order to appear in the first annual inquiry service lists for these orders. Pursuant to 19 CFR 351.225(n)(3), the petitioner and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and foreign governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Notification to Interested Parties

This notice constitutes the AD orders with respect to solar cells from India, Indonesia, and Laos pursuant to section 736(a) of the Act. Interested parties can

[11] *Id.*

[12] *Id.*

[13] *See, e.g., Certain Corrosion-Resistant Steel Products from India, India, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390, 48392 (July 25, 2016).

[14] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021) (*Final Rule*).

[15] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

[16] This segment will be combined with the ACCESS Segment Specific Information (SSI) field, which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A–000–000 that published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as ''AISL-January Anniversary.'' Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

[17] *See Procedural Guidance,* 86 FR at 53206.

[18] *See Final Rule,* 86 FR at 52335.

find a list of AD and countervailing duty orders currently in effect at *https://www.trade.gov/data-visualization/adcvd-proceedings.*

The amended Laos final determination and these AD orders are published in accordance with sections 735(e) and 736(a) of the Act, and 19 CFR 351.224(e) and 19 CFR 351.211(b).

Dated: November 4, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Orders

The merchandise covered by these orders is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.

These orders covers crystalline silicon photovoltaic cells of thickness equal to or greater than 20 micrometers, having a p/n junction formed by any means, whether or not the cell has undergone other processing, including, but not limited to, cleaning, etching, coating, and/or addition of materials (including, but not limited to, metallization and conductor patterns) to collect and forward the electricity that is generated by the cell.

Merchandise under consideration may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited to, modules, laminates, panels, building-integrated modules, building integrated panels, or other finished goods kits. Such parts that otherwise meet the definition of merchandise under consideration are included in the scope of the orders.

Excluded from the scope of these orders are thin film photovoltaic products produced from amorphous silicon (a-Si), cadmium telluride (CdTe), or copper indium gallium selenide (CIGS).

Also excluded from the scope of these orders are crystalline silicon photovoltaic cells, not exceeding 10,000 mm^2 in surface area, that are permanently integrated into a consumer good whose function is other than power generation and that consumes the electricity generated by the integrated crystalline silicon photovoltaic cell. Where more than one cell is permanently integrated into a consumer good, the surface area for purposes of this exclusion shall be the total combined surface area of all cells that are integrated into the consumer good.

Additionally, excluded from the scope of these orders are panels with surface area from 3,450 mm^2 to 33,782 mm^2 with one black wire and one red wire (each of type 22 AWG or 24 AWG not more than 206 mm in length when measured from panel extrusion), and not exceeding 2.9 volts, 1.1 amps, and 3.19 watts. For the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Also excluded from the scope of these orders are:

(1) Off grid CSPV panels in rigid form with a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include a permanently connected wire that terminates in either an 8 mm male barrel connector, or a two-port rectangular connector with two pins in square housings of different colors; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features, and foam for transport); and

(2) Off grid CSPV panels without a glass cover, with the following characteristics: (A) a total power output of 100 watts or less per panel; (B) a maximum surface area of 8,000 cm^2 per panel; (C) do not include a built-in inverter; (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and (E) each panel is (1) permanently integrated into a consumer good; (2) encased in a laminated material without stitching, or (3) has all of the following characteristics: (i) the panel is encased in sewn fabric with visible stitching, (ii) includes a mesh zippered storage pocket, and (iii) includes a permanently attached wire that terminates in a female USB–A connector.

In addition, the following CSPV panels are excluded from the scope of these orders: off-grid CSPV panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 80 watts per panel; (B) a surface area of less than 5,000 square centimeters (cm^2) per panel; (C) do not include a built-in inverter; (D) do not have a frame around the edges of the panel; (E) include a clear glass back panel; and (F) must include a permanently connected wire that terminates in a twoport rectangular connector.

Additionally excluded from the scope of these orders are off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (1) a total power output of 200 watts or less per panel; (2) a maximum surface area of 16,000 cm^2 per panel; (3) no built-in inverter; (4) an integrated handle or a handle attached to the package for ease of carry; (5) one or more integrated kickstands for easy installation or angle adjustment; and (6) a wire of not less than 3 meters either permanently connected or attached to the package that terminates in an 8 mm diameter male barrel connector.

Also excluded from the scope of these orders are off-grid crystalline silicon photovoltaic panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water: (A) a total power output of no more than 180 watts per panel at 155 degrees Celsius; (B) a surface area of less than 16,000 square centimeters (cm^2) per panel; (C) include a keep-out area of approximately 1,200 cm^2 around the edges of the panel that does not contain solar cells; (D) do not include a built-in inverter; (E) do not have a frame around the edges of the panel; (F) include a clear glass back panel; (G) must include a permanently connected wire that terminates in a two-port rounded rectangular, sealed connector; (H) include a thermistor installed into the permanently connected wire before the twoport connector; and (I) include exposed positive and negative terminals at opposite ends of the panel, not enclosed in a junction box.

Further excluded from the scope of these orders are:

(1) Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

(2) Off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 16,000 cm^2 per panel, (C) no built-in inverter, (D) an integrated handle or a handle attached to the package for ease of carry, (E) one or more integrated kickstands for easy installation or angle adjustment, and (F) a wire either permanently connected or attached to the package terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure.

Also excluded from the scope of these orders are:

(1) Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 200 watts or less per panel, (B) a maximum surface area of 10,500 cm^2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure, (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

(2) Small off-grid panels with glass cover, with the following characteristics: (A) surface

area from 3,450 mm² to 33,782 mm², (B) with one black wire and one red wire (each of type 22AWG or 28 AWG not more than 350 mm in length when measured from panel extrusion), (C) not exceeding 10 volts, (D) not exceeding 1.1 amps, (E) not exceeding 6 watts, and (F) for the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Additionally excluded from the scope of these orders are:

(1) Off grid rigid CSPV panels with a glass cover, with the following characteristics: (A) a total power output of 175 watts or less per panel, (B) a maximum surface area of 9,000 cm2 per panel, (C) do not include a built-in inverter, (D) must include a permanently connected wire that terminates in waterproof connector with a cylindrical positive electrode and a rectangular negative electrode with the positive and negative electrodes having an interlocking structure; (E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features); and

(2) Off grid CSPV panels without a glass cover, with the following characteristics, (A) a total power output of 220 watts or less per panel, (B) a maximum surface area of 16,000 cm² per panel, (C) do not include a built-in inverter, (D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell, and (E) each panel is encased in a laminated material without stitching.

Also excluded from the scope of these orders are off-grid CSPV panels in rigid form, with or without a glass cover, permanently attached to an aluminum extrusion that is an integral component of an automation device that controls natural light, whether or not assembled into a fully completed automation device that controls natural light, with the following characteristics:

(1) a total power output of 20 watts or less per panel;

(2) a maximum surface area of 1,000 cm² per panel;

(3) does not include a built-in inverter for powering third party devices.

Modules, laminates, and panels produced in a third-country from cells produced in a subject country are covered by these orders; however, modules, laminates, and panels produced in a subject country from cells produced in a third-country are not covered by these orders.

Also excluded from the scope of these orders are all products covered by the scope of the antidumping and countervailing duty orders on *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Order,* 77 FR 73018 (December 7, 2012); and *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Countervailing Duty Order,* 77 FR 73017 (December 7, 2012).

Also excluded from the scope of these orders are all products covered by the scope of the antidumping and countervailing duty orders on *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the Socialist Republic of Vietnam: Amended Final Antidumping Duty Determination; Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Antidumping duty Orders,* 90 FR 26786 (June 24, 2025); *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the Socialist Republic of Vietnam: Amended Final Antidumping Duty Determination; Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Antidumping Duty Orders; Correction,* 90 FR 29843 (July 7, 2025); and *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Malaysia and Thailand: Amended Final Countervailing Duty Determinations; Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from Cambodia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Countervailing Duty Orders,* 90 FR 26791 (June 24, 2025).

Merchandise covered by these orders is currently classified in the Harmonized Tariff System of the United States (HTSUS) under subheadings 8541.42.0010 and 8541.43.0010. Imports of the subject merchandise may enter under HTSUS subheadings 8501.71.0000, 8501.72.1000, 8501.72.2000, 8501.72.3000, 8501.72.9000, 8501.80.1000, 8501.80.2000, 8501.80.3000, 8501.80.9000, 8507.20.8010, 8507.20.8031, 8507.20.8041, 8507.20.8061, and 8507.20.8091. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of these orders is dispositive.

[FR Doc. 2026–22825 Filed 11–6–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; International Design Applications (Hague Agreement)

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comments.

SUMMARY: The United States Patent and Trademark Office (hereafter ''USPTO'' or ''Agency''), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0075 (International Design Applications (Hague Agreement)). The purpose of this notice is to allow 60 days for public comments preceding submission of the information collection to the Office of Management and Budget (OMB).

DATES: To ensure consideration, you must submit comments regarding this information collection on or before January 8, 2027.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email: InformationCollection@uspto.gov.* Include ''0651–0075 comment'' in the subject line of the message.
- *Federal eRulemaking Portal: https://www.regulations.gov.*
- *Mail:* Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.
- *Telephone:* Rafael Bacares, Senior Legal Advisor, 571–272–3276.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Rafael Bacares, Senior Legal Advisor, at: United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; 571–272–3276; or *rafael.bacares@uspto.gov* with ''0651–0075 comment'' in the subject line. Additional information about this information collection is also available at *https://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

Title I of The Patent Law Treaties Implementation Act of 2012 [1] (PLTIA) amended the patent laws to implement the provisions of the Geneva Act of the Hague Agreement Concerning International Registration of Industrial Designs (hereafter ''Hague Agreement''). The Hague Agreement is an international registration system which offers the possibility of obtaining protection for up to 100 industrial designs in designated member countries and intergovernmental organizations (referred to as ''Contracting Parties'') by filing a single international design application either directly with the International Bureau of the World Intellectual Property Organization (WIPO) or indirectly through the office of an applicant's Contracting Party. The United States is a Contracting Party to

[1] *https://www.congress.gov/112/plaws/publ211/PLAW-112publ211.pdf.*

the Hague Agreement, which took effect with respect to the United States on May 13, 2015. The Hague Agreement is administrated by the International Bureau (IB) of WIPO located in Geneva, Switzerland.

Under the Hague Agreement, a U.S. applicant can file an international design application indirectly through the United States Patent and Trademark Office (USPTO), which will forward the application to the IB upon satisfaction of certain requirements, or directly with the IB. All international design applications are subject to the following fees: (1) a basic fee, (2) a publication fee, and (3) in respect of each Contracting Party designated for protection, either a standard or individual designation fee. An international design application is also subject to an additional per word fee where the description exceeds 100 words. A transmittal fee is also required for international design applications filed indirectly through the USPTO. The fees required by the IB may be paid either directly to the IB in Swiss currency or through the USPTO as an office of indirect filing in U.S. dollars. If applicants want to pay the required fees through the USPTO as an office of indirect filing, the fees must be paid no later than the date of payment of the transmittal fee. The fees will then be forwarded to the IB after conversion to Swiss currency.

Where the U.S. is designated, the applicant will be required to pay a first part U.S. designation fee to the IB. The first part U.S. designation fee, established in Swiss currency, is based on the combined amounts of the basic filing fee (37 CFR 1.16(b)), search fee (§ 1.16(l)), and examination fee (§ 1.16(p)) for a design application. See § 1.1031(f)(1). Upon issuance of a notice of allowance by the USPTO, payment of a second part U.S. designation fee (*i.e.,* the issue fee) will be required. See § 1.1031(f)(2). The second part U.S. designation fee may be paid either directly to the USPTO in U.S. dollars or through the IB in Swiss currency.

The IB examines international design application for compliance with the applicable formal requirements under the Hague Agreement. If the applicable requirements are satisfied, the IB registers the international design to the International Register. Thereafter, the IB will publish the international registration in the International Designs Bulletin based on the publication timing selected by the applicant. The IB will provide a copy of the publication of the international registration to each Contracting Party designated by the application.

A designated Contracting Party may or may not perform a substantive examination of the international design registration. The USPTO will perform a substantive examination for patentability of the international design application, as in the case of regular U.S. design applications.

This information collection covers all the necessary information required for an international design application that is filed either through the USPTO as an office of indirect filing or directly with the IB. The information in this collection is used to register industrial designs under the provisions of the Hague Agreement. The USPTO manages two forms in this information collection, and the rest are forms managed by the IB.

II. Method of Collection

Items in this information collection may be submitted as electronic submissions. Applicants may also submit the information in paper form by mail, fax, or hand delivery.

III. Data

OMB Control Number: 0651–0075.

Forms: (PTOL = Patent Trademark Official Legal Forms; WIPO = World Intellectual Property Organization).

- PTO–1595 (Recordation Form Cover Sheet—Patents). PTO–1595 is also approved for use under USPTO information collection 0651–0027.
- PTOL–85 Part B (Fee(s) Transmittal). PTOL–85 Part B is also approved for use under USPTO information collection 0651–0033.
- WIPO DM/1 (Application for International Registration)
- WIPO DM/1/I (Annex I: Oath or Declaration of the Creator under Rule 8(1)(a)(ii) of the Regulations)
- WIPO DM/1/II (Annex II: Supporting Document(s) Concerning a Declaration to the Exception to Lack of Novelty under Section 408(c)(ii) of the Administrative Instructions)
- WIPO DM/1/III (Annex III: Information On Eligibility For Protection under Rule 7(5)(g) and Section 408(d) of the Administrative Instructions)
- WIPO DM/1/IV (Annex IV: Reduction of United States Individual Designation Fee under Section 408(b) of the Administrative Instructions)
- WIPO DM/1/V (Annex V: Supporting Document(s) Concerning Priority Claim under Article 4 of the Paris Convention)
- WIPO DM/7 (Appointment of a Representative (Power of Attorney))

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Estimated Number of Annual Respondents: 5,633 respondents.

Estimated Number of Annual Responses: 5,633 responses.

Estimated Time per Response: The USPTO estimates that the responses for this information collection will take the public approximately 15 minutes (0.25 hours) to 6 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed item(s) to the USPTO.

Estimated Total Annual Respondent Burden Hours: 25,393 hours.

Estimated Total Annual Respondent Hourly Cost Burden: $13,966,150.

TABLE 1—TOTAL REPORTING BURDEN HOURS AND HOURLY COSTS TO PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents (a)	Responses per respondent (b)	Estimated annual responses (a) × (b) = (c)	Estimated time for response (hours) (d)	Estimated burden (hour/year) (c) × (d) = (e)	Rate [2] ($/hour) (f)	Estimated annual respondent cost burden (e) × (f) = (g)
1	Application for International Registration (WIPO DM/1 filed directly with IB in which applicants have designated the U.S.	3,870	1	3,870	6 [3]	23,220	[4] $550	$12,771,000
2	Application for International Registration (WIPO DM/1 filed indirectly through the USPTO).	140	1	140	6	840	550	462,000
3	Claim and Reproduction (Drawings) filed indirectly.	140	1	140	4	560	550	308,000
4	Transmittal Letter at the time of indirect filing.	6	1	6	2	12	550	6,600
5	Appointment of a Representative (WIPO DM/7).	62	1	62	0.25 (15 minutes)	16	550	8,800
6	Petition to Excuse a Failure to Comply with a Time Limit.	1	1	1	4	4	550	2,200
7	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16.	1	1	1	4	4	550	2,200
8	Petition to Review a Filing Date	1	1	1	4	4	550	2,200
9	Fee Authorization at the time of filing indirectly.	1	1	1	0.25 (15 minutes)	0	550	0
10	Petitions to the Commissioner	7	1	7	4	28	550	15,400
11	Oath or Declaration of the Creator under Rule 8(1)(a)(ii) of the Common Regulations (WIPO DM/1/I) (Declaration of Inventorship for the Designation of the United States of America and Substitute Statement in Lieu of a Declaration of Inventorship for the Designation of the United States) filed indirectly through the USPTO.	33	1	33	0.50 (30 minutes)	17	550	9,350
12	Supporting Document(s) Concerning a Declaration to the Exception to Lack of Novelty under Section 408(c)(ii) of the Administrative Instructions (WIPO DM/1/II) filed indirectly through the USPTO.	5	1	5	0.50 (30 minutes)	3	550	1,650
13	Information on Eligibility for Protection (WIPO DM/1/III) filed indirectly through the USPTO.	3	1	3	1	3	550	1,650
14	Reduction of United States Individual Designation Fee under Section 408(b) of the Administrative Instructions (WIPO DM/1/IV) filed indirectly through the USPTO.	8	1	8	0.50 (30 minutes)	4	550	2,200
15	Supporting Document(s) Concerning Priority Claim under Article 4 of the Paris Convention (WIPO DM/1/V) filed indirectly through the USPTO.	5	1	5	0.50 (30 minutes)	3	550	1,650
16	Fee(s) Transmittal to the USPTO for an International Design Application (PTOL–85 Part B (Hague)). Second Part of the U.S. designation fee. Issue Fee.	1,350	1	1,350	0.50 (30 minutes)	675	550	371,250
	Totals	5,633	.....	5,633	.....	25,393	.....	13,966,150

Estimated Total Annual Respondent Non-hourly Cost Burden: $13,607,168. There are no capital start-up costs, maintenance costs, or recordkeeping costs associated with this information collection. However, the USPTO estimates that the total annual non-hourly cost burden for this information collection, in the form of filing fees, drawing costs, and postage, is $13,607,168.

Filing Fees

The filing fees associated with this information collection that are paid to the USPTO are listed in the table below.

[2] *2025 Report of the Economic Survey,* published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association; pg. F–35. The USPTO uses the average billing rate for intellectual property work in all firms which is $550 per hour (*https://www.aipla.org/detail/journal-issue/2025-report-of-the-economic-survey*).

TABLE 2—FILING FEES PAID TO THE USPTO

Item No.	Fee code	Item	Estimated annual responses (a)	Filing fee ($) [5] (b)	Non-hourly cost burden (a) × (b) = (c)
1	WIPO 1791	Application for International Registration submitted to WIPO—Designation Fee (first part) for the U.S. (Transmitting to the USPTO by WIPO) (undiscounted entity).	2,092	CHF1,150 $1,405.36	CHF2,405,800 $2,940,013
1	WIPO 2791	Application for International Registration submitted to WIPO—Designation Fee (first part) for the U.S. (Transmitting to the USPTO by WIPO) (small entity).	1,551	CHF460 562.14	CHF713,460 871,879
1	WIPO 3791	Application for International Registration submitted to WIPO—Designation Fee (first part) for the U.S. (Transmitting to the USPTO by WIPO) (undiscounted entity).	227	CHF230 281.07	CHF52,210 63,803
2	1781	Application for International Registration (electronic) filed indirectly through the USPTO—Transmittal Fee (set by and collected by USPTO) (undiscounted).	60	130	7,800
2	2781	Application for International Registration (electronic) filed indirectly through the USPTO—Transmittal Fee (set by and collected by USPTO) (small entity).	63	52	3,276
2	3781	Application for International Registration (electronic) filed indirectly through the USPTO—Transmittal Fee (set by and collected by USPTO) (micro entity).	17	26	442
6	1784	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay less than or equal to two years (undiscounted).	1	2,260	2,260
6	2784	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay less than or equal to two years (small entity).	1	904	904
6	3784	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay less than or equal to two years (micro entity).	1	452	452
6	1785	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay greater than two years (undiscounted entity).	1	3,000	3,000
6	2785	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay greater than two years (small entity).	1	1,200	1,200
6	3785	Petition to excuse applicant's failure to act within prescribed time limits in an international design application, delay greater than two years (micro entity).	1	600	600
7	1783	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16 (undiscounted) ..	1	195	195
7	2783	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16 (small entity)	1	78	78
7	3783	Petition to Convert to a Design Application under 35 U.S.C. Chapter 16 (micro entity)	1	39	39
8	1462	Petition to Review a Filing Date (undiscounted)	1	450	450
8	2462	Petition to Review a Filing Date (small entity)	1	180	180
8	3462	Petition to Review a Filing Date (micro entity)	1	90	90
10	1462	Petitions to Commissioner (undiscounted)	7	450	3,150
10	2462	Petitions to Commissioner (small entity)	1	180	180
10	3462	Petitions to Commissioner (micro entity)	1	90	90
16	1509	Issue Fee paid directly to USPTO for an International Design Application (undiscounted)	800	1,300	1,040,000
16	2509	Issue Fee paid directly to USPTO for an International Design Application (small entity) ...	360	520	187,200
16	3509	Issue Fee paid directly to USPTO for an International Design Application (micro entity) ...	46	260	11,960
16	1792	Application for International Registration submitted to WIPO—Issue Fee (Second part) for the U.S. (Transmitting to the USPTO by WIPO) (undiscounted).	216	CHF1,150 1,405.36	CHF248,400 303,558
16	2792	Application for International Registration submitted to WIPO—Issue Fee (Second part) for the U.S. (Transmitting to the USPTO by WIPO) (small entity).	234	CHF460 562.14	CHF107,640 131,541
16	3792	Application for International Registration submitted to WIPO—Issue Fee (Second part) for the U.S. (Transmitting to the USPTO by WIPO) (micro entity).	43	CHF230 281.07	CHF9,890 12,086
		Totals	5,730	.....	5,586,426

The USPTO also collects one fee associated with applications for international registrations that are indirectly filed to WIPO through the USPTO. The USPTO does not intake any of the money associated with this fee. Instead, the USPTO transfers the fee amounts to WIPO on behalf of the applicant filing indirectly. That fee amount is indicated here as part of this information collection but is not directly counted as part of the collection's final non-hourly cost burden total.

TABLE 3—FILING FEES PAID TO WIPO

Item No.	Fee code	Item	Estimated annual responses (a)	Filing fee ($) (b)	Non-hourly cost burden (a) × (b) = (c)
1	WIPO	Application for International Registration (electronic) filed indirectly through the USPTO—International design application fees payable to WIPO.	140	Variable [6]	Variable.
	Totals	.....	140	.....	Variable.

[3] Applications for international registration prepared in other contracting parties that are filed directly with the IB designating the U.S. The estimate time for preparation and response varies from country to country. The USPTO uses 6 hours as an estimate to account for the time for foreign applicants to prepare the applications.

[4] Applications for international registration that are filed directly with the IB and then electronically transmitted to the USPTO are prepared in other countries. The hourly rates associated with that preparation vary from country to country. The USPTO uses the $550 hourly rate to account for the estimated hourly costs.

[5] WIPO fees are required to be paid in Swiss francs (CHF). For the purposes of this information collection, the USPTO will show the current WIPO rate in CHF as well as the current conversion rate from CHF to the U.S. dollar. The USPTO is using the Wise Currency Converter to determine the appropriate exchange rate. This converter can be found here: *https://wise.com/us/currency-converter/chf-to-usd-rate.* The exchange rate used was taken on July 24, 2026.

[6] This fee amount is determined based on specific elements set under the Hague System including the basic fee, publication fee, designation fees (the amount depends on which Hague Contracting parties are designated) and additional description fee (if the description exceeds 100 words, an additional fee per word over the limit is charged by WIPO). The fees are expressed in Swiss francs and can be affected by the payment method/currency conversion.

Drawing Costs

The USPTO estimates that the costs to produce design drawings can range from $50 to $350 per sheet. Taking the average of this range, the USPTO estimates that it can cost $200 per sheet to produce design drawings. On average, 10 sheets of drawings are submitted for an application resulting in an average cost of $2,000 to produce the design drawings. The USPTO estimates that 140 respondents will file international design applications indirectly through the USPTO for transmission to the IB. The USPTO further estimates that it will receive approximately 3,870 international design applications from the IB where applicants have designated the U.S., accompanied by payment of the first part of the designated fee for substantive examination by the USPTO. The USPTO estimates that all of the 4,010 design applications will be submitted with drawings. Overall, the costs associated with submitting these drawings are estimated to be $8,020,000.

Postage Costs

Although the USPTO prefers that the items in this information collection be submitted electronically, responses may be submitted by mail through the United States Postal Service. The USPTO estimates that 1% of the 5,633 items in this information collection will be submitted in the mail, resulting in 56 mailed items. The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail legal flat-rate envelope, will be $13.25. Therefore, the USPTO estimates the total mailing costs for this information collection is $742.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information on those who intend to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. The USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be advised that the entire comment—including PII—may be made publicly available at any time. While one may request in a comment to withhold PII from public view, the USPTO cannot guarantee that it will be able to do so.

Justin Isaac,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2026–22798 Filed 11–6–26; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Determination Under the Textile and Apparel Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement (''CAFTA–DR'')

AGENCY: The Committee for the Implementation of Textile Agreements.

ACTION: Determination to add a product in unrestricted quantities to Annex 3.25 of the CAFTA–DR.

SUMMARY: The Committee for the Implementation of Textile Agreements (''CITA'') has determined that certain woven wrinkle free cotton/polyester fabric, as specified below, is not available in commercial quantities in a timely manner in the CAFTA–DR countries. The product is added to the list in Annex 3.25 of the CAFTA–DR in unrestricted quantities.

DATES: *Applicable date:* November 9, 2026.

ADDRESSES: *https://otexaprod.trade.gov/otexacapublicsite/requests/cafta* under ''Approved Requests,'' File Number: CA2026009.

FOR FURTHER INFORMATION CONTACT: Kayla Johnson, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 510–3829 or *Kayla.Johnson@trade.gov.*

SUPPLEMENTARY INFORMATION:

Authority: The CAFTA–DR; Section 203(o)(4) of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act (''CAFTA–DR Implementation Act''), Public Law 109–53; the Statement of Administrative Action accompanying the CAFTA–DR Implementation Act; and Presidential Proclamation 7987 (February 28, 2006).

Background: The CAFTA–DR provides a list in Annex 3.25 for fabrics, yarns, and fibers that the Parties to the CAFTA–DR have determined are not available in commercial quantities in a timely manner in the territory of any Party. The CAFTA–DR provides that this list may be modified pursuant to Article 3.25.4, when the United States determines that a fabric, yarn, or fiber is not available in commercial quantities in a timely manner in the territory of any Party. *See* Annex 3.25 of the CAFTA–DR; *see also* section 203(o)(4)(C) of the CAFTA–DR Implementation Act.

The CAFTA–DR Implementation Act requires the President to establish procedures governing the submission of a request and providing opportunity for interested entities to submit comments and supporting evidence before a commercial availability determination is made. In Presidential Proclamation 7987, the President delegated to CITA the authority under section 203(o)(4) of CAFTA–DR Implementation Act for modifying the Annex 3.25 list. Pursuant to this authority, on September 15, 2008, CITA published modified procedures it would follow in considering requests to modify the Annex 3.25 list of products determined to be not commercially available in the territory of any Party to the CAFTA–DR (*Modifications to Procedures for Considering Requests Under the Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement,* 73 FR 53200) (''CITA's Procedures'').

On September 29, 2026, CITA received a Commercial Availability Request (''Request'') from Dillard's Inc. (''Dillard's) and its supplier JAM Apparel LLC (''JAM'') for certain woven wrinkle free cotton/polyester fabric, as specified below. On October 1, 2026, in accordance with CITA's Procedures, CITA notified interested parties of the Request, which was posted on the dedicated website for CAFTA–DR Commercial Availability proceedings. In its notification, CITA advised that any Response with an Offer to Supply (''Response'') must be submitted by October 14, 2026, and any Rebuttal to a Response (''Rebuttal'') must be submitted by October 20, 2026, in accordance with sections 6 and 7 of CITA's Procedures. No interested entity submitted a Response to the Request advising CITA of its objection to the

Request with an offer to supply the subject product.

In accordance with section 203(o)(4)(C) of the CAFTA–DR Implementation Act, and section 8(c)(2) of CITA's Procedures, as no interested entity submitted a Response objecting to the Request and providing an offer to supply the subject product, CITA has determined to add the specified fabric to the list in Annex 3.25 of the CAFTA–DR.

The subject product has been added to the list in Annex 3.25 of the CAFTA–DR Agreement in unrestricted quantities. A revised list has been posted on the dedicated website for CAFTA–DR Commercial Availability proceedings, at *https://otexaprod.trade.gov/otexacapublicsite/shortsupply/cafta.*

Specifications: Certain Woven Wrinkle Free Cotton/Polyester Fabric

HTS: 5210.32.00; 5210.49.10; 5210.59.10.

Fiber Content: 51–75% Cotton, 25–49% Polyester.

Yarn Size—Warp: 127/2 to 212/2 metric (75/2 to 125/2 English count) Staple fiber yarns in Cotton or Cotton/Polyester.

Yarn Size—Weft: in one of the following 2 options:

—Option #1: 68/1 to 110/1 metric (40/1 to 65/1 English count) Staple fiber yarns in Polyester or Cotton/Polyester

—Option #2: 120/1 to 51.4/1 metric (75 Denier to 175 Denier) Filament yarns in Polyester

Weave Type: Twill or herringbone.

Weight: between 80 to 165 grams per sq. meter (2.36oz/sq. yd to 4.87oz/sq. yd).

Width: 137 to 157 cm (54 to 62 inch).

Coloration: Piece dyed and/or yarn dyed and/or printed.

Finishing Process: Mercerized + Wrinkle Free Finish.

Performance (include all test methods and standards that apply):

* Shrinkage +1% to −5% using AATCC 135
* Minimum Durable Press 3.0 after 3 launderings using AATCC 128–17E

Joshua Kroon,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 2026–22745 Filed 11–6–26; 8:45 am]

BILLING CODE 3510–DR–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Determination Under the Textile and Apparel Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement (''CAFTA–DR'')

AGENCY: The Committee for the Implementation of Textile Agreements.

ACTION: Determination to add a product in unrestricted quantities to Annex 3.25 of the CAFTA–DR.

SUMMARY: The Committee for the Implementation of Textile Agreements (''CITA'') has determined that certain woven wrinkle free cotton/polyester/spandex fabric, as specified below, is not available in commercial quantities in a timely manner in the CAFTA–DR countries. The product is added to the list in Annex 3.25 of the CAFTA–DR in unrestricted quantities.

DATES: *Applicable date:* November 9, 2026.

ADDRESSES: *https://otexaprod.trade.gov/otexacapublicsite/requests/cafta* under ''Approved Requests,'' File Number: CA2026010.

FOR FURTHER INFORMATION CONTACT: Kayla Johnson, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 510–3829 or *Kayla.Johnson@trade.gov.*

SUPPLEMENTARY INFORMATION:

Authority: The CAFTA–DR; Section 203(o)(4) of the Dominican Republic-Central America-United States Free Trade Agreement Implementation Act (''CAFTA–DR Implementation Act''), Public Law 109–53; the Statement of Administrative Action accompanying the CAFTA–DR Implementation Act; and Presidential Proclamation 7987 (February 28, 2006).

Background: The CAFTA–DR provides a list in Annex 3.25 for fabrics, yarns, and fibers that the Parties to the CAFTA–DR have determined are not available in commercial quantities in a timely manner in the territory of any Party. The CAFTA–DR provides that this list may be modified pursuant to Article 3.25.4, when the United States determines that a fabric, yarn, or fiber is not available in commercial quantities in a timely manner in the territory of any Party. *See* Annex 3.25 of the CAFTA–DR; *see also* section 203(o)(4)(C) of the CAFTA–DR Implementation Act.

The CAFTA–DR Implementation Act requires the President to establish procedures governing the submission of a request and providing opportunity for interested entities to submit comments and supporting evidence before a commercial availability determination is made. In Presidential Proclamation 7987, the President delegated to CITA the authority under section 203(o)(4) of CAFTA–DR Implementation Act for modifying the Annex 3.25 list. Pursuant to this authority, on September 15, 2008, CITA published modified procedures it would follow in considering requests to modify the Annex 3.25 list of products determined to be not commercially available in the territory of any Party to the CAFTA–DR (*Modifications to Procedures for Considering Requests Under the Commercial Availability Provision of the Dominican Republic-Central America-United States Free Trade Agreement,* 73 FR 53200) (''CITA's Procedures'').

On September 29, 2026, CITA received a Commercial Availability Request (''Request'') from Dillard's Inc. (''Dillard's) and its supplier JAM Apparel LLC (''JAM'') for certain woven wrinkle free cotton/polyester/spandex fabric, as specified below. On October 1, 2026, in accordance with CITA's Procedures, CITA notified interested parties of the Request, which was posted on the dedicated website for CAFTA–DR Commercial Availability proceedings. In its notification, CITA advised that any Response with an Offer to Supply (''Response'') must be submitted by October 14, 2026, and any Rebuttal to a Response (''Rebuttal'') must be submitted by October 20, 2026, in accordance with sections 6 and 7 of CITA's Procedures. No interested entity submitted a Response to the Request advising CITA of its objection to the Request with an offer to supply the subject product.

In accordance with section 203(o)(4)(C) of the CAFTA–DR Implementation Act, and section 8(c)(2) of CITA's Procedures, as no interested entity submitted a Response objecting to the Request and providing an offer to supply the subject product, CITA has determined to add the specified fabric to the list in Annex 3.25 of the CAFTA–DR.

The subject product has been added to the list in Annex 3.25 of the CAFTA–DR Agreement in unrestricted quantities. A revised list has been posted on the dedicated website for CAFTA–DR Commercial Availability proceedings, at *https://otexaprod.trade.gov/otexacapublicsite/shortsupply/cafta.*

Specifications: Certain Woven Wrinkle Free Cotton/Polyester/Spandex Fabric

HTS: 5210.32.00; 5210.49.10; 5210.59.10.

Fiber Content: 51–75% Cotton, 25–49% Polyester, 1–7% Spandex.

Yarn Size—Warp: 127/2 to 212/2 metric (75/2 to 125/2 English count); Staple fiber yarns in 100% Cotton or Cotton/Polyester.

Yarn Size—Weft: in one of the following 2 options:

—Option #1: 68/1 to 110/1 metric (40/1 to 65/1 English count) Staple fiber yarns in Polyester or Cotton/Polyester, combined with spandex filament of various deniers

—Option #2: 120/1 to 51.4/1 metric (75 Denier to 175 Denier) Filament yarns in Polyester, combined with spandex filament of various deniers

Weave Type: Twill or herringbone.

Weight: between 80 to 165 grams per sq. meter (2.36oz/sq. yd to 4.87oz/sq. yd).

Width: 137 to 157 cm (54 to 62 inch).

Coloration: Piece dyed and/or yarn dyed and/or printed.

Finishing Process: Mercerized + Wrinkle Free Finish.

Performance (include all test methods and standards that apply):

* Shrinkage +1% to –5% using AATCC 135
* Minimum Durable Press 3.0 after 3 launderings using AATCC 128–17EZ

Joshua Kroon,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 2026–22746 Filed 11–6–26; 8:45 am]

BILLING CODE 3510–DR–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, November 18, 2026—10:00 a.m.

PLACE: The hearing/meeting will be held remotely.

STATUS: Commission Hearing/Meeting—Open to the Public.

MATTERS TO BE CONSIDERED: FY 2027 Operating Plan Briefing/CPSC FY 2027/2028 Agenda and Priorities Hearing.

To observe the hearing/meeting, please use the following link: *https://events.gcc.teams.microsoft.com/event/1d3e52c8-62af-4f73-a08d-891b03c6777f@7f5de26c-a63d-475c-9b6c-4126a914e132?source=copyLinkOneEventsShareDialog.*

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 441 G Street NW, Washington, DC 20548, 301–504–7479 (Office).

Dated: November 5, 2026.

Alberta E. Mills,

Commission Secretary.

[FR Doc. 2026–22828 Filed 11–5–26; 4:15 pm]

BILLING CODE P

DEPARTMENT OF DEFENSE

Office of the Secretary

President's Military Spouse Commission; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of War (formerly the DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the President's Military Spouse Commission (''the Commission'') will take place.

DATES: Open to the public via livestream, Monday, November 16, 2026, from 1 p.m. to 2 p.m.

ADDRESSES: This meeting will be held at the White House and viewable by the public at *https://www.whitehouse.gov/military-spouse-commission/.* Registration is not required.

FOR FURTHER INFORMATION CONTACT: The Commission at *https://www.whitehouse.gov/military-spouse-commission/contact/or* Josie Beets, Designated Federal Officer, at *osd.mc-alex.ousd-p-r.mbx.spouse-employment-team@mail.mil.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to execute the provisions of Executive Order 14417. Per the Executive Order, the Commission will discuss strengthening military families, improving retention, and ensuring military spouses and families are ready to meet any challenge. The Commission will advise and assist the President on policies affecting military spouses and military families by identifying challenges and developing policy recommendations to address housing, employment, healthcare, education, childcare, and deployment-related support.

Agenda: Monday, November 16, 2026, from 1:00 p.m. to 2:00 p.m. Official Call to Order, Opening Remarks, Executive Director Welcome, Administrative Session Briefing, Briefing: Public Submissions & Survey Updates, Commission Participation, Adjournment.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public from 1:00 p.m. to 2:00 p.m. on November 16, 2026, via livestream at *https://www.whitehouse.gov/military-spouse-commission.*

Written Statements: Written comments may be received by the President's Military Spouse Commission at any time and may be made available to the Commission members for their consideration prior to the meeting. Written comments may be submitted via *https://www.whitehouse.gov/military-spouse-commission/contact/.* Please note that since the Commission operates under the provisions of the FACA, all written comments received will be treated as public documents and will be made available for public inspection. Those who make submissions are requested to avoid including personally identifiable information such as names of adults and children, phone numbers, addresses, Social Security Numbers and other contact information within the body of the written statement.

Dated: November 5, 2026.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026–22834 Filed 11–6–26; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–532]

Application for Authorization To Export Electric Energy; KPT Energy LLC

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: KPT Energy LLC (the Applicant or KPT Energy) has applied for renewed authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments must be submitted on or before December 9, 2026.

ADDRESSES: Comments or requests for more information should be addressed

by electronic mail to *Electricity.Exports@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Marina Fennel, (240) 702–6156, *Electricity.Exports@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)) and regulations thereunder (10 CFR 205.300). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export (16 U.S.C. 824a(e)). On January 8, 2026, the authority to issue such orders was delegated to the DOE's Assistant Secretary for the Office of Electricity by Redelegation Order No. S3–DEL–OE1–2026.

On July 24, 2026, KPT Energy filed an application (Application or App.) with DOE for authorization to transmit electric energy from the United States to Canada for a term of five years.

KPT Energy is a Delaware limited liability company ''with its principal place of business in Toronto, Canada.'' App at 1. KPT Energy is ''formed to be a power marketer engaging in the purchase and sale of physical and/or virtual energy in wholesale electricity markets.'' App. at 2. KPT Energy is directly and wholly owned by KPT Energy LP, which is wholly and directly owned by KPT Energy Holdings Inc. KPT Energy Holdings Inc. is directly owned by DTFC Holdings Inc. and Boof & Doof Corp., both organized under the laws of Canada. App. at 1–2. KPT Energy states that ''neither KPT Energy nor its affiliates own or operate generation or transmission facilities, nor do they have a franchised electric power service area'' and that it is ''not seeking authorization to export power on behalf of, or in conjunction with, any partners or partnerships.'' KPT energy affirms it will ''make all necessary commercial arrangements and will obtain any and all other regulatory approvals required in order to schedule and deliver power exports.'' *Id.* at 4.

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See* App. at Exhibit A.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment to the Application at *Electricity.Exports@hq.doe.gov.*

Comments concerning KPT Energy's Application should be clearly marked with OE Docket No. EA–532. Comments will be posted along with the relevant application on the program website at *www.energy.gov/oe/pending-applications.*

A final decision will be made on the requested authorization after the environmental impacts have been evaluated consistent with the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321, *et seq.*), the DOE NEPA regulations at 10 CFR part 1021, and the DOE's Implementing Procedures (June 2026) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the United States electric power supply system.

Copies of this Application are available on the program website at *www.energy.gov/oe/pending-applications* or by emailing *Electricity.Exports@hq.doe.gov.*

Signing Authority

This document of the Department of Energy was signed on October 30, 2026, by Gilbert Bindewald III, Principal Deputy Assistant Secretary, Office of Electricity, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 5, 2026.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2026–22796 Filed 11–6–26; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a virtual meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, December 2, 2026, 1 p.m. to 4 p.m. MST.

ADDRESSES: This meeting will be held virtually. To receive the virtual access information, please contact Bridget Maestas, Northern New Mexico Citizens Advisory Board (NNMCAB) Executive Director, at the telephone number or email listed below at least two days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Bridget Maestas, NNMCAB Executive Director, by Phone: 505–709–7466 or Email: *bridget.maestas@em.doe.gov.*

SUPPLEMENTARY INFORMATION: *Purpose of the Board:* At the request of the Assistant Secretary or Field Managers, the Board may provide community-based advice and recommendations concerning any EM program activities, such as clean-up activities and environmental restoration; waste management and disposition; excess facilities; future land use and long-term stewardship; communications; and budget priorities. The Board also provides an avenue to fulfill public participation requirements outlined in the Comprehensive Environmental Response, Compensation, and Liability Act (CERLA), Federal Facility Agreements, Consent Orders, Consent Decrees and Settlement Agreements.

Tentative Agenda: (agenda topics are subject to change; please contact Bridget Maestas for the most current agenda)

- Presentation to the Board
- Agency Updates

Public Participation: The meeting is open to the public and public comment can be given orally or in writing. Fifteen minutes are allocated during the meeting for public comment and those wishing to make oral comment will be given a minimum of two minutes to speak. Written comments received at least two working days prior to the meeting will be provided to the members and included in the meeting minutes. Written comments received

within two working days after the meeting will be included in the minutes. For additional information on public comment and to submit written comment, please contact Bridget Maestas. The EM SSAB, Northern New Mexico, welcomes the attendance of the public at its meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bridget Maestas at least seven days in advance of the meeting.

Meeting conduct: The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Questioning of board members or presenters by the public is not permitted.

Minutes: Minutes will be available at the following website: *https://www.energy.gov/em/nnmcab/northern-new-mexico-citizens-advisory-board.*

Signing Authority: This document of the Department of Energy was signed on November 4, 2026, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC on November 5, 2026.

Jennifer Hartzell,

Alternate Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2026–22773 Filed 11–6–26; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

National Coal Council

AGENCY: Hydrocarbons and Geothermal Energy Office (HGEO), Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the National Coal Council. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Monday, January 11, 2027; 8 a.m. to 4:30 p.m. (EDT).

ADDRESSES: The Eau Palm Beach Resort, 100 South Ocean Boulevard, Manalapan, FL 33462. The meeting will be held in the Grand Ballroom. In-person meeting. Information to access a live stream of the meeting proceedings will be available at: *https://nationalcoalcouncil.energy.gov/ncc/future-meetings*.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Giove, U.S. Department of Energy, telephone: (301) 903–4130 or email: *joseph.giove@doe.gov*.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: To provide advice, information, and recommendations to the Secretary of Energy on matters relating to coal and the coal industry.

Purpose of the Meeting: The National Coal Council will hold a meeting on January 11, 2027, to present, discuss and possibly finalize one subcommittee report, and to discuss a new report to be conducted in the future.

Tentative Agenda:

- Welcome from the Acting Assistant Secretary (HGEO) and Meeting Room Logistics
- Welcome and Congratulatory Remarks from the Secretary of Energy; Secretary of Interior, and other senior officials
- Presentation/Discussion/Vote on one NCC subcommittee study
- Announcement of one new NCC study
- Lunch (on your own)
- Several invited speakers
- Public Statements, if any; and
- Dismissal.

Public Participation: The meeting will be accessible to the public via live stream, and will be conducted by the Council Chair to ensure an orderly flow of business. To make an oral statement on any agenda item, please contact Mr. Joseph Giove (using the contact details listed above) at least fourteen (14) days prior to the meeting. Approximately 10 minutes will be reserved for public comments; individual speaking times will depend on the number of requests received but will not exceed three minutes per speaker. If you wish to attend the meeting in person, you must register fourteen (14) days in advance, as space is limited, so please contact Mr. Giove to reserve a space. Written comments are also welcome either before or after the meeting and may be submitted directly to Mr. Giove for distribution to the committee.

Minutes: The minutes of the meeting will be available at: *https://nationalcoalcouncil.energy.gov/ncc/past-meetings-and-events* or by contacting Mr. Giove. He may be reached at the email address or telephone number listed previously.

Signing Authority: This document of the Department of Energy was signed on November 4 2026, by David Borak, Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, November 5, 2026.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2026–22795 Filed 11–6–26; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12626–002]

Northern Illinois Hydropower, LLC; Notice of Request for Extension of Time To Commence and Complete Construction Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Request for Extension of Time.

b. *Project No:* 12626–002.

c. *Date Filed:* June 23, 2026.

d. *Applicant:* Northern Illinois Hydropower, LLC.

e. *Name of Project:* Dresden Island Hydroelectric Project.

f. *Location:* The unconstructed project will be located at the U.S. Army Corps of Engineers' (Corps) Dresden Island Lock and Dam on the Illinois River, near the town of Morris, in Grundy County, Illinois. The project will occupy federal land administered by the Corps.

g. *Filed Pursuant to:* Pub. L No. 119–90, 1020, 140 Stat. 820–21.

h. *Applicant Contact:* Jeremy King, Current Hydro LLC, (706) 835–8516 *Jeremy@currenthydro.com.*

i. *FERC Contact:* Zeena Aljibury, (202) 502–6065, *Zeena.aljibury@ferc.gov.*

j. *Deadline for filing comments:* December 4, 2026 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include the docket number P–12626–002. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee requests that the Commission grant a two-year extension of time from the existing deadline to commence and complete construction pursuant to Article 301 of the license of September 23, 2026, and September 23, 2029, respectively. Therefore, the licensee requests an extension until September 23, 2028, to commence construction of the project, and until September 23, 2031, to complete construction of the project. This would be the first extension of time authorized by Public Law 119–90.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *https://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; and (3) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

p. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202)502–6595 or *OPP@ferc.gov.*

(Authority: 18 CFR 2.1)

Dated: November 4, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–22804 Filed 11–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following Exempt Wholesale Generator filings:

Docket Numbers: EG27–29–000.
Applicants: TX Nazareth Solar, LLC.
Description: TX Nazareth Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 11/3/26.
Accession Number: 20261103–5155.
Comment Date: 5 p.m. ET 11/24/26.

Take notice that the Commission received the following Electric Rate filings:

Docket Numbers: ER10–1107–013.
Applicants: Pacific Gas and Electric Company.
Description: Notice of Change in Status of Pacific Gas and Electric Company.
Filed Date: 10/30/26.
Accession Number: 20261030–5478.
Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER10–1290–016.
Applicants: San Diego Gas & Electric Company.
Description: Notice of Non-Material Change in Status of San Diego Gas & Electric Company.
Filed Date: 10/30/26.
Accession Number: 20261030–5475.
Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER10–2249–016.
Applicants: Portland General Electric Company.
Description: Notice of Change in Status of Portland General Electric Company.
Filed Date: 10/29/26.
Accession Number: 20261029–5299.
Comment Date: 5 p.m. ET 11/19/26.

Docket Numbers: ER10–2437–028.
Applicants: Arizona Public Service Company.
Description: Notice of Change in Status of Arizona Public Service Company.
Filed Date: 10/29/26.
Accession Number: 20261029–5300.
Comment Date: 5 p.m. ET 11/19/26.

Docket Numbers: ER10–2881–049; ER10–2882–048; ER10–2883–046; ER10–2884–046; ER16–2509–017; ER17–2400–018; ER17–2401–018; ER17–2403–018; ER17–2404–017.
Applicants: SP Sandhills Solar, LLC, SP Pawpaw Solar, LLC, SP Decatur Parkway Solar, LLC, SP Butler Solar, LLC, Rutherford Farm, LLC, Georgia Power Company, Mississippi Power Company, Southern Power Company, Alabama Power Company.

Description: Notice of Change in Status of Alabama Power Company, et al.

Filed Date: 10/30/26.

Accession Number: 20261030–5473.

Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER11–47–022; ER12–1540–020; ER12–1541–020; ER12–1542–020; ER14–594–030; ER12–1544–020; ER20–649–016; ER14–867–016; ER14–868–017; ER19–606–012; ER16–323–018; ER10–1630–015.

Applicants: Wolf Hills Energy, LLC, Ohio Valley Electric Corporation, AEP Generation Resources Inc., AEP Retail Energy Partners, AEP Energy, Inc., AEP Energy Partners, Inc., Wheeling Power Company, Ohio Power Company, Kingsport Power Company, Kentucky Power Company, Indiana Michigan Power Company, Indiana Michigan Power Company, Appalachian Power Company, Ohio Power Company, Kingsport Power Company, Columbus Southern Power Company, Kentucky Power Company, Wheeling Power Company.

Description: Notice of Change in Status of Appalachian Power Company, et al.

Filed Date: 10/30/26.

Accession Number: 20261030–5472.

Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER12–798–002.

Applicants: Tatanka Wind Power, LLC.

Description: Notice of Change in Status of Tatanka Wind Power, LLC.

Filed Date: 10/29/26.

Accession Number: 20261029–5296.

Comment Date: 5 p.m. ET 11/19/26.

Docket Numbers: ER13–2387–014.

Applicants: Duke Energy Florida, Inc.

Description: Notice of Non-Material Change in Status of Duke Energy Florida, LLC.

Filed Date: 10/29/26.

Accession Number: 20261029–5304.

Comment Date: 5 p.m. ET 11/19/26.

Docket Numbers: ER14–225–011.

Applicants: New Brunswick Energy Marketing Corporation.

Description: Notice of Change in Status of New Brunswick Energy Marketing Corporation.

Filed Date: 10/30/26.

Accession Number: 20261030–5477.

Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER18–537–012; ER18–536–012; ER18–538–013; ER18–535–012.

Applicants: Yankee Street, LLC, Sidney, LLC, O.H. Hutchings CT, LLC, Monument Generating Station, LLC.

Description: Notice of Change in Status of Monument Generating Station, LLC, et al.

Filed Date: 10/30/26.

Accession Number: 20261030–5468.

Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER20–2314–003; ER23–1501–005; ER23–1494–004; ER23–1493–004; ER24–832–004; ER25–2856–001; ER25–2767–002; ER25–2961–001; ER11–2905–006; ER24–707–002; ER11–2904–006.

Applicants: Settlers Trail Wind Farm, LLC, Quartz Solar, LLC, Pioneer Trail Wind Farm, LLC, Lafitte Solar, LLC, Emily Solar, LLC, Casey Fork Solar, LLC, RWE Trading Americas Inc., RWE Clean Energy Wholesale Services, Inc., RWE Clean Energy Solutions, Inc., RWE Supply & Trading Americas, LLC, RWE Renewables QSE, LLC.

Description: Notice of Change in Status of RWE Renewables QSE, LLC, et al.

Filed Date: 10/30/26.

Accession Number: 20261030–5469.

Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER20–2314–004; ER23–1501–006; ER23–1494–005; ER24–832–005; ER23–1493–005; ER20–2032–005; ER23–139–006; ER17–1438–006; ER26–2624–001; ER10–2821–010; ER25–3456–002; ER20–2671–009; ER23–138–005; ER12–1329–012; ER24–153–002; ER24–1231–004.

Applicants: Settlers Trail Wind Farm, LLC, Quartz Solar, LLC, Pioneer Trail Wind Farm, LLC, Lafitte Solar, LLC, Emily Solar, LLC, Casey Fork Solar, LLC, RWE Trading Americas Inc., RWE Clean Energy Wholesale Services, Inc., RWE Clean Energy Solutions, Inc., RWE Supply & Trading Americas, LLC, RWE Renewables QSE, LLC.

Description: Notice of Change in Status of RWE Renewables QSE, LLC, et al.

Filed Date: 10/30/26.

Accession Number: 20261030–5470.

Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER21–964–005.

Applicants: Microsoft Energy LLC.

Description: Notice of Non-Material Change in Status of Microsoft Energy LLC.

Filed Date: 10/29/26.

Accession Number: 20261029–5302.

Comment Date: 5 p.m. ET 11/19/26.

Docket Numbers: ER24–548–007; ER10–3057–012.

Applicants: Dow Pipeline Company, Dow Hydrocarbons and Resources LLC.

Description: Notice of Non-Material Change in Status of Dow Hydrocarbons and Resources LLC, et al.

Filed Date: 10/30/26.

Accession Number: 20261030–5467.

Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER24–3146–003.

Applicants: Blackford Solar Energy, LLC.

Description: Notice of Change in Status of Blackford Solar Energy, LLC.

Filed Date: 10/29/26.

Accession Number: 20261029–5297.

Comment Date: 5 p.m. ET 11/19/26.

Docket Numbers: ER25–3417–002.

Applicants: WS-Sarish LLC.

Description: Notice of Change in Status of WS-Sarish LLC.

Filed Date: 10/30/26.

Accession Number: 20261030–5474.

Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER25–3477–002.

Applicants: Pleasant Prairie Solar Energy LLC.

Description: Notice of Change in Status of Pleasant Prairie Solar Energy LLC.

Filed Date: 10/29/26.

Accession Number: 20261029–5303.

Comment Date: 5 p.m. ET 11/19/26.

Docket Numbers: ER25–3558–001.

Applicants: Twelvemile Energy II, LLC.

Description: Notice of Change in Status of Twelvemile Energy II, LLC.

Filed Date: 10/29/26.

Accession Number: 20261029–5298.

Comment Date: 5 p.m. ET 11/19/26.

Docket Numbers: ER26–2147–002.

Applicants: 45MG 8me LLC.

Description: Notice of Change in Status of 45MG 8me LLC.

Filed Date: 10/30/26.

Accession Number: 20261030–5476.

Comment Date: 5 p.m. ET 11/20/26.

Docket Numbers: ER27–409–000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: 5027 Sunflower Solar Project & Evergy Metro SNUFCA to be effective 1/4/2027.

Filed Date: 11/4/26.

Accession Number: 20261104–5053.

Comment Date: 5 p.m. ET 11/25/26.

Docket Numbers: ER27–410–000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: 5028 Swan Interconnection/Sunflower Solar/Evergy SNUFCA to be effective 1/4/2027.

Filed Date: 11/4/26.

Accession Number: 20261104–5054.

Comment Date: 5 p.m. ET 11/25/26.

Docket Numbers: ER27–411–000.

Applicants: Mid-Atlantic Interstate Transmission, LLC.

Description: 205(d) Rate Filing: MAIT submits an amended IA—SA No. 6647 to be effective 1/4/2027.

Filed Date: 11/4/26.

Accession Number: 20261104–5067.

Comment Date: 5 p.m. ET 11/25/26.

Docket Numbers: ER27–412–000.

Applicants: Southern California Edison Company.

Description: Tariff Amendment: Termination of GIA & DSA, O.L.S.

Energy-Chino (WDT1405/SA Nos. 1025–1026) to be effective 1/4/2027.

Filed Date: 11/4/26.

Accession Number: 20261104–5111.

Comment Date: 5 p.m. ET 11/25/26.

Docket Numbers: ER27–413–000.

Applicants: Duke Energy Progress, LLC.

Description: Tariff Amendment: Cancellation of Tariff Volume No. 6—Cost Bates Rates to be effective 1/1/2027.

Filed Date: 11/4/26.

Accession Number: 20261104–5132.

Comment Date: 5 p.m. ET 11/25/26.

Docket Numbers: ER27–414–000.

Applicants: CLEAResult Consulting, Inc.

Description: Compliance filing: CLEAResult Consulting, Inc. Baseline MBR Filing to be effective 10/23/2026.

Filed Date: 11/4/26.

Accession Number: 20261104–5137.

Comment Date: 5 p.m. ET 11/25/26.

Docket Numbers: ER27–415–000.

Applicants: CLEAResult Consulting, Inc.

Description: Compliance filing: CLEAResult Consulting, Inc. Baseline MBR Filing to be effective 10/23/2026.

Filed Date: 11/4/26.

Accession Number: 20261104–5138.

Comment Date: 5 p.m. ET 11/25/26.

Docket Numbers: ER27–416–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of ICSA, SA No. 7293; NQ–123 re: Network UPG not needed to be effective 1/4/2027.

Filed Date: 11/4/26.

Accession Number: 20261104–5151.

Comment Date: 5 p.m. ET 11/25/26.

Take notice that the Commission received the following Electric Securities filings:

Docket Numbers: ES27–6–000.

Applicants: Ameren Transmission Company of Illinois.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Ameren Transmission Company of Illinois.

Filed Date: 10/30/26.

Accession Number: 20261030–5471.

Comment Date: 5 p.m. ET 11/20/26.

Take notice that the Commission received the following Foreign Utility Company Status filings:

Docket Numbers: FC27–2–000.

Applicants: LUMA Energy, LLC.

Description: LUMA Energy, LLC submits Notice of Self-Certification of Foreign Utility Company Status.

Filed Date: 11/2/26.

Accession Number: 20261102–5357.

Comment Date: 5 p.m. ET 11/23/26.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov*.

Dated: November 4, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–22790 Filed 11–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP27–157–000.

Applicants: Texas Eastern Transmission, LP.

Description: 4(d) Rate Filing: ATM2 Project—NRAs and Non-conforming Agreements eff 11–1–26 to be effective 11/1/2026.

Filed Date: 11/4/26.

Accession Number: 20261104–5055.

Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: RP27–158–000.

Applicants: Texas Eastern Transmission, LP.

Description: 4(d) Rate Filing: Negotiated Rates—PSEG Pwr Release to PSEG En Res eff 11–1–26 to be effective 11/1/2026.

Filed Date: 11/4/26.

Accession Number: 20261104–5077.

Comment Date: 5 p.m. ET 11/16/26.

Docket Numbers: RP27–159–000.

Applicants: Enable Gas Transmission, LLC.

Description: 4(d) Rate Filing: Amended NRA Filing—Tenaska Marketing Ventures_2 to be effective 11/5/2026.

Filed Date: 11/4/26.

Accession Number: 20261104–5081.

Comment Date: 5 p.m. ET 11/16/26.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov*.

Dated: November 4, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–22791 Filed 11–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13757–002]

FFP Missouri 5, LLC; Notice of Request for Extension of Time To Commence and Complete Construction Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Request for Extension of Time.

b. *Project No:* 13757–002.

c. *Date Filed:* June 1, 2026.

d. *Applicant:* FFP Missouri 5, LLC.

e. *Name of Project:* Emsworth Locks and Dam Hydroelectric Project.

f. *Location:* The unconstructed project is located at the U.S. Army Corps of Engineers' (Corps) Emsworth Locks and Dam facility on the Ohio River in Allegheny County, Pennsylvania, and will occupy federal land administered by the Corps.

g. *Filed Pursuant to:* Public Law No. 119–90, 1020, 140 Stat. 820–21.

h. *Applicant Contact:* Erik Steimle, Rye Development, *erik@ryedevelopment.com.*

i. *FERC Contact:* Zeena Aljibury, (202) 502–6065, *Zeena.aljibury@ferc.gov.*

j. *Deadline for filing comments:* December 4, 2026 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include the docket number P–13757–002. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee requests that the Commission grant a two-year extension of time from the existing deadline to commence and complete construction pursuant to Article 301 of the license of May 5, 2027, and May 5, 2030, respectively. Therefore, the licensee requests an extension until May 5, 2029, to commence construction of the project, and until May 5, 2032, to complete construction of the project. This would be the first extension of time authorized by Public Law 119–90.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; and (3) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

p. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

(Authority: 18 CFR 2.1)

Dated: November 4, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–22801 Filed 11–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13755–002]

FFP Missouri 12, LLC; Notice of Request for Extension of Time To Commence and Complete Construction Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Request for Extension of Time.

b. *Project No:* 13755–002.

c. *Date Filed:* June 1, 2026.

d. *Applicant:* FFP Missouri 12, LLC.

e. *Name of Project:* Allegheny Lock and Dam 2 Hydroelectric Project.

f. *Location:* The unconstructed project is located at the U.S. Army Corps of Engineers' (Corps) Allegheny Lock and Dam 2 on the Allegheny River in Allegheny County, Pennsylvania. The project occupies federal land administered by the Corps.

g. *Filed Pursuant to:* Public Law No. 119–90, 1020, 140 Stat. 820–21.

h. *Applicant Contact:* Erik Steimle, Rye Development, LLC, 745 Atlantic Avenue, 8th Floor, Boston, MA 02111, *erik@ryedevelopment.com.*

i. *FERC Contact:* Aneela Mousam, (202) 502–8357, *aneela.mousam@ferc.gov.*

j. *Deadline for filing comments:* December 4, 2026 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866)

208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include the docket number P–13755–002. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee requests that the Commission grant a two-year extension of time from the existing deadline of March 13, 2027, to March 13, 2029, to commence project construction pursuant to Article 301 of the license. Additionally, the licensee requests a two-year extension of time from March 13, 2030, to March 13, 2032 to complete project construction. This would be the first 2-year extension authorized by Public Law 119–90.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; and (3) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

p. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202)502–6595 or *OPP@ferc.gov.*

(Authority: 18 CFR 2.1)

Dated: November 4, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–22808 Filed 11–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12717–002]

Northern Illinois Hydropower, LLC; Notice of Request for Extension of Time To Commence and Complete Construction Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Request for Extension of Time.

b. *Project No:* 12717–002.

c. *Date Filed:* June 30, 2026.

d. *Applicant:* Northern Illinois Hydropower, LLC.

e. *Name of Project:* Brandon Road Hydroelectric Project.

f. *Location:* The unconstructed project will be located at the U.S. Army Corps of Engineers' (Corps) Brandon Road Lock and Dam on the Des Plaines River, near the village of Rockdale, in Will County, Illinois. The project will occupy federal land administered by the Corps.

g. *Filed Pursuant to:* Public Law No. 119–90, 1020, 140 Stat. 820–21.

h. *Applicant Contact:* Jeremy King, Current Hydro LLC, (706) 835–8516, *Jeremy@currenthydro.com.*

i. *FERC Contact:* Zeena Aljibury, (202) 502–6065, *Zeena.aljibury@ferc.gov.*

j. *Deadline for filing comments:* December 4, 2026 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include the docket number P–12717–002. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee requests that the Commission grant a two-year extension of time from the existing deadline to commence and complete construction pursuant to Article 301 of the license of July 22,

2026, and July 22, 2029, respectively. Therefore, the licensee requests an extension until July 22, 2028, to commence construction of the project, and until July 22, 2031, to complete construction of the project. This would be the first extension of time authorized by Public Law 119–90.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *https://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; and (3) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

p. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

(Authority: 18 CFR 2.1.)

Dated: November 4, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–22803 Filed 11–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[AD26–8–000]

Reliability Technical Conference; Notice Inviting Post-Technical Conference Comments

On Wednesday, October 21, 2026, the Federal Energy Regulatory Commission (Commission) convened its annual Commissioner-led Reliability Technical Conference to discuss policy issues related to the reliability and security of the Bulk-Power System.

All interested persons are invited to file post-technical conference comments to address issues raised during the technical conference or identified in the Third Supplemental Notice for this Technical Conference issued on October 15, 2026. Commenters are invited to reference material previously filed in this docket but are encouraged to avoid repetition or replication of their previous comments. Comments must be submitted on or before 30 days from the date of this Notice.

Comments, identified by docket number, may be filed electronically or paper filed. Electronic filing through *https://www.ferc.gov* is preferred. Documents must be filed in acceptable native applications and print-to-.pdf, but not in scanned or picture format. Instructions are available on the Commission's website: *http://www.ferc.gov/docs-filing/efiling.asp.*

Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, submissions sent via the U.S. Postal Service must be addressed to: Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street NE, Washington, DC 20426. Submissions sent via any other carrier must be addressed to:

Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, Maryland 20852.

For more information about this Notice, please contact:

Lodie White (Technical Information), Office of Energy Reliability, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, (202) 502–8453, *Lodie.White@ferc.gov.*

Hampden T. Macbeth (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, (202) 502–8957, *Hampden.Macbeth@ferc.gov.*

(Authority: 16 U.S.C. 825h.)

Dated: November 3, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–22762 Filed 11–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13160–004]

Red River Hydro LLC; Notice of Request for Extension of Time To Commence and Complete Construction Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Request for Extension of Time.

b. *Project No:* 13160–004.

c. *Date Filed:* May 18, 2026.

d. *Applicant:* Red River Hydro LLC.

e. *Name of Project:* Overton Lock and Dam Project.

f. *Location:* The unconstructed project is located at the U.S. Army Corps of Engineers' (Corps) John H. Overton Lock and Dam on the Red River in Rapides Parish, Louisiana. The project occupies federal land managed by the Corps.

g. *Filed Pursuant to:* Public Law 119–90, 1020, 140 Stat. 820–21.

h. *Applicant Contact:* Erik Steimle, Rye Development, *erik@ryedevelopment.com.*

i. *FERC Contact:* Zeena Aljibury, (202) 502–6065, *Zeena.aljibury@ferc.gov.*

j. *Deadline for filing comments:* December 4, 2026 5:00 p.m. Eastern Time.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/*

ecomment.asp. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include the docket number P–13160–004. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. Description of Request: The licensee requests that the Commission grant two consecutive two-year extensions of time to commence and complete project construction since the last extension of time required the licensee to start construction by April 2, 2024, and a single 2-year extension deadline would be April 2, 2026, which already passed. Therefore, the licensee requests an extension until April 2, 2028, for starting construction. Additionally, the licensee requests an extension of time to April 2, 2030 to complete project construction. This would be the first extension of time authorized by Public Law 119–90.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; and (3) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

p. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202)502–6595 or *OPP@ferc.gov.*

(Authority: 18 CFR 2.1)

Dated: November 4, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026–22805 Filed 11–6–26; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2026–0067; FRL–13510–01–OCSPP]

Pesticides; Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations and/or Amend Registrations To Terminate Certain Uses With a 30-Day Comment Period (June 2026)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces the Agency's receipt of and solicits comments on requests by registrants to voluntarily cancel their pesticide registration of certain products and/or to amend their product registrations to terminate one or more uses. In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA provides a periodic notice of receipt addressing requests received by EPA since the last notice of receipt was issued and uses the month and year in the title to help distinguish one document from the other. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments during the comment period that would merit further review of the requests or the request is withdrawn by the registrant. If these requests are granted, EPA will issue an order in the **Federal Register** cancelling the listed product registrations, after which any sale, distribution, or use of the products listed in this document will only be permitted after the registrations have been cancelled if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments and withdrawal requests must be received on or before December 9, 2026.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2026–0067, online at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, are available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Christopher Green, Regulatory & Information Services Division, Office of Mission Critical Operations, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2707; email address: *green.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public and may be of interest to a wide range of stakeholders including environmental, human health, and

agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides.

B. What action is the Agency taking?

This document announces receipt by EPA of requests from registrants to voluntarily cancel their pesticide registration and/or amend their product registrations to terminate one or more uses of the products listed in Unit II, that are currently registered under FIFRA section 3 (7 U.S.C. 136a) or section 24(c) (7 U.S.C. 136v(c)). Unless the Agency determines that there are substantive comments that warrant further review of the requests or the registrants withdraw their requests, EPA intends to issue an order in the **Federal Register** canceling and/or amending the affected registrations.

C. What is EPA's authority for taking this action?

FIFRA section 6(f)(1) (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. Before acting on a request for voluntary cancellation, EPA must provide at least a 30-day public comment period on the request. FIFRA further provides that, before acting on a request for voluntary cancellation or termination of any minor agricultural use, EPA must provide a 180-day comment period unless:

1. The registrants request a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants in Table 3 of Unit II have requested that EPA waive the 180-day comment period. Accordingly, this document provides a 30-day comment period on these requests.

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through email or *https://www.regulations.gov.* If you wish to include CBI in your comment, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. In addition to one complete version of the comment that includes CBI, a copy of the comment without CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

E. How can a registrant withdraw their request for voluntary cancellation?

Registrants who choose to withdraw their request for voluntary cancellation should submit a withdrawal request in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

II. Requests to Voluntarily Cancel and/or Amend Certain Registrations

The registrations with pending voluntary requests for cancellation are listed in sequence by registration number (or company number and 24(c) number) in Table 1 of this unit.

TABLE 1—REGISTRATIONS WITH PENDING VOLUNTARY REQUESTS FOR CANCELLATION

Registration No.	Company No.	Product name	Active ingredient
100–1067	100	Paraquat Concentrate ES	Paraquat dichloride (061601/1910–42–5)—(45.6%).
241–341	241	Pendulum 3.3 EC Herbicide	Pendimethalin (108501/40487–42–1)—(37.4%).
241–360	241	Pre-M 3.3 EC Turf Herbicide	Pendimethalin (108501/40487–42–1)—(37.4%).
5481–654	5481	317–19	Azoxystrobin (128810/131860–33–8)—(4.37%).
48273–8	48273	Marman Atila, Glyphosate MP	Glyphosate, isopropylamine salt (103601/38641–94–0)—(41%).
67346–1	67346	Ethylene Fluid	Ethanol (001501/64–17–5)—(90%).
85678–74	85678	Redeagle Paraquat TK	Paraquat dichloride (061601/1910–42–5)—(44.5%).
85678–75	85678	RE Paraquat Concentrate	Paraquat dichloride (061601/1910–42–5)—(44.54%).
89275–1	89275	Willowood Paraquat Technical	Paraquat dichloride (061601/1910–42–5)—(47.1%).
90330–2	90330	Paraquat Manufacturing Concentrate	Paraquat dichloride (061601/1910–42–5)—(43.13%).
94730–56	94730	GCS Paraquat Technical II	Paraquat dichloride (061601/1910–42–5)—(45.64%).
TX–100007	264	Baythroid XL	Beta-Cyfluthrin (118831/1820573–27–0)—(12.7%).
TX–110001	264	Leverage 360 Insecticide	Imidacloprid (129099/138261–41–3)—(21%), beta-Cyfluthrin (118831/1820573–27–0)—(10.5%).
WA–090015	19713	Drexel Simazine 4L	Simazine (080807/122–34–9)—(42.1%).
WA–090016	19713	Drexel Simazine 4L	Simazine (080807/122–34–9)—(42.1%).

The registrant of the product identified in Table 1A of this unit has requested 18 months to sell existing stocks of the product.

TABLE 1A—REGISTRATIONS WITH PENDING VOLUNTARY REQUESTS FOR CANCELLATION, CONT'D.

Registration No.	Company No.	Product name	Active ingredient
91813–17	91813	Oryzalin Technical	Oryzalin (104201/19044–88–3)—(98.3%)..

The product registrations with pending voluntary requests for amendments to terminate uses are listed in sequence by registration number (or company number and 24(c) number) in Table 2 of this unit.

TABLE 2—PRODUCT REGISTRATIONS WITH PENDING VOLUNTARY REQUESTS FOR AMENDMENT

Registration No.	Company No.	Product name	Active ingredient	Uses to be terminated
66222–243	66222	Fluensulfone 480EC	Fluensulfone (050410/318290–98–1)—(40%).	Cranberry use.
66222–290	66222	Fluensulfone 480EC CA	Fluensulfone (050410/318290–98–1)—(40%).	Cranberry use.
81598–16	81598	Oxamyl 42% MUP	Oxamyl (103801/23135–22–0)—(42%).	Bearing apple use, cherry use, peach use & pear orchard crops use.
81598–17	81598	Oxamyl Technical	Oxamyl (103801/23135–22–0)—(97.41%).	Bearing apple use, cherry use, peach use & pear orchard crops use.
89459–66	89459	Permethrin E-Pro Termiticide/Insecticide.	Permethrin (109701/52645–53–1)—(36.8%).	Termite use, sheep use & goats use.

The name and address of record for the requesting registrants are listed in sequence by EPA company number in Table 3 of this unit. The company number corresponds to the first part of the EPA registration numbers of the products listed in Tables 1, 1A and 2 of this unit.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

Company No.	Company name and address
100	Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419–8300.
241	BASF Agricultural Solutions US, LLC, 2 TW Alexander Drive, Research Triangle Park, NC 27713.
264	Bayer CropScience, LLC, 800 North Lindbergh Blvd., Saint Louis, MO 63167.
5481	Amvac Chemical Corporation, 15440 Laguna Canyon Road, Suite 100, Irvine, CA 92618.
19713	Drexel Chemical Company, P.O. Box 13327, Memphis, TN 38113–0327.
48273	Marman USA, Inc., Agent Name: Nufarm Americas, Inc., 4000 Aerial Center Pkwy., Suite 101, Morrisville, NC 27560.
66222	Makhteshim Agan of North America, Inc., D/B/A Adama, 8601 Six Forks Road, Suite 300, Raleigh, NC 27615.
67346	Precision Generators, LLC, 200 Golden Oak Court, Suite 250, Virginia Beach, VA 23452.
81598	Albaugh North America Limited, 4900 Stockyards Expressway, Saint Joseph, MO 64504.
85678	RedEagle International, LLC, Agent Name: Wagner Regulatory Associates, Inc., 7217 Lancaster Pike, Suite A, P.O. Box 640, Hockessin, DE 19707.
89275	Willowood Paraquat, LLC, C/O Generic Crop Science, LLC, 1887 Whitney Mesa Drive #9740, Henderson, NV 89014–2069.
89459	Central Garden & Pet Company, 1501 East Woodfield Road, Suite 200W, Schaumburg, IL 60173.
90330	US Raymat Ag, LLC, Agent Name: Pyxis Regulatory Consulting, Inc., 535 Dock Street, Suite 211, Tacoma, WA 98402.
91813	UPL Delaware, Inc., P.O. Box 12219, Research Triangle Park, NC 27709.
94730	Generic Crop Science, LLC, Agent Name: Wagner Regulator Associates, Inc., 7217 Lancaster Pike, Suite A, Hockessin, DE 19707–0640.

III. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States, and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation, which will be the date of publication of the cancellation order in the **Federal Register**. In any order issued in response to these requests, EPA anticipates including the following provisions for the treatment of any existing stocks of the products listed in Unit II:

For voluntary cancellations of the registrations listed in Table 1 of Unit II, registrants will be permitted to sell and distribute existing stocks of voluntarily canceled products for 1 year after the effective date of the cancellation order. Thereafter, registrants will be prohibited from selling or distributing the products identified in Table 1 of Unit II, except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

For the product identified in Table 1A of Unit II, the registrant has requested 18 months after the date of publication of the cancellation order in the **Federal Register** to sell existing stocks. Thereafter, the registrants will be prohibited from selling or distributing the product identified in Table 1A of Unit II, except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Once EPA has approved labels for the products listed in Table 2 of Unit II, (amended to reflect the requested amendments to terminate uses), registrants will be permitted to sell or distribute products under the previously approved labeling for a period of 18 months after the date of publication of the cancelation order in the **Federal Register**, unless other restrictions have been imposed. Thereafter, registrants will be prohibited from selling or distributing the products whose labels include the terminated uses identified in Table 2 of Unit II, except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Persons other than the registrant will generally be allowed to sell, distribute, or use existing stocks of the canceled

products and/or products whose labels include the terminated uses until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products and/or terminated uses.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 4, 2026.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2026–22769 Filed 11–6–26; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than November 24, 2026.

A. Federal Reserve Bank of San Francisco (Keith Dudley, Vice President), 101 Market Street, San Francisco, California 94105–1579. Comments can also be sent electronically to *SF.Supervision.Comments.Applications@sf.frb.org:*

1. *James M. Edmunds, Seattle, Washington; and Megan F. Clubb and Clifford W. Kontos, both of Walla Walla, Washington;* as a group acting in concert, to retain voting shares of Baker Boyer Bancorp, and thereby indirectly retain voting shares of Baker Boyer National Bank, both of Walla Walla, Washington.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–22827 Filed 11–6–26; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0300; Docket No. 2026–0562; Sequence No. 1]

Information Collection; General Services Administration Acquisition Regulation; Implementation of Information Technology Security Requirements

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and OMB regulations, GSA invites the public to comment on an extension concerning the implementation of information technology security requirements. GSA invites comments on: whether the proposed collection of information is necessary, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through March 31, 2027. GSA proposes that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: GSA will consider all comments received by January 8, 2027.

ADDRESSES: GSA invites interested persons to submit comments on this collection through *https://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at *GSARegSec@gsa.gov.*

Instructions: All items submitted must cite OMB Control No. 3090–0163, Contract Solicitation Information. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business-confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Thomas O'Linn, Procurement Analyst, at telephone 816–589–3783 (Ext. 13291), or *GSARpolicy@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and any Associated Form(s)

OMB Control No. 3090–0300, Implementation of Information Technology Security Requirements.

B. Needs and Uses

The General Services Acquisition Regulations (GSAR) requires that contractors accessing information systems that support the operations and assets of GSA, another agency, contractor, or other source, to comply with GSA's IT security policies including GSA IT's security policies outlined in CIO 09–48, IT Security Procedural Guide: Security and Privacy IT Acquisition Requirements and CIO 12–2018, IT Policy Requirements Guide.

Due to the Revolutionary GSAR Overhaul (RGO), there are no program changes. Once RGO rulemaking is complete, GSA will assess and revise this information collection as needed.

C. Annual Burden

Respondents: *35.*

Responses Per Respondent: *2.*

Total Annual Responses: *70.*

Hours Per Response: *5.*

Total Burden Hours: *350.*

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division (MVCB), at *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–0300, Implementation

of Information Technology Security Requirements, in all correspondence.

Richard Speidel,

Deputy Chief Data Officer, General Services Administration.

[FR Doc. 2026–22731 Filed 11–6–26; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–27–1319; Docket No. CDC–2026–1783]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on an existing information collection project titled National Surveillance of Community Water Systems and Corresponding Populations with the Recommended Fluoridation Level. This surveillance program collects the fluoridation status of, and population served by the nation's 52,000 community water systems (CWS) which serve the 50 states and the District of Columbia.

DATES: CDC must receive written comments on or before January 8, 2027.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2026–1783 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

National Surveillance of Community Water Systems and Corresponding Populations with the Recommended Fluoridation Level—(OMB Control No 0920–1319, Exp. 2/28/2027)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Community water fluoridation is the process of adjusting the fluoride concentration of a Community Water Systems (CWS) to the level beneficial for prevention of dental caries as recommended by the US Public Health Service (PHS). Community water fluoridation is a major factor contributing to the large decline in caries in the U.S. in the past 75 years and is recognized as one of 10 great public health achievements of the twentieth century. Community water fluoridation reduces dental caries by 25% and is a safe, and is the most cost-effective way to deliver fluoride to people of all ages, regardless of education and income level. It is especially important for populations with limited access to preventive dental measures. CDC is authorized to collect the information under the Public Health Service Act. This data collection aligns with CDC's strategy to use public health surveillance to inform programs and policies to improve the oral health of the nation by reducing disparities and expanding access to effective prevention programs.

CDC uses the Water Fluoridation Reporting System (WFRS) to collect water fluoridation coverage and quality throughout the U.S. Respondents to the information collection are state fluoridation managers or other state government officials designated by the state dental director or drinking water administrator. State participation in the data collection is voluntary. This data allows CDC and states to monitor the performance and efficiency of their water fluoridation programs, which will improve and extend program delivery.

CDC requests OMB approval for an estimated 2,783 annual burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State Official	Fluoridation status and population	50	1	37.5	1,875
State Official	Fluoride testing data	33	1	27.5	908
Total					2,783

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2026–22821 Filed 11–6–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Board on Radiation and Worker Health (ABRWH). This is a virtual meeting. It is open to the public, limited only by the space available and the number of audio conference lines and internet conference access, with a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. The public is also welcome to listen to the meeting by joining the audio conference (information below). The audio conference line has 150 ports for callers.

DATES: The meeting will be held on December 2, 2026, from 10 a.m. to 6:15 p.m., EST and a public comment session will be held at 5:15 p.m., EST, and will conclude at 6:15 p.m., EST, or following the final call for public comment, whichever comes first. Written comments must be received on or before November 19, 2026.

ADDRESSES: You may submit comments by mail to: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226. Email: *ocas@cdc.gov*.

Written comments received in advance of the meeting will be included in the official record of the meeting.

Meeting Information: The USA toll-free dial-in numbers are: +1 404 718 3800 (U.S. East Coast) and +1 888 994 4478 (U.S West Coast), passcode 792 701 067#. The meeting ID is: 290 652 778 894 9670; passcode is 4T4aq29X; and the Web conference by Teams meeting connection is: *https://teams.microsoft.com/meet/290652778894967 0?p=4sri51vlDfNwtk0bqZ*.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone: (513) 533–6800, Email: *ocas@cdc.gov*.

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines, which have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 14109 (September 29, 2023) on March 22, 2024. Unless continued by the President, the Advisory Board will terminate on September 30, 2027, consistent with Executive Order 14354 of September 29, 2025.

Purpose: The Advisory Board is charged with a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Considered: The agenda will include discussions on the following: NIOSH program, Department of Labor, Department of Energy, and Special Exposure Cohort (SEC) petitions status updates; procedure reviews finalization/document approvals; IREP Rounding Update; United Nuclear Corporation SEC #00267 Petition Evaluation Report and Board Work Session. Agenda items are subject to change as priorities dictate. For additional information, please contact Toll Free 1–800–232–4636.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2026–22775 Filed 11–6–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–27–1461]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Overdose Response Strategy Data Collection'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 20, 2026, to obtain comments from the public and affected agencies. CDC received four public comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Overdose Response Strategy Data Collection (OMB Control No. 0920—1461. Exp. 8/31/2028)—Revision—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Drug overdose death rates, including those involving synthetic opioids (such as fentanyl) and stimulants (such as cocaine and methamphetamine) rose over the past several decades in the United States, becoming a topic of national importance. Drug overdoses remain the leading cause of injury-related death in the United States. CDC predicts that around 67,000 Americans died from a drug overdose in the 12-month period ending April 2026.

The Overdose Response Strategy (ORS) is a unique collaboration between public health and public safety agencies designed to help local communities reduce drug overdoses and save lives by sharing timely data, pertinent intelligence, and evidence-based and innovative strategies.

ORS teams support public health and public safety entities in their jurisdictions by:

- Sharing data systems to inform rapid and effective community overdose prevention efforts.
- Supporting immediate, evidence-based response efforts that can directly reduce overdose deaths.
- Designing and using promising strategies at the intersection of public health and public safety.
- Disseminating information to support the implementation of evidence-informed overdose prevention strategies.

As the ORS is one of CDC's flagship overdose prevention programs, and partnering with public safety is one of CDC's key overdose prevention strategies, a greater understanding of the impact and effectiveness of the ORS is needed to inform program enhancements and improvements.

This ICR focuses on a survey and a reporting tool that ORS teams and their partners will complete to provide critical data to CDC for program monitoring, to inform technical assistance and guidance documents produced by CDC or other partners, and to assess the extent to which the ORS program is achieving the goal of supporting public health and public safety partnerships to reduce drug overdose. It will also provide CDC with the capacity to respond in a timely manner to requests for information about the program from the Department of Health and Human Services (HHS), the White House, Congress, and other sources. Information collected will be disseminated to ORS teams and to the public via an annual Program Evaluation Report and an ORS Annual Report. Data from both reports will largely be used to develop programmatic reports, tools, and implementation guides for the purposes of program improvement.

We are requesting changes to the approved OMB data collection instruments and updating the approved data collection instruments to align with the program's updated logic model and evaluation questions, which resulted from strategic planning activities and evaluation planning activities carried out in 2025 and 2026. Revisions requested are to update the logic model, revise and streamline surveys to better align with updated logic model, and to update data collection and analysis by combining previously approved surveys. These changes are expected to significantly improve the efficiency and utility of the data collection activities. Based on these changes, CDC requests OMB approval for a reduction in annual burden from 653 hours to 327 hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
ORS Respondents	Invitation email	262	1	2/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
ORS Respondents	Reminder email	262	1	2/60
ORS Public Health Analysts	ORS Annual Evaluation Survey	61	1	15/60
	ORS Quarterly Reporting Template	61	4	30/60
ORS Drug Intelligence Officers	ORS Annual Evaluation Survey	61	1	15/60
	ORS Quarterly Reporting Template	61	4	30/60
Public health and public safety partners	ORS Annual Evaluation Survey	140	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2026–22820 Filed 11–6–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–27–1359]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''National Survey of Syringe Services Programs (NSSSP)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 2, 2026 to obtain comments from the public and affected agencies. CDC received 26 comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

The National Survey of Syringe Services Programs (NSSSP) (OMB Control No. 0920–1359, Exp. 1/31/2027)—Revision—National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The primary purpose of the National Survey of Syringe Services Programs (NSSSP) is to strengthen and improve the ability of CDC and local and state partners to monitor and evaluate syringe services programs (SSPs) nationally, with the overall goal of supporting, sustaining, and improving SSPs nationwide and reducing infectious disease and other harms related to drug use. Findings from the 2022–2025 survey successfully characterized operational characteristics and services, funding resources, community relations, and key operational successes and challenges. The 2026 survey is currently being implemented. Revisions are being requested to address the increasing number of SSPs nationwide, updated infectious disease and substance use prevention, testing, and treatment modalities, additional SSP services provided, and additional information on overdose prevention and reversals.

The project will include all SSPs that are listed in a publicly available directory of all known SSPs in the United States maintained by the North American Syringe Exchange Network (NASEN; *https://nasen.org*). The project will also include SSPs in NASEN's directory that do not wish to be publicly listed but have agreed to be contacted for research purposes, SSPs belonging to NASEN's buyers' club that are not part of the directory, respondents to prior RTI Arnold Ventures Surveys of SSPs that are not part of NASEN's directory, and other SSPs proactively identified through searching state health department websites, funding agencies, state and regional networks, regional conferences, partner organization networks or webinars and via social media.

SSPs will be sent a letter of invitation to participate in a 35-minute program survey. Participating programs will have the option of completing the survey via different modalities to enhance feasibility and comfort in completing the survey, for example via the Research Electronic Data Capture (REDCap) or a similarly secure web-based application. Other modalities for survey administration will include a coordinated telephone or videoconferencing interview. SSPs will be sent reminder letters for an approximately 6-month data collection period.

The survey will include questions on operational characteristics and services, funding resources, community relations,

and key operational successes and challenges. Approximately 1000 SSPs will be able to participate in the survey. We anticipate that approximately 20% of SSPs will decline to complete the survey, yielding 800 completed surveys per year. However, given that it is challenging to predict future response rates, we are requesting enough burden hours to allow 100% of SSPs to respond to the survey. We estimate that it will take 35 minutes to complete the survey, regardless of how the respondent chooses to complete it (*i.e.,* self-administered online or interviewer-administered by phone or videoconferencing). SSPs that do not respond to the initial survey invitation will be given reminders to complete the survey over the duration of the survey implementation period.

CDC requests OMB approval for an estimated 583 annualized burden hours. Participation of respondents is voluntary and there is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
All participating SSPs	National Survey of Syringe Services Programs	1,000	1	35/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2026–22819 Filed 11–6–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–21]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 8, 2027.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By Regular Mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier: __/OMB Control Number: __, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Withholding Medicare Payments to Recover Medicaid Overpayments and Supporting Regulations in 42 CFR 447.31; *Use:* Certain Medicaid providers that are subject to offsets for the collection of Medicaid overpayments may terminate or substantially reduce their participation in Medicaid, leaving the state Medicaid agency unable to recover the amounts due. Recovery procedures allow for determining the amount of overpayments and offsetting the overpayments by withholding the provider's Medicare payments. To effectuate the withholding, the state agency must provide their respective CMS regional office with certain documentation that identifies the provider and the Medicaid overpayment amount. The agency must also demonstrate that the provider was

notified of the overpayment and that demand for the overpayment was made. An opportunity to appeal the overpayment determination must be afforded to the provider by the Medicaid state agency. Lastly, Medicaid state agencies must notify CMS when to terminate the withholding; *Form Number:* CMS–R–21 (OMB control number: 0938–0287); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 54; *Total Annual Responses:* 27; *Total Annual Hours:* 81. (For policy questions regarding this collection contact Stuart Goldstein at 410–786–0694.)

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–22794 Filed 11–6–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval: Public Comment Request; Organ Procurement and Transplantation Network Board of Directors and Committee Member Applications and Forms

Correction

In notice document 2026–21857, appearing on pages 67589 through 67592 in the issue of Tuesday, October 27, 2026, make the following correction:

On page 67589, in the third column, in the **DATES** section, on the second line, ''October 27, 2026'' should read, ''November 27, 2026''.

[FR Doc. C1–2026–21857 Filed 11–6–26; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be partially open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website: *https://videocast.nih.gov/watch/d7d1c3b9-bb39-11f1-82c0-124f0a52e769.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Date: January 26, 2027.

Open: 9:30 a.m. to 3:30 p.m.

Agenda: Call to Order; Consideration of Minutes; NIAMS Director's Report and Discussion; Concepts; Open Discussion.

Address: National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Closed: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Address: National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Timothy Erik Edgerton, MBA, Acting Deputy Director, Division of Extramural Activities, Grants Management Branch, Division of Extramural Activities, 6701 Democracy Blvd., Suite 838, Bethesda, MD 20892, (301) 594–7760, *edgertont@mail.nih.gov.*

Registration is not required to attend the open portion of this meeting.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.niams.nih.gov/about/working-groups/advisory-council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research; 93.AR4, Arthritis, Musculoskeletal and Skin Diseases Research—Training Institutional (TI); 93.AR6, Arthritis, Musculoskeletal and Skin Diseases Research—Other Research (OR); 93.AR5, Arthritis, Musculoskeletal and Skin Diseases Research—Research Centers (RC); 93.AR7, Arthritis, Musculoskeletal and Skin Diseases Research—SBIR/STTR; 93.AR1, Arthritis, Musculoskeletal and Skin Diseases Research—Research Projects; 93.AR3, Arthritis, Musculoskeletal and Skin Diseases Research—Training Individual (TR), National Institutes of Health, HHS)

Dated: November 5, 2026.

Rosalind M. Niamke,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–22800 Filed 11–6–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2025–0147]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0100

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0100, Advanced Notice of Vessel Arrival; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before December 9, 2026.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov.* Search for docket number [USCG–2025–0147]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.*

Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally,

copies are available from: COMMANDANT (CG–C5I–P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone (571) 607–4058, or email *hqs-dg-m-cg-61-pii@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C., chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG–2025–0147, and must be received by December 9, 2026.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. If you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the *https://www.reginfo.gov,* comment-submission web page. OIRA posts its decisions on ICRs online at *https://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0100.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (90 FR 25061, June 13, 2025) required by 44 U.S.C. 3506(c)(2). That notice elicited two submissions. One submission was unrelated to the notice, and one submission had four ICR-related comments. First, the commenter stated that they appreciate the ongoing efforts to reduce administrative burdens and streamline reporting requirements to U.S. Authorities. Second, the commenter supports the implementation of Maritime Single Windows (MSW) and emphasizes their critical role in enhancing customs and port cooperation. Third, the commenter supports the development of international standards to allow for the systematic collection of Advance Passenger Information (API) and Booking Reservation Information (BRI) from cruise passenger vessel operators and the alignment of any passenger and crew data standards with the International Maritime Organization Facilitation Convention. Fourth, the commenter recommends that the Coast Guard add to its website a point of contact to resolve data transmission challenges. To assist vessel operators in the submission of advance notice of arrival data and resolve any data transmission challenges, the Coast Guard currently has on our National Vessel Movement Center (NVMC) web page (*www.nvmc.uscg.gov*) links to User Guides, Frequently Asked Questions, an email address and contact phone numbers that are staffed 24/7. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Advanced Notice of Vessel Arrival.

OMB Control Number: 1625–0100.

Summary: 46 U.S.C. 70001 authorizes the Coast Guard to require pre-arrival messages from any vessel entering a port or place in the United States.

Need: This information is required under 33 CFR 146 and 33 CFR 160 subpart C to control vessel traffic, develop contingency plans, and enforce regulations.

Forms: None.

Affected Public: Vessel owners and operators.

Number of Respondents: 16,105 Unique Vessels.

Notice of Arrival (Initial and Update): 13,705.

Waiver Request: 1,200.

Notice of Hazardous Conditions: 1,200.

Frequency: On occasion.

Number of Responses per Respondent:

Notice of Arrival (Initial): 8.312.

Notice of Arrival (Update): 12.156.

Waiver Request: 1.

Notice of Hazardous Conditions: 1.

Estimated Time per Response:

Notice of Arrival (Initial): 1.03 hours.

Notice of Arrival (Update): 12 minutes.

Waiver Request: 1 hour.

Notice of Hazardous Conditions: 30 minutes.

Hour Burden Estimate: The estimated burden has decreased from 202,021 hours to 152,155 hours a year; due to a decrease in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: November 4, 2026.

Bradley E. White,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2026–22733 Filed 11–6–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Electronic Export Manifest for Truck Cargo Test

Correction

In notice document 2026–19414 beginning on page 60383 in the issue of Wednesday, September 23, 2026, make the following corrections:

1. On page 60383, in the first column, under **ADDRESSES**, in the second paragraph ''*tocbptruckexportmanifest@cbp.dhs.gov*'' should read ''to *cbptruckexportmanifest@cbp.dhs.gov*''.

2. On page 60386, in the first column, under Application Process and Acceptance, in the fourth line, ''*CBPTruckExportManifestatcbptruckexportmanifest@cbp.dhs.gov*'' should read ''*CBPTruckExportManifest@cbp.dhs.gov*''.

[FR Doc. C1–2026–19414 Filed 11–6–26; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7094–N–11; OMB Control No. 2506–0219]

60-Day Notice of Proposed Information Collection: Youth Homelessness System Improvement (YHSI)

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 8, 2027.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.regulations.gov.* Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Urnell Johnson, PRA Supervisor, Correspondence Unit, Department of Housing and Urban Development, 451 7th Street SW, Room 7232, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Karen DeBlasio, Director, Office of Special Needs Assistance Programs, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW, Room 7262, Washington, DC 20410; email *Karen.M.DeBlasio@hud.gov,* telephone (202) 402–4773 (This is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available supporting documents for the proposed collection may be obtained from Ms. DeBlasio.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Youth Homeless Systems Improvement (YHSI).

OMB Approval Number: 2506–0219.

Type of Request: Renewal.

Form Number: SF–424 Application for Federal Assistance.

Description of the need for the information and proposed use:

Congress appropriated funds to the Department of Housing and Urban Development in FY2022–FY2026 to competitively award funds to selected communities to support them in establishing and implementing a response system for youth homelessness or for improving their existing response system. The YHSI projects focus on systems change to improve the capacity and increase collaboration with youth in the community; establish partnership with other youth-serving systems; connect housing and homelessness service providers to education, job training, and employment skills organizations; improve the centralized or coordinated assessment system also known as the Coordinated Entry Systems (CES); and improve data collection and use between systems that work with at-risk and homeless youth. This information collection revision is to monitor the progress of funded YHSI projects.

Estimated Number of Respondents: 86 YHSI grant recipients.

Estimated Number of Responses: 172.

Frequency of Response: Biannual.

Average Hours per Response: 2.

Total Estimated Burdens: $22,482.12.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

44 U.S.C. 3507.

Ronald J. Kurtz,

Assistant Secretary for Community Planning and Development.

[FR Doc. 2026–22770 Filed 11–6–26; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R4–ES–2026–2542; FXES11130400000–278–FF04E00000]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Status Reviews for 81 Southeastern Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of status reviews.

SUMMARY: We, the U.S. Fish and Wildlife Service, are initiating 5-year status reviews under the Endangered Species Act of 1973, as amended, for 81 species (ESA; 16 U.S.C. 1531 *et seq.*). A 5-year status review is based on an assessment of the best scientific and commercial data available at the time of the review. We ask the public to submit any new information relevant to the status of any of the species listed in this notice or their habitats.

DATES: These status reviews were announced on November 9, 2026.

ADDRESSES: We will accept new information about these or any listed species at any time. For instructions on how and where to submit information for a species named in these status reviews, see table 1 in the **SUPPLEMENTARY INFORMATION** section. Additional information on status reviews is available at *https://www.fws.gov/project/five-year-status-reviews.*

FOR FURTHER INFORMATION CONTACT: To request information, contact the

appropriate person in Table 1 in the **SUPPLEMENTARY INFORMATION** section. For general information or to submit information by mail, contact Bradly Potter, via phone at 517–643–7965, via email at *R4Recovery@fws.gov,* or via U.S. mail at U.S. Fish and Wildlife Service, 1875 Century Boulevard, Atlanta, GA 30345.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, are announcing 5-year status reviews under the ESA for 81 species which include 47 animal species and 34 plant species. A 5-year status review is based on the best scientific and commercial data available at the time of the review. We ask the public to submit at any time any new information relevant to the status of any of the species listed in Table 1 below.

Why do we conduct 5-year status reviews?

Under the ESA, we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List) in title 50 of the Code of Federal Regulations (CFR) at 50 CFR 17.11 (for wildlife) and 50 CFR 17.12 (for plants). Section 4(c)(2)(A) of the ESA requires us to review each listed species' status at least once every 5 years. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing species under active review. For additional information about 5-year status reviews, refer to our fact sheet at *https://www.fws.gov/project/five-year-status-reviews.*

What information do we consider in our reviews?

A 5-year status review considers the best scientific and commercial data regarding the species. Such information includes:

(A) Species biology, including but not limited to population trends, distribution, abundance, demographics, habitat requirements, tolerance thresholds, and genetics;

(B) Habitat conditions, including but not limited to amount, distribution, and suitability;

(C) Conservation measures that have been or are planned to be implemented to benefit the species;

(D) Current threats and trends in relation to the five listing factors (as defined in section 4(a)(1) of the ESA (16 U.S.C. 1533(a)(1)); and

(E) Other new information, data, or corrections, including, but not limited to, taxonomic or nomenclature changes, identification of erroneous information contained in the List, and any improved analytical methods.

Any new information will be considered during the 5-year status review and ongoing recovery programs for the species.

Which species are under review?

This notice announces 5-year status reviews for the species listed in Table 1. For additional information on the species, see our website at *https://ecos.fws.gov/ecp/* and enter the species name in the search box.

TABLE 1—SPECIES UNDER REVIEW

Taxonomic group	Common name	Scientific name	Listing status (see note)	Locations where the species is known to occur	Email contact
		Animals			
Amphibian	Guajon	*Eleutherodactylus cooki*	T	PR	*caribbean_es@fws.gov.*
Amphibian	Golden coqui	*Eleutherodactylus jasperi*	T	PR	*caribbean_es@fws.gov.*
Amphibian	Puerto Rican crested toad	*Peltophryne lemur*	T	PR	*caribbean_es@fws.gov.*
Birds	White-necked crow	*Corvus leucognaphalus*	E	Dominican Republic, Haiti.	*caribbean_es@fws.gov.*
Birds	Elfin-woods warbler	*Setophaga angelae*	T	PR	*caribbean_es@fws.gov.*
Birds	Roseate tern	*Sterna dougallii dougallii*	T	FL, PR, VI	*caribbean_es@fws.gov.*
Clams	Cumberland elktoe	*Alasmidonta atropurpurea*	E	KY, TN.	*cookeville@fws.gov.*
Clams	Appalachian elktoe	*Alasmidonta raveneliana*	E	NC, SC, TN	*fw4esasheville@fws.gov.*
Clams	Tapered pigtoe	*Fusconaia burkei*	T	AL, FL	*Florida_5YR@fws.gov.*
Clams	Finerayed pigtoe	*Fusconaia cuneolus*	E	AL, TN, VA	*cookeville@fws.gov.*
Clams	Narrow pigtoe	*Fusconaia escambia*	T	AL, FL	*Florida_5YR@fws.gov.*
Clams	Atlantic pigtoe	*Fusconaia masoni*	T	NC, VA	*Raleigh_ES@fws.gov.*
Clams	Southern sandshell	*Hamiota australis*	T	AL, FL	*Florida_5YR@fws.gov.*
Clams	Louisiana pearlshell	*Margaritifera hembeli*	T	LA	*lafayette@fws.gov.*
Clams	Suwannee moccasinshell	*Medionidus walkeri*	T	FL, GA	*Florida_5YR@fws.gov.*
Clams	Choctaw bean	*Obovaria choctawensis*	E	AL, FL	*Florida_5YR@fws.gov.*
Clams	Canoe Creek clubshell	*Pleurobema athearni*	E	AL	*alabama@fws.gov*
Clams	Fuzzy pigtoe	*Pleurobema strodeanum*	T	AL, FL	*Florida_5YR@fws.gov.*
Clams	Cumberland pigtoe	*Pleuronaia gibber*	E	TN	*cookeville@fws.gov.*
Clams	Southern kidneyshell	*Ptychobranchus jonesi*	E	AL, FL	*Florida_5YR@fws.gov.*
Clams	Round ebonyshell	*Reginaia rotulata*	E	AL, FL	*Florida_5YR@fws.gov.*
Crustaceans	Slenderclaw crayfish	*Cambarus cracens*	E	AL	*alabama@fws.gov.*
Crustaceans	Squirrel Chimney Cave shrimp.	*Palaemonetes cummingi*	T	FL	*Florida_5YR@fws.gov.*
Crustaceans	Kentucky cave shrimp	*Palaemonias ganteri*	E	KY	*kentuckyes@fws.gov.*
Crustaceans	Panama City crayfish	*Procambarus econfinae*	T	FL	*Florida_5YR@fws.gov.*
Fishes	Atlantic Sturgeon (Gulf subspecies).	*Acipenser oxyrinchus (=oxyrhynchus) desotoi.*	T	AL, FL, GA, LA, MS	*Florida_5YR@fws.gov.*
Fishes	Bluemask (=jewel) darter	*Etheostoma akatulo*	E	TN	*cookeville@fws.gov.*
Fishes	Kentucky arrow darter	*Etheostoma spilotum*	T	KY, VA	*kentuckyes@fws.gov.*
Fishes	Barrens topminnow	*Fundulus julisia*	E	TN	*cookeville@fws.gov.*
Fishes	Cape Fear shiner	*Notropis mekistocholas*	E	NC	*Raleigh_ES@fws.gov.*
Fishes	Blackside dace	*Phoxinus cumberlandensis*	T	KY, TN, VA	*kentuckyes@fws.gov.*
Insects	Miami tiger beetle	*Cicindelidia floridana*	E	FL	*Florida_5YR@fws.gov.*
Mammals	Carolina northern flying squirrel.	*Glaucomys sabrinus coloratus*	E	NC, TN, VA	*fw4esasheville@fws.gov.*
Mammals	Silver rice rat	*Oryzomys palustris natator*	E	FL	*Florida_5YR@fws.gov.*
Mammals	Lower Keys marsh rabbit	*Sylvilagus palustris hefneri*	E	FL	*Florida_5YR@fws.gov.*

TABLE 1—SPECIES UNDER REVIEW—Continued

Taxonomic group	Common name	Scientific name	Listing status (see note)	Locations where the species is known to occur	Email contact
Reptiles	American crocodile	*Crocodylus acutus*	T	FL	*Florida_5YR@fws.gov.*
Reptiles	Mona ground iguana	*Cyclura stejnegeri*	T	PR	*caribbean_es@fws.gov.*
Reptiles	Puerto Rican boa	*Epicrates inornatus*	E	PR	*caribbean_es@fws.gov.*
Reptiles	Black pinesnake	*Pituophis melanoleucus lodingi*	T	AL, MS	*mississippi_field_office@fws.gov.*
Snails	Painted snake coiled forest snail.	*Anguispira picta*	T	TN	*cookeville@fws.gov.*
Snails	Lacy elimia (snail)	*Elimia crenatella*	T	AL	*alabama@fws.gov.*
Snails	Round rocksnail	*Leptoxis ampla*	T	AL	*alabama@fws.gov.*
Snails	Plicate rocksnail	*Leptoxis plicata*	E	AL	*alabama@fws.gov.*
Snails	Painted rocksnail	*Leptoxis taeniata*	T	AL	*alabama@fws.gov.*
Snails	Flat pebblesnail	*Lepyrium showalteri*	E	AL	*alabama@fws.gov.*
Snails	Cylindrical lioplax (snail)	*Lioplax cyclostomaformis*	E	AL	*alabama@fws.gov.*
Snails	Rough hornsnail	*Pleurocera foremani*	E	AL	*alabama@fws.gov.*
		Plants			
Ferns and Allies	No common name	*Elaphoglossum serpens*	E	PR	*caribbean_es@fws.gov.*
Ferns and Allies	No common name	*Polystichum calderonense*	E	PR	*caribbean_es@fws.gov.*
Ferns and Allies	No common name	*Tectaria estremerana*	E	PR	*caribbean_es@fws.gov.*
Flowering Plants	Price's potato-bean	*Apios priceana*	T	AL, IL, KY, MS, TN	*mississippi_field_office@fws.gov.*
Flowering Plants	Four-petal pawpaw	*Asimina tetramera*	E	FL	*Florida_5YR@fws.gov.*
Flowering Plants	No common name	*Auerodendron pauciflorum*	E	PR	*caribbean_es@fws.gov.*
Flowering Plants	Palma de manaca	*Calyptronoma rivalis*	T	PR	*caribbean_es@fws.gov.*
Flowering Plants	Golden sedge	*Carex lutea*	E	NC	*Raleigh_ES@fws.gov.*
Flowering Plants	Fragrant prickly-apple	*Cereus eriophorus* var. *fragrans*	E	FL	*Florida_5YR@fws.gov.*
Flowering Plants	No common name	*Chamaecrista glandulosa* var. *mirabilis.*	E	PR	*caribbean_es@fws.gov.*
Flowering Plants	Garber's spurge	*Chamaesyce garberi*	T	FL	*Florida_5YR@fws.gov.*
Flowering Plants	Alabama leather flower	*Clematis socialis*	E	AL, GA	*mississippi_field_office@fws.gov.*
Flowering Plants	Short-leaved rosemary	*Conradina brevifolia*	E	FL	*Florida_5YR@fws.gov.*
Flowering Plants	Apalachicola rosemary	*Conradina glabra*	E	FL	*Florida_5YR@fws.gov.*
Flowering Plants	No common name	*Cranichis ricartii*	E	PR	*caribbean_es@fws.gov.*
Flowering Plants	Higüero de sierra	*Crescentia portoricensis*	E	PR	*caribbean_es@fws.gov.*
Flowering Plants	Beautiful pawpaw	*Deeringothamnus pulchellus*	E	FL	*Florida_5YR@fws.gov.*
Flowering Plants	Uvillo	*Eugenia haematocarpa*	E	PR	*caribbean_es@fws.gov.*
Flowering Plants	Harper's beauty	*Harperocallis flava*	E	FL	*Florida_5YR@fws.gov.*
Flowering Plants	No common name	*Leptocereus grantianus*	E	PR	*caribbean_es@fws.gov.*
Flowering Plants	Pondberry	*Lindera melissifolia*	E	AL, AR, GA, MS, MO, NC, SC, TN.	*mississippi_field_office@fws.gov.*
Flowering Plants	Scrub lupine	*Lupinus aridorum*	E	FL	*Florida_5YR@fws.gov.*
Flowering Plants	Mohr's Barbara's buttons	*Marshallia mohrii*	T	AL, GA	*mississippi_field_office@fws.gov.*
Flowering Plants	No common name	*Myrcia paganii*	E	PR	*caribbean_es@fws.gov.*
Flowering Plants	Canby's dropwort	*Oxypolis canbyi*	E	DE, GA, MA, NC, SC	*charleston_recovery@fws.gov.*
Flowering Plants	White fringeless orchid	*Platanthera integrilabia*	T	AL, GA, KY, MS, SC, TN.	*cookeville@fws.gov.*
Flowering Plants	Chupacallos	*Pleodendron macranthum*	E	PR	*caribbean_es@fws.gov.*
Flowering Plants	Miccosukee gooseberry	*Ribes echinellum*	T	FL, SC	*Florida_5YR@fws.gov..*
Flowering Plants	No common name	*Schoepfia arenaria*	T	PR	*caribbean_es@fws.gov..*
Flowering Plants	Marron bacora	*Solanum conocarpum*	E	VI	*caribbean_es@fws.gov..*
Flowering Plants	Erubia	*Solanum drymophilum*	E	PR	*caribbean_es@fws.gov..*
Flowering Plants	Bariaco	*Trichilia triacantha*	E	PR	*caribbean_es@fws.gov.*
Flowering Plants	Wide-leaf warea	*Warea amplexifolia*	E	FL	*Florida_5YR@fws.gov.*
Flowering Plants	St. Thomas prickly-ash	*Zanthoxylum thomasianum*	E	PR, VI	*caribbean_es@fws.gov.*

Note: E= endangered; T= threatened.

New Information

To ensure that a 5-year status review is based on the best available scientific and commercial information, we ask that any new information is submitted using one of the methods identified under **ADDRESSES** (also see **FOR FURTHER INFORMATION CONTACT**). When submitting information, please support said information by supplying documentation such as maps; references; methods used to gather and analyze the data; and/or copies of any pertinent scientific journal articles, other publications, reports, or letters by knowledgeable sources. Before including your address, phone number, email address, or other personal identifying information in your submission, you should be aware that your entire submission—including your personal identifying information—may be made publicly available at any time.

Authority

We publish this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Michael Oetker,

Regional Director, Southeast Region, U.S. Fish and Wildlife Service.

[FR Doc. 2026–22818 Filed 11–6–26; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO- BSD–CONC—NPS0043831; PPWOBSADC0 PPMVSCS1Y.Y00000; OMB Control Number 1024–NEW]

Agency Information Collection Activities; National Park Service Concessioner Services Customer Satisfaction Survey

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing a new a information collection.

DATES: Interested persons are invited to submit comments, which NPS must receive on or before December 9, 2026.

ADDRESSES: Written comments and suggestions on the information collection requirements should be submitted by the date specified above in DATES to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to the NPS Information Collection Clearance Officer (ADIR–ICCO), 13461 Sunrise Valley Drive, (MS–263) Herndon, VA 20191 (mail); or *phadrea_ponds@nps.gov* (email). Please reference Office of Management and Budget (OMB) Control Number 1024–NEW in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: Katy Canetta, Concession Specialist, WASO Commercial Services Program, Contract Management Branch, at katy_canetta@*nps.gov* (email) or (307) 250–6535 (telephone). Please reference OMB Control Number 1024–NEW (Concessioner's Satisfaction Survey) in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the Information Collection Request (ICR) at *http://www.reginfo.gov/public/do/PRAMain*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A *FederalRegister* notice with a 60-day public comment period soliciting comments on this collection of information was published on July 25, 2024 (89 FR 60449). No comments were received.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this information collection request (ICR). Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

A*bstract:* The National Park Service (NPS) is responsible for preserving park resources and ensuring they remain unimpaired for future generations, as required under the 1916 Organic Act and the 1970 General Authorities Act. Through its Commercial Services Program (CSP), the NPS manages more than 400 concession contracts that provide essential visitor services, including lodging, food, retail, and guided recreation. To meet statutory requirements—such as those outlined in the Concessions Management Improvement Act of 1998—the NPS evaluates concessioner performance and ensures that services are delivered safely, lawfully, and at reasonable prices.

The proposed information collection will help the CSP and individual parks assess visitor experiences with concession-provided services. Feedback gathered through this collection will allow the NPS to evaluate concessioner performance, understand visitor expectations, and identify areas for improvement. These insights will guide management decisions that enhance service quality and support positive visitor experiences across the National Park System.

Title of Collection: National Park Service Concessioner Services Customer Satisfaction Survey.

OMB Control Number: 1024–NEW.

Form Number: None.

Type of Review: New Collection

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 522,000.

Estimated Completion Time per Response: 5 minutes.

Total Estimated Number of Annual Burden Hours: 43,500.

Respondent's Obligation: Voluntary.

Frequency of Collection: On occasion.

Total Estimated Annual Non hour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2026–22736 Filed 11–6–26; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1512]

Certain Foundry Coke; Notice of a Commission Determination Not To Review an Initial Determination Granting Complainants' Motion To Amend the Complaint and Notice of Investigation and To Terminate the Investigation as to Certain Claims

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 10) granting Complainants' motion to amend the Complaint and Notice of Investigation to assert claims 1–5 and 7–13 of U.S. Patent No. 12,600,915 (''the '915 patent'') against Respondents MTX Group a.s., OKK Koksovny, a.s., METALIMEX a.s., METALIMEX Deutschland GmbH, and AMEX Coal Sp. z o.o. (collectively, ''MTX Group''), and Complainants' motion to terminate the investigation as to all asserted claims of U.S. Patent No. 12,331,367 (''the '367 patent'') with respect to all Respondents.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on July 20, 2026, based on a complaint filed on behalf of SunCoke Technology and Development LLC and Jewell Coke Company L.P. (collectively, ''SunCoke''), both of Lisle, Illinois. 91 FR 45,282–283 (July 20, 2026). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain foundry coke by reason of the infringement of certain claims of the '915 patent and the '367 patent. The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The Commission's notice of investigation names the following seven (7) respondents: MTX Group, a.s. of Prague, Czech Republic; OKK Koksovny, a.s. of Ostrava-Přívoz, Czech Republic; METALIMEX a.s. of Prague, Czech Republic; METALIMEX Deutschland GmbH of Duisburg, Germany; AMEX Coal Sp. z o.o. of Sopot, Poland; Italiana Coke S.r.l. of Genova, Italy; and Terminal Alti Fondali Savona S.r.l. of Savona, Italy. The Office of Unfair Import Investigations is not named as a party in this investigation.

On September 21, 2026, SunCoke filed a motion to amend the Complaint and Notice of Investigation to assert claims 15 and 7–13 of the '915 patent against Respondents MTX Group and to terminate this investigation in part as to all asserted claims of the '367 patent with respect to all Respondents. No party opposed the motion.

On October 5, 2026, the ALJ issued the subject ID (Order No. 10) granting SunCoke's motion to amend the Complaint and Notice of Investigation to add allegations of infringement of claims 1–5 and 7–13 of the '915 patent against MTX Group and to terminate the investigation in part as to all asserted claims of the '367 patent with respect to all Respondents. The ID found SunCoke demonstrated good cause for amending the Complaint and Notice of Investigation and SunCoke's proposed amendments will not prejudice the public interest or the rights of the parties participating in this investigation. ID at 4. The ID also found the motion is unopposed, complies with the Commission's Rules, and that there are no extraordinary circumstances that prevent terminating the investigation as to all asserted claims of the '367 patent. *Id.* at 4–5. No petitions for review were filed.

The Commission has determined not to review the subject ID. The Notice of Investigation shall be amended to add allegations of infringement as to claims 1–5 and 7–13 of the '915 patent against MTX Group. Moreover, all claims, including claims 1–4, 7–10, 12, and 14–21, of the '367 patent are hereby terminated from the investigation.

The Commission vote for this determination took place on November 4, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.

Issued: November 4, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22730 Filed 11–6–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1442]

Certain Glow Fish Tape Systems, Safety Helmet Systems, and Components Thereof; Notice of a Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and Cease and Desist Order; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''the Commission'') has determined that respondent Milwaukee Electric Tool Corporation of Brookfield, Wisconsin (''Milwaukee'') has violated section 337 of the Tariff Act of 1930, as amended, by importing, selling for importation, or selling in the United States after importation certain glow fish tape systems and components thereof that infringe claim 6 of U.S. Patent No. 12,187,573 (''the '573 patent''). The Commission has determined that the appropriate remedies are a limited exclusion order (''LEO'') and cease and desist order (''CDO'') against Milwaukee, and that the public interest factors do not preclude issuance of such remedial orders. The Commission has also determined to set a bond in the amount of 100 percent (100%) of the entered value of the covered products imported during the period of Presidential review. This investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Carl Bretscher, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–2382. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On March 19, 2025, the Commission instituted this investigation based on a complaint, as supplemented, filed by Klein Tools, Inc. of Lincolnshire, Illinois (''Klein''), accusing Milwaukee of violating section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), by importing into the United States, selling for importation, or selling in the United States after importation certain glow fish tape systems, safety helmet systems, and components thereof by reason of the infringement of the asserted claims of the '573 patent and U.S. Patent Nos. 11,713,209 (''the '209 patent'') and 11,452,327 (''the '327 patent''). 90 FR 12790 (Mar. 19, 2025). The complaint further alleges that a domestic industry exists. *Id.* The Office of Unfair Import Investigations did not participate in the investigation. *Id.*

On May 30, 2025, the Commission amended the notice of investigation to include allegations of infringement of certain asserted claims of U.S. Patent No. 12,268,265 (''the '265 patent''). Order No. 6 (May 1, 2025), *unreviewed by* Comm'n Notice (May 30, 2025). The '265 patent and related '327 patent are collectively referred to as the ''Helmet Patents.'' The '209 patent and related '573 patent are collectively referred to as the ''Glow Fish Tape Patents.''

The Commission subsequently partially terminated the investigation with respect to certain asserted claims of the '327 patent, '209 patent, and '573 patent due to Klein's withdrawal of the complaint with respect to those claims. Order No. 14 (Nov. 20, 2025), *unreviewed by* Comm'n Notice (Dec. 12, 2025); Order No. 19 (Jan. 5, 2026), *unreviewed by* Comm'n Notice (Jan. 28, 2026).

On January 20, 2026, the Commission granted Klein's motion for summary determination that it has satisfied the technical and economic prongs of the domestic industry requirement for the Glow Fish Tape Patents. Order No. 17 (Dec. 19, 2025), *unreviewed by* Comm'n Notice (Jan. 20, 2026).

The presiding Chief Administrative Law Judge (''CALJ'') held an evidentiary hearing from January 5–8, 2026. At the time of the hearing, the asserted claims of the Helmet Patents still at issue were claims 8, 10, and 17 of the '327 patent and claims 1–4 of the '265 patent. The asserted claims of the Glow Fish Tape Patents still at issue were claim 6 of the '209 patent and claim 6 of the '573 patent.

On June 5, 2026, the CALJ issued a final Initial Determination on Violation of Section 337 (''FID'') and a Recommendation on Remedy and Bond (''RD''). With respect to the Helmet Patents, the FID finds that: (i) Milwaukee infringed the '265 patent but not the '327 patent; (ii) the asserted claims of the Helmet Patents are not invalid as obvious or for failing the written description requirement under 35 U.S.C. 112; and (iii) Klein has satisfied both the technical and economic prongs of the domestic industry requirement for both Helmet Patents. With respect to the Glow Fish Tape Patents, the FID finds that: (i) Milwaukee did not infringe the '209 patent or '573 patent; (ii) the asserted claims of the Glow Fish Tape Patent are not invalid as obvious under 35 U.S.C. 103 or for failing the written description requirement; and (iii) Klein has satisfied the technical prong of the domestic industry requirement with respect to claim 6 of each Glow Fish Tape Patent (to supplement the CALJ's earlier summary determination that Klein has satisfied both the economic and technical prongs with respect to claims 1 and 5 of the Glow Fish Tape Patents in Order No. 17, *supra*). The FID concludes that Milwaukee has violated section 337 with respect to the '265 patent (a Helmet Patent) but not the '327 patent or either of the Glow Fish Tape Patents.

The RD recommends that, if a violation is found, the Commission issue an LEO and a CDO against Milwaukee. The RD also recommends that the Commission set a bond in the amount of 100 percent of the entered value of covered products that are imported during the 60-day period of Presidential review.

On June 22, 2026, both Milwaukee and Klein filed petitions and/or contingent petitions for review of certain adverse findings in the FID. On June 30, 2026, each party filed its respective response to the opposing party's petition.

On July 10, 2026, Klein's counsel submitted a letter to the Commission identifying certain allegedly false statements in Milwaukee's opposition to Klein's petition. On the same date, Milwaukee's counsel submitted a response, to which it attached a copy of a letter to Klein's counsel dated July 8, 2026, explaining why Milwaukee's representations are allegedly correct. Upon review of the letters, the Commission declined to consider them because they are not permissible under the Commission's rules.

The parties did not submit statements concerning the public interest pursuant to Commission Rule 210.50(a)(4)(i), 19 CFR 210.50(a)(4)(i). The Commission also did not receive any submissions in response to its request for submissions from interested third parties or government agencies on remedy and the public interest factors. 91 FR 43402–03 (July 15, 2026).

On September 9, 2026, the Commission determined to review the FID in part. 91 FR 57383 (Sept. 9, 2026). With respect to the Helmet Patents, the Commission determined to review the FID's findings that: (i) the asserted claims of the '265 patent and '327 patent are not obvious under 35 U.S.C. 103; and (ii) Klein satisfied the economic prong of the domestic industry requirement. With respect to the Glow Fish Tape Patents, the Commission determined to review: (i) the construction of the claim term ''wherein at least a portion of the case is configured to allow the luminescent material to be energized by light passing through the portion'' in the '573 patent and related infringement and validity findings; (ii) the FID's finding of non-infringement of the '209 and '573 patents, both literal and under the doctrine of equivalents; and (iii) the FID's finding that the asserted claims of the Glow Fish Tape Patents are not invalid as obvious. The Commission determined not to review, and thereby adopted, the other findings in the FID. The Commission directed the parties to brief certain violation issues on review and remedy, the public interest, and bond.

Pursuant to the Commission's directions, the parties filed their initial responses to the Commission's questions on September 18, 2026, and their respective replies to the opposing party's initial response on September 25, 2026.

Having reviewed the FID, the parties' submissions, and the record below, the Commission has determined to reverse the FID and find that Milwaukee has violated section 337 by importing into the United States, selling for importation, or selling in the United States after importation certain glow fish tape products and components thereof that infringe claim 6 of the '573 patent (a Glow Fish Tape Patent). As further explained in the Commission Opinion issued concurrently herewith, the Commission has also determined to adopt the FID's findings that the asserted claims of the Glow Fish Tape Patents are not invalid as obvious and to adopt, with modifications, the FID's

finding that claim 6 of the '209 patent is not infringed. With respect to the Helmet Patents, the Commission has determined to reverse the FID's finding that Milwaukee has violated section 337 with respect to the '265 patent and to find instead that the asserted claims of the '265 patent are invalid as obvious. The Commission, having previously determined to adopt the FID's finding that the asserted claims of the '327 patent are not infringed (91 FR at 57384), takes no position on whether the '327 patent claims are also invalid as obvious or whether Klein has satisfied the domestic industry requirement with respect to the Helmet Patents.

The Commission has determined that the appropriate remedy is: (i) an LEO prohibiting the importation of certain glow fish tape products and components thereof that infringe claim 6 of the '573 patent; and (ii) a CDO against Milwaukee. The Commission has determined that the public interest factors do not preclude issuance of a remedy. The Commission has set a bond in the amount of 100 percent (100%) of the entered value of infringing products imported during the period of Presidential review (19 U.S.C. 1337(j)).

The Commission issues its opinion herewith setting forth its determinations on certain issues. This investigation is hereby terminated.

The Commission's orders and opinion were delivered to the President and United States Trade Representative on the day of their issuance.

The Commission vote for this determination took place on November 4, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.
Issued: November 4, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–22768 Filed 11–6–26; 8:45 am]

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DEPARTMENT OF JUSTICE

Antitrust Division

United States of America, et al. v. RealPage, Inc., et al.; Response of the United States to Public Comments

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that the Response of the United States to Public Comments on the Proposed Final Judgment in *United States of America et al.* v. *RealPage et al.,* Civil Action No. 24–cv–00710, regarding Defendant Willow Bridge Property Company, LLC, has been filed in the United States District Court for the Middle District of North Carolina, together with the comments. Copies of the public comments and the United States' Response are also available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr.*

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

In the United States District Court for the Middle District of North Carolina

UNITED STATES OF AMERICA Plaintiff, vs. *WILLOW BRIDGE PROPERTY COMPANY, LLC,* Defendant.

No. 1:24–cv–00710

Response of Plaintiff United States to Public Comments on the Proposed Final Judgment

Pursuant to the requirements of the Antitrust Procedures and Penalties Act (the ''APPA'' or ''Tunney Act''), 15 U.S.C. 16(b)–(h), the United States submits this response to the two public comments received regarding the proposed Final Judgment as to Defendant Willow Bridge Property Company, LLC (Doc. 200–1).[1]

After careful consideration of the submitted comments, the United States continues to believe that the proposed Final Judgment will provide an effective and appropriate remedy for the antitrust violations alleged in the Complaint.

After this response and the public comments have been published in the **Federal Register** pursuant to 15 U.S.C § 16(d), the United States will move the Court to enter the proposed Final Judgment.

I. Procedural History

On August 23, 2024, the United States, along with several States (''Plaintiffs''), filed a civil antitrust Complaint against RealPage, Inc. (''RealPage'') (Doc. 1). On January 7, 2025, Plaintiffs amended their civil Complaint (the ''Complaint'') to add Willow Bridge Property Company, LLC (''Willow Bridge'') and five other landlords as Defendants (Doc. 47) alleging that Willow Bridge's agreements with RealPage and other landlords to share information and align pricing violate Section 1 of the Sherman Act, 15 U.S.C. 1. The Complaint seeks to enjoin Defendants from sharing and exploiting competitively sensitive data.

On July 6, 2026, the United States filed a proposed Final Judgment (Doc. 200–1) as to Willow Bridge, which is designed to remedy the loss of competition alleged in the Complaint due to Willow Bridge's conduct, and a Stipulation and Proposed Order (Doc. 200), in which Willow Bridge consented to entry of the proposed Final Judgment after compliance with the requirements of the Tunney Act.[2] Also on the same date, the United States filed a Competitive Impact Statement describing the proposed Final Judgment as to Willow Bridge. (Doc. 202)

The United States arranged for the publication of the Complaint, proposed Final Judgment, and Competitive Impact Statement in the **Federal Register** on July 16, 2026, see 15 U.S.C. 16(b)–(c); 91 FR 43,774 (July 16, 2026), and caused notice regarding the same, together with directions for the submission of written comments relating to the proposed Final Judgment, to be published in the *Washington Post* and the *Greensboro News and Record* from July 14 to July 21, 2026. The 60-day period for public comment has now ended. The United States received two comments in response, which are described below and attached as Exhibits 1 & 2 hereto.

II. The Complaint and The Proposed Final Judgment

The Complaint alleges that, by unlawfully sharing its confidential and competitively sensitive information with RealPage for use in its and competing landlords' pricing, Willow Bridge violated Section 1 of the Sherman Act, 15 U.S.C. 1. Under their licensing agreements with RealPage, Willow Bridge and competing landlords have provided RealPage with daily, competitively sensitive, nonpublic information for use in RealPage's revenue management software relating to the landlords' leasing businesses, including details like how many leases have been renewed, for what terms, and at what price. The transactional data that Willow Bridge and other landlords have agreed to provide to RealPage includes current, forward-looking, granular, and highly competitively sensitive information. RealPage has

[1] The United States has redacted personally identifiable information from the comments prior to filing them with this response. If the Court requests unredacted versions, the United States will provide unredacted comments under seal.

[2] The Stipulation and Proposed Order, and the proposed Final Judgment, pertain only to Willow Bridge's conduct. They do not propose to resolve the anticompetitive conduct alleged in the Complaint against any other Defendant. Nor do they resolve the claims of any other Plaintiff besides the United States.

used Willow Bridge's competitively sensitive, nonpublic information to influence rental prices and other recommendations across rental properties managed by competing landlords. Willow Bridge's rental prices and related recommendations were likewise influenced by its competitors' competitively sensitive, nonpublic information obtained from RealPage. In each relevant market, RealPage and participating landlords, including Willow Bridge, have sufficient market power, including market and data penetration, to harm renters and the competitive process through this unlawful sharing of confidential and competitively sensitive information. Moreover, Willow Bridge and other landlords can achieve any procompetitive objective of revenue management software without sharing this kind of information.

The Complaint also alleges that Willow Bridge and other landlords, by adopting and using RealPage's revenue management software, agreed with RealPage to align their pricing and thereby violate Section 1 of the Sherman Act, 15 U.S.C. 1. RealPage has entered into agreements with Willow Bridge and its competing landlords relating to how to price rental units, including through the licensing of its revenue management software—AI Revenue Management (''AIRM''), YieldStar, and Lease Rent Options (''LRO'')—to landlords, and the provision by landlords of their competitively sensitive, nonpublic transactional data to RealPage for training and running its revenue management software. Adoption and use of RealPage's revenue management software by Willow Bridge and other landlords have the likely effect of causing competing landlords to employ the same or very similar strategies, processes, and decisions relating to their pricing of rental units. Willow Bridge and other landlord users understand this likely effect, which here dampens the competitive process that benefits renters.

The proposed Final Judgment imposes several requirements and restrictions on Willow Bridge that address the United States' anticompetitive concerns regarding Willow Bridge's conduct alleged in the Complaint. Specifically:

i. Willow Bridge must not license or use any revenue management product that uses third-party nonpublic data to recommend or set prices;

ii. Willow Bridge must not license or use any revenue management product that pools information from Willow Bridge properties that have different owners;

iii. Willow Bridge must not disclose, solicit, or use competitively sensitive information from competitors that can be used to set rental prices or generate pricing;

iv. Willow Bridge must cooperate in this civil antitrust proceeding (*United States et al.* v. *RealPage et al.*);

v. Willow Bridge must adopt a written antitrust compliance policy and designate a chief antitrust compliance officer who will train Willow Bridge employees on the policy;

vi. Willow Bridge must allow the United States to inspect its documents and to interview its employees to ensure compliance with the Final Judgment;

vii. If Willow Bridge uses a revenue management product, Willow Bridge will be subject to a monitor unless Willow Bridge obtains a certification that meets certain requirements, including an affirmation that the product complies with all required limitations regarding use of competitors' competitively sensitive data; and

viii. If, in the future, the Court finds that Willow Bridge has violated the terms of the proposed Final Judgment, Willow Bridge will be subject to a court-appointed monitor.

Under the terms of the Stipulation and Order, Willow Bridge must abide by and comply with the provisions of the proposed Final Judgment until it is entered by the Court or until the time for all appeals of any Court ruling declining entry of the proposed Final Judgment has expired.

The United States and Willow Bridge have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the APPA. Entry of the proposed Final Judgment will terminate this action with respect to the United States' claims against Willow Bridge, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof by Willow Bridge.

III. Standard of Judicial Review

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the Tunney Act as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one, as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States* v. *Hewlett Packard Enterprise Co.,* No. 25–CV–00951–PCP, 2026 WL 2349970, at *16 (N.D. Cal. Aug. 12, 2026); *United States* v. *U.S. Airways Grp., Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that a court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable''); *United States* v. *Keyspan Corp.,* 763 F. Supp. 2d 633, 637–38 (S.D.N.Y. 2011); *see SEC* v. *Citigroup Global Markets Inc.,* 673 F.3d 158, 168 (2d Cir. 2012) (''We are bound in such matters to give deference to an executive agency's assessment of the public interest.'').

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA, a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62; *United States* v. *Apple, Inc.,* 889 F. Supp. 2d 623, 631 (S.D.N.Y. 2012) (citing *Microsoft,* 56 F.3d at 1458, 1461–62). With respect to the adequacy of the relief secured by the proposed

Final Judgment, a court may ''not make de novo determination of facts and issues.'' *United States* v. *W. Elec. Co.,* 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead, ''[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General.'' *W. Elec. Co.,* 993 F.2d at 1577 (quotation marks omitted). ''The court should bear in mind the *flexibility* of the public interest inquiry: the court's function is not to determine whether the resulting array of rights and liabilities is one that will *best* serve society, but only to confirm that the resulting settlement is within the *reaches* of the public interest.'' *Microsoft,* 56 F.3d at 1460 (quotation marks omitted); *see also United States* v. *Deutsche Telekom AG,* No. 19–2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would ''have enormous practical consequences for the government's ability to negotiate future settlements,'' contrary to congressional intent. *Microsoft,* 56 F.3d at 1456. ''The Tunney Act was not intended to create a disincentive to the use of the consent decree.'' *Id.*[3]

''Because enforcement by consent decree is an alternative to enforcement by trial or abandonment of the litigation altogether and often reflects the United States's assessment of litigation risk, a proposed settlement does not need to replicate the full relief that [the] United States sought in its complaint.'' *Hewlett Packard Enter.,* 2026 WL 2349970, at *17. The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft,* 56 F.3d at 1461 (recognizing courts should give ''due respect to the Justice Department's . . . view of the nature of its case''); *United States* v. *Iron Mountain, Inc.,* 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) (''In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'') (internal citations omitted); *United States* v. *Republic Servs., Inc.,* 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting ''the deferential review to which the government's proposed remedy is accorded''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (''A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case''). In determining whether a proposed settlement is in the public interest, a district court ''is not permitted to reject the proposed remedies merely because the court believes other remedies are preferable.'' *United States* v. *Morgan Stanley,* 881 F. Supp. 2d 563, 567 (S.D.N.Y. 2012) (quoting *United States* v. *Abitibi–Consol. Inc.,* 584 F. Supp. 2d 162, 165 (D.D.C. 2008)). The ultimate question is whether ''the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.' '' *Microsoft,* 56 F.3d at 1461 (*quoting W. Elec. Co.,* 900 F.2d at 309).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *United States* v. *Keyspan Corp.,* 763 F. Supp. 2d 633 637–38 (S.D.N.Y. 2011) (''The Court's function is not to determine whether the proposed [d]ecree results in the balance of rights and liabilities that is the one that will best serve society, but only to ensure that the resulting settlement is 'within the reaches of the public interest.'' (quoting *United States* v. *Alex. Brown & Sons, Inc.,* 963 F. Supp. 235, 238 (S.D.N.Y. 1997)); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60. *See also Heckler* v. *Chaney,* 470 U.S. 821, 832 (1985) (quoting U.S. Const. art. II, § 3) (recognizing that the decision about which claims to bring ''has long been regarded as the special province of the Executive Branch.'').

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using consent judgments proposed by the United States in antitrust enforcement, Public Law 108–237 § 221, and added the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). ''A court can make its public interest determination based on the competitive impact statement and response to public comments alone.'' *U.S. Airways,* 38 F. Supp. 3d at 76 (citing *Enova Corp.,* 107 F. Supp. 2d at 17).

IV. Summary of Public Comments and the United States' Response

The United States received two public comments in response to the proposed Final Judgment. The comments were submitted by private individuals, whom the United States will refer to by each individual's initials: MC (''MC Comment'') and JD (''JD Comment'').

A. The MC Comment

MC's comment requests that the United States consider whether the proposed Final Judgment adequately addresses the role of pricing algorithms in renewal pricing, including situations where renewal prices offered are materially higher than prices quoted to prospective tenants for the same apartment unit, and ''whether monitoring under the decree should

[3] *See also United States* v. *BNS, Inc.,* 858 F.2d 456, 464 (9th Cir. 1988) (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass'').

examine the differences between renewal and new-tenant prices.'' [4] The terms of the proposed Final Judgment with Willow Bridge do not make a distinction between renewal pricing and new-tenant pricing. Therefore, the limitations imposed on the use, disclosure, pooling, combination, or training of Nonpublic Data apply equally to recommendations regarding renewal pricing and new-tenant pricing generated by revenue management software.[5]

Furthermore, the Complaint did not allege anticompetitive conduct related to differences between renewal pricing and new-tenant pricing. (*See, e.g.,* Doc. 47, ¶ 62 (''Every morning, the landlord's property manager chooses whether to accept the floor plan price recommendation, keep the previous day's rent, or override the recommendation. These options are the same for new leases and renewal leases.'') & ¶ 107 (''Specifically, he urged the group to 'push up new and renewal pricing where demand [is] solid' and warned against over-relying on concessions. They were instead to 'trust the science' of YieldStar.'').) MC's requests therefore are not relevant to the United States' claims and not germane to Tunney Act review.

The fact that Willow Bridge may choose to price its apartment units differently to existing tenants and prospective tenants does not, in of itself, present a competitive concern, absent evidence that such a pricing strategy uses Nonpublic Data shared by Willow Bridge's competitors or aligns with the pricing strategy used by Willow Bridge's competitors in a local rental market. The terms of the proposed Final Judgment ensure that any differential pricing of renewals and new leases by Willow Bridge is not a result of the types of anticompetitive conduct alleged in the Complaint.

MC further requests that the United States consider whether the proposed Final Judgment should require Willow Bridge to provide notification to tenants on a property's use of ''automated revenue management systems.'' [6] Such a requirement would go beyond addressing the United States' claims regarding the sharing of competitively sensitive data among landlords and the use of revenue management software to align their pricing. The use of an ''automated revenue management system'' or software with a rental property, standing alone, does not raise competitive concerns. What matters is whether such a system or software is being trained on or otherwise uses Nonpublic Data shared by Willow Bridge's competitors and whether such a system or software, during operation, ''automates'' pricing recommendations and/or decision-making for Willow Bridge and its competitors who are also using the system or software. The proposed Final Judgment effectively addresses such scenarios associated with Willow Bridge's use of an ''automated revenue management system.'' More is therefore not required.

Finally, MC requests that the United States consider whether the proposed Final Judgment should require Willow Bridge to provide ''meaningful human review'' of renewal prices.[7] Similar to MC's other requests, this request questions whether a landlord like Willow Bridge should be allowed to use revenue management software, and specifically software that may automatically generate pricing recommendations for renewals and new leases. As explained above, the United States' Complaint does not allege that Willow Bridge's use of a revenue management system or software, standing alone, is anticompetitive. What matters is whether such a system or software is being trained on or otherwise uses Nonpublic Data shared by Willow Bridge's competitors and whether such a system or software, during operation, ''automates'' pricing recommendations and/or decision-making for Willow Bridge and its competitors who are also using the system or software. The proposed Final Judgment effectively addresses such scenarios associated with Willow Bridge's use of revenue management software, and a requirement of ''meaningful human review'' is neither relevant nor necessary to address the competitive concerns raised by the Complaint.

B. The JD Comment

JD first requests that the United States investigate whether their specific rental property uses a RealPage or other third-party revenue management product and whether their specific property's rental prices were calculated with the use of competitively sensitive information.[8] JD further requests that the United States explain ''whether potentially affected renters will have any process to learn whether their property or its data was within the investigation or remedial program.'' [9] A renter can ''evaluate whether the decree protects that renter.'' [10] In the United States' judgment, the type of process requested by JD is not necessary. The proposed Final Judgment applies to *all* conventional multifamily rental properties, located within the United States or its territories, that are serviced by Willow Bridge (defined as ''Willow Bridge Properties'').[11] It therefore would apply to JD's specific rental property if it is a Willow Bridge Property. As for JD's request for any investigative information specific to their rental property, the United States is prohibited by statute from disclosing these materials.[12] The United States notes, however, that the Complaint identifies multiple geographic markets in Appendices A & B, which the public may consult to understand the scope and extent of the competitive harms being addressed by the proposed Final Judgment.

JD also requests that the proposed Final Judgment require independent technical verification of third-party revenue management products.[13] Although the proposed Final Judgment does not require independent technical verification, it requires third-party revenue management providers to provide certifications that the software complies with the terms of the proposed Final Judgment.[14] Furthermore, the United States has the right to obtain and inspect the code and pseudocode of Willow Bridge's proprietary revenue management software.[15]

JD recommends that the United States require Willow Bridge's internal annual audit to include a ''statistically and operationally meaningful sample.'' [16] The proposed Final Judgment requires an internal audit of employees ''engaged in or overseeing Willow Bridge's revenue management of multifamily rental properties in the United States and its territories,'' and at least 12 ''randomly selected, local, regional, or supervisory employees who manage property operations.'' [17] This is sufficient to capture the scope and diversity of Willow Bridge's revenue management operations, and there is no need to expand or otherwise modify the

[4] MC Comment at 2 (requests nos. 1, 2, and 5).

[5] Willow Bridge Proposed Final Judgment, ¶¶ IV.A–C and V.A.1 (Doc. 200–1).

[6] MC Comment at 2 (request no. 3).

[7] *Id.* at 2 (request no. 4).

[8] JD Comment at 1–2.

[9] *Id.* at 2.

[10] *Id.*

[11] Willow Bridge Proposed Final Judgment ¶ II.T (Doc. 200–1); Willow Bridge Competitive Impact Statement at 12 (Doc. 202).

[12] *See* 15 U.S.C. 1313(c)(3).

[13] JD Comment at 3.

[14] Willow Bridge Proposed Final Judgment ¶ V.E (Doc. 200–1).

[15] Willow Bridge Proposed Final Judgment ¶ X.D (Doc. 200–1).

[16] JD Comment at 3.

[17] Willow Bridge Proposed Final Judgment ¶ VII.A (Doc. 200–1).

audit requirement. Importantly, the proposed Final Judgment provides the United States broad rights to ensure compliance with the Final Judgment. These include access to ''electronic copies of all books, ledgers, accounts, records, data, and documents'' and to Willow Bridge's employees for interviews relating to any matters contained in the Final Judgment.[18]

JD also requests that Willow Bridge be required to provide a public annual compliance report. The compliance report should include, according to the commenter, ''the number of properties and units under each category of revenue-management product'' and information regarding compliance and corrective actions.[19] An annual compliance report of this nature is not necessary. Moreover, such a report would be at odds with the proposed Final Judgment's prohibitions against public disclosure of information and documents obtained pursuant to any of its provisions.[20] Disclosure would also create a risk that competitively sensitive information relating to Willow Bridge will be made public which could lead to coordination among competing landlords.

JD recommends that the proposed Final Judgment make ''unmistakably clear'' that structured datasets containing competitors' nonpublic information may not be accessed, used, combined, retained without controls, and require ''documented segregation, access restriction, deletion or defensible inaction, and testing to prevent legacy data from entering recommendations or model training.'' [21] The proposed Final Judgment already includes such a provision. Paragraph VI.C. of states that Willow Bridge must not ''use or access, as part of setting rental prices or generating rental pricing recommendations for any Willow Bridge property, any External Nonpublic Data . . . including such data derived from any RealPage Revenue Management Product.'' [22]

JD also points to the definition of ''Willow Bridge Property'' and notes that it excludes ''student, affordable, age-restricted or senior, and military housing.'' [23] The commenter requests that if ''operational differences justify particular exceptions, those exceptions should be narrowly tailored.'' The United States' Complaint alleges a product market for conventional multifamily conventional housing that does not include student, age-restricted, and military housing (Doc. 47, ¶ 183). This portion of the commenter's request is therefore outside the scope of the Complaint and is not subject to Tunney Act consideration.

JD proposes that early termination of the Final Judgment by the United States should be based on a ''reasoned public determination,'' and involve a process that includes ''public notice.'' [24] The proposed Final Judgment already provides that a request for early termination would involve a public notice to the Court (and to Willow Bridge) that continuation of the Final Judgment is no longer necessary or in the public interest.[25]

JD questions the proposed Final Judgment's cap of 15 employees and 60 total hours for cooperation with the litigation.[26] This comment fails to recognize that cooperation is not the only way that the United States can develop evidence. In any investigation or litigation, the United States always has procedural tools to compel the production of documents and testimony.[27] The cap in the proposed Final Judgment, which is the product of a negotiated settlement, does not in any way hamstring the United States' ability to obtain discovery in its litigation against any other defendant in this action.

Finally, JD asks why the proposed Final Judgment does not include any monetary relief.[28] The proposed Final Judgment does not provide for restitution because it is not one of the remedies sought by the United States in its Complaint.

* * * * *

To the extent that commenters wish to raise the possibility of additional unlawful conduct not addressed by the Complaint brought in this matter, members of the public are encouraged to submit information about any antitrust violation, including potentially unlawful exchanges of information between competitors, to the Department of Justice Antitrust Division's Citizen Complaint Center (*https://www.justice.gov/atr/webform/pcsf-citizen-complaint*).

V. Conclusion

After careful consideration of the public comments, the United States continues to believe that the proposed Final Judgment provides an effective and appropriate remedy for the antitrust violations alleged in the Complaint against Willow Bridge and is therefore in the public interest. The United States will move this Court to enter the proposed Final Judgment after the comments and this response are published in a manner approved by the Court, as required by 15 U.S.C. 16(d).

Dated: November 5, 2026
Respectfully submitted,
By: /s/ Henry C. Su

Henry C. Su,
David A. Geiger,
Danielle G. Hauck
Attorneys
United States Department of Justice, Antitrust Division, 450 Fifth Street NW, Suite 7100, Washington, DC 20530, Telephone: (202) 307–6200, Email: *henry.su@usdoj.gov*.

Certificate of Service

I hereby certify that on November 5, 2026, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

By: /s/ Henry C. Su
/s/ Henry C. Su
Henry C. Su

Certificate of Word Count

I hereby certify that, based on the word count tool in Microsoft Word, the foregoing document contains 4,814 words, exclusive of the caption, signature lines, certificate of service, and any cover page or index, and it therefore complies with the limitation on length set forth in Local Civil Rule 7.3(d).
Dated: November 5, 2026

By: /s/ Henry C. Su
/s/ Henry C. Su
Henry C. Su

EXHIBIT 1—MC Comment (Redacted)

From: [REDACTED]
To: ATR-Public-Comments-Tunney-Act-MB
Subject: [EXTERNAL] Public Comment—Willow Bridge Proposed Final Judgment—1:24–cv–00710
Date: Monday, September 14, 2026 11:54:14 p.m.
Attachments: image0.png, image1.png, image2.png, image3.png

Good evening,

I am submitting this comment regarding the proposed Final Judgment involving Willow Bridge Property Company LLC in *United States et al.* v. *RealPage, Inc. et al.,* Civil Action No. 1:24–cv–00710.

I am a current resident of [REDACTED] in Dallas, Texas, a Willow Bridge-managed community.

My current lease expires [REDACTED]. On [REDACTED], I received a renewal offer for my apartment that included the following rates:

[18] Willow Bridge Proposed Final Judgment ¶ X.A (Doc. 200–1).

[19] JD Comment at 3–4.

[20] Willow Bridge Proposed Final Judgment ¶ XI (Doc. 200–1).

[21] JD Comment at 4.

[22] Willow Bridge Proposed Final Judgment ¶ VI.C (Doc. 200–1).

[23] JD Comment at 4.

[24] *Id.*

[25] Willow Bridge Proposed Final Judgment ¶ XIV (Doc. 200–1).

[26] JD Comment at 4.

[27] *See* 15 U.S.C. 1312, Fed. R. Civ. P. 30, 34 & 45.

[28] JD Comment at 4.

10 months—$1,734/month
11 months—$1,628/month
13 months—$1,622/month
14 months—$1,629/month
15 months—$1,631/month

I recently checked my property's public website and discovered that my exact apartment, is already being marketed to a prospective new resident, with availability beginning [REDACTED].

The publicly advertised rates for Apartment [REDACTED] include:

10 months—$1,536/month
11 months—$1,526/month
13 months—$1,517/month
14 months—$1,524/month
15 months—$1,527/month
16 months—$1,517/month

Thus, Willow Bridge is currently offering prospective new renters materially lower rents for the exact same apartment than it offered me to remain in the apartment. Additionally, a concession of 4 weeks free is being offered to all one bedroom floor plans that has been explicitly denied to me.

For example, my 10-month renewal rate was $1,734, while the publicly advertised 10-month rate for my apartment is $1,536—a difference of $198 per month. My 14-month renewal rate was $1,629 compared with an advertised $1,524, and my 15-month renewal rate was $1,631 compared with an advertised $1,527.

I have screenshots of the public listing and a copy of my written renewal offer documenting these amounts.

I do not know whether my renewal rates or the currently advertised rates were generated, recommended, or influenced by RealPage, AIRM, YieldStar, or another revenue-management system. I am not asserting that this pricing discrepancy alone proves an antitrust violation.

However, because the government's allegations against Willow Bridge concern algorithmic rental pricing and the use of competitively sensitive information in determining rents, I believe this current pricing experience is relevant to whether the proposed Final Judgment adequately protects renters.

In particular, I respectfully ask the Department to consider whether the proposed decree adequately addresses:

1. pricing algorithms used for lease renewals, not merely rents quoted to prospective tenants;

2. situations in which incumbent tenants are offered materially higher prices than the contemporaneous public price for their own apartment;

3. whether tenants should be told when an automated revenue-management system materially influenced their renewal rate;

4. whether Willow Bridge should be required to provide meaningful human review of renewal prices; and

5. whether monitoring under the decree should examine differences between renewal pricing and new-tenant pricing at the same property.

I am providing this information so that the Department and Court have the benefit of a current Willow Bridge resident's experience while evaluating whether the proposed relief is sufficient to protect competition and renters.

Thank you for considering my comment.
[REDACTED]
Dallas, Texas

[Screenshots Redacted]

Exhibit 2—JD Comment (Redacted)
From: [REDACTED]
To: ATR-Public-Comments-Tunney-Act-MB
Subject: [EXTERNAL] Public Comment—Proposed Willow Bridge Final Judgment—*U.S.* v. *RealPage*, No. 1:24–cv–00710
Date: Friday, September 11, 2026 1:27:48 p.m.

Dear Ms. Hauck:

I am a [REDACTED] resident of [REDACTED] in Chula Vista, California, a multifamily community publicly listed/managed by Willow Bridge Property Company.

I have lived at [REDACTED] for approximately one year, and Willow Bridge has managed the community throughout my residency. My own tenancy has raised unresolved financial and pricing-related concerns involving Willow Bridge's administration of rent and other housing charges. I do not claim in this comment that those concerns resulted from RealPage, competitor data, or an antitrust violation. They are why the adequacy and verifiability of this decree are concrete questions for me rather than abstract policy concerns. I am willing to provide relevant records through a nonpublic channel if the Department determines that a property-level inquiry is warranted.

I respectfully ask the Antitrust Division to *strengthen the proposed Final Judgment with Willow Bridge Property Company LLC,* or explain on the public record why the existing provisions are sufficient, before asking the Court to find the settlement in the public interest.

My relationship to a Willow Bridge-managed community explains why the decree matters to me; it is not offered as evidence that the alleged antitrust conduct occurred at [REDACTED]. This comment relies only on the public record: the amended complaint, proposed Final Judgment, Competitive Impact Statement, **Federal Register** notice, Willow Bridge's public property listing, and the Department's public case materials. It does not ask the Department to decide any private tenancy dispute. The amended complaint contains allegations, not adjudicated facts, and Willow Bridge's consent to the proposed judgment is not an admission of liability. Those limits make independent verification of future compliance more important, not less.

Property-Specific Public-Interest Question: [REDACTED]

My concern is not abstract. Willow Bridge's current public website presents [REDACTED] as one of its communities. The California Department of Real Estate currently lists the [REDACTED] address as a branch of Willow Bridge Management Inc., a corporation using the DBAs ''Willow Bridge'' and ''Willow Bridge Property Company.'' A 2022 City of Chula Vista staff report described [REDACTED] as a [REDACTED] property owned by John Hancock Life Insurance Company (U.S.A.) since 2015. I cite the City report as a dated public representation, not as proof of current title.

DOJ's amended complaint alleges that Willow Bridge used RealPage's AIRM and YieldStar products. It also alleges more broadly that RealPage obtained confidential transactional data through products including OneSite, Performance Analytics with Benchmarking, and Business Intelligence—including data from units that did not necessarily use AIRM or YieldStar—and made such data available for pricing recommendations. The complaint does not identify [REDACTED] or Chula Vista, and I do not claim that [REDACTED] used any of these products or that its data entered the challenged system. The absence of property-level public information is precisely why I ask DOJ to examine the question.

I respectfully request that the Department, within its existing investigative, preservation, and compliance authority:

1. determine whether [REDACTED] used AIRM, YieldStar, LRO, OneSite, Performance Analytics with Benchmarking, Business Intelligence, or another RealPage or third-party revenue-management or data product during the period relevant to the complaint and proposed judgment;

2. determine whether [REDACTED] nonpublic rents, concessions, applications, lease terms, renewals, occupancy, availability, or other competitively sensitive information were transmitted, pooled, benchmarked, used for model training, or made available to generate recommendations for [REDACTED] or competing properties;

3. determine whether pricing or leasing recommendations used at [REDACTED] were influenced by competitors' nonpublic information;

4. preserve the relevant property-level contracts, product records, data-flow records, configurations, recommendations, overrides, communications, and audit trails, and ensure that the decree's legacy-data and compliance provisions reach [REDACTED] and similarly situated properties managed for third-party owners; and

5. to the extent consistent with law-enforcement and confidentiality constraints, explain in DOJ's response to public comments whether potentially affected renters will have any process to learn whether their property or its data was within the investigation or remedial program.

These requests do not assume the answers. They ask DOJ to test a concrete property against the precise data flows, products, owner-manager relationships, and renter harms alleged in its own complaint.

They also expose a practical transparency problem: a renter cannot evaluate whether the decree protects that renter if property-level coverage is known only to Willow Bridge, its vendors, and the government.

Voucher-Assisted Residents and Public Funds

[REDACTED] makes the property-level pricing question more consequential. In the federal [REDACTED] program, the public housing agency may not approve the initial rent until it determines that the rent to owner

is reasonable, must redetermine reasonableness before an increase, and must compare the requested rent with comparable unassisted units. The payment standard and gross rent also affect the housing-assistance-payment calculation. See 24 CFR 982.505 and 982.507.

Accordingly, if competitor-informed or algorithmically influenced pricing affected a requested initial rent, renewal increase, comparable-unit submission, concession, or other pricing input for a voucher-assisted unit, the effects could reach the resident's housing cost, the agency's rent-reasonableness process, and the expenditure of public subsidy funds. I do not assert that this occurred in my tenancy. I ask DOJ to determine whether it occurred at [REDACTED] or other Willow Bridge-managed properties and, if the evidence indicates an effect on assisted units or agency rent determinations, to coordinate as appropriate with HUD and the administering public housing agencies.

The final judgment should also require Willow Bridge to identify whether covered products or data practices were used in connection with voucher-assisted units at otherwise conventional properties. Its exclusion of ''affordable housing'' must not be interpreted to remove an entire conventional property—or individual units—from the decree merely because some residents use tenant-based rental assistance.

I have separately submitted housing-accountability reports to the HUD Office of Inspector General and VA Office of Inspector General and initiated a housing intake with the California Civil Rights Department. These are distinct processes. I do not represent that any of those agencies has opened an investigation, accepted a formal complaint, or made findings. I identify them only because overlapping voucher, rent, property-management, and communications records may warrant preservation or appropriate interagency referral if DOJ identifies a nexus to the conduct alleged in this case.

The proposed judgment contains meaningful protections. It broadly restricts the use and disclosure of competitors' nonpublic, property-specific information; limits revenue-management products that pool data across different owners; prohibits agreements with other property managers or owners to use a product; restricts price floors, automatic acceptance, and financial incentives tied to accepting recommendations; bars participation in RealPage meetings; preserves Department inspection rights; and provides contempt and cost-shifting remedies. These are material safeguards.

The public-interest question, however, is whether those safeguards can be verified and enforced across Willow Bridge's national operating footprint. The Competitive Impact Statement states that Willow Bridge manages more than 240,000 units. Against that scale, several provisions appear too dependent on self-reporting, vendor assurances, small samples, and nonpublic oversight.

1. Require Independent Technical Verification and an Initial Monitoring Period

The proposed judgment permits Willow Bridge to use a third-party revenue-management product if the provider certifies that the product meets the decree's requirements. It also appears to permit use of a RealPage product without a separate certification if a final judgment is entered against RealPage. A monitoring trustee is not automatic: monitoring is principally tied to use of an uncertified product or a judicial finding of a violation.

Vendor certification is useful evidence, but it is not independent verification. The alleged conduct involved data flows, model training, product settings, information exchanges, and operational practices that can change after a certification is issued. Reliance on a separate judgment against RealPage also does not establish that Willow Bridge's configuration and use of a product are compliant in practice.

I ask the Department to require:

—independent technical validation before initial use and after material product, model, data-source, or configuration changes;
—testing of actual data inputs, model-training data, access controls, recommendation settings, overrides, and outputs—not only review of a vendor's written representations; and
—an independent monitoring trustee for at least the first two years, with risk-based authority to examine products and practices whether or not a violation has already been proved.

If the Department believes these protections are unnecessary, its response should explain how vendor certification and a contingent monitor provide equivalent assurance.

2. Scale the Audit Program to Willow Bridge's Footprint and Risk

The proposed judgment requires an annual audit of revenue-management personnel and at least 12 randomly selected local, regional, or supervisory property-operations employees. A minimum sample of 12 employees is difficult to reconcile with a company managing more than 240,000 units. Random selection alone can also miss markets, properties, transition periods, or teams presenting the greatest risk.

The final judgment should require a statistically and operationally meaningful sample tied to the number of properties, units, markets, products, and owners involved. The sample should include risk-based selections, not merely random ones, and should test management transitions, complaints, unusual override patterns, product changes, and markets where multiple competing properties use the same software. The audit should examine owners' instructions and approvals when those instructions affect product use or pricing practices.

3. Add Public, Aggregated Compliance Reporting

The proposed judgment gives the Department access to significant nonpublic information, but it does not appear to require a public annual compliance report. Monitoring reports are generally protected from disclosure, and the public may never learn whether a monitor was appointed, what products were used, whether violations were detected, or whether corrective action occurred.

Confidential business information should remain protected. But confidentiality does not require complete public opacity. The final judgment should require an annual public report stating, in aggregated and noncommercial terms:

—the number of properties and units using each category of revenue-management product;
—the number and type of audits, technical tests, complaints, and substantiated violations;
—the general nature and completion status of corrective actions;
—whether a monitoring trustee is serving and the scope of completed review; and
—whether the Department has granted, rejected, or conditioned any request affecting compliance.

Public reporting would allow affected renters and the Court to assess whether the decree is functioning without disclosing rents, algorithms, personal data, or competitively sensitive information.

4. Clarify Legacy-Data Controls and the Housing-Category Exclusions

The proposed judgment requires Willow Bridge to identify certain structured datasets containing competitors' nonpublic information, but states that the identification provisions do not apply to data maintained in OneSite, Yardi Voyager, or other property-management software. The final judgment should make unmistakably clear that this storage-location language is not permission to access, use, combine, retain without controls, or repurpose prohibited information. It should require documented segregation, access restriction, deletion or defensible inactivation, and testing sufficient to prevent legacy data from entering recommendations or model training.

The definition of ''Willow Bridge Property'' also excludes student, affordable, age-restricted or senior, and military housing. The public record should explain why residents and owners in those sectors do not require the decree's core protections against competitor data exchange and cross-owner pooling. The judgment should also clarify that an otherwise conventional multifamily property is not excluded merely because individual households use tenant-based rental assistance. If operational differences justify particular exceptions, those exceptions should be narrowly tailored; the core information-sharing prohibitions should apply wherever the competitive risk exists.

5. Condition Any Early Termination on a Public Compliance Record

The proposed judgment lasts five years but permits termination after three years upon notice by the United States. Early termination should require a reasoned public determination based on completed independent testing, a record of corrective action, and the absence of unresolved material violations. The Department should provide public notice before early termination and give the Court and the public a meaningful opportunity to assess the compliance record.

6. Explain the Limits of the Remedy and Cooperation Provisions

The proposed judgment requires cooperation but caps voluntary interviews under that provision at 15 employees and 60 total hours. Formal discovery and civil investigative demands remain available. Even so, given the alleged duration, nationwide scope, and technical nature of the conduct, the Department should explain why those ceilings are appropriate for voluntary cooperation, or replace them with a reasonable-necessity standard.

The Competitive Impact Statement also recognizes that private parties may pursue damages and that the proposed judgment will have no prima facie effect in private litigation. The settlement contains no restitution or monetary relief for renters. I recognize that a Tunney Act review is not an individual claims process and that the Court's role is not to rewrite the government's case. Still, the Department should explain why forward-looking relief without monetary redress is adequate in light of the complaint's allegations and what public compliance information will allow potentially affected renters to understand whether the challenged practices have actually stopped.

Requested Disposition

I respectfully ask the Department to modify the proposed Final Judgment to include the safeguards above before entry. At minimum, the Department's response to public comments should address each concern with enough specificity for the Court to evaluate whether the decree's verification, transparency, duration, coverage, and cooperation provisions are adequate for a company of Willow Bridge's scale.

The decree should not depend on the public simply trusting the participants and vendors whose future conduct it is designed to constrain. Durable relief requires independent testing, proportionate auditing, limited but meaningful transparency, and a public basis for any early termination.

Respectfully submitted,

[REDACTED]

Sources Used:

1. U.S. Department of Justice, Antitrust Division, case page, *U.S. and Plaintiff States v. RealPage, Inc.*, updated Sept. 4, 2026: *https://www.justice.gov/atr/case/us-and-plaintiff-states-v-realpage-inc*
2. Proposed Final Judgment as to Willow Bridge Property Company LLC, filed July 6, 2026:
3. Competitive Impact Statement as to Willow Bridge Property Company LLC, filed July 6, 2026: *https://www.justice.gov/atr/media/1451166/dl*
4. Amended Complaint, filed Jan. 7, 2025: *https://www.justice.gov/atr/media/1383471/dl*
5. **Federal Register** public-inspection notice, scheduled for publication July 16, 2026: *https://public-inspection.federalregister.gov/2026-14345.pdf*
6. U.S. Department of Justice, ''Justice Department Reaches Proposed Settlement with Willow Bridge, One of America's Largest Landlords,'' July 7, 2026: *https://www.justice.gov/opa/pr/justice-department-reaches-proposed-settlement-willow-bridge-one-americas-largest-landlords*
7. Willow Bridge Property Company, [REDACTED]
8. California Department of Real Estate, Willow Bridge Management Inc., corporation license 01319176 and branch listing: *https://www2.dre.ca.gov/publicasp/pplinfo.asp?License_id=01319176*
9. City of Chula Vista, 2022 staff report describing [REDACTED]
10. Electronic Code of Federal Regulations, 24 CFR 982.505, housing-assistance-payment calculation: *https://www.ecfr.gov/current/title-24/subtitle-B/chapter-IX/part-982/subpart-K/section-982.505*
11. Electronic Code of Federal Regulations, 24 CFR 982.507, reasonable rent: *https://www.ecfr.gov/current/title-24/subtitle-B/chapter-IX/part-982/subpart-K/section-982.507--*

[REDACTED]

''It is impossible to think of anything at all in the world, or even beyond it, that could be considered good *without limitation* except a good will.''

—Immanuel Kant (Groundwork of the Metaphysics of Morals)

[FR Doc. 2026–22832 Filed 11–6–26; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Membership of the Senior Executive Service and Senior Professional Standing Performance Review Boards

AGENCY: Department of Justice.

ACTION: Notice of Department of Justice's standing members of the Senior Executive Service and Senior Professional Performance Review Boards.

SUMMARY: Pursuant to the requirements of 5 U.S.C. 4314(c)(4), the Department of Justice announces the membership of its 2026 Senior Executive Service (SES) and Senior Professional (SP) Standing Performance Review Boards (PRBs). The purpose of a PRB is to provide fair and impartial review of SES and SP performance appraisals, executive development plans, and award recommendations/pay adjustments. The PRBs will make recommendations regarding the final performance ratings to be assigned, SES/SP awards and/or pay adjustments to be awarded.

FOR FURTHER INFORMATION CONTACT: Noah Fortinsky, Director and Deputy Chief Human Capital Officer, Office of Human Capital, Justice Management Division, Department of Justice, Washington, DC 20530; (202) 445–8033.

Noah Fortinsky,

Deputy Chief Human Capital Officer.

2026 Federal Register

List of Names (Alphabetical Order)

Brown Cutlar, Shanetta Y
Gabby, John J
Garza, Fernando G
Haar, Daniel E
Jag, Rachel L
Jones, Timothy W
Malphrus, Garry D
Maxey, Peter M
McManus, Doug
Merkle, Phillip K
Miller, Gwendolyn S
O'Neal, Jason N
Pelletier, Johnathan
Sage, Jessica
Serano, Alessandra
Taylor II, William N

[FR Doc. 2026–22813 Filed 11–6–26; 8:45 am]

BILLING CODE 4410–CH–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0095]

Agency Information Collection Activities; Proposed eCollection; eComments Requested; Reinstatement of a Previously Approved Collection; Title: National Standards To Prevent, Detect, and Respond to Prison Rape Feedback Package

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Office of Justice Programs (OJP), Bureau of Justice (BJA), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until January 8, 2027.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Leanetta Jessie, 999 N Capitol St NE, *leanetta.jessie@usdoj.gov;* or (202) 598–1160.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should

address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the (component), including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Reinstatement of a previously approved collection.

2. *The Title of the Form/Collection:* Prison Rape Elimination Act (PREA).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* OMB #1105–0095.

Affected Public who will be asked or required to respond, as well as a brief abstract:

Affected Public: Federal, State, and Tribal.

Abstract: The information collected through the PREA OAS is used by DOJ-certified PREA auditors to assess whether confinement facilities comply with the PREA Standards. Facilities submit documentation and responses through the system, and auditors review those materials, conduct interviews, perform on-site assessments, evaluate compliance with individual standards, and prepare audit reports.

The information enables auditors to:

—Assess facility policies, procedures, and operational practices against PREA Standards;

—Verify implementation of safeguards designed to prevent, detect, and respond to sexual abuse and sexual harassment;

—Document compliance findings and corrective actions;

—Generate standardized audit reports; and

—Provide information necessary for DOJ oversight of PREA auditors and PREA implementation efforts nationwide.

The information collection also supports state and local correctional agencies in demonstrating compliance with PREA and assists states, territories, and the District of Columbia in meeting statutory certification requirements associated with PREA implementation.

4. *Obligation to Respond:* Affected public the affected public are individuals. The obligation to respond is voluntary.

5. *Total Estimated Number of Respondents:* 13,000. One PREA Coordinator per facility.

6. *Estimated Time per Respondent:* 8 Hours.

7. *Frequency:* Once every three years.

8. *Total Estimated Annual Time Burden:* 104,000 hours.

9. *Total Estimated Annual Other Costs Burden:*

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Enterprise Portfolio Management, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: November 5, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–22816 Filed 11–6–26; 8:45 am]

BILLING CODE 4410–18–P

OFFICE OF PERSONNEL MANAGEMENT

Privacy Act of 1974; System of Records

AGENCY: U.S. Office of Personnel Management.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Office of Personnel Management (OPM) proposes to modify and republish in full a system of records previously titled ''OPM/Central-21, Federal Employee Viewpoint Survey'' which will be renamed ''OPM/Central-21, Annual Employee Survey.'' The modification is necessary to reflect the replacement of OPM's centrally administered Federal Employee Viewpoint Survey (FEVS) with the Annual Employee Survey (AES). Under the revised model, executive agencies administer the AES to their own employees and provide OPM and the Office of Management and Budget (OMB) only de-identified data for governmentwide analysis and reporting. OPM/Central-21 will cover identifiable records OPM maintains when administering the AES to OPM employees and retained records from prior FEVS administrations. It will not cover identifiable AES records maintained by other agencies.

DATES: Submit comments on or before December 9, 2026. These changes are effective December 10, 2026.

ADDRESSES: You may submit written comments using the Federal eRulemaking Portal at *https://www.regulations.gov.* All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* without change, including any personal identifiers.

FOR FURTHER INFORMATION CONTACT: For general questions, please contact Jeanne Jacobson, Acting Deputy Associate Director, Workforce Strategy, Design, and Insights, Workforce Policy and Innovation, by email at *wsdi@opm.gov* or by mail at Deputy Associate Director, Workforce Strategy, Design, and Insights, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415–0001.

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, the OPM proposes to modify and republish in full a system of records previously titled ''OPM/Central-21, Federal Employee Viewpoint Survey'' which will be renamed ''OPM/Central-21, Annual Employee Survey.''

Section 1128 of the National Defense Authorization Act for Fiscal Year 2004 requires executive agencies to conduct an annual employee survey and requires OPM to prescribe common survey questions. OPM previously administered the Federal Human Capital Survey and then the FEVS as centralized governmentwide surveys that included the required annual employee survey items. Beginning with the AES, each agency will administer OPM's common form questions to its own employees using the methodology and platform selected by that agency. Participating agencies may maintain the identifiers they use to administer their surveys. Agencies will submit to OPM and OMB only the following fields: individual respondent level records for each required AES item, survey methodology information as it applies (survey administration dates, distribution method, eligible population size and description, sample or census, number of respondents, survey completion requirements, sampling approach, sample size, nonresponse bias study results) and weighting

methodology as it applies (poststratification method and know limitations). The submission will contain aggregate responses and combine individual respondent level data at the agency level for the 10 required items. OPM will apply protections to ensure no individual employees can be identified in any governmentwide reporting. OPM will separately administer the AES to its own employees and may maintain limited identifying information for that administration. OPM will also continue to maintain legacy FEVS records until they are disposed of in accordance with applicable records schedules.

This notice changes the system name; updates the system location, system manager, authority, purpose, categories of individuals and records, record sources, storage, retrieval, retention, safeguards, and access and amendment procedures; and revises routine use (h). The revisions distinguish current AES records from legacy FEVS records and clarify that de-identified AES data received from other agencies are outside this system when they do not identify individual respondents and OPM does not retrieve them by an individual identifier.

In accordance with 5 U.S.C. 552a(r), OPM has provided notice of the modified system of records to the Office of Management and Budget and to Congress. The modified system of records will be included in OPM's updated inventory of record systems.

Signing Statement

The Director of OPM, Scott Kupor, reviewed and approved this document and has authorized the undersigned to electronically sign and submit this document to the Office of the Federal Register for publication.

U.S. Office of Personnel Management.

Alexys Stanley,

Federal Register Liaison.

SYSTEM NAME AND NUMBER:

OPM/Central-21, Annual Employee Survey.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained by Workforce Strategy, Design, and Insights, Workforce Policy and Innovation, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415–0001.

SYSTEM MANAGER(S):

Deputy Associate Director, Workforce Strategy, Design, and Insights, Workforce Policy and Innovation, U.S. Office of Personnel Management, 1900 E. Street NW, Washington, DC 20415–0001.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 1103 and 4702; section 1128 of the National Defense Authorization Act for Fiscal Year 2004, Public Law 108–136, set out as a note to 5 U.S.C. 7101; 5 CFR 5.2(b) and 9.2; and 5 CFR part 250, subparts B and C.

PURPOSE(S) OF THE SYSTEM:

The purpose of the system is to permit OPM to administer the voluntary Annual Employee Survey (AES) to OPM employees; determine eligibility and distribute invitations and reminders; collect and maintain voluntary survey responses; evaluate leadership, management practices, and employee satisfaction; analyze OPM's results; publish aggregate OPM survey results; and produce aggregate survey results or de-identified survey data for OMB's governmentwide analysis, workforce planning, and reporting. The system also permits OPM to maintain and analyze retained records from prior FEVS administrations for authorized statistical, workforce planning, research, reporting, and historical purposes. AES data received from other agencies are outside this system only when they do not identify an individual and OPM does not retrieve them by an individual's name, assigned identifying number or symbol, respondent code, linkage key, or other identifying particular. OPM will assess whether small groups or combinations of reported attributes could permit an individual to be identified and will require aggregation or suppression as needed. Removing direct identifiers alone does not make records de-identified if OPM can still link them to an individual.

OPM will provide its employees with a Privacy Act Statement with the AES invitation and survey instrument, identifying the authority, purposes, and routine uses of the collection; that participation is voluntary, and the effect of not responding. Agencies administering their own AES will provide an appropriate notice for their collections and separately assess applicable Privacy Act notice, privacy compliance documentation, and vendor requirements.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current or former OPM employees whose AES records are maintained in this system and current or former Federal employees whose records remain in retained legacy FEVS datasets.

CATEGORIES OF RECORDS IN THE SYSTEM:

Current AES records maintained by OPM may include:

a. Full name;

b. OPM work email address;

c. OPM organization, work unit name, or code;

d.The minimum employment information obtained from OPM personnel or human resources records that OPM uses to determine AES eligibility and assign results to organizational reporting units: Employment information needed to identify the survey population, survey eligibility, administer the survey, or calculate survey results, including tenure, type of appointment, appointment authority, service computation date, duty location, occupation classification or series, organizational/work component names and codes, pay status, work schedule, pay plan, pay grade, step, and supervisory status. ;

e. Responses to the AES common form questions and any OPM-approved supplemental questions; and

f. Survey administration and technical information retained by OPM:a system-generated survey record identifier, invitation and reminder status, completion status, date and time participant interacts with the survey, last page viewed, and information about the device being used (operating system, browser information, pointing method). OPM uses these fields for the survey software to operate, troubleshooting technical issues and limited research purposes to better understand survey participation, retains them indefinitely for trending and research purposes and limits access to only authorized OPM personnel whose official duties require access. As an anonymous, open link, survey there is nothing collected by the survey software that would identify an individual for the 10 prescribed items. In some certain circumstances, specific responses to demographics may create the potential for identification in the system.

Legacy FEVS records retained by OPM may include:

a. Full name;

b. Email address;

c. Social Security number, or other unique employee identification number;

d. Agency;

e. Agency subcomponent;

f. Organizational/Work component names and codes (up to nine levels of work unit information may be obtained);

g. Appointment authority;

h. Type of appointment;

i. Work schedule;

j. Tenure;

k. Service computation date;

l. Duty location and core based statistical area;
m. Occupational classification or series;
n. Personnel Office identifier;
o. Pay status;
p. Grade level;
q. Pay plan;
r. Base and adjusted salary;
s. Retirement plan;
t. Supervisory status;
u. Ethnicity and Race/National Origin indicator;
v. Sex;
w. Date of birth;
x. Responses to the FEVS survey questions, including demographic information.

RECORD SOURCE CATEGORIES:

Current AES records maintained by OPM are obtained from OPM personnel or human resources records used to establish eligibility and administer the survey and from OPM employees who voluntarily respond. Legacy FEVS records were obtained from OPM's Enterprise Human Resource Integration system, participating Federal agencies, and individuals who voluntarily completed the FEVS. De-identified AES data received from other agencies are outside this system when they do not identify individual respondents and OPM does not retrieve them by an individual's name, assigned identifying number or symbol, or other identifying particular. Removing direct identifiers alone does not exclude records that OPM retrieves by an individual identifier, including a respondent code.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside OPM as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

a. To the Department of Justice, including Offices of the U.S. Attorneys; another Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body; another party in litigation before a court, adjudicative, or administrative body; or to a court, adjudicative, or administrative body. Such disclosure is permitted only when it is relevant or necessary to the litigation or proceeding and one of the following is a party to the litigation or has an interest in such litigation:

(1) OPM, or any component thereof;

(2) Any employee or former employee of OPM in his or her official capacity;

(3) Any employee or former employee of OPM in his or her individual capacity where the Department of Justice or OPM has agreed to represent the employee;

(4) The United States, a Federal agency, or another party in litigation before a court, adjudicative, or administrative body, upon the OPM General Counsel's approval, pursuant to 5 CFR part 295 or otherwise.

b. To the appropriate Federal, State, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates or is relevant to a violation or potential violation of civil or criminal law or regulation.

c. To a member of Congress from the record of an individual in response to an inquiry made at the request of the individual to whom the record pertains.

d. To the National Archives and Records Administration (NARA) for records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

e. To appropriate agencies, entities, and persons when (1) OPM suspects or has confirmed that there has been a breach of the system of records, (2) OPM has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, OPM (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with OPM's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

f. To another Federal agency or Federal entity, when OPM determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

g. To contractors, grantees, experts, consultants, or volunteers performing or working on a contract, service, grant, cooperative agreement, or other assignment for OPM when OPM determines that it is necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to OPM employees.

h. To a Federal agency whose current or former employees' legacy FEVS records are maintained in this system, when OPM determines that the disclosure is necessary to resolve a specific legacy survey administration issue or prepare a legacy survey report. OPM will disclose only the minimum information necessary and will use aggregate information when it is sufficient.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored electronically in OPM-authorized information systems. Access is limited to authorized personnel whose official duties require access to the records.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Before or during AES survey administration, OPM retrieves records by name, work email address, or a unique identifier. If OPM retains a code or linkage key that permits it to locate an individual's response after AES administration, that response remains retrievable by an individual identifier. OPM retrieves retained FEVS records by name, email address, or other unique identifier (SSN or equivalent personnel identifier) for authorized analysis and reporting, subject to current access controls. OPM may also search retained FEVS survey data by work unit or other characteristics to produce statistical results. . Removal of direct identifiers does not prevent individual retrieval if an assigned identifier or retained linkage key still permits OPM to locate an individual's records.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

OPM retains and disposes of AES records and legacy FEVS records under the applicable National Archives and Records Administration (NARA) Records Schedule Number N1–478–92–001.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

OPM limits access to OPM-maintained AES records to authorized personnel whose official duties require access. The OPM AES platform uses multifactor authentication, encryption, audit monitoring, security and privacy training, and physical safeguards. The AES platform is part of the TTEC Humanify Enterprise—Government (Humanify Enterprise—G) Platform which is FedRAMP Certified These safeguards comply with the Federal

Information Security Modernization Act of 2014, applicable OMB policies, and standards and guidance issued by the National Institute of Standards and Technology (NIST).

RECORD ACCESS PROCEDURES:

Individuals seeking access to their records in this system may email a request to *foia@opm.gov* or mail a request to the Office of Personnel Management, Office of the Chief Information Officer-FOIA, 1900 E Street NW, Washington, DC 20415–0001. The email or letter should include the words ''Privacy Act Request,'' state that the request relates to ''OPM/Central-21, Annual Employee Survey,'' and clearly describe the requested records. To help locate the records, the request should identify the work email address used for the survey, if known, the current or former employing Federal agency, and the approximate survey year. Requesters must provide identity verification information in accordance with 5 CFR 297.201, including full name, signature, home address, date and place of birth, and other applicable identifying information. Social Security number requirements will be applied in accordance with 5 CFR 297.201(b)(2) for records in this system that include that identifier. OPM may be unable to locate an individual's survey response if neither direct identifiers nor retained respondent codes or linkage keys permit retrieval of that response by an individual identifier.

Individuals requesting access must also comply with OPM's Privacy Act regulations regarding verification of identity and access to records (5 CFR 297).

CONTESTING RECORD PROCEDURES:

Individuals seeking to amend records about themselves may email a request to *foia@opm.gov* or mail a request to the Office of Personnel Management, Office of the Chief Information Officer-FOIA, 1900 E Street NW, Washington, DC 20415–0001 and provide the record-location and identity-verification information described under ''Record Access Procedures.'' The request must precisely identify the information to be amended, state the requested correction and the reasons for it, and include available supporting documentation.

OPM may be unable to locate an individual's survey response for amendment if neither direct identifiers nor retained respondent codes or linkage keys permit retrieval of that response by an individual identifier. Individuals requesting amendment must also follow OPM's Privacy Act regulations regarding verification of identity and amendment to records (5 CFR 297).

NOTIFICATION PROCEDURES:

See ''Record Access Procedures.''

HISTORY:

82 FR 57489 (12/05/2017).

[FR Doc. 2026–22837 Filed 11–6–26; 8:45 am]

BILLING CODE 6325–46–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106815; File No. SR–FICC–2026–011]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Remove a Requirement That Sponsoring Members Report Certain Events Impacting Their Sponsored Members

November 4, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 29, 2026, Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. FICC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of modifications to FICC's Government Securities Division (''GSD'') Rulebook (''Rules'')[5] to remove the requirement that Sponsoring Members provide FICC with written notice of certain events impacting their Sponsored Members.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FICC is proposing changes to Rule 3A, which describes GSD's sponsored membership service (''Sponsored Service''). Specifically, the proposed rule change would remove the requirement that a Sponsoring Member provide FICC with written notice (i) when it becomes aware that its Sponsored Member is no longer in compliance with applicable requirements of Rule 3A, and (ii) before the effective date of any ''Reportable Event'' applicable to a Sponsored Member.[6] As described below, FICC has implemented changes to the requirements applicable to Sponsored Members and has enhanced its monitoring of Sponsored Members. As a result of such previously implemented changes, FICC believes these reporting requirements for Sponsoring Members are no longer necessary.

Overview of Sponsored Service, Sponsored Member Requirements and FICC Monitoring

FICC, through GSD, serves as a central counterparty and provides real-time trade matching, clearing, risk management and netting for cash purchases and sales of U.S. Treasury securities as well as repurchase and reverse repurchase transactions involving U.S. Treasury securities (''repos'').[7] GSD's central counterparty services are available directly to entities that are approved to be Netting Members and indirectly to other market participants through its indirect access

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] Terms not defined herein are defined in the Rules, *available at http://www.dtcc.com/legal/rules-and-procedures.*

[6] ''Reportable Event'' is defined in Rule 1 as ''an event that would effect a change in control of a Netting Member or could have a substantial impact on such Member's business and/or financial condition, including, but not limited to: (a) material organizational changes including mergers, acquisitions, changes in corporate form, name changes, changes in the ownership of a Netting Member or its Affiliates, and material changes in management, (b) material changes in business lines, including new business lines undertaken, and (c) status as a defendant in litigation which could reasonably impact the Netting Member's financial condition or ability to conduct business.'' *Id.*

[7] GSD also clears and settles certain transactions on securities issued or guaranteed by U.S. government agencies and government sponsored enterprises.

models—the Sponsored Service or Agent Clearing Service.[8]

The Sponsored Service permits Netting Members, approved by FICC as ''Sponsoring Members,'' to sponsor firms, referred to as ''Sponsored Members,'' into GSD membership.[9] The Sponsoring Member is permitted to submit to FICC for comparison, novation and netting certain types of eligible transactions. For operational and administrative purposes, a Sponsored Member appoints its Sponsoring Member to act as processing agent with respect to the Sponsored Member's satisfaction of its securities and funds-only settlement obligations.

A Sponsored Member is an Indirect Participant of GSD and the legal counterparty to FICC for any submitted transactions. However, the Sponsoring Member unconditionally guarantees to FICC the Sponsored Member's performance under a Sponsoring Member Guaranty, which guarantees to FICC the payment and performance of a Sponsored Member's obligations to FICC. Therefore, FICC relies on the financial resources of the Sponsoring Member in relying upon the Sponsoring Member Guaranty.

FICC recently adopted enhancements to its access models designed to facilitate access to clearance and settlement services of all eligible secondary market transactions in U.S. Treasury securities in accordance with the Securities and Exchange Commission's final rule regarding Standards for Covered Clearing Agencies for U.S. Treasury Securities and Application of the Broker-Dealer Customer Protection Rule With Respect to U.S. Treasury Securities.[10] Among these enhancements, FICC removed the eligibility requirement that Sponsored Members either be ''qualified institutional buyers,'' as such term is defined by Rule 144A under the Securities Act of 1933, or otherwise satisfy the financial requirements of such definition.[11] With this change, Section 3(a) of Rule 3A now provides only that a Person shall be eligible to become a Sponsored Member if it is sponsored into membership by a Sponsoring Member, as provided under the Rules.

FICC monitors the risks presented by its Indirect Participants in various ways, consistent with the requirements of Rule 17ad–22(e)(19) under the Act.[12] For example, FICC may request information from direct clearing members periodically through its annual or ad hoc due diligence requests, as required by Section 2(d) of Rule 3A and Section 2 of Rule 3.[13] This monitoring may include the request and review of information related to direct clearing members' Indirect Participants, where applicable, and controls the direct clearing member has in place to monitor and manage the risk presented by those Indirect Participants.[14]

FICC also maintains procedures pursuant to which it actively monitors adverse news events impacting Sponsored Members. FICC has recently enhanced these procedures to use Sponsored Members' Legal Entity Identifiers (''LEIs'') in that monitoring. By relying on a Sponsored Member's LEI, rather than its legal name, FICC can continue to identify adverse news events even after a Sponsored Member has changed its name.[15] FICC uses a compliance tool sourced from a third-party vendor to conduct this monitoring.

Proposed Changes To Remove Sponsored Member Reporting

FICC is proposing to amend Section 2(g) of Rule 3A by removing the requirement that a Sponsoring Member submits written notice to FICC (i) when it becomes aware that a Sponsored Member is no longer in compliance with the requirements of Section 3(a) of Rule 3A, and (ii) prior to the effective date of any Reportable Event applicable to a Sponsored Member.

First, the proposal to remove the requirement that FICC be notified when a Sponsoring Member becomes aware of a Sponsored Member is no longer in compliance with the requirements of Section 3(a) of Rule 3A would correct an error in the Rules. FICC has already removed the requirements applicable to Sponsored Members that were in Section 3(a) of Rule 3A.[16] Therefore, this part of the reporting requirement is no longer applicable. The proposed changes would also remove a statement from Section 3(b) of Rule 3A that refers to the requirements that were previously in Section 3(a) of Rule 3A and was also left in the Rules in error.

Second, the proposal to remove the requirement that FICC be notified prior to the effective date of any Reportable Event applicable to a Sponsored Member could facilitate greater access to this indirect participation model by removing an obligation for Sponsoring Members that has limited value in managing the risks presented by the Sponsored Service.

As noted above, FICC employs a daily monitoring tool that identifies instances of adverse news impacting a Sponsored Member. Such adverse news includes regulatory enforcement actions and when a Sponsored Member is named as a defendant in criminal litigation. These events are among the types of events that are captured in the definition of Reportable Event, as these events could have a ''substantial impact'' on the Sponsored Member's business or financial condition and include when the Sponsored Member is named as a defendant in litigation. Therefore, FICC does not believe it is necessary to require separate reporting of these events by Sponsoring Members.

Additionally, FICC has recently enhanced this monitoring to use Sponsored Members' LEIs to ensure its monitoring continues to be effective even if a Sponsored Member has changed its legal name. Therefore, notice of any changes to a Sponsored Member's name, which are also included in the Reportable Event reporting requirement, is no longer required to ensure this monitoring remains effective.

FICC has considered the other organizational events that may be considered a Reportable Event and has determined that it is not necessary to receive reporting on these events to effectively manage the risks presented by its limited relationship with Sponsored Members. As described above, FICC risk manages the Sponsored Service primarily at the Sponsoring Member level, not the Sponsored Member level. For example, a Sponsoring Member is responsible under Section 10 of Rule 3A for posting to FICC the Required Fund Deposit for its sponsored activity and, while

[8] *See* Rule 2 (Members) (providing that FICC shall make its services available to entities that are approved to be Members of GSD); Rule 3A (Sponsoring Members and Sponsored Members) (describing the Sponsored Service) and Rule 8 (Agent Clearing Service) (describing the Agent Clearing Service), *supra* note 5.

[9] *See* Rule 3A, *supra* note 5.

[10] Securities Exchange Act Release No. 99149 (Dec. 13, 2023), 89 FR 2714 (Jan. 16, 2024) (S7–23–22).

[11] *See* Securities Exchange Act Release No. 101694 (Nov. 21, 2024), 89 FR 93784 (Nov. 27, 2024) (SR–FICC–2024–005).

[12] 17 CFR 240.17ad–22(e)(19).

[13] *See supra* note 5.

[14] *See* Rule 3 (Ongoing Membership Requirements), Section 2 (requiring Netting Members to submit to FICC information that FICC may reasonably require); and Rule 3A (Sponsoring Members and Sponsored Members), Section 2(d) (requiring Sponsoring Members to submit reports and information within timeframes and in formats required by FICC) and Section 2(f) (requiring that Sponsoring Members' books and records, as related to Sponsored Member Trades, shall be open to the inspection of FICC), *supra* note 5.

[15] *See* Rule 3A, Section 2(d) (requiring that Sponsoring Members submit to FICC the LEI for each Sponsored Member, such that FICC has a current LEI for each Sponsored Member at all times), *supra* note 5.

[16] *See supra* note 11.

Sponsored Members are principally liable to FICC for their settlement obligations, the Sponsoring Member is also required under Section 2(c) of Rule 3A to provide a guaranty to FICC for such obligations.[17]

Further, pursuant to Sections 2(d) and 2(f) of Rule 3A and Section 2 of Rule 3, Sponsoring Members may be required to provide to FICC reports or other information that FICC may require, including, for example, responses to annual or ad hoc due diligence requests.[18] FICC utilizes these due diligence requests to identify, monitor and manage the risks Sponsoring Members and their Sponsored Members may present to it. FICC may take action where it identifies risks through this due diligence process, which could include, for example, outreach to the Sponsoring Members, additional reporting from the Sponsoring Members or other appropriate risk management measures permitted by the Rules.

Therefore, FICC believes its existing monitoring and risk management practices with respect to the Sponsored Service, which do not directly rely on Sponsoring Member reporting of Reportable Events impacting a Sponsored Member, continue to facilitate effective risk management of exposures created through the Sponsored Service without this reporting requirement.

2. Statutory Basis

FICC believes the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, FICC believes the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act [19] and Rule 17ad–22(e)(19), promulgated under the Act,[20] for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions.[21] The proposed rule change would remove a reporting requirement from the Rules because that part of that requirement is no longer applicable and refers to a membership requirement that has already been removed from the Rules. The proposal would therefore ensure the Rules remain accurate and clear. When the Rules clearly and accurately set forth the rights and obligations of GSD Members, including Sponsoring Members, the Rules support the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.[22]

FICC has determined that the other part of the reporting requirement that would be removed from the Rules has limited risk management value relative to FICC's existing and enhanced monitoring tools and in light of FICC's approach to risk manage the Sponsored Service primarily at the Sponsoring Member level, not the Sponsored Member level. In this way, the proposal would also ensure that the obligations of membership are reasonable and necessary. Having reasonable membership obligations encourages participation in central clearing. Therefore, FICC believes the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.[23]

Rule 17ad–22(e)(19) under the Act requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor, and manage the material risks to the covered clearing agency arising from arrangements in which firms that are indirect participants in the covered clearing agency rely on the services provided by direct participants to access the covered clearing agency's payment, clearing, or settlement facilities.[24] By eliminating requirements that are both no longer applicable and are no longer reasonable and necessary, the proposal would ensure that the Rules are reasonably designed to manage the risks arising from indirect participation models. FICC has evaluated its existing and enhanced risk management measures and believes that they adequately address the risks that these requirements were originally designed to mitigate. Therefore, FICC believes the proposed changes are consistent with Rule 17ad–22(e)(19) under the Act.[25]

(B) Clearing Agency's Statement on Burden on Competition

FICC does not believe the proposed rule changes would have any impact on competition. The proposed changes would apply equally to all Sponsoring Members by removing a reporting obligation that currently applies to all Sponsoring Members with respect to their Sponsored Members. Therefore, the change does not create any disproportionate impact on certain firms versus other firms with the same membership type at FICC. As described above, the proposal to remove this reporting obligation is to correct an error in the Rules that continues to refer to a membership requirement that has been removed, and to remove a requirement that has limited value in managing the risks presented by Sponsored Members that are adequately managed through FICC's existing and enhanced monitoring tools. FICC does not believe such proposed changes would have any effect on participants' respective competitive positions.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. If any written comments are received, they will be publicly filed as Exhibit 2 to this filing, as required by Form 19b–4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b–4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at www.sec.gov/rules-regulations/how-submit-comment.* General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the SEC's Division of Trading and Markets at *tradingandmarkets@sec.gov* or 202–551–5777.

FICC reserves the right to not respond to any comments received.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the

[17] *See supra* note 5.

[18] *See supra* note 14.

[19] 15 U.S.C. 78q-1(b)(3)(F).

[20] 17 CFR 240.17ad–22(e)(19).

[21] 15 U.S.C. 78q–1(b)(3)(F).

[22] *Id.*

[23] *Id.*

[24] 17 CFR 240.17ad–22(e)(19).

[25] *Id.*

Act [26] and Rule 19b–4(f)(6) thereunder.[27]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FICC–2026–011 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE, Washington, DC 20549.

All submissions should refer to File Number SR–FICC–2026–011. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of FICC and on DTCC's website (*www.dtcc.com/legal/sec-rule-filings*). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR–FICC–2026–011 and should be submitted on or before November 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22755 Filed 11–6–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106810; File No. SR–IEX–2026–45]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 11.271 Regarding the Resumption of Trading Following a Level 3 Market-Wide Circuit Breaker Halt

November 4, 2026.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 2, 2026, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) of the Act,[4] and Rule 19b–4 thereunder,[5] the Exchange proposes to amend Rule 11.271 (''Trading Halts Due to Extraordinary Market Volatility'') concerning the resumption of trading following a Level 3 market-wide circuit breaker halt in connection with the upcoming expansion of trading by other national securities exchanges to 23 hours per day, 5 days per week. The Exchange has designated this proposal as non-controversial pursuant to Section 19(b)(3)(A)(iii) of the Act [6] and provided the Commission with the notice required by Rule 19b–4(f)(6)(iii) thereunder.[7]

The text of the proposed rule change is available at the Exchange's website at *https://www.iex.io/resources/regulation/rule-filings* and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 11.271 (''Trading Halts Due to Extraordinary Market Volatility'') concerning the resumption of trading following a Level 3 market-wide circuit breaker (''MWCB'') halt in connection with the upcoming extension of trading by other national securities exchanges to 23 hours per day, 5 days per week. Although only some exchanges will offer overnight trading, the uniform Level 3 MWCB rules of every exchange are being modified, as explained further below.

Background

The MWCB mechanism under Rule 11.271 provides an important, automatic mechanism that is invoked to promote stability and investor confidence during a period of significant stress when U.S. securities markets experience extreme broad-based declines. All U.S. equity exchanges and FINRA (collectively, the self-regulatory organizations or ''SROs'') adopted uniform rules relating to the MWCB mechanism in 2012, which are designed to slow the effects of extreme price movement through coordinated trading halts across U.S. securities markets when severe price declines reach levels that may exhaust market liquidity.[8] Currently, market-wide

[26] 15 U.S.C. 78s(b)(3)(A).

[27] 17 CFR 240.19b–4(f)(6).

[28] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6)(iii).

[8] *See* Securities Exchange Act Release No. 67090 (May 31, 2012), 77 FR 33531 (June 6, 2012) (SR–BATS–2011–038; SR–BYX–2011–025; SR–BX–2011–068; SR–CBOE–2011–087; SR–C2–2011–024; SR–CHX–2011–30; SR–EDGA–2011–31; SR–EDGX–2011–30; SR–FINRA–2011–054; SR–ISE–2011–61; SR–NASDAQ–2011–131; SR–NSX–2011–11; SR–NYSE–2011–48; SR–NYSEAmex–2011–73; SR–NYSEArca–2011–68; SR–Phlx–2011–129) (''MWCB Approval Order''). IEX's MWCB rule has been effective since its approval for registration as a national securities exchange in 2016. *See* Securities

circuit breaker rules provide for trading halts in all U.S. cash equities and equity options markets during a severe market decline as measured by a single-day decline in the S&P 500 Index during Regular Market Hours.

Pursuant to Rule 11.271, a market-wide trading halt will be triggered if the S&P 500 Index declines in price by specified percentages from the prior day's closing price of that index. Currently, the triggers are set at three circuit breaker thresholds: 7% (Level 1), 13% (Level 2), and 20% (Level 3). A market decline that triggers a Level 1 or Level 2 halt after 9:30 a.m. Eastern Time and before 3:25 p.m. Eastern Time would halt market-wide trading for 15 minutes, while a similar market decline at or after 3:25 p.m. Eastern Time would not halt market-wide trading. If a Level 3 Market Decline occurs at any time during the trading day, trading in all stocks will halt on the Exchange for the remainder of the trading day, and will resume the following trading day at 8:00 a.m. Eastern Time.

Proposal

The Exchange now proposes to amend Rule 11.271 to reflect the upcoming extended trading hours, *i.e.,* 23/5 trading, that other exchanges will participate in. When 23/5 trading begins on December 6, 2026, the Exchange's current trading sessions will not change. The Exchange operates three separate trading sessions between 8:00 a.m. Eastern Time and 5:00 p.m. Eastern Time. These are the Pre-Market Session, which operates from 8:00 a.m. Eastern Time to 9:30 a.m. Eastern Time; the Regular Market Session, which operates from 9:30 a.m. Eastern Time to 4:00 p.m. Eastern Time; and the Post-Market Session, which operates from 4:00 p.m. Eastern Time to 5:00 p.m. Eastern Time.[9] Consistent with the uniform rules in place across all SROs, current Rule 11.271(b)(2) provides that if a Level 3 MWCB occurs at any time during the trading day, trading in all stocks will halt on the Exchange for the remainder of the trading day. Currently, that means that the earliest that any exchange would re-open trading after a Level 3 MWCB is at 4:00 a.m. Eastern Time the following day, since no SROs are open for trading before 4:00 a.m. Eastern Time.

Unless amended, when 23/5 trading is launched, the current rule's reference to halting ''for the remainder of the trading day'' would require SROs participating in 23/5 trading to re-open trading at an earlier time, *i.e.,* 9:00 p.m. Eastern Time on the same calendar day, when those SROs' systems would generally become available for overnight trading. The Exchange does not believe that this is an expected or desired result and is therefore amending this rule in coordination with the other SROs such that trading on any SRO will not resume until 4:00 a.m. Eastern Time or later on the following trading day, consistent with current market practice. This proposed rule change is therefore not intended to make any substantive changes to the MWCB mechanism. Rather, the proposed rule change would preserve the current resumption time following a Level 3 MWCB.

To effect this change, the Exchange proposes to delete the language in Rule 11.271(b)(2) that provides that trading in all stocks will halt on the Exchange ''for the remainder of the trading day'' if a Level 3 MWCB occurs at any time during the trading day, and replace it with new language that explicitly provides that trading in all stocks would halt on the Exchange until 4:00 a.m. Eastern Time or later on the following trading day.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[10] Specifically, the Exchange believes the proposed rule change is consistent with Section 6(b)(5) of the Act[11] in that it is designed to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and, in general, to protect investors and the public interest.

The MWCB mechanism described in Rule 11.271 is an important, automatic mechanism that is invoked to promote stability and investor confidence during periods of significant stress when U.S. securities markets experience extreme broad-based declines. The proposed rule change, when applied uniformly by all SROs, would ensure that the current 4:00 a.m. Eastern Time resumption time following a Level 3 halt continues to apply under 23/5 trading, notwithstanding current rule text implying that the resumption time would coincide with the start of overnight trading on SROs operating an overnight session.

Rather than leave the rule in place as is, which would result in an earlier resumption time than originally contemplated when the rule was adopted, the Exchange, the other U.S. equity exchanges, and FINRA met alongside industry representatives to determine the appropriate resumption time. Following those discussions, the collective decision was made to retain the 4:00 a.m. Eastern Time resumption time, notwithstanding the fact that an earlier resumption time would be possible with the introduction of 23/5 trading. The proposed rule change codifies this decision into the Exchange's rules. The Exchange understands that the other SROs will also be filing similar proposed rule changes. As a result, the market as a whole, including on- and off-exchange, will continue to be subject to harmonized rules for the resumption of trading following a Level 3 MWCB.

While the SROs had previously decided to tie the resumption time following a Level 3 halt to an SRO's normal hours of operation, the upcoming transition to 23/5 trading raises various concerns that warrant a change from the current approach.

First, the Exchange notes that the MWCB mechanism was designed to provide a cooling off period where market participants would be provided with additional time to evaluate the market events that led to the decline before determining how to position their trading activity for the next day. With the introduction of 23/5 trading and the start of overnight trading on some SROs at 9:00 p.m. Eastern Time, however, this cooling-off period could be materially shortened, reducing one of the key benefits that the MWCB mechanism was designed to provide in the first place. Rather than shorten the cooling-off period and risk this benefit, the Exchange believes the market would be better served by a change to the length of the associated trading halt that mirrors current market practice. Under the proposed rule, as is the case today, after a Level 3 halt, all SROs would re-open trading at 4:00 a.m. Eastern Time or later, and no SRO would offer an overnight trading session starting on the day of a Level 3 halt.

Second, overnight trading may be subject to different liquidity and participation considerations than the current pre-market sessions that start at or after 4:00 a.m. Eastern Time. Notably, while retail investors have expressed interest in overnight trading, the Exchange expects that institutional investors will take more time to

Exchange Act Release No. 78101 (June 17, 2016), 81 FR 41142 (June 23, 2016) (File No. 10–222).

[9] *See* Rules 1.160(z), (aa), and (gg). The IEX Rule Book uses the terms ''Regular Market Hours'' and ''Regular Market Session'' interchangeably. *See* Rule 1.160(gg).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

transition to a round-the-clock model. However, such institutional participation may be of heightened importance following a Level 3 halt, as these investors are likely to have views on the underlying market events that led to the Level 3 MWCB in the first place. The Exchange is concerned that opening during hours that such participants do not normally trade may impact the quality of price discovery at a time of significant market volatility. Waiting until 4:00 a.m. Eastern Time to resume trading would facilitate broader participation and therefore price discovery.

Finally, the Exchange notes that the Commission recently approved an amendment to the Plan to Address Extraordinary Market Volatility (''LULD Plan'') that would establish new price protections from 9:00 p.m. Eastern Time to 4:00 a.m. Eastern Time.[12] While these price bands would help to assure a fair and orderly market during normal market conditions, it is possible that they would instead prevent normal price discovery following a Level 3 MWCB. Rather than allowing trading to resume with such price bands in effect, which would represent a change from the current trading reopening following a Level 3 MWCB, the Exchange believes that requiring SROs to wait until 4:00 a.m. Eastern Time or later to resume trading would ensure that price discovery can occur unimpeded during pre-market trading, as it does today, which may further inform prices going into the opening auction and regular market hours trading following a Level 3 halt.

Given the factors discussed above, the Exchange believes that trading in all securities on the Exchange should not resume before 4:00 a.m. Eastern Time on the trading day after a Level 3 halt. This decision, which the Exchange understands will also be reflected in the rules of the other SROs, would promote a fair and orderly market at a time of significant market volatility, and thereby protect investors and the public interest. In addition, while the actual Level 3 resumption time would not be changing in practice—as proposed, the current resumption time and future resumption time would both be 4:00 a.m. Eastern Time at the earliest—the Exchange believes that it is appropriate to amend its rules to ensure that its rules reflect the upcoming changes due to 23/5 trading. Without this change, market participants may mistakenly believe that the Exchange intends for trading to re-open on overnight trading exchanges at 9:00 p.m. Eastern Time following a Level 3 halt. The proposed rule change would therefore facilitate operational transparency while providing for a fair and orderly market.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposal would ensure the continued, uninterrupted operation of a consistent mechanism to halt trading across U.S. securities markets. Further, the Exchange understands that the other SROs intend to file proposed rule changes to ensure a consistent resumption time at 4:00 a.m. Eastern Time or later across markets. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has designated this rule filing as non-controversial under Section 19(b)(3)(A) of the Act[13] and Rule 19b-4(f)(6) thereunder.[14] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[16] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–IEX–2026–45 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–IEX–2026–45. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–IEX–2026–45 and should be submitted on or before November 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22752 Filed 11–6–26; 8:45 am]

BILLING CODE 8011–01–P

[12] *See* Securities Exchange Act Release No. 106042 (August 5, 2026), 91 FR 51515 (August 10, 2026) (Order Granting Approval of the Twenty-Seventh Amendment to the National Market System Plan to Address Extraordinary Market Volatility to Establish Temporary Price Band Protections in Overnight Trading).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 15 U.S.C. 78s(b)(2)(B).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106825; File No. SR–ICC–2026–013]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to ICC's Fee Schedule

November 4, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4,[2] notice is hereby given that on October 27, 2026, ICE Clear Credit LLC (''ICC'' or ''ICE Clear Credit'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared primarily by ICC. ICC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and paragraph (f)(2) of Rule 19b–4 thereunder,[4] such that the proposed rule change was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to modify its Client Volume Incentive Program within its credit default swap (''CDS'') client fee schedule (the ''client fee schedule'') for the CDS Clearing Service. These revisions do not require any changes to the CDS Clearing Participant fee schedule[5] or the ICC CDS Clearing Rules.[6]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC proposes to modify its Client Volume Incentive Program within ICC's client fee schedule. ICC maintains a client fee schedule[7] that is publicly available on its website, which ICC proposes to update in connection with the proposed amendments to the Client Volume Incentive Program. Such proposed changes to the Client Volume Incentive Program are set forth in Exhibit 5 and described in detail as follows. ICC proposes to make such changes effective following any applicable regulatory review or approval process.[8]

Currently, clearing fees applicable to clients of Clearing Participants are charged in accordance with the product, amount and currency set out in the client fee schedule and subject to any incentive programs or fee discounts described in the client fee schedule. In particular, the Client Volume Incentive Program in the client fee schedule applies automatically to all clients of Clearing Participants, without further action by clients or Clearing Participants, and provides a tiered discount schedule (the ''Discount Schedule'') based on client fees billed during the calendar year. Specifically, for any client with annual billed fees across all ICC CDS instrument categories (*i.e.,* index CDS, single name CDS, and index option CDS) that exceed U.S. dollar (''USD'') equivalent of $1 million, such client is entitled to a fee discount as follows: (i) for billed annual fees greater than $1 million USD equivalent and less than or equal to $6.94 million USD equivalent, a progressive discount from 1% to 100%: the discount percentage increases by 1% for each $60,000 in billed client fees; [9] and (ii) for billed annual fees greater than $6.94 million USD equivalent, a 100% discount. The Client Volume Incentive Program applies to client clearing activity only, and Clearing Participants are not eligible to participate in the program.

The proposed changes are designed to provide additional discounts under the Client Volume Incentive Program. The Discount Schedule described above will remain unchanged. Instead, ICC proposes to make additional discounts available to clients who meet any of the following criteria. ICC proposes a footnote to specify that these additional discounts begin in 2027. On January 1, 2027, the following changes would be implemented, and such footnote would be automatically removed.

ICC proposes the following discounts under the Client Volume Incentive Program for clients that satisfy the following proposed criteria. Under the first proposed criteria, clients that achieve a 100% discount[10] in the preceding calendar year will qualify for a lower fee cap of $3 million USD equivalent for this calendar year. To re-qualify for such lower fee cap for the subsequent calendar year, clients must achieve a 100% discount based on the Discount Schedule for this calendar year. Under the second proposed criteria, clients whose paid clearing fees after rebate reach $3 million USD equivalent by September 30 of this calendar year based on the Discount Schedule are not subject to additional clearing fees for the remainder of this calendar year. ICC proposes an additional clarification to add ''Discount Schedule'' as a defined term to refer to the chart under the Client Incentive Program that sets out the tiered discount schedule. The Client Volume Incentive Program will continue to apply to client clearing activity only, and Clearing Participants are not eligible to participate in the program.

(b) Statutory Basis

ICC believes that the proposed changes are consistent with the requirements of the Act, including Section 17A of the Act[11] and the regulations thereunder applicable to it. More specifically, the proposed rule change establishes or changes a member due, fee or other charge imposed by ICC under Section 19(b)(3)(A)(ii) of the Act[12] and Rule 19b–4(f)(2)[13] thereunder. ICC believes the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

[5] Clearing Participant fee details available at *https://www.theice.com/publicdocs/clear_credit/ICE_Clear_Credit_Fees_Clearing_Participant.pdf.*

[6] ICC's CDS Clearing Rules are available on ICC's public website at *https://www.ice.com/publicdocs/clear_credit/ICE_Clear_Credit_Rules.pdf.*

[7] Client fee details available at: *https://www.theice.com/publicdocs/clear_credit/ICE_Clear_Credit_Fees.pdf.* As specified, all fees are charged directly to a client's Clearing Participant.

[8] The proposed rule change is filed for immediate effectiveness but will not be implemented until the change is certified in accordance with Commodity Futures Trading Commission Regulation 40.6.

[9] As an example, a client that is billed a total of $1,120,000.00 in fees would be entitled to a 1% discount for the first $60,000 in fees over $1 million (or $600) and a 2% discount for the second $60,000 in fees over $1 million (or $1,200), for a total discount of $1,800.

[10] A 100% discount is achieved once a client's billed annual fees in USD equivalent reach $6.94 million. This results in a client's paid clearing fees capping (''fee cap'') at $3.97 million USD equivalent.

[11] 15 U.S.C. 78q–1.

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

[13] 17 CFR 240.19b–4(f)(2).

ICC, in particular, to Section 17A(b)(3)(D),[14] which requires that the rules of the clearing agency provide for the equitable allocation of reasonable dues, fees, and other charges among its participants.

ICC believes that the additional discounts in the client fee schedule have been set at an appropriate level. In determining the appropriate discount level and program structure, ICC took into account factors such as client clearing volume, related revenue, costs and expenses, and the goal of increasing market participation in the clearing service, including the expected impacts of different fee levels. In ICC's view, its client fees, after taking into account the updated discounts under the incentive program, will be reasonable and appropriate for its business as the discounts take into account anticipated volumes, costs and expenses, and revenues under each contract type, and they consider current and past market activity as well as anticipated market activity with respect to clearing CDS contracts at ICC. The Client Volume Incentive Program continues to be designed to encourage the clearing of contracts at ICC by clients while properly compensating ICC for the risks, costs and expenses of clearing CDS contracts.

Moreover, the updated discount will be available to all clients clearing contracts at ICC, based on their clearing activity. The Client Volume Incentive Program under the amended client fee schedule will continue to automatically, and without further action by clients or Clearing Participants, apply to all clients. ICC's fee schedules, including the proposed additional discounts under the incentive program, will continue to be transparent and to apply equally to market participants clearing indexes, single names, and index option CDS contracts at ICC. Therefore, the proposed rule change provides for the equitable allocation of reasonable dues, fees and other charges among participants, within the meaning of Section 17A(b)(3)(D) of the Act.[15] ICC therefore believes that the proposed rule change is consistent with the requirements of Section 17A of the Act[16] and the regulations thereunder applicable to it and is appropriately filed pursuant to Section 19(b)(3)(A) of the Act[17] and paragraph (f)(2) of Rule 19b–4[18] thereunder.

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed rule change would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act. As discussed above, the proposed changes to ICC's client fee schedule modify the Client Volume Incentive Program for clearing all categories of CDS contracts at ICC and which continues to be available to all clients based on their clearing activity. The implementation of such changes does not preclude other market participants from offering similar incentive programs. Moreover, ICC does not believe that the amendments would adversely affect the cost of clearing for clients, the ability of market participants to access clearing services, or the market for cleared services generally. Accordingly, ICC does not believe the amendments impose any burden on competition not necessary or appropriate in furtherance of the purpose of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[19] and paragraph (f) of Rule 19b–4[20] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICC–2026–013 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–ICC–2026–013. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website *(http://www.sec.gov/rules/sro.shtml*). Copies of such filings will be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.ice.com/clear-credit/regulation.*

Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to File Number SR–ICC–2026–013 and should be submitted on or before November 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22760 Filed 11–6–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106812; File No. SR–SAPPHIRE–2026–37]

Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Fees Applicable to the Floor Market Maker Fee and Floor Broker Breakup Credit for Transactions in Non-Penny Classes

November 4, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 27, 2026, MIAX Sapphire, LLC (''MIAX

[14] 15 U.S.C. 78q–1(b)(3)(D).
[15] 15 U.S.C. 78q–1(b)(3)(D).
[16] 15 U.S.C. 78q–1.
[17] 15 U.S.C. 78s(b)(3)(A).
[18] 17 CFR 240.19b–4(f)(2).
[19] 15 U.S.C. 78s(b)(3)(A).
[20] 17 CFR 240.19b–4(f)(2).
[21] 17 CFR 200.30–3(a)(12).
[1] 15 U.S.C. 78s(b)(1).
[2] 17 CFR 240.19b–4.

Sapphire'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Sapphire Options Exchange Fee Schedule (''Fee Schedule'') to: (1) increase the per contract fee assessed to Floor Market Makers for QFO and cQFO transactions in non-Penny classes that trade against all other origins; and (2) increase the per contract Floor Broker Breakup Credit for QFO and cQFO transactions in non-Penny classes (all terms defined below).

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to: (1) increase the per contract fee assessed to Floor Market Makers [3] for Qualified Floor Order (''QFO'') [4] and Complex Qualified Floor Order (''cQFO'') [5] transactions [6] in non-Penny classes [7] that trade against all other origins; and (2) increase the per contract Floor Broker [8] Breakup Credit for QFO and cQFO transactions in non-Penny classes. The Exchange originally filed this proposal on August 31, 2026.[9] On October 27, 2026, the Exchange withdrew SR–SAPPHIRE–2026–35 and refiled this proposal.

Background of Fees and Rebates for Transactions on the Trading Floor

The Exchange assesses fees for transactions on the Trading Floor [10] based on origin and provides rebates in certain situations. Currently, for Priority Customers [11] and Professional Customers,[12] the Exchange does not assess a per contract fee for QFO and cQFO transactions in SPY/QQQ/IWM, Penny classes (excluding SPY/QQQ/IWM), and non-Penny classes. The Exchange assesses a $0.25 per contract fee for QFO and cQFO transactions in SPY/QQQ/IWM, Penny classes (excluding SPY/QQQ/IWM), and non-Penny classes for Away Market Maker,[13] Firm, and Broker-Dealer origins. The Exchange does not assess a fee for QFO and cQFO transactions in SPY/QQQ/IWM, Penny classes (excluding SPY/QQQ/IWM), and non-Penny classes for Firm and Broker-Dealer origins that are facilitating a Priority Customer or Professional Customer order. The Exchange assesses Floor Market Makers a fee of $0.50 per contract for QFO and cQFO transactions in all classes that trade against all other origins.[14] The Exchange provides a rebate of ($0.10) per contract for QFO and cQFO transactions in SPY/QQQ/IWM, Penny classes (excluding SPY/QQQ/IWM), and non-Penny classes for Floor Broker origins on both the agency and contra sides when that side is billable. The Exchange provides a Floor Broker Breakup Credit of ($0.20) per contract for QFO and cQFO transactions in SPY/QQQ/IWM, Penny classes (excluding SPY/QQQ/IWM), and non-Penny classes.[15] The Exchange also assesses lower fees for Away Market Maker Facilitation transactions based on the monthly percentage of order volume that is broken up and depending on whether certain volume thresholds are met for each qualifying QFO or cQFO. The Away Market Maker Facilitation rates apply to any Trading Floor transaction where a Member firm Away Market Maker directs a paired order to the Trading Floor, where the agency order is a customer of the affiliated Member firm, and where the contra-side of the transaction is the Away Market Maker of the Member firm.[16]

Proposal to Increase the Floor Market Maker Fee for QFO and cQFO Transactions in Non-Penny Classes

The Exchange proposes to amend the table of QFO and cQFO fees and rebates in section 1)c)i) of the Fee Schedule to increase the fee assessed to Floor Market Makers for QFO and cQFO transactions in non-Penny classes that trade against all other origins. Currently, the Exchange assesses Floor Market Makers a fee of $0.50 per contract for QFO and cQFO transactions in non-Penny classes that trade against all other origins. The Exchange now proposes to assess Floor Market Makers a fee of $0.94 per contract for QFO and cQFO transactions in non-Penny classes that trade against all other origins. The purpose of this change is for business and competitive reasons. The Exchange believes that even with the proposed increased fee,

[3] The term ''Floor Market Maker'' means a Floor Participant of the Exchange located on the Trading Floor who has received permission from the Exchange to trade in options for his own account. *See* the Definitions section of the Fee Schedule and Exchange Rule 2105.

[4] *See* Exchange Rule 2040.

[5] *See* Exchange Rule 2040(a)(4).

[6] A QFO or cQFO must be entered as a two-sided order, with an initiating side and a contra side and the QFO and cQFO fees, rebates, and applicable fee and rebate caps will apply to both sides of the order. Further, cQFO fees and rebates are per executed side per leg. *See* Fee Schedule, Section 1)c)i).

[7] *See* Exchange Rule 510(c).

[8] The term ''Floor Broker'' means an individual who is registered with the Exchange for the purpose, while on the Trading Floor, of accepting and handling options orders. A Floor Broker must be registered as a Floor Participant prior to registering as a Floor Broker. A Floor Broker may take into his own account, and subsequently liquidate, any position that results from an error made while attempting to execute, as Floor Broker, an order. *See* the Definitions section of the Fee Schedule and Exchange Rule 2015. The term ''Floor Participant'' means Floor Brokers as defined in Rule 2015 and Floor Market Makers as defined in Rule 2105(b). *See id.* and Exchange Rule 100.

[9] *See* Securities Exchange Act Release No. 106314 (September 9, 2026), 91 FR 58231 (September 14, 2026) (SR–SAPPHIRE–2026–35).

[10] The term ''Trading Floor'' or ''Floor'' means the physical trading floor of the Exchange located in Miami, Florida. The Trading Floor shall consist of one ''Crowd Area'' or ''Pit'' where Floor Participants will be located and option contracts will be traded. The Crowd Area or Pit shall be marked with specific visible boundaries on the Trading Floor, as determined by the Exchange. A Floor Broker must represent all orders in an ''open outcry'' fashion in the Crowd Area. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[11] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See id.*

[12] The term ''Professional Customer'' for the purposes of the Fee Schedule, shall mean a Public Customer that is not a Priority Customer. *See* the Definitions section of the Fee Schedule. The term ''Public Customer'' means a person that is not a broker or dealer in securities. *See id.*

[13] The term ''Away Market Maker'' for the purposes of the Fee Schedule, shall mean a non MIAX Sapphire Market Maker.

[14] *See* Fee Schedule, Section 1)c)i).

[15] The Floor Broker Breakup Credit will apply to the Floor Broker that submits the QFO or cQFO instead of the Floor Broker rebate for executions that trade with a Floor Market Maker. *See id.*

[16] *See* Fee Schedule, Section 1)c)i), Away Market Maker Facilitation Breakup Table.

the Exchange's transaction fees for Floor Market Makers will remain competitive with the fees assessed by other equity options exchanges that offer trading floors for transactions by their market makers in non-penny classes when trading against all other origins.[17]

Proposal To Increase the Floor Broker Breakup Credit for QFO and cQFO Transactions in Non-Penny Classes

Next, the Exchange proposes to amend the table of QFO and cQFO fees and rebates in section 1)c)i) of the Fee Schedule to increase the per contract Floor Broker Breakup Credit for QFO and cQFO transactions in non-Penny classes. Currently, the Exchange provides a Floor Broker Breakup Credit of ($0.20) per contract for QFO and cQFO transactions in SPY/QQQ/IWM, Penny classes (excluding SPY/QQQ/IWM), and non-Penny classes. The Exchange now proposes to increase the Floor Broker Breakup Credit to ($0.25) per contract for QFO and cQFO transactions in non-Penny classes. The purpose of this change is for business and competitive reasons. The Exchange believes this change may encourage additional Floor Broker liquidity in non-Penny Classes. Additional liquidity in non-Penny classes may benefit all market participants because it will attract additional liquidity to the Exchange by providing more trading opportunities. Further, additional liquidity helps contribute to a robust trading environment on the Exchange's Trading Floor, particularly as it continues to ramp up operations, having launched only a year ago.

* * * * *

The proposed changes are immediately effective.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[18] in general, and furthers the objectives of Section 6(b)(5) of the Act,[19] in particular, in that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposal is consistent with Section 6(b)(4) of the Act[20] because it represents an equitable allocation of reasonable dues, fees and other charges among its Members or issuers using its facilities.

Proposal To Increase the Floor Market Maker Fee for QFO and cQFO Transactions in Non-Penny Classes

The Exchange believes the proposal to amend the Floor Market Maker origin to increase the fee to $0.94 per contract for QFO and cQFO transactions in non-Penny classes is reasonable, equitably allocated, and not unfairly discriminatory because, even with the proposed increase, the Exchange believes the proposed fee will not discourage Floor Market Maker order flow. The Exchange notes that even with the proposed increase to the Floor Market Maker fee for transactions in non-Penny classes proposed herein, the Exchange's proposed fee of $0.94 per contract for the Floor Market Maker origin in non-Penny classes remains competitive with, and lower than (in at least one instance), the fee charged by other equity options exchanges to their floor market makers for transactions in non-penny classes.[21]

The Exchange believes that increasing fees for QFO and cQFO transactions by Floor Market Makers in non-Penny classes, but not for other market participants, represents an equitable, non-discriminatory allocation of fees because the proposal is based on the type of business transacted by Floor Market Makers on the Exchange, and Floor Market Makers are not obligated to engage in transactions on the Trading Floor. Rather, Floor Market Makers trade for their own accounts and benefit from having access to interact with orders that are made available in open outcry on the Trading Floor. Despite higher fees for certain Floor Market Maker transactions since this proposal was initially established for September 1st effectiveness, the Exchange has continued to observe consistent Floor Market Maker interest on the Trading Floor in non-Penny classes where the fee was specifically increased, demonstrating that this fee has not deterred, and likely will not deter Floor Market Maker participation.

Proposal To Increase the Floor Broker Breakup Credit for QFO and cQFO Transactions in Non-Penny Classes

The Exchange believes the proposal to increase the Floor Broker Breakup Credit to ($0.25) per contract for QFO and cQFO transactions in non-Penny classes is reasonable, equitably allocated and not unfairly discriminatory because the Exchange believes this change may encourage additional Floor Broker liquidity in non-Penny Classes. The Exchange believes additional liquidity in non-Penny classes, to the extent the proposed change accomplishes this goal, may benefit all Floor Participants because it will attract additional liquidity to the Exchange by providing more trading opportunities. Further, additional liquidity helps contribute to a robust trading environment on the Exchange's Trading Floor, particularly as it continues to ramp up operations, having launched only a year ago. The Exchange believes the proposed increased Floor Broker Breakup Credit in non-Penny classes is equitable and not unfairly discriminatory because it will apply equally to all Floor Brokers who submit orders in non-Penny classes on the Trading Floor and have those orders broken up by trading with a Floor Market Maker.

In addition, the proposal is also consistent with Section 6(b)(5) of the Act[22] because it perfects the mechanisms of a free and open market and a national market system and protects investors and the public interest because it applies equally to all eligible Floor Broker QFOs and cQFOs that are broken up and access to the Exchange is offered on terms that are not unfairly discriminatory. The Exchange believes it is equitable to apply the proposed enhanced breakup credit only to Floor Brokers and not Floor Market Makers. Floor Market Makers represent their own interest on the Trading Floor and, therefore, the Exchange believes these market participants may not need a similar incentive. Additionally, Floor Market Makers may choose to conduct their business on a trading floor or in an electronic market, unlike Floor Brokers, who have a business model that is naturally tied to the physical trading space. The Exchange believes the proposed rule change is equitable because the proposed enhanced breakup credit applies to all Floor Brokers who submit orders that are broken up, regardless of the type of business transacted on the Exchange. The Exchange also believes that providing

[17] *See* Nasdaq PHLX LLC (''PHLX'') Rules, Options 7: Pricing Schedule, Section 4 (assessing PHLX market makers a fee of $1.00 per contract for floor transactions in non-penny symbols); BOX Exchange LLC (''BOX'') Fee Schedule, Section V.A. (assessing BOX market makers a fee of $1.00 per contract for manual transactions in non-penny classes); NYSE American LLC (''NYSE American'') Options Fee Schedule, Section I.A. (assessing NYSE American market makers a fee of $0.90 per contract for manual transactions in non-penny classes); NYSE Arca, Inc. (''NYSE Arca'') Options Fees and Charges, page 6, Transaction Fee for Manual Executions—Per Contract (assessing NYSE Arca market makers a fee of $0.90 per contract for manual transactions in non-penny classes).

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

[20] 15 U.S.C. 78f(b)(4).

[21] *See supra* note 17.

[22] 15 U.S.C. 78f(b)(5).

the proposed breakup credit to Floor Brokers is equitable because it is intended to support Floor Brokers' role in facilitating the execution of open outcry orders, a function which benefits all market participants on the Trading Floor.

The Exchange believes the Floor Broker Breakup Credit is consistent with Section 6(b)(4) of the Act [23] because it will continue to encourage market participants to execute orders on the Trading Floor. The Exchange believes that the Floor Broker Breakup Credit could continue to improve liquidity on the Exchange to the benefit of all market participants. The Exchange notes that providing breakup credits to certain market participants is not new or novel. The Exchange's affiliate, Miami International Securities Exchange, LLC (''MIAX Options''), provides for a similar concept in its fee schedule. For example, MIAX Options encourages market participants to participate in PRIME and cPRIME Auctions and provides a higher breakup credit to market participants for breakups in non-penny classes.[24] Further, for PRIME Auctions, MIAX Options offers a higher breakup credit in non-penny classes for Members that submit Priority Customer orders as compared to other origins if a certain breakup threshold is met.[25] In addition, the proposal is also consistent with Section 6(b)(5) of the Act [26] because it perfects the mechanisms of a free and open market and a national market system and protects investors and the public interest because it applies equally to all Floor Broker QFOs and cQFOs which are subject to a breakup and access to the Exchange is offered on terms that are not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Inter-Market Competition

The Exchange believes the proposed changes do not impose an undue burden on inter-market competition because the changes are to remain competitive with other options exchanges that offer a trading floor. The Exchange believes the proposed changes will help the Exchange remain competitive in order to be able to provide market participants with another choice of where to execute such floor transactions. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges that offer trading floors. Because competitors are free to modify their own fees or rebates in response to this proposal, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee and rebate changes in this market may impose any burden on competition is limited.

Intra-Market Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule changes would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed change to amend the Floor Market Maker origin to increase the fee to $0.94 per contract for QFO and cQFO transactions in non-Penny classes will not discourage Floor Market Maker order flow. This is because even with the change, the Exchange's proposed fee of $0.94 per contract for the Floor Market Maker origin in non-Penny classes remains competitive with, and lower than (in at least one instance), the fee charged by other equity options exchanges to their floor market makers for transactions in non-penny classes.[27]

The Exchange believes the proposed change to increase the Floor Broker Breakup Credit for QFO and cQFO transactions in non-Penny classes will encourage the submission of additional non-Penny class liquidity to a public exchange's Trading Floor, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all Floor Participants, especially as the Trading Floor continues to ramp up operations since it launched in September 2025. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders.

The Exchange believes that the proposed fee assessed to Floor Market Maker QFOs and cQFOs in non-Penny classes and the proposed enhanced Floor Broker break credit in non-Penny classes may encourage Floor Broker open outcry order flow and would not disincentivize Floor Market Maker activity on the Trading Floor. The Exchange does not believe that Floor Market Makers will be discouraged from transacting on the Trading Floor, as Floor Market Makers trade for their own accounts and benefit from having access to interact with orders that are made available in open outcry on the Trading Floor. The Exchange also believes that Floor Market Maker fees relative to other market participants do not impose an undue burden on competition because Floor Market Makers are not obligated to engage in transactions on the Trading Floor. To the extent that there is an additional competitive burden on Floor Market Makers, the Exchange believes that any such burden would be appropriate because Floor Brokers serve an important function in facilitating the execution of orders and price discovery for all market participants. Further, to the extent this proposal is successful, it may increase trading opportunities for Floor Market Makers because Floor Market Makers trade for their own accounts and benefit from having the opportunity to interact with orders that are made available in open outcry on the Trading Floor. Greater liquidity benefits all market participants on the Exchange and increased order flow would increase opportunities for execution of other trading interest. The proposed modifications would apply and be available to all similarly-situated market participants that execute open outcry orders on the Trading Floor, and, accordingly, the proposed changes would not impose a disparate burden on competition among market participants on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[28] and Rule 19b–4(f)(2) [29] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission

[23] 15 U.S.C. 78f(b)(4).

[24] *See* MIAX Options Fee Schedule, Sections 1)a)v)–vi).

[25] *See* MIAX Options Fee Schedule, Section 1)a)v), including footnote ''*''.

[26] 15 U.S.C. 78f(b)(1) and (b)(5).

[27] *See supra* note 17.

[28] 15 U.S.C. 78s(b)(3)(A)(ii).

[29] 17 CFR 240.19b–4(f)(2).

summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–SAPPHIRE–2026–37 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–SAPPHIRE–2026–37. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR–SAPPHIRE–2026–37 and should be submitted on or before November 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22754 Filed 11–6–26; 8:45 am]

BILLING CODE 8011–01–P

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106822; File No. SR–NasdaqTX–2026–054]

Self-Regulatory Organizations; Nasdaq Texas, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Introduce Conforming Changes to Nasdaq Texas Rules in Connection With the Establishment of Fees for Nasdaq TotalView Plus and Nasdaq Basic Plus

November 4, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 27, 2026, Nasdaq Texas, LLC (''Nasdaq Texas'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees at (i) Equity 7, Section 119 to waive the market data distributor fees for Nasdaq Texas TotalView for firms that consolidate it with certain other feeds for external redistribution; (ii) Equity 7, Section 123 to waive the fees for firms purchasing Nasdaq TotalView Plus; (iii) Equity 7, Section 139 to reflect the addition of Nasdaq Basic Plus as a product offering subject to a consolidation fee; and (iv) Equity 7, Section 147 to clarify that firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus or both shall pay monthly administrative fees and data consolidation fees, each as described further below.[3]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaqtx/rulefilings,* and at the principal office of the Exchange.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] This filing replaces SR–NasdaqTX–2026–043, which was withdrawn and replaced on October 27, 2026. It was previously filed as SR–NasdaqTX–2026–041, which was withdrawn and replaced on September 8, 2026, and SR–NasdaqTX–2026–040, which was withdrawn on August 31, 2026.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to introduce conforming changes to Nasdaq Texas rules in connection with the establishment of fees for Nasdaq TotalView Plus and Nasdaq Basic Plus by the Nasdaq Stock Exchange. Specifically, the Exchange proposes to amend fees at (i) Equity 7, Section 119 to waive the market data distributor fees for Nasdaq Texas TotalView for firms that consolidate it with certain other feeds for external redistribution; (ii) Equity 7, Section 123 to waive the fees for firms purchasing Nasdaq TotalView Plus; (iii) Equity 7, Section 139 to reflect the addition of Nasdaq Basic Plus as a product offering subject to a consolidation fee; and (iv) Equity 7, Section 147 to clarify that firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus or both shall pay monthly administrative fees and data consolidation fees, each as described further below.

Nasdaq TotalView Plus and Nasdaq Basic Plus Fees

The Nasdaq Stock Market LLC (''Nasdaq'') recently introduced two new products, Nasdaq TotalView Plus and Nasdaq Basic Plus,[4] which consolidate Depth-of-Book [5] and Top-of-Book [6] information currently

[4] *See* Securities Exchange Act Release No. 105997 (July 28, 2026), 91 FR 48466 (July 31, 2026) (SR–Nasdaq–2026–061) (a proposal to introduce Nasdaq TotalView Plus and Nasdaq Basic Plus, two new data feeds which will offer consolidated Top-of-Book and Depth-of-Book information currently disseminated by Nasdaq, Nasdaq Texas and Nasdaq PSX).

[5] The underlying Depth-of-Book products are Nasdaq TotalView, Nasdaq Texas TotalView, and PSX TotalView.

[6] The underlying Top-of-Book products are Nasdaq Basic (which includes both best bid and offer and last sale information), Nasdaq Texas BBO,

disseminated by Nasdaq, the Exchange, and Nasdaq PHLX LLC equities (''Nasdaq PSX''). Nasdaq has submitted to the Commission a fee filing designed to set fees for Nasdaq TotalView Plus and Nasdaq Basic Plus at or below fees currently charged for the Depth-of-Book and Top-of-Book products offered by Nasdaq, Nasdaq Texas, and Nasdaq PSX. This, together with the networking and connectivity savings inherent in lowering the number of data feeds, is designed to maximize the distribution of consolidated data feeds to investors throughout the 23 hour, 5 days per week schedule set to begin in December 2026.

Nasdaq will offer Nasdaq TotalView Plus for the same Professional and Non-Professional Subscriber and enterprise license fees as Nasdaq TotalView.[7] To ensure that market data vendors will be able to offer competing consolidated data products, any firm that certifies to Nasdaq that it will consolidate Nasdaq TotalView, Nasdaq Texas TotalView and Nasdaq PSX TotalView into a data feed solely for external redistribution shall be exempt from Nasdaq Texas Market Data Distributor Fees[8] and Nasdaq PSX Market Data Distributor Fees,[9] and the Monthly External Distributor Fees for the Nasdaq Stock Market LLC at Equity 7, Section 119(b) shall be reduced by $350 per month.[10] These three discounts will ensure that vendors will be able to cover the cost of consolidating the underlying fees.

Nasdaq will offer Nasdaq Basic Plus for the same Professional and Non-Professional Subscriber, enterprise license, and Distributor fees as Nasdaq Basic. To ensure that other market data vendors will be able to offer competing consolidated data products, Nasdaq proposes to charge the same monthly administrative and data consolidation fees for Nasdaq Basic Plus as are currently charged for Nasdaq Last Sale Plus to both Internal Distributors[11] and External Distributors[12] to cover the costs of data feed consolidation to be incurred by market data vendors.

With respect to the Market Data Enterprise License for Display Usage,[13] which currently offers both Nasdaq TotalView and Nasdaq Basic in the same enterprise license, Nasdaq proposes to offer the Nasdaq TotalView Plus and Nasdaq Basic Plus feeds for the same fees currently charged for the Nasdaq TotalView and Nasdaq Basic.

As a result of the introduction of Nasdaq TotalView Plus and Nasdaq Basic Plus and their related fees, the Exchange is proposing amendments to Equity 7, Sections 119, 123, 139, and 147 to make conforming changes to its fee schedule to align with the fees outlined in Nasdaq's Equity 7, Sections 123, 132, 139, and 147 for these new products.

Market Data Distributor Fees

The purpose of the first fee amendment is to issue a fee waiver for External Market Data Distributor Fees of $1,620 per month, in Equity 7, Section 119, for vendors that certify to Nasdaq that they will consolidate Nasdaq TotalView, Nasdaq Texas TotalView and Nasdaq PSX TotalView into a data feed solely for external redistribution. The same discount would not apply to non-vendors. Vendors would be able to apply this fee reduction, together with the waiver of Nasdaq PSX Market Data Distributor Fees, and the $350 per month reduction in Monthly External Distributor Fees for the Nasdaq Stock Market, to cover the cost of forming their own consolidated feed, thereby allowing vendors to compete with Nasdaq in the sale of consolidated data products using the depth of book data from Nasdaq affiliates.

Nasdaq Texas TotalView Fees

The purpose of the second fee amendment is to issue a fee waiver for Nasdaq Texas TotalView fees in Equity 7, Section 123 to any firm that purchases Nasdaq TotalView Plus. Nasdaq Texas TotalView disseminates all individual Nasdaq Texas Equities System participant orders and quotes displayed in the system, the aggregate size of such orders and quotes at each price level, and the trade data for executions that occur within the Nasdaq Texas Equities System.[14] This will be a fee waiver of (i) monthly Subscriber fees of $22.25 (operative January 1, 2026), and $22.25 (operative January 1, 2026) for NYSE and regional issues for display usage or non-display usage not based upon Direct Access,[15] and (ii) Non-Display Usage fees of $58.50 (operative January 1, 2026) per month for each Professional Subscriber.[16]

This is to ensure that Nasdaq can offer Nasdaq TotalView Plus for the same Subscriber fees as Nasdaq TotalView.

Administrative and Consolidation Fees

The purpose of the third and fourth fee amendments is to clarify that firms that receive Nasdaq Basic Plus, in addition to or in lieu of Nasdaq Last Sale Plus, will also pay the monthly administrative fee applicable to Nasdaq Texas Last Sale and Nasdaq Texas BBO, and that distributors of Nasdaq Last Sale Plus or Nasdaq Basic Plus will pay a data consolidation fee of $350 per month. Currently, firms that receive Nasdaq Last Sale Plus must pay the administrative and consolidation fees,[17] and this amendment extends the same to purchasers of Nasdaq Basic Plus,[18] as both Nasdaq Last Sale Plus and Nasdaq Basic Plus contain the same Nasdaq Texas Last Sale and Nasdaq Texas BBO feeds. The Nasdaq Texas BBO Feeds consist of real-time market information from the Nasdaq Texas Market Center.[19]

This fee is designed to cover the data consolidation costs of market data vendors to ensure that they will be able to offer competing consolidated data products to the new Nasdaq Basic Plus product, which contains both NTX Last Sale and Nasdaq Texas BBO.

As a conforming change, the Exchange proposes to modify both Equity 7, Section 139(b)(1) and Equity 7, Section 147(b) to state that firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus or both shall pay the monthly administrative fees for NTX Last Sale and Nasdaq Texas BBO, as well as a data consolidation fee of $350 per month.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[20] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[21] in particular, in that it

Nasdaq Texas Last Sale, PSX BBO, and PSX Last Sale.

[7] Internal and External Distributor, as well as Direct Access fees, may apply to purchasers of Nasdaq Plus products depending on the customer's use case. *See* Nasdaq Rules, Equity 7, Section 119(b).

[8] *See* Equity 7, Section 119(a).

[9] *See* Nasdaq PHLX Rules, Equity 7, Section 3 (Market Data Distributor Fees).

[10] *See* Nasdaq Stock Market Rules, Equity 7, Sections 119(b) and 119(d). There are two Monthly External Distributor Fees at Section 119(b), one for Nasdaq-listed security depth entitlements and one for Non Nasdaq-listed security depth entitlements.

[11] ''Internal Distributors'' are Distributors that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus data and then distribute that data to one or more Subscribers within the Distributor's own entity.

[12] ''External Distributors'' are Distributors that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus data and then distribute that data to one or more Subscribers outside the Distributor's own entity.

[13] *See* Nasdaq Stock Market Rules, Equity 7, Section 132.

[14] *See* Equity 7, Section 123.

[15] *See* Equity 7, Section 123(a)(1).

[16] *See* Equity 7, Section 123(a)(2).

[17] *See* Equity 7, Section 139(b).

[18] Firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus would either be liable for Nasdaq Last Sale fees or Nasdaq Basic fees, but not both.

[19] *See* Equity 7, Section 147. ''Nasdaq Texas BBO for Nasdaq'' contains the Nasdaq Texas's best bid and offer for Nasdaq-listed securities. ''Nasdaq Texas BBO for NYSE'' contains Nasdaq Texas's best bid and offer for NYSE-listed securities. ''Nasdaq Texas BBO for Amex'' contains Nasdaq Texas's best bid and offer for Amex-listed securities.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(4) and (5).

provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers because the proposal: (i) offers more customer choice; (ii) protects competition by covering the data consolidation costs of market data vendors; (iii) does not increase the fee for any Nasdaq Texas product, but simply waives certain fees or applies consolidation costs to firms purchasing certain data feeds; (iv) conforms fees for Nasdaq Texas products to the recent Nasdaq filings related to the offer of Nasdaq TotalView Plus and Nasdaq Basic Plus; and (v) offers products to all market participants on a non-discriminatory basis.

1. More Customer Choice

The proposal will expand choice by allowing customers to select whether to purchase best bid and offer information through the separate data feeds of Nasdaq Basic, Nasdaq Texas Last Sale, Nasdaq Texas BBO, and PSX Last Sale, and PSX BBO (or any combination thereof) separately or in a single feed. Purchasing Nasdaq Basic Plus or Nasdaq TotalView Plus will allow some customers to optimize consumption by ingesting information from multiple markets in a single connection, which may result in cost savings for subscribers based on a more efficient configuration of data feeds. Nothing in this proposal will change the quantity or quality of Depth-of-Book or Top-of-Book information available in the market, as the underlying feeds will remain available, and the proposed feeds are simply amalgamations of those underlying feeds.

2. No Competitive Advantage Relative To Market Data Vendors

In offering Nasdaq Basic Plus and Nasdaq TotalView Plus, Nasdaq will be acting as a redistributor of Depth-of-Book [22] and Top-of-Book [23] products from Nasdaq, Nasdaq Texas, and Nasdaq PSX.[24]

Nasdaq Basic Plus and Nasdaq TotalView Plus will be compiled from the same underlying feeds from Nasdaq, Nasdaq Texas, and Nasdaq PSX that are distributed to the purchasers of those feeds. With respect to speed, the path for the distribution of the information by the Exchange will not be faster than the path for distribution that would be used by a market data vendor to distribute similar, independently created products.

With respect to information, the same source of the market data to be used by the Exchange to create the two proposed products will also be available to any other market data vendor. The Nasdaq system that will create and support Nasdaq Basic Plus and Nasdaq TotalView Plus will access the underlying feeds from Nasdaq, Nasdaq Texas, and Nasdaq PSX from the same point as any market data vendor.

With respect to cost, Nasdaq will ensure that market data vendors are able to compete with the proposed fees by introducing waivers of distributor fees for Nasdaq Texas and Nasdaq PSX and a reduction of $350 per month in external distributor fees for the Nasdaq Stock Market, for distributors of Nasdaq TotalView Plus and a consolidation fee for Nasdaq Basic Plus. These proposals will allow vendors to cover the costs of consolidation for Depth-of-Book and Top-of-Book feeds, respectively.[25] The Exchange is filing this proposal to implement conforming changes for a Nasdaq Stock Exchange proposal filed separately.

The proposed fee waiver for Nasdaq TotalView Plus will exempt any firm that certifies to Nasdaq that it will consolidate Nasdaq TotalView, Nasdaq Texas TotalView and Nasdaq PSX TotalView into a data feed solely for external redistribution from Nasdaq Texas Market Data Distributor Fees [26] and Nasdaq PSX Market Data Distributor Fees,[27] and shall also receive a fee reduction of $350 per month in External Distributor fees from the Nasdaq Stock Market. This substantial savings in distributor fees offered only to external distributors—$1,620 per month for Nasdaq Texas,[28] $1,390 per month for PSX TotalView,[29] and $350 for the Nasdaq Stock Market—will allow vendors to cover the cost of consolidation of Depth-of-Book feeds and will ensure that market data vendors will be able to offer consolidated data products that compete with Nasdaq TotalView Plus.

The proposed fees for Nasdaq Basic Plus include monthly administrative fees for Nasdaq Last Sale, NTX Last Sale, and PSX Last Sale and a data consolidation fee of $350 per month for Internal Distributors and External Distributors of Nasdaq Basic Plus.[30] This is the current fee charged for Nasdaq Last Sale Plus to ensure that market data vendors will be able to offer competing feeds.

Nasdaq introduced a consolidation fee for both Nasdaq Basic Plus and Nasdaq Last Sale Plus because Nasdaq Basic Plus includes last sale information. Nasdaq expects vendors to use the same processes and servers to consolidate both best bid and offer and last sale information, and therefore the same consolidation fee should be sufficient to cover all data consolidation costs, enabling vendors to compete in consolidating and distributing data from multiple exchanges. The Exchange is proposing to amend its rules to permit that competition.

3. No Fee Increases

Nothing in the proposal involves an increase to the fees currently charged by Nasdaq Texas for its data feeds. Any subscriber to solely a Nasdaq Texas feed will continue to pay the same fees as are currently set, without any change. The subscriber fee waivers and consolidation fees proposed herein are to ensure that any purchaser of a *compiled* product, whether it is Nasdaq TotalView Plus, Nasdaq Basic Plus, or the feeds necessary to compile a competing product containing the same information as Nasdaq TotalView Plus and/or Nasdaq Basic Plus, is not at a cost disadvantage compared to other purchasers of the same information.

The proposed data consolidation fee for Nasdaq Basic Plus is exactly the same fee as currently charged for Nasdaq Last Sale Plus, and customers of Nasdaq Last Sale Plus would pay no additional consolidation fee for Nasdaq Basic Plus. These consolidation and administrative fees are not new, but are simply being expanded to Nasdaq's new product, and do not increase the fees charged to purchasers of Nasdaq Texas data.

Rather, the proposed set of fee waivers of external distributor fees for Nasdaq Texas and Nasdaq PSX and $350 reduction for the Nasdaq Stock Market for data vendors lowers fees below current fees.

[22] The underlying Depth-of-Book products are Nasdaq TotalView, Nasdaq Texas TotalView, and PSX TotalView.

[23] The underlying Top-of-Book products are Nasdaq Basic (which includes both best bid and offer and last sale information), Nasdaq Texas BBO, Nasdaq Texas Last Sale, PSX BBO, and PSX Last Sale.

[24] *See* Securities Exchange Act Release No. 105997 (July 28, 2026), 91 FR 48466 (July 31, 2026) (SR–Nasdaq–2026–061); SR–NASDAQ–2026–065.

[25] There is no consolidation fee for Nasdaq TotalView because the waiver of distributor fees is sufficient to cover the costs of consolidation without any additional fee.

[26] *See* Equity 7, Section 119.

[27] *See* Nasdaq PHLX Rules, Equity 7, Section 3.

[28] *See* Equity 7, Section 119(a).

[29] *See* Nasdaq PHLX Rules, Equity 7, Section 3 (Market Data Distributor Fees).

[30] Firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus would either be liable for Nasdaq Last Sale fees or Nasdaq Basic fees, but not both.

The proposed waiver of all subscriber fees, including both Professional and Non-Professional fees, Non-Display Usage fees, and enterprise license fees for Nasdaq Texas data for Nasdaq TotalView Plus will actually lower fees further, as purchasers of Nasdaq TotalView Plus will be charged the same fees as currently charged for Nasdaq TotalView alone. The proposed Nasdaq TotalView Plus fees therefore offer customers a discount below current fees.

4. Conforming Amendments

The proposal conforms fees for Nasdaq Texas products to the recent Nasdaq filings related to the offer of Nasdaq TotalView Plus and Nasdaq Basic Plus.[31] In order for Nasdaq's proposed fees to be effective,[32] Nasdaq Texas must update its rules to ensure that they do not conflict with Nasdaq's. The proposed amendments to Equity 7, Sections 119, 123, 139, and 147 are conforming changes made to align the Exchange's rules to Nasdaq's.

5. No Unfair Discrimination

The proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers because the proposed feeds are optional data fees available to all market participants on a non-discriminatory basis.

In summary, the proposal provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers because the proposal: (i) offers more customer choice; (ii) protects competition by reducing fees for market data vendors; (iii) does not increase the fee for any Nasdaq Texas product, but simply waives certain fees or applies consolidation costs to firms purchasing certain data feeds; (iv) conforms fees for Nasdaq Texas products to the recent Nasdaq filings related to the offer of Nasdaq TotalView Plus and Nasdaq Basic Plus; and (v) offers products to all market participants on a non-discriminatory basis.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The proposal merely implements fee waivers for certain purchasers and consolidation and administrative fees for others, which any other exchange could propose.

Nothing in the Proposal burdens intra-market competition (the competition among consumers of exchange data), because the products related to the fee changes—Nasdaq TotalView Plus and Nasdaq Basic Plus—will be offered to all market participants at the same price and any market participant that elects to purchase either Nasdaq TotalView Plus or Nasdaq Basic Plus may do so on a non-discriminatory basis.

Moreover, as explained above, the proposed fees offer no competitive advantage relative to market data vendors, and are in fact designed to promote competition. There is no change to (or advantage in) speed or information. With respect to cost, the Exchange proposes to ensure that market data vendors are able to compete with the proposed fees by introducing a set of fee waivers and a fee reduction for Nasdaq TotalView Plus that is exclusively available to market data vendors and a consolidation fee for Nasdaq Basic Plus. These Nasdaq feeds are completely voluntary products in that Nasdaq is not required by any rule or regulation to make this data available and potential subscribers may purchase it only if they voluntarily choose to do so. Information is compiled from underlying feeds from Nasdaq, Nasdaq Texas, and Nasdaq PSX, which will remain available for purchase.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[33]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–NasdaqTX–2026–054 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NasdaqTX–2026–054. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NasdaqTX–2026–054 and should be submitted on or before November 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22757 Filed 11–6–26; 8:45 am]

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[31] *See* SR–Nasdaq–2026–091.

[32] *See id.*

[33] 15 U.S.C. 78s(b)(3)(A)(ii).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106821; File No. S7–2026–26]

Order Under Section 36 of the Securities Exchange Act of 1934 (the ''Exchange Act'') Granting Conditional Exemptive Relief From Section 15(c)(3) of and Rule 15c3–3a, Note H Under the Exchange Act Relating to Certain Centrally Cleared U.S. Treasury Transactions

November 4, 2026.

I. Introduction

A. Overview of Exemptive Order

The Securities and Exchange Commission (''Commission'') is granting exemptive relief to broker-dealers from certain provisions of Note H to Item 15 of Exhibit A to Exchange Act Rule 15c3–3 (''Rule 15c3–3a, Note H'' or ''Note H'') pursuant to section 36 [1] of the Exchange Act. More specifically, the Commission is granting exemptive relief from the application of Exchange Act section 15(c)(3) [2] and Rule 15c3–3a, Note H(b)(1) and (b)(2)(i) thereunder to permit broker-dealers to include a debit in their Rule 15c3–3a customer and proprietary securities accounts of other broker-dealers (''PAB'') [3] reserve computations (collectively ''reserve computations'') for margin required and on deposit with a qualified clearing agency [4] resulting from transactions in U.S. Treasury securities in customer accounts that have been cleared, settled, and novated by the clearing agency in cases where the qualified clearing agency has calculated customer margin on either a net, omnibus or gross, customer-by-customer basis, and the broker-dealer has delivered the margin collateral on a net, omnibus basis.[5]

B. Background

Rule 15c3–3 under the Exchange Act, the broker-dealer customer protection rule, requires broker-dealers that hold customer cash and securities (''carrying broker-dealers'') to treat these assets in a manner that facilitates their prompt return to the customers if the broker-dealer fails financially. To meet this objective, Rule 15c3–3 requires a carrying broker-dealer to take two primary steps to safeguard customer assets, which are designed to protect customers by segregating their securities and cash from the carrying broker-dealer's proprietary business activities. The first step requires carrying broker-dealers to maintain physical possession or control over customers' fully paid and excess margin securities.[6] The second step requires that a carrying broker-dealer maintain a reserve of cash or qualified securities (*e.g.,* U.S. Treasury securities) in an account at a third-party bank that is at least equal in value to the net cash owed to customers determined by a computation pursuant to a formula set forth in Exchange Act Rule 15c3–3a, the customer reserve computation.[7] The goal of Rule 15c3–3 is to place a broker-dealer in a position where it is able to wind down and return customer assets in an orderly self-liquidation without the need for financial assistance.

On December 13, 2023, the Commission adopted rules under the Exchange Act to amend the standards applicable to certain clearing agencies to enhance risk management practices for central counterparties in the U.S. Treasury market and facilitate additional clearing of U.S. Treasury securities.[8] In the Treasury Clearing Adopting Release, the Commission adopted amendments to Rule 15c3–3a to permit margin required and on deposit at qualified clearing agencies providing central counterparty services for U.S. Treasury securities to be included by broker-dealers as a debit in the reserve computations, subject to certain conditions.[9]

i. Gross vs. Net Customer Position Margin Requirement

Among the conditions necessary for including customer position margin as a debit in the reserve computations is that customer position margin must be treated in accordance with rules that must be adopted by the qualified clearing agency.[10] Paragraph (b)(2)(i) of Note H requires the qualified clearing agency to calculate a separate margin amount for each customer of the broker-dealer on a gross basis, and requires the broker-dealer to deliver that amount of margin for each customer on a gross, customer-by-customer basis.[11] The Commission adopted this requirement to ensure that the risk of one customer's positions could not be offset by the risk of another customer's positions in determining the amount of customer margin the broker-dealer would need to have on deposit at the qualified clearing agency.[12] Thus, under existing Note H requirements, a broker-dealer is not permitted to deliver assets belonging to one customer to meet the margin requirement of another customer, and margin must be calculated and delivered on a gross basis.[13]

ii. Delivery of Customer Cash or Securities on Customer-by-Customer Basis

Another condition, set forth in paragraph (b)(1) of Note H, provides that the customer position margin must consist of any of the following when delivered by the broker-dealer to meet a margin requirement resulting from that particular customer's U.S. Treasury securities positions that have cleared, settled, and novated at the qualified clearing agency: (i) cash owed to the customer; or (ii) U.S. Treasury securities or qualified customer securities held in custody by the broker-dealer for the customer.[14] Paragraph (b)(1) of Note H

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[1] 15 U.S.C. 78mm. Section 36(a)(1) of the Exchange Act gives the Commission the authority to exempt any person, security or transaction or any class or classes of persons, securities or transactions, conditionally or unconditionally, from any Exchange Act provision by rule, regulation or order, to the extent that the exemption is necessary or appropriate in the public interest and consistent with the protection of investors.

[2] 15 U.S.C. 78o(c)(3).

[3] *See* 17 CFR 15c3–3(a)(16) (defining PAB account as a proprietary securities account of a broker-dealer (which includes a foreign broker-dealer, or a foreign bank acting as a broker-dealer) other than a delivery-versus-payment account or a receipt-versus-payment account. The term does not include an account that has been subordinated to the claims of creditors of the carrying broker-dealer.)

[4] *See* Note H(a) (defining a ''qualified clearing agency'' as a clearing agency registered with the Commission under section 17A of the Exchange Act that clears, settles, and novates transactions in U.S. Treasury securities).

[5] *See* Note H(b)(2)(i) to Exhibit A to Rule 15c3–3, 17 CFR 240.15c3–3a.

[6] *See* 17 CFR 240.15c3–3(d).

[7] *See* 17 CFR 240.15c3–3a (Formula for determination of customer and PAB account reserve requirements of broker-dealers under 17 CFR 240.15c3–3.).

[8] *See Standards for Covered Clearing Agencies for U.S. Treasury Securities and Application of the Broker-Dealer Customer Protection Rule With Respect to U.S. Treasury Securities,* Exchange Act Release No. 99149 (Dec. 13, 2023), 89 FR 2714 (Jan. 16, 2024) (''Treasury Clearing Adopting Release'').

[9] *See id.* at 2760–68. *See also* Note H to Exhibit A to Rule 15c3–3, 17 CFR 240.15c3–3a. The following types of transactions in U.S. Treasury securities in customer accounts that have been cleared, settled, and novated by the clearing agency are covered by the Item 15 debit: (1) purchases and sales of U.S. Treasury securities; and (2) U.S. Treasury securities repurchase and reverse repurchase agreements (together ''customer position margin'').

[10] *See* Treasury Clearing Adopting Release, at 2764. *See also* Note H(b)(2) to Exhibit A to Rule 15c3–3, 17 CFR 240.15c3–3a.

[11] *See* Note H(b)(2)(i) to Exhibit A to Rule 15c3–3, 17 CFR 240.15c3–3a.

[12] *See* Treasury Clearing Adopting Release, 89 FR at 2764. For a discussion of the Commission's consideration of the alternative of tailoring the requirement to permit a debit based on a margin amount posted to the qualified clearing agency that is calculated on a net basis across all the broker-dealer's customers, as is the case under Item 13 and Note F in Rule 15c3–3a for margin required and on deposit with the Options Clearing Corporation for all option contracts written or purchased in customer accounts, *see id.* at 2764–65.

[13] *See* Treasury Clearing Adopting Release, 89 FR at 2764.

[14] *See* Note H(b)(1)(i) and (ii).

also permits a broker-dealer to temporarily prefund a specific customer's margin requirement, subject to strict limitations.[15]

iii. Commission Approval of Qualified Clearing Agency Rules

The final condition to the application of the Item 15 debit, set out in paragraph (b)(3) of Note H, requires the Commission to have approved rules of the qualified clearing agency that meet the conditions of Note H and has published (and not subsequently withdrawn) a notice that broker-dealers may include the debit permitted by Note H.[16] At present, the Commission has published notices approving the rules of three qualified clearing agencies under paragraph (b)(3) of Note H, and has not subsequently withdrawn any of them.[17]

C. SIFMA's Application for Exemptive Relief

Pursuant to procedures set forth in Rule 240.0–12 of the Exchange Act, the Securities Industry and Financial Markets Association (''SIFMA'') filed an application for exemptive relief from section 15(c)(3) of the Exchange Act and Rule 15c3–3a, Note H(b)(1) and (2)(i) thereunder pursuant to section 36 of the Exchange Act on June 24, 2026.[18] SIFMA requested that the Commission grant exemptive relief to permit broker-dealers to include an Item 15 debit in their customer reserve computation in cases where the broker-dealer has delivered the margin collateral on a net, omnibus basis, rather than on a gross, customer-by-customer basis.[19] The requested relief would apply to customer accounts at a qualified clearing agency where the qualified clearing agency calculates customer margin on either a net, omnibus or gross, customer-by-customer basis that otherwise meets the conditions of Note H (*i.e.,* the conditions that are not exempted under SIFMA's proposed request).[20] Further, SIFMA requested that any exemptive order issued by the Commission provide broker-dealers with the same relief as to their PAB account holders and PAB reserve computation under Rule 15c3–3a, subject to the same conditions.[21]

Section 36 of the Exchange Act authorizes the Commission to conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from certain provisions of the Exchange Act or certain rules or regulations thereunder, by rule, regulation, or order, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.

On July 24, 2026, the Commission issued a Notice of Application seeking comment on the Application. The Notice of Application was published in the **Federal Register** on July 30, 2026 to provide interested persons the opportunity to comment.[22] The Commission did not receive any comments on the Notice of an Application.[23]

II. Discussion of Exemptive Relief

A. Statement of Relief

Since the Commission's adoption of the Treasury Clearing Adopting Release, broker-dealers undertaking implementation have raised concerns in letters and meetings with Commission staff about the inefficiencies and costs of the gross basis requirement.[24] For example, SIFMA stated in its Application that implementing a strict customer-by-customer framework would require broker-dealers to use highly granular systems to map customer positions, margin requirements, and collateral flows to individual customers across all clearance, settlement, and internal records, as well as complex intraday reconciliation and enhanced data infrastructure.[25] In a letter sent to the Commission before submitting its Application, SIFMA also stated that the cost concerns raised from individual segregation due to the requirement to calculate customer margin and deliver margin collateral on a gross, customer-by-customer basis would discourage broker-dealers from onboarding smaller market participants, who typically rely on qualified clearing agency direct netting members for clearing U.S. Treasury transactions.[26] As a result, SIFMA added, a qualified clearing agency's direct participants would be unable to apply the reserve formula debit for these indirect participant accounts, leading to increased capital constraints for broker-dealers in meeting customer margin requirements.[27]

SIFMA further indicated in its Application that the systems and infrastructure needed to fulfill the gross,

[15] *See* Note H(b)(1)(iii). Specifically, if delivering proprietary U.S. Treasury securities to the qualified clearing agency as margin collateral, the broker-dealer must: (1) not use other types of securities collateral acceptable to the qualified clearing agency; (2) not owe the customer or hold in custody for the customer sufficient cash, U.S. Treasury securities, and/or qualified customer securities to meet a margin requirement resulting from that customer's U.S. Treasury securities positions cleared, settled, and novated at the qualified clearing agency at the time the margin requirement arose; and (3) call for the customer to deliver a sufficient amount of cash, U.S. Treasury securities, and/or qualified customer securities to meet the margin requirement on the day the margin requirement arose, and must receive a sufficient amount of cash, U.S. Treasury securities, and/or qualified customer securities to meet the margin requirement by the close of the next business day after the margin requirement arose. *See also* Treasury Clearing Adopting Release, 89 FR at 2763.

[16] *See* Note H(b)(3) to Exhibit A to Rule 15c3–3, 17 CFR 240.15c3–3a.

[17] *See Notice pursuant to Rule 15c3–3a, Note H(b)(3) Regarding Application of the Customer Protection Rule Reserve Computations with Respect to U.S. Treasury Securities,* Exchange Act Release No. 34–101729 (Nov. 25, 2024), 89 FR 94801 (Nov. 29, 2024) (''FICC Note H Approval Notice''); *Notice pursuant to Rule 15c3–3a, Note H(b)(3) Regarding Application of the Customer Protection Rule Reserve Computations with Respect to U.S. Treasury Securities,* Exchange Act Release No. 105193 (Apr. 10, 2026); 91 FR 19241 (April 14, 2026) (''CME Securities Clearing Inc. Note H Approval Notice''); *Notice pursuant to Rule 15c3–3a, Note H(b)(3) Regarding Application of the Customer Protection Rule Reserve Computations with Respect to U.S. Treasury Securities,* Exchange Act Release No. 106267 (Sept. 3, 2026); 91 FR 57406 (Sept. 9, 2026) (''ICE Clear Credit LLC Note H Approval Notice'').

[18] *See Notice of an Application of the Securities Industry and Financial Markets Association for an Exemption Pursuant to Section 36 of the Securities Exchange Act of 1934 from Certain Conditions of Note H to Exchange Act Rule 15c3–3a,* Exchange Act Release No. 105980 (July 24, 2026), 91 FR 48201 (July 30, 2026) (''Notice of Application''). The application for exemptive relief (''Application'') is attached as an Appendix to the Notice of Application, available at: *https://www.sec.gov/files/rules/exorders/2026/34-105980.pdf.*

[19] *See* Notice of Application, 91 FR at 48202.

[20] *See id.* at 48203.

[21] *See id.*

[22] The comment period ended on August 31, 2026. *See* Notice of Application, 91 FR at 48204.

[23] *See* Notice of Application [File No. S7–2026–26].

[24] *See, e.g.,* Application, at 2.

[25] *See* Application at 3.

[26] *See* Letter from Kevin Zambrowicz, Deputy General Counsel (Institutional) & Managing Director, SIFMA, to the Honorable Gary Gensler, Chair, Commission (Oct. 23, 2024) (Application of the Broker-Dealer Customer Protection Rule with Respect to U.S. Treasury Securities Clearing), available at: *https://www.sec.gov/comments/S7-23-22/s72322-834280-2549193.pdf.*

[27] *See id. See* also Letter from Kevin Zambrowicz, Deputy General Counsel, SIFMA, to the Honorable Paul Atkins, Chair, Commission (Nov. 19, 2025) (Treasury Clearing—The OCC-Model Approach under Rule 15c3–3), available at: *https://www.sec.gov/comments/S7-23-22/s72322-834300-2549193.pdf* (stating that the ability of broker-dealers to reflect a reserve formula debit in instances where customer margin for U.S. Treasury transactions is delivered to a qualified clearing agency through an omnibus segregated account structure is critical to ensuring that broker-dealers can continue to intermediate cleared access for indirect participants, particularly buy-side clients and smaller market participants, without facing undue liquidity strain stemming from the current inability to reflect the reserve formula debit—an operational gap leading to reserve requirements that do not accurately reflect the actual risk posed to broker-dealers and the financial system.).

customer-by-customer margin calculation and posting requirements are not aligned with the existing net, omnibus-based operational models used in the intermediation of U.S. Treasury securities transactions, and would become increasingly difficult to scale as clearing expands to a broader set of market participants and intermediated relationships.[28] Where broker-dealers elect not to fully implement the systems and processes necessary to support gross, customer-level margining (and thus cannot use the Item 15 debit), SIFMA has indicated that the resulting reserve computation treatment may not reflect the economic substance of customer facilitation activity in U.S. Treasury clearing, which could lead to duplicative capital and liquidity requirements misaligned with the actual risk exposure to broker-dealers intermediating customer access to central clearing.[29]

The Commission finds that allowing the inclusion of a debit in Item 15 of the reserve computations where a qualified clearing agency has calculated the required customer margin on either a net, omnibus or gross, customer-by-customer basis, and the broker-dealer has delivered the required customer margin collateral on a net, omnibus basis, when subject to the conditions detailed below, is necessary or appropriate in the public interest, and is consistent with the protection of investors.

The operational complexities and challenges of the gross, customer-by-customer margin and delivery requirements have proven greater than anticipated before broker-dealers began to implement them. While the Commission originally adopted Note H to require posting margin on a gross, customer-by-customer basis for customer protection, the operational complexity of the gross calculation and delivery approach and the attendant potential negative impact for clearing of U.S. Treasury securities transactions warrant allowing alternative margin calculation and delivery approaches, with the enumerated conditions to ensure that the exemptions in this order do not diminish the customer protection objectives of Rules 15c3–3 and 15c3–3a.

This relief would also provide broker-dealers with more flexibility to efficiently intermediate access to centrally cleared U.S. Treasury markets while preserving the customer protection framework under Rule 15c3–3. Further, this relief would alleviate certain capital and operational constraints that can arise through a gross, customer-by-customer margining and delivery requirement, particularly when broker-dealers serve smaller or indirect customers, thereby supporting broader market access, enhancing liquidity, and advancing the Commission's goal of promoting a deep, resilient, and inclusive U.S. Treasury market. Finally, the alternative margin calculation and delivery approaches will support a broker-dealer's customer facilitation activity in U.S. Treasury clearing, particularly in light of the expansion of these activities and the increased number of qualified clearing agencies.

The conditions of this order, discussed below in section II.B, are designed to permit the Item 15 debit only in circumstances that provide protections to customers consistent with the customer protection objectives of Rules 15c3–3 and 15c3–3a without requiring a gross, customer-by-customer calculation and collection of customer margin. For example, Rule 15c3–3 requires broker-dealers to take steps to safeguard customer assets by segregating their securities and cash from the carrying broker-dealer's proprietary business activities.[30] The conditions in this order are designed to ensure that customer margin is appropriately segregated and that a broker-dealer cannot use customer cash and securities to finance its proprietary business activities. Further, consistent with the conditions in Note H not exempted under this order, the conditions of this order explicitly limit the exemption to customer margin required and on deposit with a qualified clearing agency for customer transactions in U.S. Treasury securities. These conditions help reduce the likelihood of certain risks that may undermine the customer protection objectives of Rule 15c3–3, including that broker-dealers may not appropriately safeguard customer cash and securities or may improperly include debits in their customer reserve computation.

Accordingly, after careful consideration of the Application, the Commission is issuing, pursuant to section 36 of the Exchange Act, conditional exemptive relief to permit broker-dealers to include an Item 15 debit in their customer reserve computation in cases where a qualified clearing agency has calculated customer margin on either a net, omnibus or gross, customer-by-customer basis, and the broker-dealer has delivered the margin collateral on a net, omnibus basis, rather than on a gross, customer-by-customer basis. Further, the Commission is providing broker-dealers with the same relief as to their PAB account holders and PAB reserve computation under Rule 15c3–3a, subject to the same conditions. This relief will permit either: (1) the calculation and delivery of customer margin on a net, omnibus basis,[31] or (2) the calculation of margin on a gross, customer-by-customer basis and the delivery of margin on a net, omnibus basis. The following discussion describes conditions of the exemptive relief provided by this order.

B. Discussion of Conditions

The first condition limits the relief to margin that is required and on deposit with a qualified clearing agency in connection with (1) purchases and sales of U.S. Treasury securities; and (2) U.S. Treasury securities repurchase and reverse repurchase agreements in customer accounts that have been cleared, settled, and novated by the qualified clearing agency. This condition is designed to reflect that the relief provided hereby is limited to only those transactions covered under Item 15 of Rule 15c3–3a and Note H.[32] This condition also will continue to ensure that margin required and on deposit at a qualified clearing agency as a result of the broker-dealer's proprietary positions may not be included as a debit in the reserve computations. Therefore, this condition is designed to effectuate a fundamental aspect of Rule 15c3–3 that a broker-dealer cannot use customer cash or securities to finance its proprietary business activities.[33]

The second condition provides that the broker-dealer must deliver the following types of cash and securities to the qualified clearing agency to meet the

[28] *See* Application at 3–4.

[29] *See id.* at 4. As SIFMA further stated in the Application, the frictions caused by these constraints and increased costs of central clearing could ultimately reduce participation and liquidity in the U.S. Treasury market, which would undermine the Commission's initial policy objectives in the Treasury Clearing Adopting Release of expanded central clearing, by discouraging efficient access pathways and increasing operational burdens without a corresponding reduction in systemic risk. *See id.*

[30] *See* section I.B. of this order. *See also* Treasury Clearing Adopting Release, 89 FR at 2761.

[31] Margin calculated on a ''net, omnibus basis'' refers to margin calculations where the transactions in U.S. Treasury securities for different customers are netted together as one combined portfolio to calculate initial margin requirements at a qualified clearing agency.

[32] *See* 17 CFR 240.15c3–3a, Item 15. This condition also will continue to limit the relief to *required* margin which prevents the broker-dealer from depositing cash or securities at a qualified clearing agency that are not needed to meet a margin requirement in order to artificially increase the debit (which could potentially reduce the broker-dealer's required deposit).

[33] *See* Treasury Clearing Adopting Release, 89 FR at 2761.

customer margin requirement: (1) cash; (2) U.S. Treasury securities; (3) qualified customer securities; [34] or (4) any combination of items (1)–(3).[35] This condition limits the scope of assets that are permissible to use as collateral delivered to the qualified clearing agency to those currently permitted under Note H to Rule 15c3–3a. The Commission is retaining the limitation on the permitted use of proprietary securities as margin collateral to U.S. Treasury securities to ensure that only the safest, most liquid securities of the broker-dealer are ever commingled with the customer cash and securities.[36]

The third condition limits the amount the broker-dealer is permitted to include in the Item 15 debit in the reserve computations to equal the least of: (1) the amount of margin collected from customers in connection with customer U.S. Treasury securities transactions; (2) the amount of margin required for customer U.S. Treasury securities positions; or (3) the total of: (a) cash, (b) U.S. Treasury securities, and (c) qualified customer securities delivered by the broker-dealer to meet a margin requirement arising from customer U.S. Treasury securities positions.[37]

Given the greater operational flexibility that net, omnibus margining and posting entails, this third condition is designed to make sure that the permitted Item 15 debit is conservative and directly related to customer-related credit items consistent with the requirements of Rule 15c3–3.[38] Specifically, the condition is designed to protect investors by specifying that broker-dealers can only obtain the full amount of the potential debit under Item 15 when they collect from customers the full amount of margin required for their U.S. Treasury securities positions, and subsequently deliver the full amount of that margin to the qualified clearing agency to meet such margin requirements.

The ''least of'' structure under the third condition will permit broker-dealers to post margin collateral on a net, omnibus basis, which may result in one customer's collateral being used to cover another customer's margin requirement. However, customers will continue to be afforded the customer protections provided by Rule 15c3–3, as well as the other provisions of Note H, which remain applicable under this exemptive relief. This includes the protections afforded to customers by the continued requirement that broker-dealers include free credit balances and other credit balances in customers' securities accounts as credits in Item 1, and the market value of customers' securities on deposit at a qualified clearing agency in Item 2, of their customer reserve computations.[39]

Further, the third condition explicitly limits the permitted Item 15 debit to permissible cash and securities collateral delivered to a qualified clearing agency. Consistent with the first condition, the broker-dealer may not include in the Item 15 debit amounts on deposit at a qualified clearing agency that exceed the margin requirement resulting from its customers' cleared U.S. Treasury securities positions.

The fourth condition requires that the broker-dealer must maintain books and records sufficient to identify the amount of customer margin collected and delivered to the qualified clearing agency. These books and records will permit the Commission, Commission staff or the broker-dealer's designated examining authority to examine for compliance with the specific conditions of this exemptive order. This condition also will facilitate compliance with the third condition to this order by helping ensure the broker-dealer only includes in the Item 15 debit the appropriate, permitted amount within its reserve computations. In doing so, this fourth condition will also help ensure that the relief provided in this order remains consistent with the customer protection objectives of Rule 15c3–3 by better ensuring compliance with both the conditions of this exemptive order and the other requirements of Rule 15c3–3 and Note H thereunder.

The fifth condition requires that the rules of the qualified clearing agency must have been amended as necessary to reflect the conditions of this exemptive order. This condition is designed to require that broker-dealers may only include an Item 15 debit in their reserve computations pursuant to this order where the rules of the qualified clearing agency have been amended to reflect the conditions of this exemptive order. This will also ensure that the rules of a qualified clearing agency that are amended in accordance with the conditions of this order adequately implement the customer protection objectives of Rule 15c3–3 and Rule 15c3–3a.[40]

The fifth condition also is designed, for similar reasons to those discussed in the Treasury Clearing Adopting Release pertaining to adoption of paragraph (b)(3) of Note H, which, as discussed in section I.B.iii. above, requires the Commission to have approved rules of the qualified clearing agency that meet the conditions of Note H and publish a notice (and not subsequently withdrawn the notice) that broker-dealers may include an Item 15 debit in their reserve computations for a particular qualified clearing agency.[41] The Commission is not hereby withdrawing any previously published notices approving the rules of any qualified clearing agency that meet the conditions of Note H, and broker-dealers may continue to rely upon them to include a debit in Item 15 of their reserve computations when complying with the requirements of Note H.[42] To the extent a qualified clearing agency amends its rules to comply with the conditions of this order, broker-dealers may include an Item 15 debit in their reserve computations if they comply with the other conditions of this order, including the seventh condition, discussed below, which conditions this exemptive relief on continued compliance with the other applicable conditions of Note H not exempted under this order.

The sixth condition provides that the broker-dealer must adopt and implement written policies and

[34] As used in Note H, the term ''qualified customer securities'' means the securities of a customer of the broker-dealer (other than U.S. Treasury securities) that are held in custody by the broker-dealer for the customer and that under the rules of the qualified clearing agency are eligible to be used to margin U.S. Treasury securities positions of the customer that are cleared, settled, and novated by the qualified clearing agency. *See* Note H(c) to Rule 15c3–3a.

[35] The words ''proprietary or customer'' were omitted before the words ''cash'' or ''U.S. Treasury securities'' as described in the Application, because the eligible collateral under this exemptive relief that is cash or U.S. Treasury securities would necessarily be either proprietary or customer assets. As this exemptive relief is to permit broker-dealers to deliver the margin collateral to a qualified clearing agency on a net, omnibus basis, the use of these terms within the scope of this condition is unnecessary.

[36] *See* Treasury Clearing Adopting Release, 89 FR at 2763.

[37] The word ''customer'' was omitted before the words ''cash'' or ''U.S. Treasury securities'' as described in the Application. Eligible collateral under this exemptive relief that is cash or U.S. Treasury securities would be either proprietary or customer assets, as this exemptive relief is to permit broker-dealers to deliver the margin collateral to a qualified clearing agency on a net, omnibus basis.

[38] *See* paragraph (e)(2) to Rule 15c3–3 (stating that ''with respect to each computation required pursuant to paragraph (e)(1) of Rule 15c3–3, a broker-dealer must not accept or use any of the amounts under items comprising total credits under the formula referred to in paragraph (e)(1) of Rule 15c3–3 except for the specified purposes indicated under items comprising total debits under the formula''.).

[39] *See* 17 CFR 240.15c3–3a, Items 1 and 2.

[40] *See* Treasury Clearing Adopting Release, 89 FR at 2768.

[41] *See* Note H(b)(3) to Exhibit A to Rule 15c3–3, 17 CFR 240.15c3–3a. *See also* Treasury Clearing Adopting Release, 89 FR at 2767–68.

[42] *See* FICC Note H Approval Notice, CME Securities Clearing Inc. Note H Approval Notice, and ICE Clear Credit LLC Note H Approval Notice.

procedures reasonably designed to ensure ongoing compliance with the conditions of this exemptive order. This condition will help ensure firms develop the operational and process controls necessary to ensure that they can comply with the conditions of this order on an ongoing basis.

The seventh condition provides that to the extent a broker-dealer delivers margin to a qualified clearing agency pursuant to this relief, such margin must remain subject to the other applicable conditions of Note H not exempted under this order, including paragraphs (b)(2)(ii) through (v). The Commission is adopting this condition to explicitly reflect the limitation on the scope of the exemptive relief this order provides. Further, this condition is designed to ensure that broker-dealers comply with the other applicable conditions of Note H not exempted under this order, which were designed to permit a debit under circumstances that provide protections to customers.

The relief is narrowly tailored to what is necessary to permit a broker-dealer to include an Item 15 debit in the reserve computations without a gross calculation and delivery requirement, in a manner that is consistent with the customer protection objectives of Rule 15c3–3.

For the reasons discussed above, providing this exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.

III. Conclusion

Accordingly, *it is hereby ordered*, pursuant to section 36(a)(1) of the Exchange Act, that a broker-dealer is exempt from the requirement in paragraph (b)(2)(i) of Note H of Rule 15c3–3a to deliver the separate margin amount for each customer of the broker-dealer calculated by the qualified clearing agency on a gross, customer-by-customer basis, as well as the requirement in paragraph (b)(1) of Note H of Rule 15c3–3a for a broker-dealer to deliver customer cash or securities to a qualified clearing agency on a gross, customer-by-customer basis or to temporarily prefund a specific customer's margin requirement, provided the conditions below are met. Under this conditional exemption, broker-dealers may include a debit in their reserve computations for margin required and on deposit with a qualified clearing agency resulting from transactions in U.S. Treasury securities in customer accounts that have been cleared, settled, and novated by the clearing agency, in cases where the broker-dealer has delivered the margin collateral on a net, omnibus basis. This relief applies to customer accounts at a qualified clearing agency where the qualified clearing agency calculates margin on either a net, omnibus or gross, customer-by-customer basis, subject to the following conditions:

(1) *Eligibility Limitation:* The relief applies solely to margin required and on deposit with a qualified clearing agency in connection with the following types of transactions in U.S. Treasury securities in customer accounts that have been cleared, settled, and novated by the qualified clearing agency: (1) purchases and sales of U.S. Treasury securities; and (2) U.S. Treasury securities repurchase and reverse repurchase agreements.

(2) The broker-dealer delivers the following cash and securities to the qualified clearing agency to meet the customer margin requirement:

(i) cash;

(ii) U.S. Treasury securities;

(iii) qualified customer securities; or

(iv) any combination of clauses (i) through (iii) above.

(3) *Permitted Debit.* The amount the broker-dealer includes in the Item 15 debit in the reserve computations must equal the least of:

(i) the amount of margin collected from customers in connection with U.S. Treasury securities transactions of the broker-dealer's customers that are cleared, settled, and novated by the qualified clearing agency;

(ii) the amount of margin required for U.S. Treasury securities positions of the broker-dealer's customers that are cleared, settled, and novated by the qualified clearing agency; or

(iii) the total of: (A) cash, (B) U.S. Treasury securities, and (C) qualified customer securities delivered by the broker-dealer to the qualified clearing agency to meet margin requirements arising from U.S. Treasury positions of the broker-dealer's customers that are cleared, settled and novated at the qualified clearing agency.

(4) *Documentation:* The broker-dealer must maintain books and records sufficient to identify the amount of customer margin collected and delivered to the qualified clearing agency.

(5) *Qualified Clearing Agency Rulebook Amendments.* The rules of the qualified clearing agency must have been amended to reflect the conditions of this exemptive order.

(6) *Procedures:* The broker-dealer must adopt and implement written policies and procedures reasonably designed to ensure ongoing compliance with the conditions of this exemptive order.

(7) To the extent a broker-dealer delivers margin to a qualified clearing agency consistent with this exemptive order, such margin must remain subject to the other applicable conditions of Note H not exempted under this order, including paragraphs (b)(2)(ii) through (v).

By the Commission.

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106809; File No. SR–CBOE–2026–084]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Definition of Clearing Corporation in its Rules and Make Corresponding Changes Throughout its Rules

November 4, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 23, 2026, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend the definition of Clearing Corporation in its Rules and make corresponding changes throughout its Rules, as well as update Rule 5.2 regarding units of trading. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/options/regulation/rule_filings/cone/*), and at the principal office of the Exchange.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the definition of Clearing Corporation in its Rules and make corresponding changes throughout its Rules, as well as update Rule 5.2 regarding units of trading. For background, Rule 1.1 currently defines the ''Clearing Corporation and OCC'' as The Options Clearing Corporation. Prior to October 22, OCC was the only clearing corporation registered under Section 17A of the Securities and Exchange Act to clear options listed on a national securities exchange.[3] However, the Securities and Exchange Commission (the ''Commission'') recently approved an application of Cboe Clear US, LLC (''CCUS'') seeking temporary registration as a clearing agency under Section 17A of the Act.[4] Further, it is possible additional entities could register as a clearing agency under the Act to clear listed options. As indicated in a separate Exchange rule filing the Commission recently approved,[5] the Exchange intends to clear certain options through CCUS. This proposed rule change would accommodate the clearing of options listed for trading on the Exchange and cleared by either OCC or CCUS (or any other clearing agencies that become registered under Section 17A of the Act).

The proposed rule change amends the definition of Clearing Corporation in Rule 1.1 to mean the clearing agency registered to clear listed options under Section 17A of the Act that is the issuer of and clearing agency for the applicable option or at which a Clearing Trading Permit Holder[6] is a clearing member. The proposed rule change separately defines OCC as The Options Clearing Corporation, as the Exchange retains certain references to OCC with respect to certain options that will continue to be issued and cleared by OCC. Additionally, the proposed Rule change amends the definition of Rules of the Clearing Corporation in Rule 1.1 to mean the governing documents and rules of the Clearing Corporation, and all written interpretations thereof, as they may be in effect from time to time; in other words, the rules of the Clearing Corporation will refer to the governing documents and rules of the applicable registered clearing agency. The proposed rule change amends various other rule provisions to refer to the Clearing Corporation rather than OCC and to otherwise modify those provisions so they contemplate multiple registered clearing agencies (*e.g.,* add that a reference to Clearing Corporation means the ''applicable'' Clearing Corporation or the Clearing Corporation ''that is the issuer of the applicable options'').[7] Pursuant to the proposed definition of Clearing Corporation, these Rules, as well as current Rules that reference Clearing Corporation, will refer to the applicable registered clearing agency in the context of the Rule rather than OCC.

The proposed rule change similarly amends Rule 3.61 regarding letters of guarantee and authorization to account for the existence of multiple registered clearing agencies that clear options listed on the Exchange and Clearing TPHs being Clearing Members of more than one of such clearing agencies. First, subparagraph (a)(4) currently provides if the Clearing Corporation restricts the activities of a Clearing TPH or suspends a Clearing TPH as a Clearing Member of the Clearing Corporation, the Exchange may take action as necessary to give effect to the restriction or suspension. For example, if the Clearing Corporation restricts transactions cleared by a clearing Trading Permit Holder that is a Clearing Member of that Clearing Corporation to ''closing only'' transactions, the Exchange may similarly restrict transactions on the Exchange for clearance by that Clearing TPH as a Clearing Member of the Clearing Corporation to ''closing only'' transactions. Similarly, if the Clearing Corporation suspends a Clearing TPH, the Exchange may prevent access and connectivity to the Exchange by the suspended Clearing TPH. The proposed rule change amends this provision so actions the Exchange may take against a Clearing TPH pursuant to this provision are in response to actions taken by the specific Clearing Corporation that took action against the Clearing TPH. While the proposed rule change provides that the Exchange may restrict transactions to closing only in options a Clearing Corporation issues if that Clearing Corporation similarly restricts that Clearing TPH, the proposed rule change does not prevent the Exchange from exercising its authority to impose restrictions on a Clearing TPH provided by other Rules. Further, if the Exchange prevents access and connectivity to the Exchange by a Clearing TPH that is suspended by one Clearing Corporation, that Clearing TPH will not be able to access and connect to the Exchange to participate in transactions in options issued by another Clearing Corporation. If a CTPH is suspended as a Clearing Member by one Clearing Corporation in accordance with rules of that Clearing Corporation, the Exchange believes such action by that Clearing Corporation makes it appropriate for the Exchange to prevent access to the Exchange in all options, even if another Clearing Corporation does not take similar action against that CTPH.

[3] 15 U.S.C. 78q–1.

[4] *See* Securities Exchange Act Release No. 106723 (October 22, 2026) (Order Granting an Application, as Amended, for Temporary Registration as a Clearing Agency under Section 17A of the Securities Exchange Act of 1934).

[5] *See* Securities Exchange Act Release No. 106659 (October 13, 2026), 91 FR 65854 (October 16, 2026) (SR–CBOE–2026–061).

[6] A Clearing Trading Permit Holder is a Trading Permit Holder (as defined in the Exchange's Bylaws) (''TPH'') that has been admitted to membership in the Clearing Corporation pursuant to the provisions of the Rules of the Clearing Corporation and is self-clearing or that clears transactions for other Trading Permit Holders. *See* Rule 1.1. Pursuant to the proposed rule change, a Clearing TPH is a TPH admitted to membership in any registered clearing agency and could clear transactions in options issued and cleared by that registered clearing agency. The proposed rule change makes minor updates to the definition of Clearing TPH in Rule 1.1 to account for the possibility of multiple registration clearing agencies that clear options listed on the Exchange.

[7] *See* Rules 1.1 (definitions of Capacity and Rules of the Clearing Corporation), 3.61(a) and (d), 4.5, Interpretation and Policy .04, 4.6, 5.2 (the Exchange notes there are certain instances in which the Exchange may establish the unit of trading for an option rather than the applicable Clearing Corporation, as set forth in the Exchange and Clearing Corporation Rules), 5.10, 5.11, 5.53(a)(2) (the proposed rule change also makes nonsubstantive changes to this provision to provide that Market-Makers must comply with ''applicable'' Rules of the Exchange and adds the phrase ''rules of'' before ''the Federal Reserve Board,'' in addition streamlining the provision by replacing ''as well as the'' with a comma), 5.65 (which leaves the reference to OCC but adds that an exchange may clear options through any other Clearing Corporation to account for the possibility that options trading on a national securities exchange that would be subject to linkage rules may clear through a registered clearing agency other than OCC), 6.3, 6.4 (modifying the name of the Rule), 8.30, Interpretation and Policy .04(a)(9) (which also makes the term ''national securities exchange'' lower-cased since it is not a defined term), 10.3(a)(9) and Interpretations and Policies .03 and .06

Similarly, the proposed rule change amends subparagraphs (a)(5) and (6) to account for the possibility of multiple clearing agencies by providing that the effectiveness of a Clearing TPH's letters of guarantee and authorization is tied to that Clearing TPH's status as a Clearing Member at the Clearing Corporation to which those letters relate. In other words, if a Clearing TPH is a Clearing Member of two Clearing Corporations, it will have letters of guarantee and authorization on file with the Exchange for each such Clearing Corporation. If the Clearing TPH's status as a Clearing Member of one Clearing Corporation is terminated or suspended (but the Clearing TPH remains an active Clearing Member the other Clearing Corporation), only the letters of guarantee and authorization on file with the Exchange with respect to the Clearing Corporation at which the Clearing TPH's membership was terminated will be invalidated. The Exchange believes it is appropriate for the effectiveness of a Clearing TPH's letters of guarantee and authorization to be dependent on the Clearing TPH's membership at the Clearing Corporation to which those letters apply. This ultimately results in the same action that occurs today and merely applies these rule provisions to each Clearing Corporation separately.[8]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[9] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [11] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest because it render the Exchange's Rules clearing agency-neutral. Specifically, the proposed rule change will accommodate the clearing of options listed for trading on the Exchange by any registered clearing agency, rather than just OCC. As noted above, the CCUS recently became temporarily registered under the Act to clear listed options, including certain options the Exchange intends to list soon. To the extent the Commission approves CCUS's application, or the application for registration as an options clearing agency under Section 17A of the Act of any other entity, the proposed rule change will update the Exchange's Rules to account for clearing of any options the Exchange lists for trading that may be issued and cleared by any such entity.

The Exchange also believes the proposed rule changes to Rule 3.61 will promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system. Specifically, the proposed rule change will allow the Exchange to take the same actions it may take against a Clearing TPH today in response to actions taken by a Clearing Corporation against the Clearing TPH but aligns the Exchange's actions with the actions of the specific Clearing Corporation that took actions against the Clearing TPH. Further, the proposed rule change ties the effectiveness of a Clearing TPH's letters of guarantee and authorization at the Exchange to the Clearing TPH's membership at the specific Clearing Corporation to which those letters apply. This ultimately results in the same action that occurs today and merely applies these rule provisions to each Clearing Corporation separately.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change to amend the definition of Clearing Corporation (and make conforming changes) will impose any burden on intramarket competition, because it applies to all clearing agencies registered to clear options pursuant to Section 17A of the Act (including OCC) in the same manner. Any Rules referencing a Clearing Corporation or the Rules of the Clearing Corporation will apply to that entity in the same manner as they do to OCC today. Thus, any TPH that decides to become a clearing member of any Clearing Corporation other than OCC will have the same responsibilities and obligations under the Exchange's Rules applicable to Clearing TPHs as Clearing TPHs that are clearing members of OCC. The Exchange does not believe the proposed rule change to amend the definition of Clearing Corporation (and make conforming changes) will impose any burden on intermarket competition, and in fact may relieve any burden on or otherwise promote competition, because it may facilitate competition with respect to clearing listed options, which may benefit market participants.

The Exchange does not believe the proposed rule changes to Rule 3.61 will impose any burden on intramarket competition because they will apply to all Clearing TPHs in the same manner. The proposed rule change does not permit the Exchange to take action against a Clearing TPH the Rules do not already permit in response to action taken by the Clearing Corporation; rather, the proposed rule change ties these permissible Exchange actions to actions taken by the specific Clearing Corporation(s) against the Clearing TPH. Further, the Exchange does not believe the proposed rule changes to Rule 3.61 will impose any burden on intermarket competition, because it ties actions the Exchange may take against a Clearing TPH to actions a specific Clearing Corporation took action against the Clearing TPH.

[8] The additional language that if a Clearing TPH's status as a TPH is terminated or suspended, then all existing letters of guarantee and authorization from that Clearing TPH for all Clearing Corporations are invalid, is within current subparagraphs (a)(5) and (6). The proposed rule change merely separates it out, but has no substantive impact on how that authority will be applied.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Id.*

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [14] and Rule 19b–4(f)(6) thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6) [16] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[17] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay to immediately account for the existence of two registered clearing agencies that clear options listed on the Exchange. The proposal would render the Exchange's Rules clearing agency-neutral, and thereby accommodate the clearing of options listed for trading on the Exchange by any registered clearing agency, rather than just OCC. The Exchange states that its proposed rule will have no impact on how options currently listed for trading on the Exchange are cleared. To the extent the Exchange lists options cleared by a registered clearing agency other than OCC, such options will trade on the Exchange in the same manner as they do with other options today and the Exchange will submit options for clearing to such entity as set forth in its Rules (and thus as it currently does for OCC). For these reasons, the Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings under Section 19(b)(2)(B) [19] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CBOE–2026–084 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CBOE–2026–084. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CBOE–2026–084 and should be submitted on or before November 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22751 Filed 11–6–26; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 15 U.S.C. 78s(b)(2)(B).

[20] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. IC–36320A; File No. 811–22684]

Daxor Corporation

November 4, 2026.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of an application for deregistration under section 8(f) of the Investment Company Act of 1940 (the ''Act'').

SUMMARY OF APPLICATION: Applicant requests an order declaring that it has ceased to be an investment company.[1]

APPLICANT: Daxor Corporation.

FILING DATES: The application was filed on February 9, 2026, and amended on May 21, 2026, June 17, 2026, September 4, 2026, and October 9, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the request will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicant with a copy of the request by email, if an email address is listed for the Applicant below, or personally or by mail, if a physical address is listed for the Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time, on November 30, 2026, and should be accompanied by proof of service on the Applicant, in the

[1] The Commission issued a notice of application on September 4, 2026, Release No. IC–36320. Applicant subsequently amended the application to add additional information regarding ongoing litigation to which Applicant is a party.

form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicant: Robert J. Michel, Daxor Corporation, 107 Meco Lane, Oak Ridge, TN 37830; and Peter D. Fetzer, Foley & Lardner LLP, 777 East Wisconsin Avenue, Milwaukee, WI 53202.

FOR FURTHER INFORMATION CONTACT: Adam M. Large, Senior Special Counsel, or Thomas M. Ahmadifar, Branch Chief, at (202) 551–6720 or *IMOCC@sec.gov* (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number at the top of this document, or for the Applicant using the Company name search field on the SEC's EDGAR system. The SEC's EDGAR system may be searched at *https://www.sec.gov/search-filings.* You may also call the SEC's Office of Investor Education and Assistance at (202) 551–8090.

Applicant's Representations:

1. Applicant was originally incorporated in New York State as Iatric Corporation in May 1971 for cryobanking services and discontinued these services through its wholly-owned subsidiary, Scientific Medical Systems in 2017. In October 1971, the name Iatric Corporation was changed to Idant Corporation. In May 1973, the name Idant Corporation was changed to Daxor Corporation.

2. Applicant currently operates as a radiopharmaceutical company and medical device manufacturer selling Volumex Test Kits used with its BVA Companion Analyzer.

3. The Applicant states that it is not engaged in the business of investing, reinvesting, owning, holding or trading in securities. In the past, the Applicant was dependent upon earnings from its investment portfolio to fund operations and was required under the Act to register with the Commission as an investment company. Specifically, on March 30, 2012, the company filed a Form N–8A with the Commission to register as a closed-end management investment company under the Act.

4. Applicant states that it liquidated the remainder of its investment securities (as defined in section 3(a) of the Act) (''Investment Securities'') over the course of 2024 and 2025. As of December 31, 2024 and June 30, 2025, in aggregate, Applicant's investment securities represented approximately 3.11% and 1.10%, respectively, of Applicant's total assets measured at fair value on an unconsolidated basis (exclusive of Government securities and cash items).

5. Applicant further states that, as of December 31, 2025, Applicant held no Investment Securities, and Applicant continued to hold no Investment Securities as of the filing date of its Second Amended Application.

6. Applicant states that it is no longer dependent upon earnings from its investment portfolio to fund operations, and Applicant is and holds itself out as a radiopharmaceutical company and medical device manufacturer selling Volumex Test Kits used with its BVA Companion Analyzer.

7. Applicant expects to continue to earn a majority of its gross income from its medical device operations and expects to have no income from Investment Securities, as it will hold funds pending use in its operating business in cash items or Government securities.

8. Applicant represents that it has always conducted its business as an operating company, and that it had never primarily been in, or held itself out to be in, the business of investing, reinvesting, owning, holding or trading in securities. Applicant further represents that its registration under the Act resulted from the percentage of its total assets that at one time consisted of investment securities, and not from the nature of its business. As such, because Applicant did not change the nature of its business, Applicant states that neither the disposition of its investment securities, nor its resulting cessation of investment company status, nor the filing of the Application, required the authorization of a majority of Applicant's outstanding voting securities under Section 13(a)(4) of the Act.

9. Applicant represents that it is not currently a party to any litigation or administrative proceeding that is material to its status as an ''investment company'' under the Act. Applicant states that it is party to litigation concerning alleged misappropriation of intellectual property by a former employee and to a related employment action brought by that former employee; however, Applicant represents that neither proceeding is material to the Applicant and that neither bears upon the determination of whether the Applicant has ceased to be an investment company within the meaning of the Act. Applicant represents that it has timely complied with its obligations to file annual and other reports with the Commission.

10. Applicant represents that its common stock has continuously been traded since its initial public offering. Specifically, the company's common stock is traded on Nasdaq under the symbol DXR. As of May 19, 2025, the company's authorized securities consisted of 10,000,000 shares of common stock.

11. Further, Applicant represents that it is, and will remain, subject to the reporting requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended (the ''Exchange Act. Following deregistration as an investment company under the Act, Applicant will continue to file periodic and current reports with the Commission under the Exchange Act, including reports on Forms 10–K, 10–Q and 8–K, as an operating company.

Applicant's Legal Analysis:

1. Section 8(f) of the Act provides that whenever the Commission, upon application or its own motion, finds that a registered investment company has ceased to be an investment company, the Commission shall so declare by order and upon the taking effect of such order, the registration of such company shall cease to be in effect.

2. Section 3(a)(1)(A) of the Act defines an ''investment company'' as any issuer that ''is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, or trading in securities.'' Section 3(a)(1)(C) of the Act defines an ''investment company'' as any issuer that ''is engaged or proposes to engage in the business of investing, reinvesting, owning, holding, or trading in securities, and owns or proposes to acquire investment securities having a value exceeding 40 per centum of the value of such issuer's total assets (exclusive of Government securities and cash items) on an unconsolidated basis.'' [2]

3. Section 3(b)(1) of the Act provides that ''[n]otwithstanding paragraph (1)(C) of subsection (a), none of the following

[2] Section 3(a)(2) of the Act defines ''investment securities'' as ''all securities except (A) Government securities, (B) securities issued by employees' securities companies, and (C) securities issued by majority-owned subsidiaries of the owner which (i) are not investment companies, and (ii) are not relying on the exception from the definition of investment company in paragraph (1) or (7) of subsection (c).''

persons is an investment company within the meaning of this title: (1) any issuer primarily engaged, directly or through a wholly owned subsidiary or subsidiaries, in a business or businesses other than that of investing, reinvesting, owning, holding, or trading in securities.'' Rule 3a-1 under the Act states that ''[n]otwithstanding section 3(a)(1)(C) of the Act, an issuer will be deemed not to be an investment company under the Act, provided, that: (a) no more than 45 percent of the value (as defined in section 2(a)(41) of the Act) of such issuer's total assets (exclusive of Government securities and cash items) consists of, and no more than 45 percent of such issuer's net income after taxes (for the last four fiscal quarters combined) is derived from, securities other than: (1) Government securities; (2) securities issued by employees' securities companies; (3) securities issued by majority-owned subsidiaries of the issuer (other than subsidiaries relying on the exclusion from the definition of investment company in section 3(b)(3) or (c)(1) of the Act) which are not investment companies; and (4) securities issued by companies: (i) which are controlled primarily by such issuer; (ii) through which such issuer engages in a business other than that of investing, reinvesting, owning, holding or trading in securities; and (iii) which are not investment companies; (b) the issuer is not an investment company as defined in section 3(a)(1)(A) or 3(a)(1)(B) of the Act and is not a special situation investment company; and (c) the percentages described in paragraph (a) of this section are determined on an unconsolidated basis, except that the issuer shall consolidate its financial statements with the financial statements of any wholly-owned subsidiaries.''

4. Applicant states that it is no longer an investment company as defined in section 3(a)(1)(A) or section 3(a)(1)(C). As noted above, Applicant states that, as of December 31, 2025, as well as through the date of the filing of its Second Amended Application, it did not hold any investment securities (exclusive of Government securities and cash items). Applicant asserts that it is primarily engaged in the business of owning, operating, and managing its business as a radiopharmaceutical company and medical device manufacturer.

Applicant argues that its historical development, its public representations, the activities of its directors and officers, the nature of its present assets and the sources of its present income support this assertion. Applicant states that it is thus qualified for an order of the Commission pursuant to section 8(f) of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22749 Filed 11–6–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106811; File No. SR–IEX–2026–44]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Pursuant to IEX Rule 15.110(a) and (c) To Amend the IEX Equities Fee Schedule

November 4, 2026.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on October 29, 2026, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) of the Act,[4] and Rule 19b–4 thereunder,[5] the Exchange is filing with the Commission a proposed rule change to amend the Exchange's equities fee schedule applicable to Members [6] (the ''IEX Equities Fee Schedule''),[7] pursuant to IEX Rule 15.110(a) and (c), to introduce an additional criteria to qualify for one of its displayed liquidity adding rebate tiers. Changes to the IEX Equities Fee Schedule pursuant to this proposal are effective upon filing,[8] and will be operative on December 1, 2026.

The text of the proposed rule change is available at the Exchange's website at *https://www.iexexchange.io/resources/regulation/rule-filings* and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the Transaction Fees section of its Fee Schedule, pursuant to IEX Rule 15.110(a) and (c), to introduce an additional way to qualify for one of its Displayed Liquidity Adding Rebate Tiers [9] for executions priced at or above $1.00 per share.[10] Specifically, the Exchange proposes to modify Displayed Liquidity Adding Rebate Tier 8 to introduce an additional eligibility basis, as described below. IEX is not proposing to change the amounts of any rebates or fees, or the overall tiering pricing structure in the Transaction Fees section of the Fee Schedule.

Displayed Liquidity Adding Rebate Tiers

IEX currently offers Members nine Displayed Liquidity Adding Rebate Tiers based on the Member's trading or quoting activity in the immediately preceding month.[11] These rebates,

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

[6] *See* IEX Rule 1.160(s).

[7] *See* IEX Equities Fee Schedule, available at *https://www.iex.io/resources/trading/fee-schedule.*

[8] 15 U.S.C. 78s(b)(3)(A)(ii).

[9] *See* footnote 4 to the Transaction Fees, Base Rates table and Fee Code Combinations and Associated Fees table of the IEX Equities Fee Schedule, *supra* note 4.

[10] Nothing in this rule filing affects trades below $1.00 per share (''sub-dollar trades''), which will continue to receive a rebate equal to 0.15% of the total dollar value of the execution (''TDV'') for displayed liquidity adding executions. Sub-dollar trades will continue to have no impact on any of the rebate or fee tier calculations for trades with an execution price of $1.00 per share or more.

[11] IEX Equities Fee Schedule, *supra* note 4, Base Rates table (Base Fee Code ML) and Fee Code Combinations and Associated Fees table, footnote 4. Pursuant to Rule 610(d) of Regulation NMS, all IEX Equities transaction fees and rebates are determinable at the time of execution. Accordingly, all transaction fees and rebates that depend on a Member's trading or quoting activity are based on that activity in the immediately preceding month. *See* Securities Exchange Act Release No. 104541

Continued

which apply equally to executions of Tape A, Tape B, and Tape C securities, are as follows:

• Tier 1: provides Member the Exchange's base fee of FREE for all displayed liquidity adding executions priced at or above $1.00 per share (''Added Displayed Liquidity'') if the Member added less than 5,000,000 ADV [12] of displayed liquidity.

• Tier 2: provides Member a rebate of $0.0010 per share for all Added Displayed Liquidity if the Member traded at least 10,000,000 non-displayed ADV [13] and less than 20,000,000 non-displayed ADV.

• Tier 3: provides Member a rebate of $0.0014 per share for all Added Displayed Liquidity if the Member: (1) added at least 5,000,000 ADV of displayed liquidity and less than 15,000,000 ADV of displayed liquidity; or (2) traded at least 20,000,000 non-displayed ADV; or (3) had an NBBO Time [14] of at least 50% in at least 250 ETPs.[15]

• Tier 4: provides Member a rebate of $0.0016 per share for all Added Displayed Liquidity if the Member: (1) added at least 15,000,000 ADV of displayed liquidity and less than 20,000,000 ADV of displayed liquidity; or (2) had an NBBO Time of at least 50% in at least 750 ETPs.

• Tier 5: provides Member a rebate of $0.0018 per share for all Added Displayed Liquidity if the Member: (1) added at least 20,000,000 ADV of displayed liquidity and less than 25,000,000 ADV of displayed liquidity; or (2) traded at least 30,000,000 non-displayed ADV.

• Tier 6: provides Member a rebate of $0.0020 per share for all Added Displayed Liquidity if the Member: (1) added at least 25,000,000 ADV of displayed liquidity and less than 30,000,000 ADV of displayed liquidity; or (2) traded at least 40,000,000 non-displayed ADV.

• Tier 7: provides Member a rebate of $0.0021 per share for all Added Displayed Liquidity if the Member added at least 30,000,000 ADV of displayed liquidity and less than 40,000,000 ADV of displayed liquidity.

• Tier 8: provides Member a rebate of $0.0022 per share for all Added Displayed Liquidity if the Member added at least 40,000,000 ADV of displayed liquidity and less than 50,000,000 ADV of displayed liquidity.

• Tier 9: provides Member a rebate of $0.0023 per share for all Added Displayed Liquidity if the Member added at least 50,000,000 ADV of displayed liquidity.

The Exchange proposes to modify Tier 8 to add an additional means of qualifying for that rebate tier. Specifically, the Exchange proposes to extend the Tier 8 pricing incentive to Members that add at least 35,000,000 ADV of displayed liquidity, if at least 25,000,000 ADV of the Added Displayed Liquidity was in non-ETP securities. The proposed change is designed to incentivize Members to increase their non-ETP quoting. Thus, under the proposed new qualifying criteria, a Member would qualify for Tier 8 in the current month if, in the immediately preceding month, it added at least 35,000,000 ADV of displayed liquidity, of which at least 25,000,000 ADV was in non-ETP securities. If a Member qualifies for Tier 8 through the new qualification criteria, the associated rebate of $0.0022 per share will be applied to the Member's transactions in the same manner as they currently are: to the Member's executions of displayed liquidity adding orders priced at or above $1.00 per share.

Accordingly, the Exchange proposes to amend the description of Base Fee Code ML (''Add displayed liquidity'') in the Base Rates table and to amend the Tier 8 row in the Displayed Liquidity Adding Rebate Tier table in Footnote 4 to the Transaction Fees section of the IEX Equities Fee Schedule, to introduce the new alternative means of qualifying for Tier 8, which is described above.

IEX is proposing no other changes to the IEX Equities Fee Schedule. As noted above, changes to the IEX Equities Fee Schedule pursuant to this proposal are effective upon filing and will be operative on December 1, 2026.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b) [16] of the Act in general, and furthers the objectives of Sections 6(b)(4) [17] and 6(b)(5) [18] of the Act in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. For the reasons set forth below, the Exchange believes that the proposed rule change is reasonable, equitable, and not designed to permit unfair discrimination.

The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. Based upon informal discussions with market participants, IEX believes that Members and other market participants may be more incentivized to send displayed orders to IEX if the proposed fee structure were adopted. Accordingly, IEX has designed the proposed changes to the rebate tier's qualification criteria to attract and incentivize displayed orders while providing a fee structure that is fair, equitable, and not designed to permit unfair discrimination because the proposed changes will apply equally to all Members who satisfy the criteria.

The Exchange believes that the proposed new criteria for qualifying for Displayed Liquidity Adding Rebate Tier 8 is reasonable because it is designed to incentivize Members to add a meaningful volume of displayed non-ETP liquidity on IEX. The proposed modification to the qualifying criteria for Displayed Liquidity Adding Rebate Tier 8 is within the range of rebates

(January 5, 2026), 91 FR 737 (January 8, 2026) (SR–IEX–2025–39) (amending the Exchange's fee schedule applicable to Members to comply with Rule 610(d) of Regulation NMS).

[12] The IEX Equities Fee Schedule defines ''ADV'' as average daily volume calculated as the number of shares added or removed (as applicable) that execute at or above $1.00 per share, per day. ADV is calculated on a monthly basis, based on trading activity in the immediately preceding month, unless otherwise indicated in the Fee Schedule. Routed shares executed away from IEX, and shares executed in auctions and the Opening Process, are not included in the ADV calculation. The Exchange also excludes from its calculation of ADV any trading day on which the Exchange's system experiences a disruption that lasts for more than 60 minutes during Regular Market Hours and any day with a scheduled early market close. With prior notice to the Exchange, a Member may aggregate its ADV with other Members with which it is affiliated pursuant to Rule 12b–2 under the Act. *See* IEX Equities Fee Schedule, *supra* note 4, Transaction Fees, Definitions and Notes.

[13] ''Non-displayed ADV'' refers to executions with the following Fee Code Combinations: MI, MIB, TI, TIB, TIY, TIYB, TIR, TLW, TLWB, and MIA. *See* IEX Equities Fee Schedule, *supra* note 4, Transaction Fees, Definitions.

[14] ''NBBO Time'' means the Member's Percent Time at NBB plus the Member's Percent Time at NBO. ''Percent Time at NBB'' and ''Percent Time at NBO'' mean, respectively, the aggregate of the percentage of time during Regular Market Hours in which a Member has a displayed order of at least one round lot at the national best bid (''NBB'') or the national best offer (''NBO''). When applied to transaction fees or rebates, NBBO Time is calculated using the Member's quoting activity in the immediately preceding month. For tiers that include NBBO Time as a required criterion, the Exchange determines on a daily basis the number of securities in which the Member met the NBBO Time threshold for that day and, at the end of the month, takes the average (rounded to the nearest whole number) of those daily counts. *See* IEX Equities Fee Schedule, *supra* note 4, Transaction Fees, Definitions and Notes.

[15] The term ''ETPs'' includes any security traded on the Exchange, under unlisted trading privileges pursuant to Rule 19b–4(e) of the Act, as a UTP Derivative Security pursuant to IEX Rule 16.160.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(4).

[18] 15 U.S.C. 78f(b)(5).

offered by competing exchanges, and thus the Exchange does not believe that the proposal raises any new or novel issues not already considered by the Commission in the context of other exchanges' fees.

Finally, to the extent this proposed fee change is successful in incentivizing the entry and execution of displayed non-ETP orders on IEX, such greater non-ETP liquidity will benefit all market participants by increasing price discovery and price formation as well as market quality and execution opportunities in those non-ETP securities. And, as discussed above, IEX does not believe that any aspect of this proposal raises new or novel issues not already considered by the Commission.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market in which market participants can readily favor competing venues if fee schedules at other venues are viewed as more favorable. Consequently, the Exchange believes that the degree to which IEX fees could impose any burden on competition is extremely limited, and does not believe that such fees would burden competition between Members or competing venues. Moreover, as noted in the Statutory Basis section, the Exchange does not believe that the proposed changes raise any new or novel issues not already considered by the Commission.

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because, while different rebates and fees are assessed on Members, these rebate and fee tiers are not based on the type of Member entering the orders that match, but rather on the Member's own trading activity on the Exchange. Further, the proposed fee change is intended to encourage market participants to bring increased order flow to the Exchange and contribute to the public price discovery process, which benefits all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) [19] of the Act.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [20] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2026–44 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–IEX–2026–44. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–IEX–2026–44 and should be submitted on or before November 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22753 Filed 11–6–26; 8:45 am]

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[19] 15 U.S.C. 78s(b)(3)(A)(ii).

[20] 15 U.S.C. 78s(b)(2)(B).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106824; File No. SR–NASDAQ–2026–095]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Set Fees for Nasdaq TotalView Plus and Nasdaq Basic Plus

November 4, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1], and Rule 19b–4 thereunder,[2] notice is hereby given that on November 2, 2026, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to set fees for Nasdaq TotalView Plus and Nasdaq Basic Plus at or below fees currently charged for the combined underlying Depth-of-Book and Top-of-Book products offered by the Nasdaq U.S. Equity Markets.[3]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] This filing replaces SR-Nasdaq-2026–091, which was withdrawn on November 2, 2026. It was previously filed as SR–Nasdaq–2026–076, which was withdrawn on October 21, 2026, SR–Nasdaq–2026–071, which was withdrawn on September 8, 2026, and SR–Nasdaq–2026–070, which was withdrawn on August 31, 2026.

rulebook/nasdaq/rulefilings, and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to set fees for Nasdaq TotalView Plus and Nasdaq Basic Plus [4] at or below the fees currently charged for the combined underlying Depth-of-Book and Top-of-Book products offered by the Nasdaq U.S. Equity Markets.[5]

The proposed fees will provide customers with the option of lowering market data, networking, and connectivity costs by replacing three separate feeds with one, and setting fees for these two new consolidated data products [6] at a level that is at or below current market data fees for the combined underlying products.[7]

The Exchange believes that this proposal will facilitate the transition to overnight trading in December 2026. As discussed in the product filing for Nasdaq TotalView Plus and Nasdaq Basic Plus,[8] liquidity may be limited for certain stocks in the overnight session. The two new consolidated data products will address this issue by providing investors with a broader view of the market than any of the individual underlying individual exchange feeds, thereby improving the ability of investors to analyze trading in a lower liquidity environment.

Nasdaq TotalView Plus

Nasdaq TotalView Plus includes, with respect to stocks listed on Nasdaq or on any exchange other than Nasdaq, all orders and quotes from all members of any of the Nasdaq U.S. Equity Markets and displayed on a Nasdaq U.S. Equity Market, including all information currently disseminated through Nasdaq TotalView,[9] Nasdaq Texas TotalView,[10] and PSX TotalView,[11] and the aggregate size of such orders and quotes at each price level in the execution functionality of the Nasdaq U.S. equity markets.

Nasdaq Basic Plus

Nasdaq Basic Plus offers the best bid and offer and last sale information for stocks listed on any of the Nasdaq U.S. Equity Markets or any exchange other than Nasdaq and displayed on any of the Nasdaq U.S. Equity Markets or the FINRA/Nasdaq TRF, including all information currently disseminated through Nasdaq Basic,[12] Nasdaq Texas BBO feeds,[13] Nasdaq Texas Last Sale,[14] PSX BBO Feeds,[15] and PSX Last Sale.[16]

Proposed Fees

As set forth in detail below, Nasdaq proposes to set fees for Nasdaq TotalView Plus and Nasdaq Basic Plus at or below fees currently charged for the Depth-of-Book and Top-of-Book products offered by the Nasdaq U.S. Equity Markets. This, together with the networking and connectivity savings inherent in lowering the number of data feeds, is designed to maximize the distribution of consolidated data feeds to investors throughout the 23 hour, 5 days per week schedule set to begin in December 2026.

The Exchange proposes to offer Nasdaq TotalView Plus for the same Professional and Non-Professional Subscriber and enterprise license fees as Nasdaq TotalView.[17] To ensure that market data vendors will be able to offer competing consolidated data products, any firm that certifies to Nasdaq that it will consolidate Nasdaq TotalView, Nasdaq Texas TotalView and Nasdaq PSX TotalView into a data feed solely

[4] *See* Securities Exchange Act Release No. 105997 (July 28, 2026), 81 FR 48466 (July 31, 2026) (SR–Nasdaq–2026–061) (a proposal to introduce Nasdaq TotalView Plus and Nasdaq Basic Plus, two new data feeds which will offer consolidated Top-of-Book and Depth-of-Book information currently disseminated by Nasdaq, Nasdaq Texas, and Nasdaq PSX).

[5] The Nasdaq Stock Market LLC (''Nasdaq''), Nasdaq Texas, LLC (''Nasdaq Texas''), and Nasdaq PHLX LLC equities (''Nasdaq PSX'').

[6] *See* Supra, n.4.

[7] As discussed in further detail below, the proposed fees are also structured to provide market data vendors an incentive to offer their own consolidated market data feeds in competition with Nasdaq TotalView Plus and Nasdaq Basic Plus to widespread dissemination of consolidated data to investors.

[8] *See* Supra, n.4.

[9] *See* Nasdaq Stock Market Rules, Equity 7, Section 123.

[10] Nasdaq Texas TotalView disseminates all individual Nasdaq Texas Equities System participant orders and quotes displayed in the system, the aggregate size of such orders and quotes at each price level, and the trade data for executions that occur within the Nasdaq Texas Equities System. *See* Nasdaq Texas LLC Rules, Equity 7, Section 123.

[11] PSX TotalView disseminates all individual Nasdaq PSX participant orders displayed in Nasdaq PSX, the aggregate size of such orders at each price level, and the trade data for executions that occur within Nasdaq PSX. *See* Nasdaq PHLX LLC Rules, Equity 7, Section 3, PSX TotalView.

[12] Including ''Nasdaq Basic for Nasdaq,'' ''Nasdaq Basic for NYSE,'' and ''Nasdaq Basic for NYSE American.''

[13] The Nasdaq Texas BBO Feeds consist of real-time market information from the Nasdaq Texas Market Center. *See* Nasdaq Texas, LLC, Equity 7, Section 147. ''Nasdaq Texas BBO for Nasdaq'' contains the Nasdaq Texas's best bid and offer for Nasdaq-listed securities. ''Nasdaq Texas BBO for NYSE'' contains Nasdaq Texas's best bid and offer for NYSE-listed securities. ''Nasdaq Texas BBO for Amex'' contains Nasdaq Texas's best bid and offer for Amex-listed securities.

[14] Nasdaq Texas Last Sale is a proprietary data feed containing real-time last sale information for trades executed on Nasdaq Texas. *See* Nasdaq Texas, LLC, Equity 7, Section 139(a). ''Nasdaq Texas Last Sale for Nasdaq'' contains all transaction reports for Nasdaq-listed securities. ''Nasdaq Texas Last Sale for NYSE/Amex'' contains all such transaction reports for NYSE- and Amex-listed securities. ''Nasdaq Texas Last Sale for NYSE/Amex'' also includes transaction reports from other Tape B listing venues, as set forth under Nasdaq Stock Market Rules, Equity 7, Section 139(a) ('''Nasdaq Last Sale for NYSE/NYSE American' contains all such transaction reports for NYSE-listed stocks and stocks listed on NYSE American and other Tape B listing venues.'').

[15] PSX BBO Feeds consist of real-time market information from PSX. *See* Nasdaq PHLX LLC, Equity 7, Section 3 (PSX BBO Feeds). ''PSX BBO for Nasdaq'' contains PSX's best bid and offer for Nasdaq-listed securities. ''PSX BBO for NYSE'' contains PSX's best bid and offer for NYSE-listed securities. ''PSX BBO for NYSE Amex'' contains PSX's best bid and offer for NYSE Amex-listed securities.

[16] PSX Last Sale is a proprietary data feed containing real-time last sale information for trades executed on Nasdaq PSX. *See* Nasdaq PHLX LLC, Equity 7, Section 3 (PSX Last Sale and Nasdaq Last Sale Plus Data Feeds). ''PSX Last Sale for Nasdaq'' contains all transaction reports for Nasdaq-listed securities on Nasdaq PSX. ''PSX Last Sale for NYSE/NYSE Amex'' contains all such transaction reports on Nasdaq PSX for securities listed on NYSE, NYSE Amex, and other exchanges. The phrase ''other exchanges'' refers to other Tape B listing venues, as set forth under Nasdaq Stock Market Rules, Equity 7, Section 139(a) ('''Nasdaq Last Sale for NYSE/NYSE American' contains all such transaction reports for NYSE-listed stocks and stocks listed on NYSE American and other Tape B listing venues.'').

[17] Internal and External Distributor, as well as Direct Access fees, may apply to purchasers of Nasdaq Plus products depending on the customer's use case. *See* Nasdaq Rules, Equity 7, Section 119(b). The Exchange is not proposing to change Distributor or Direct Access fees with this filing.

for external redistribution shall be exempt from Nasdaq Texas Market Data Distributor Fees [18] and Nasdaq PSX Market Data Distributor Fees,[19] and the Monthly External Distributor Fees at Equity 7, Section 119(b) shall be reduced by $350 per month.[20] These three discounts will ensure that vendors will be able to cover the cost of consolidating the underlying feeds.

The Exchange proposes to offer Nasdaq Basic Plus for the same Professional and Non-Professional Subscriber, enterprise license, and Distributor fees as Nasdaq Basic. To ensure that other market data vendors will be able to offer competing consolidated data products, Nasdaq proposes to charge the same monthly administrative and data consolidation fees for Nasdaq Basic Plus as are currently charged for Nasdaq Last Sale Plus to both Internal Distributors [21] and External Distributors [22] to cover the costs of data feed consolidation to be incurred by market data vendors.

With respect to the Market Data Enterprise License for Display Usage,[23] which currently offers both Nasdaq TotalView and Nasdaq Basic in the same enterprise license, the Exchange proposes to offer the Nasdaq TotalView Plus and Nasdaq Basic Plus feeds for the same fees currently charged for the Nasdaq TotalView and Nasdaq Basic.

Details for each of the proposed fees follow.[24]

TotalView Plus

Subscriber Fees

Nasdaq proposes to offer Nasdaq TotalView Plus for the same Professional and Non-Professional Subscriber fees as Nasdaq TotalView. This is, in effect, a waiver of Subscriber [25] and Non-Display Usage [26] fees for Texas TotalView [27] and Entitlement fees for Nasdaq PSX TotalView.[28]

Current Professional Subscriber fees for Nasdaq TotalView are $84 per month (operative January 1, 2026).[29] Non-Display Usage fees based upon Direct Access depend on the number of Subscribers: $412 per month for 1–39 Subscribers (operative January 1, 2026); $16,490 per month for 40–99 Subscribers (operative January 1, 2026); $32,990 per month for 100–249 Subscribers (operative January 1, 2026); and $75,000.00 per month per firm for over 250 Subscribers.

Non-Professional Subscriber fees for Nasdaq TotalView are $15 per month.[30]

All of these Professional and Non-Professional Subscriber fees and Non-Display Usage fees will be the same for both Nasdaq TotalView and Nasdaq TotalView Plus.

Enterprise License Fees

Nasdaq offers two monthly enterprise licenses for Nasdaq TotalView, one for $25,000,[31] and another for $500,000.[32]

The $25,000 per month enterprise license offers customers the right to provide Nasdaq TotalView for Display Usage for Internal Distribution, or for External Distribution to both Professional and Non-Professional Subscribers with whom the firm has a brokerage relationship.[33] Purchasers of this license also pay a monthly fee of $9 for each Non-Professional Subscriber and a monthly fee of $60 for each Professional Subscriber for Display Usage based upon Direct or Indirect Access.

The $500,000 per month enterprise license offers customers Nasdaq Level 2 or Nasdaq TotalView for Display Usage by Professional or Non-Professional Subscribers with whom the firm has a brokerage relationship.[34]

Nasdaq proposes to offer Nasdaq TotalView Plus with each enterprise license for the same monthly charge as Nasdaq TotalView.

Distributor Fees for Depth-of-Book Data

Nasdaq charges fees for distributors of its Depth-of-Book data.[35] Internal Distributors are charged a fee of $1,125 per month (operative January 1, 2026) for Nasdaq-listed security depth entitlements and $565 per month (operative January 1, 2026) for non-Nasdaq-listed security depth entitlements.[36] External Distributors are charged a fee of $2,820 per month (operative January 1, 2026) for Nasdaq-listed security depth entitlements and $1,410 per month (operative January 1, 2026) for non-Nasdaq-listed security depth entitlements.[37] These fees apply to all distributors of real-time Depth-of-Book data, which would include Nasdaq TotalView Plus.

Fee Waiver for Vendors of TotalView Plus

To ensure that market data vendors will be able to offer competing consolidated data products, any firm that certifies to Nasdaq that it will consolidate Nasdaq TotalView, Nasdaq Texas TotalView and Nasdaq PSX TotalView into a data feed solely for external redistribution shall be exempt from External Market Data Distributor Fees for Nasdaq Texas of $1,620 per month [38] and the Monthly External Distributor fee for PSX TotalView of $1,390,[39] and Monthly External Distributor Fees at Equity 7, Section 119(b) shall be reduced by $350 per month.[40]

[18] *See* Nasdaq Texas Rules, Equity 7, Section 119(a)

[19] *See* Nasdaq PHLX Rules, Equity 7, Section 3 (Market Data Distributor Fees).

[20] *See* Nasdaq Stock Market Rules, Equity 7, Sections 119(b) and 119(d). There are two Monthly External Distributor Fees at Section 119(b), one for Nasdaq-listed security depth entitlements and one for Non Nasdaq-listed security depth entitlements.

[21] ''Internal Distributors'' are Distributors that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus data and then distribute that data to one or more Subscribers within the Distributor's own entity.

[22] ''External Distributors'' are Distributors that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus data and then distribute that data to one or more Subscribers outside the Distributor's own entity.

[23] *See* Nasdaq Stock Market Rules, Equity 7, Section 132.

[24] In addition, Nasdaq is proposing to correct references to the Nasdaq NTX exchange at Equity 7, Section 139(e) as a non-substantive modification.

[25] The monthly charge for each Subscriber of Nasdaq Texas TotalView for Nasdaq is currently $22.25 (operative January 1, 2026), and $22.25 (operative January 1, 2026) for NYSE and regional issues for display usage or non-display usage not based upon Direct Access. *See* Nasdaq Texas Rules, Equity 7, Section 123(a)(1).

[26] For non-display usage of Nasdaq Texas TotalView for all issues based upon Direct Access, Distributors currently pay a monthly fee of $58.50 (operative January 1, 2026) for each Professional Subscriber. *See* Nasdaq Texas Rules, Equity 7, Section 123(a)(2).

[27] *See* Nasdaq Texas Rules, Equity 7, Section 123. Nasdaq Texas TotalView disseminates all individual Nasdaq Texas Equities System participant orders and quotes displayed in the system, the aggregate size of such orders and quotes at each price level, and the trade data for executions that occur within the Nasdaq Texas Equities System.

[28] *See* Nasdaq PHLX Rules, Equity 7, Section 3(a)(1)). The monthly charge for the PSX TotalView entitlement is $44.50 (operative January 1, 2026) for each Subscriber for display usage or for non-display usage not based upon Direct Access. The charge paid by non-professional subscribers for access to PSX TotalView Service through an authorized vendor is $1.00 per Subscriber per month. *See* Nasdaq PHLX Rules, Equity 7, Section 3(b).

[29] *See* Nasdaq Stock Market Rules, Equity 7, Section 123(b)(1)(B).

[30] *See id.* Section 123(b)(2)(A).

[31] *See id.* Section 123(c)(1).

[32] *See id.* Section 123(c)(2).

[33] *See id.* Section 123(c)(1).

[34] This license does not apply to Distributor fees.

[35] A ''distributor'' of Nasdaq data is any entity that receives a feed or data file of Nasdaq data directly from Nasdaq or indirectly through another entity and then distributes it either internally (within that entity) or externally (outside that entity). *See* Nasdaq Rules, Equity 7, Section 119(c).

[36] *See* Nasdaq Stock Market Rules, Equity 7, Section 119(b).

[37] *See id.*

[38] *See* Nasdaq Texas Rules, Equity 7, Section 119(a).

[39] *See* Nasdaq PHLX Rules, Equity 7, Section 3 (Market Data Distributor Fees).

[40] *See* Nasdaq Stock Market Rules, Equity 7, Sections 119(b) and 119(d).

The waiver of market data distributor fees for Nasdaq Texas and Nasdaq PSX, together with the proposed reduction of $350 per month in Monthly External Distributor Fees for the Nasdaq Stock Market, will cover the cost of consolidation for vendors. A vendor that seeks to create its own consolidated feed that includes Nasdaq TotalView, Nasdaq Texas TotalView and Nasdaq PSX TotalView would currently pay external distributor fees of $2,820 per month (operative January 1, 2026) for Nasdaq-listed security depth entitlements and $1,410 per month (operative January 1, 2026) for non-Nasdaq-listed security depth entitlements,[41] as well as External Market Data Distributor Fees for Nasdaq Texas of $1,620 per month,[42] and the Monthly External Distributor fee for PSX TotalView of $1,390.[43] A vendor that certifies to Nasdaq that it will consolidate these Nasdaq feeds to formulate its own product would save $350 per month in its monthly Market Data Distributor fees for the Nasdaq Stock Market, and also save $1,620 per month,[44] and $1,390 per month,[45] in external market data distributor fees for Nasdaq Texas and Nasdaq PSX, respectively. This is a total fee reduction of $3,360 per month. The same discount would not apply to non-vendors. Vendors would be able to apply these savings to cover the cost of forming their own consolidated feed, thereby allowing vendors to compete with Nasdaq in the sale of consolidated data products using the Depth-of Book data from Nasdaq affiliates.

Basic Plus

Subscriber Fees

Nasdaq proposes to offer Nasdaq Basic Plus for the same Professional and Non-Professional Subscriber fees as Nasdaq Basic. This is not a fee change, as there are currently no charges for Nasdaq Texas BBO feeds,[46] Nasdaq Texas Last Sale,[47] PSX BBO Feeds,[48] and PSX Last Sale.[49]

The current monthly per Subscriber charges for Nasdaq Basic, or Derived Data therefrom, are $14.10 for Nasdaq Basic for Nasdaq, $7.20 for Nasdaq Basic for NYSE, and $7.20 for Nasdaq Basic for NYSE American.[50]

For Non-Professional Subscribers, there currently is a monthly charge of $0.50 for Nasdaq Basic for Nasdaq, $0.25 for Nasdaq Basic for NYSE, $0.25 for Nasdaq Basic for NYSE American.[51] For Nasdaq Basic Plus, there will be a single charge of $1.00 that will cover Nasdaq Basic for Nasdaq, Nasdaq Basic for NYSE, and Nasdaq Basic for NYSE American.

Enterprise License Fees

Nasdaq offers three monthly enterprise licenses for Nasdaq Basic: a broker-dealer enterprise license for $155,000 per month,[52] another broker-dealer enterprise license for $100,000 per month,[53] and a Media Enterprise license for $100,000.[54]

The broker-dealer enterprise license for $155,000 per month offers internal Professional Subscribers access to Nasdaq Basic for Nasdaq, Nasdaq Basic for NYSE, and Nasdaq Basic for NYSE American, or Derived Data therefrom.[55] The broker-dealer must obtain a separate enterprise license for each External Distributor that controls display of the product if it wishes such External Distributor to be covered by an enterprise license rather than per-Subscriber fees. The license also offers access to Nasdaq Last Sale data for its own stock price and the stock price of up to ten of its competitors or peers, for display use on the broker-dealer's internal website.

The broker-dealer enterprise license for $100,000 per month offers any Nasdaq Basic Product, or Derived Data therefrom, through any electronic system approved by Nasdaq to an unlimited number of Professional and Non-Professional Subscribers who are natural persons and with whom the broker-dealer has a brokerage relationship.[56] This includes the right to distribute Nasdaq Last Sale data to the general investing public for Display Usage and to distribute Nasdaq Basic to the general investing public via television, websites, mobile devices, or any other unrestricted means of transmission for Display Usage.[57] A separate enterprise license is required for each discrete electronic system for distribution of Nasdaq Basic that is approved by Nasdaq and used by the broker-dealer.

The Media Enterprise License for $100,000 per month offers the right to distribute all or part of Nasdaq Basic for Display Usage to the general investing public.[58] Information may be made available via television, websites, mobile devices, or any other unrestricted means of transmission for Display Usage, to an unlimited number of Users. An External Distributor may use a Hosted Display Solution to distribute the data, provided that the External Distributor purchases a separate Media Enterprise License for each such Hosted Display Solution. Data may only be used for informational and non-trading purposes and distribution of Derived Data is not permitted.

With each enterprise license listed above, Nasdaq proposes to offer Nasdaq Basic Plus for the same fee as Nasdaq Basic.

Distributor Fees

Nasdaq proposes to offer Nasdaq Basic Plus for the same Distributor fees as Nasdaq Basic.

Each Distributor of any Nasdaq Basic product currently pays a fee of $1,680 for internal distribution or a fee of $2,140 for external, or external and internal, distribution.[59] A Distributor may also pay $1,500 per month to create and distribute Derived Data from Nasdaq Basic to an unlimited number of non-professional subscribers.[60] In addition, a Distributor that employs a Hosted Display Solution of distribute Derived Data taken from Nasdaq Basic pays a fee of $400 per month for each Hosted Display Solution.[61]

[41] *See* Nasdaq Stock Market Rules, Equity 7, Section 119(b).

[42] *See* Nasdaq Texas Rules, Equity 7, Section 119(a).

[43] *See* Nasdaq PHLX Rules, Equity 7, Section 3 (Market Data Distributor Fees).

[44] *See* Nasdaq Texas Rules, Equity 7, Section 119(a).

[45] *See* Nasdaq PHLX Rules, Equity 7, Section 3 (Market Data Distributor Fees).

[46] *See* Nasdaq Texas Rules, Equity 7, Section 147.

[47] *See* Nasdaq Texas, Rules, Equity 7, Section 139(a).

[48] *See* Nasdaq PHLX Rules, Equity 7, Section 3, (PSX BBO Feeds).

[49] *See* Nasdaq PHLX Rules, Equity 7, Section 3 (PSX Last Sale and Nasdaq Last Sale Plus Data Feeds).

[50] *See* Nasdaq Stock Market Rules, Equity 7, Section 147(b)(1).

[51] *See id.* Section 147(b)(2).

[52] *See id.* Section 147(b)(4).

[53] *See id.* Section 147(b)(5).

[54] *See id.* Section 147(b)(6).

[55] *See id.* Section 147(b)(4).

[56] *See id.* Section 147(b)(5).

[57] Use of the Nasdaq Basic data obtained through this license by any Professional Subscriber is limited to the context of the brokerage relationship between that person and the broker-dealer, except that a Distributor may make Nasdaq Basic data obtained through this license available to up to and including 4,500 internal Subscribers operating on an electronic system approved by Nasdaq, which may be used by Professional Subscribers employed by the broker-dealer in support of brokerage services to investors; any distribution to over 4,500 internal Subscribers, or any usage by Professional Subscribers not in support of brokerage services to investors on an approved platform, would be subject to any applicable fees set forth in Equity 7, Section 147(b).

[58] *See* Nasdaq Stock Market Rules, Equity 7, Section 147(b)(6).

[59] *See* Nasdaq Stock Market Rules, Equity 7, Section 147(c)(1).

[60] *See* Nasdaq Stock Market Rules, Equity 7, Section 147(c)(2).

[61] *See* Nasdaq Stock Market Rules, Equity 7, Section 147(c)(3).

The Exchange proposes that all of these fees also apply to Nasdaq Basic Plus.

Data Consolidation Fee for Nasdaq Basic

Firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus or both shall pay the monthly administrative fees for Nasdaq Last Sale, NTX Last Sale, and PSX Last Sale. Additionally, Internal Distributors [62] or External Distributors [63] of Nasdaq Last Sale Plus or Nasdaq Basic Plus or both shall pay a data consolidation fee of $350 per month. Firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus would either be liable for Nasdaq Last Sale fees or Nasdaq Basic fees, but not both.

This fee is designed to cover the data consolidation costs of market data vendors to ensure that they will be able to offer competing consolidated data products.

As a conforming change, the Exchange proposes to modify Nasdaq Last Sale Plus to state that firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus or both shall pay the monthly administrative fees for Nasdaq Last Sale, NTX Last Sale, and PSX Last Sale, as well as a data consolidation fee of $350 per month.

Market Data Enterprise License for Display Usage

Nasdaq proposes to offer both Nasdaq TotalView Plus and Nasdaq Basic Plus through its Market Data Enterprise License for Display Usage.

A Distributor that is also a broker-dealer or an investment adviser may pay a monthly enterprise license fee of $600,000 to distribute, for Display Usage only, Depth-of-Book data and Nasdaq Basic to an unlimited number of internal and external recipients, to be used only in the context of a brokerage relationship with a broker-dealer or an engagement with an investment adviser, as well as Nasdaq Basic under the terms and conditions set forth at Equity 7, Section 147(b)(6), and NLS and NLS Plus for unlimited external distribution through one of the mechanisms for the general investing public identified at Equity 7, Section 139(b). Alternatively, a Distributor eligible for the enterprise license may purchase a full twelve months of the enterprise license in advance for a monthly fee of $500,000, which may be paid in monthly installments.

Nasdaq proposes to include Nasdaq TotalView Plus and Nasdaq Basic Plus within this license for no additional fee.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[64] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[65] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers because the proposal: (i) offers more customer choice; (ii) prepares investors for overnight trading in potentially low-liquidity environments; (iii) protects competition by covering the data consolidation costs of market data vendors; (iv) proposes fees at or below current levels for Nasdaq and its affiliates; (v) proposes fees that are comparable to those of other exchanges; (vi) sets fees for a voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and potential subscribers may purchase it only if they voluntarily choose to do so; and (vii) offers products to all market participants on a non-discriminatory basis.

1. More Customer Choice

The proposal will expand choice by allowing customers to select whether to purchase best bid and offer information through the separate data feeds of Nasdaq Basic, Nasdaq Texas BBO and PSX BBO (or any combination thereof) separately or in a single feed. Purchasing Nasdaq Basic Plus or Nasdaq TotalView Plus will allow some customers to optimize consumption by ingesting information from multiple markets in a single connection, which may result in cost savings for subscribers based on a more efficient configuration of data feeds. Nothing in this proposal will change the quantity or quality of Depth-of-Book or Top-of-Book information available in the market, as the underlying feeds will remain available, and the proposed feeds are simply amalgamations of those underlying feeds.

2. Prepare for Overnight Trading

Although the consolidation of Top-of-Book and Depth-of-Book data feeds from multiple affiliated exchanges is not new, the Exchange believes that such feeds will become more important with the commencement of overnight trading in December 2026. Because liquidity may be limited for certain stocks in the overnight session, the proposed consolidated feeds will provide investors with a broader view of the market than independent feeds, improving the ability of the investor to analyze market data in a lower liquidity environment. As such, we believe that the creation of these new feeds will facilitate the transition of investors to an overnight trading environment.

3. No Competitive Advantage Relative to Market Data Vendors

In offering Nasdaq Basic Plus and Nasdaq TotalView Plus, Nasdaq will be acting as a redistributor of Depth-of-Book [66] and Top-of-Book [67] products from Nasdaq, Nasdaq Texas, and Nasdaq PSX.

Nasdaq Basic Plus and Nasdaq TotalView Plus will be compiled from the same underlying feeds from Nasdaq, Nasdaq Texas, and Nasdaq PSX that are distributed to the purchasers of those feeds. With respect to speed, the path for the distribution of the information by the Exchange will not be faster than the path for distribution that would be used by a market data vendor to distribute similar, independently created products.

With respect to cost, the Exchange proposes to ensure that market data vendors are able to compete with the proposed fees by introducing a fee adjustment for distributors of Nasdaq TotalView Plus and a consolidation fee for Nasdaq Basic Plus. These proposals will allow vendors to cover the costs of consolidation for Depth-of-Book and Top-of-Book feeds, respectively.[68]

The proposed fee adjustment for Nasdaq TotalView Plus applies to any firm that certifies to Nasdaq that it will consolidate Nasdaq TotalView, Nasdaq Texas TotalView and Nasdaq PSX TotalView into a data feed solely for external redistribution. Such firms will receive a waiver of Nasdaq Texas Market Data Distributor Fees,[69] Nasdaq

[62] ''Internal Distributors'' are Distributors that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus data and then distribute that data to one or more Subscribers within the Distributor's own entity.

[63] ''External Distributors'' are Distributors that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus data and then distribute that data to one or more Subscribers outside the Distributor's own entity.

[64] 15 U.S.C. 78f(b).

[65] 15 U.S.C. 78f(b)(4) and (5).

[66] The underlying Depth-of-Book products are Nasdaq TotalView, Nasdaq Texas TotalView, and PSX TotalView.

[67] The underlying Top-of-Book products are Nasdaq Basic (which includes both best bid and offer and last sale information), Nasdaq Texas BBO, Nasdaq Texas Last Sale, PSX BBO, and PSX Last Sale.

[68] There is no consolidation fee for Nasdaq TotalView because the waiver of distributor fees for Nasdaq Texas and Nasdaq PSX, coupled with the $350 waiver of Nasdaq Stock Market distributor fees, is sufficient to cover the costs of consolidation without any additional fee.

[69] *See* Nasdaq Texas Rules, Equity 7, Section 119.

PSX Market Data Distributor Fees,[70] and a reduction of $350 per month in the Nasdaq Monthly External Distributor Fee.[71] This substantial savings—$1,620 per month for Nasdaq Texas,[72] and $1,390 per month for PSX TotalView,[73] and $350 per month for Nasdaq—will allow vendors to cover the cost of consolidation of Depth-of-Book feeds and will ensure that market data vendors will be able to offer consolidated data products that compete with Nasdaq TotalView Plus.

The proposed fee reduction of $350 per month below the price otherwise available is designed to have the same net impact on vendors as the proposed data consolidation fee of $350 for Nasdaq Basic Plus and the current $350 fee for NLS Plus. The Basic and NLS fees are designed to cover the costs of data feed consolidation. Nasdaq expects the proposed fee reduction for TotalView Plus to do the same, enabling vendors to apply some or all of that savings to consolidating the underlying feeds.

Nasdaq expects that amount of that reduction will be sufficient to cover the costs of consolidation for this Depth-of Book feed. In Nasdaq's experience, consolidating Depth-of-Book data should cost about the same, or somewhat less than, the cost of consolidating Top-of-Book data, notwithstanding the fact that Depth-of-Book products necessarily transmit more information than Top-of-Book products because they include multiple layers of bids and offers, rather than just one.

Consolidating best bid and offer information for Nasdaq Basic Plus requires continuously ''unpacking'' incoming market data, evaluating quotes across venues, determining the best bid and offer, constructing a consolidated view, and republishing that result. Consolidating last-sale data for NLS Plus requires that the provider ensure that trades are delivered in sequence across multiple sources, requiring timestamp management, gap detection, and validation logic to maintain the integrity of the combined feed. Depth-of-Book data, by contrast, is largely a pass-through; there is minimal transformation, calculation, or decision-making applied to the content. While the lower processing cost is somewhat, but not fully, offset by the amount of data being processed, Nasdaq believes that the net effect is that the cost of consolidating a Depth-of-Book feed is less than, and certainly no more than, the cost of consolidating a Top-of-Book feed. In an abundance of caution, Nasdaq proposes to set the fee reduction at $350, which will be more than sufficient to cover the vendor's cost of consolidating Depth-of-Book data.

The proposed reduction of $350 is within range of consolidation fees for competing exchange groups. It is above the NYSE Pillar Depth Consolidation Fee of $250,[74] but below the Cboe One Premium data consolidation fee of $1,000.[75]

The proposed fees for Nasdaq Basic Plus include monthly administrative fees for Nasdaq Last Sale, NTX Last Sale, and PSX Last Sale and a data consolidation fee of $350 per month for Internal Distributors and External Distributors of Nasdaq Basic Plus.[76] This is the current fee charged for Nasdaq Last Sale Plus to ensure that market data vendors will be able to offer competing feeds. The proposed fee is also within the range of similar fees charged by other exchange groups. It is above the NYSE BQT Access Fee of $250[77] but below the $1,000 data consolidation fee for the Cboe One Summary feed.[78]

The Exchange proposes a consolidation fee for both Nasdaq Basic Plus and Nasdaq Last Sale Plus because Nasdaq Basic Plus includes last sale information. Nasdaq expects vendors to use the same processes and servers to consolidate both best bid and offer and last sale information, and therefore the same consolidation fee should be sufficient to cover all data consolidation costs for both, enabling vendors to compete with the Exchange in consolidating and distributing data from multiple exchanges.

4. Proposes Fees at or Below Current Levels

All of the proposed fees are at or below the fees currently charged by Nasdaq and its affiliates for its exchange-only data feeds.

For Nasdaq Basic Plus, all subscriber fees, including both Professional and Non-Professional fees, and enterprise license fees, are exactly the same as currently charged for Nasdaq Basic alone. The proposed data consolidation fee for Nasdaq Basic Plus is exactly the same fee as currently charged for Nasdaq Last Sale Plus, and customers of Nasdaq Last Sale Plus would pay no consolidation fee for Nasdaq Basic Plus. Given that Nasdaq Basic Plus provides information for three exchanges at the same price currently charged for only the Nasdaq exchange, the proposed fees will allow customers to purchase the data of three exchanges for the fees currently charged by just one.

For Nasdaq TotalView Plus, all subscriber fees, including both Professional and Non-Professional fees, Non-Display Usage fees, and enterprise license fees are proposed to be exactly the same as currently charged for Nasdaq TotalView alone. The proposed waiver of Nasdaq Texas Market Data Distributor Fees and Nasdaq PSX Market Data Distributor Fees, as well as the $350 per month reduction of the Nasdaq Monthly External Distributor Fee, will lower fees even further. The proposed Nasdaq TotalView Plus fees therefore offer customers a discount below current fees.

5. Proposed Fees Are Comparable to Those of Other Exchanges

Exchange groups affiliated with both NYSE and Cboe offer consolidated data products comparable to Nasdaq Basic Plus and Nasdaq TotalView Plus.

For Top-of-Book products, the proposed Nasdaq Basic Plus feed is comparable to the NYSE BQT feed, which provides best bid and offer and last sale information for the New York Stock Exchange and its affiliates,[79] and the Cboe One feed, which disseminates the aggregate best bid and offer of all displayed orders traded on Cboe's affiliated exchanges.[80]

For Depth-of-Book products, the proposed Nasdaq TotalView Plus feed is comparable to the NYSE Pillar Depth feed, which provides a consolidated view of the ten best price levels on both the bid and offer sides across the NYSE Group's combined limit order books for the NYSE-affiliated exchanges,[81] and

[70] *See* Nasdaq PHLX Rules, Equity 7, Section 3.

[71] *See* Nasdaq Stock Market Rules, Equity 7, Sections 119(b) and 119(d).

[72] *See* Nasdaq Texas Rules, Equity 7, Section 119(a).

[73] *See* Nasdaq PHLX Rules, Equity 7, Section 3 (Market Data Distributor Fees).

[74] *See* NYSE Proprietary Market Data Pricing Guide (October 9, 2026) at 31, available at *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf.*

[75] *See* Cboe Market Data Product Price List, available at *https://cdn.cboe.com/resources/membership/US_Market_Data_Product_Price_List.pdf.*

[76] Firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus would either be liable for Nasdaq Last Sale fees or Nasdaq Basic fees, but not both.

[77] *See* NYSE Proprietary Market Data Pricing Guide (October 9, 2026) at 29, available at *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf.*

[78] *See* Cboe Market Data Product Price List, available at *https://cdn.cboe.com/resources/membership/US_Market_Data_Product_Price_List.pdf.*

[79] *See* Securities Exchange Act Release No. 73553 (November 6, 2014), 79 FR 67491 (November 13, 2014) (SR–NYSE–2014–40).

[80] *See* Securities Exchange Act Release No. 82423 (December 29, 2017), 83 FR 579 (January 4, 2018) (SR–CboeEDGA–2017–004).

[81] *See* Securities Exchange Act Release No. 100030 (April 25, 2024), 89 FR 35260 (May 1, 2024)

the Cboe One Premium feed, which disseminates aggregated Depth-of-Book information for up to twelve price levels for the Cboe-affiliated exchanges.[82]

As shown below, the combined market share of the Nasdaq- NYSE- and Cboe-affiliated exchanges for the period July 2025 to June 2026 is similar, with the combined market share of the Nasdaq U.S. Equity exchanges over the past year at approximately 14.58 percent,[83] somewhat below the market share of the NYSE affiliates at 18.83 percent,[84] and above the market share of 9.59 percent for Cboe affiliates.[85]

Exchange	Market share (%)
Nasdaq	14.21
Nasdaq Texas	0.26
PSX	0.11
NYSE	8.20
ARCA	10.34
AMEX	0.29
NYSE Texas	0.35
NSX	0.33
IEX	3.43
MEMX	2.19
MIAX	0.95
LTSE	0.01
BATS	3.62
BATSY	0.65
EDGA	0.82
EDGX	4.50
24x	0.06

The Nasdaq- NYSE- and Cboe-affiliated exchange groups each offer different fee schedules, which will impact the fees paid by particular customers differently, depending on the type of customer and its use cases. Although these fee schedules are similar in many respects—all of these groups offer specific Professional and Non-Professional user fees, for example—they differ in important respects that limit the Exchange's ability to compare overall fee levels outside of the context of a particular customer and service order. The NYSE-affiliated exchanges charge access fees, for example, while the Nasdaq-affiliated exchanges do not. Therefore, the fees cannot be compared directly without knowing the details of a particular customer and its specific use cases.

With respect to Top-of-Book information, Nasdaq Basic Plus proposes subscriber fees of $14.10 for Nasdaq Basic for Nasdaq, $7.20 for Nasdaq Basic for NYSE, and $7.20 for Nasdaq Basic for NYSE American,[86] as well as Non-Professional fees of $0.50 for Nasdaq Basic for Nasdaq, $0.25 for Nasdaq Basic for NYSE, and $0.25 for Nasdaq Basic for NYSE American,[87] as discussed above. The Exchange also proposes a data consolidation fee of $350 per month and payment of monthly administrative fees for Nasdaq Last Sale, NTX Last Sale, and PSX Last Sale. There are also enterprise licenses of $100,000 per month [88] and $155,000 per month [89] for broker-dealers for various use cases, and a Media Enterprise license of $100,000.[90]

For Top-of-Book information from NYSE affiliates (Best Quotes & Trades), the per user access fee is $850, the access fee is $6,250, the redistribution fee is $2,500, the professional user fee is $18, the non-professional user fee is $1, and there is an enterprise license for Enterprise Fee: $50,000, and a digital media enterprise license for $65,000.[91]

For Top-of-Book information from Cboe affiliates (Cboe One Summary), external distribution fees are $5,000, professional user fees are $10, Non-Professional User fees are $0.25, Digital Media fees are $15,000, data consolidation fees are $1,000, and there is an enterprise license of $50,000.[92]

Although, as noted above, fees cannot be compared directly without understanding the type of customer, the number of end users, how that customer is using the data, and related information, they can be compared indirectly by analyzing overall market prices. As explained above, the proposed fees are essentially the same as those currently charged for the underlying Nasdaq products, which are, by definition, at current market prices. As the Exchange is proposing no new fees, the new products will also be at current market prices, and therefore continue to be comparable to the fees charged by other exchanges.

The same analysis holds for Depth-of-Book products.

As set forth in detail above, the Exchange proposes the following fees for Nasdaq TotalView Plus: Professional Subscriber fees of $84 per month,[93] Non-Display Usage fees based on a tiered structure,[94] and Non-Professional Subscriber fees of $15 per month.[95] The Exchange also proposes to offer enterprise licenses for $25,000 per month [96] and $500,000 per month.[97] The Exchange also proposes to waive External Market Data Distributor Fees for Nasdaq Texas and the Monthly External Distributor fee for PSX TotalView, and reduce the Nasdaq Monthly External Distributor Fee by $350 per month, for any firm that certifies to Nasdaq that it will consolidate Nasdaq TotalView, Nasdaq Texas TotalView and Nasdaq PSX TotalView into a data feed solely for external redistribution.[98]

For comparison, the NYSE Pillar Depth Feed has an Access Fee of $5,000, an Access & Redistribution Fee of $5,750, a Consolidation Fee of $250, a Multiple Datafeed Fee of $600, a Non-Display Fee of $10,000 (with $30,000 cap for Category 3), a Professional User Fee of $66, a Non-Professional User Fee of $10, a Non-Pro Enterprise User Fee Cap of $55,000 and a Professional & Non-Professional User Fee Cap: $135,550.[99]

The Cboe One Premium feed as an External Distribution fee of $12,500, a Professional User fee of $15, a Non-Professional User fee of $0.50, a Digital Media fee of $25,000, a Data Consolidation fee of $1,000, and an Enterprise license of $100,000.[100]

As is true for Top-of-Book consolidated data fees, the Depth-of-Book consolidated data fees depend on the type of customer, the number of end users, and how that customer is using the data. Nevertheless, the proposed fees are essentially the same as those currently charged for the underlying

(SR–NYSE–2024–24) (introducing the NYSE Pillar Depth feed as immediately effective pursuant to Section 19(b)(3)(A)(iii) of the Act and Rule 19b–4(f)(6) thereunder).

[82] *See* Securities Release Act Release No. 105190 (April 9, 2026), 91 FR 19233 (April 14, 2026) (SR–CboeEDGX–2026–020).

[83] This is composed of 14.21 percent for Nasdaq, 0.26 percent for Nasdaq Texas, and 0.11 percent for Nasdaq PSX.

[84] This is composed of 8.2 percent for NYSE, 10.34 percent for NYSE Arca, 0.29 percent for Amex, and 0.35 percent for NYSE Texas.

[85] Composed of 3.62 percent for BATS, 0.65 percent for BATSY, 0.82 percent for EDGA, and 4.50 percent for EDGX.

[86] *See* Nasdaq Stock Market Rules, Equity 7, Section 147(b)(1).

[87] *See id.,* Section 147(b)(2).

[88] *See id.,* Section 147(b)(5).

[89] *See id.,* Section 147(b)(4).

[90] *See id.,* Section 147(b)(6).

[91] *See* NYSE Proprietary Market Data Pricing Guide (October 9, 2026) at 29, available at *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf.*

[92] *See* Cboe Market Data Product Price List, available at *https://cdn.cboe.com/resources/membership/US_Market_Data_Product_Price_List.pdf.*

[93] *See* Nasdaq Stock Market Rules, Equity 7, Section 123(b)(1)(B).

[94] $412 per month for 1–39 Subscribers; $16,490 per month for 40–99 Subscribers; $32,990 per month for 100–249 Subscribers; and $75,000.00 per month per firm for over 250 Subscribers.

[95] *See* Nasdaq Stock Market Rules, Equity 7, Section 123(b)(1)(A).

[96] *See id.,* Equity 7, Section 123(c)(1).

[97] *See id.,* Section 123(c)(2).

[98] *See* Nasdaq PHLX Rules, Equity 7, Section 3 (Market Data Distributor Fees).

[99] *See* NYSE Proprietary Market Data Pricing Guide (October 9, 2026) at 31, available at *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf.*

[100] *See* Cboe Market Data Product Price List, available at *https://cdn.cboe.com/resources/membership/US_Market_Data_Product_Price_List.pdf.*

Nasdaq products, which are, by definition, at current market prices. As the Exchange is proposing no new fees, the new products will also be at current market prices, and therefore continue to be comparable to the fees charged by other exchanges.

6. Products Are Voluntary

Nasdaq Basic Plus and Nasdaq TotalView Plus are voluntary products, in that the Exchange is not required by any rule or regulation to make this data available and potential subscribers may purchase it only if they voluntarily choose to do so. As noted above, all of the underlying exchange Top-of-Book and Depth-of-Book products will remain available at current prices, and customers may decline to purchase Nasdaq Basic Plus and Nasdaq TotalView Plus for any reason, including cost.

7. No Unfair Discrimination

The proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers because the proposed feeds are optional data fees available to all market participants on a non-discriminatory basis.

In summary, the proposal provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers because the proposal: (i) offers more customer choice; (ii) prepares investors for overnight trading in potentially low-liquidity environments; (iii) protects competition by covering the data consolidation costs of market data vendors; (iv) proposes fees at or below current levels; (v) proposes fees that are comparable to those of other exchanges; (vi) sets fees for a voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and potential subscribers may purchase it only if they voluntarily choose to do so; and (vii) offers products to all market participants on a non-discriminatory basis.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other options exchanges to compete. As set forth in detail above, the proposed fees are comparable to the Depth-of-Book and Top-of-Book products offered by both NYSE-affiliated and Cboe-affiliated exchange groups, and either or both of those groups can propose fee changes to compete.

Nothing in the Proposal burdens intra-market competition (the competition among consumers of exchange data), because Nasdaq TotalView Plus and Nasdaq Basic Plus will be offered to all market participants at the same price and any market participant that elects to purchase either Nasdaq TotalView Plus or Nasdaq Basic Plus may do so on a non-discriminatory basis.

Moreover, as explained above, the proposed fees offer no competitive advantage relative to market data vendors. With respect to speed, the path for the distribution of the information by the Exchange will not be faster than the path for distribution that would be used by a market data vendor to distribute similar, independently created products. With respect to information, the same source of the market data to be used by the Exchange to create the two proposed products will also be available to any other market data vendor. With respect to cost, the Exchange proposes to ensure that market data vendors are able to compete with the proposed fees by introducing fee waivers for Nasdaq Texas External Market Data Distributor Fees and PSX TotalView Monthly External Distributor fees, and a $350 per month reduction in the Nasdaq Monthly External Distributor Fee that is exclusively available to market data vendors, as well as a consolidation fee for Nasdaq Basic Plus.

Nasdaq Basic Plus and Nasdaq TotalView Plus are completely voluntary products in that the Exchange is not required by any rule or regulation to make this data available and potential subscribers may purchase it only if they voluntarily choose to do so. Information is compiled from underlying feeds from Nasdaq, Nasdaq Texas, and Nasdaq PSX which will remain available for purchase.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[101]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NASDAQ–2026–095 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2026–095. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR–NASDAQ–2026–095 and should be submitted on or before November 30, 2026.

[101] 15 U.S.C. 78s(b)(3)(A)(ii).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[102]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22759 Filed 11–6–26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106819; File No. SR–BOX–2026–21]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Rules To Govern the Trading of FLEX Equity Options in Electronic Auctions

November 4, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 21, 2026, BOX Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rules 5055 (FLEX Equity Options) and 7240 (Complex Orders), and to add Rules 7155 (FLEX Price Improvement Period (''FLEX PIP'')) and 7275 (FLEX Solicitation Auction) to govern the trading of FLEX Equity Options in electronic auctions. The text of the proposed rule change is available from the principal office of the Exchange, and also on the Exchange's internet website at *https://rules.boxexchange.com/rulefilings.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FLEX Equity Options are customized options contracts that allow investors to tailor contract terms for exchange-listed equity options. FLEX Equity Options are designed to meet the needs of investors for greater flexibility in selecting the terms of options within the parameters of the Exchange's rules. FLEX Equity Options are not preestablished for trading and are not listed individually for trading on BOX. Rather, investors select FLEX Equity Option terms and are limited by the parameters set forth in Rule 5055 in their selection of those terms. As a result, FLEX Equity Options allow investors to specify more specific, individualized investment objectives than may be available to them in the standardized options market.

FLEX Equity Options and FLEX Open Outcry (''FOO'') Orders were approved for trading on BOX on May 15, 2024.[3] FOO Orders are limited solely to the BOX Trading Floor.[4] The Exchange now proposes to adopt rules that will govern the listing and trading of FLEX Equity Options on the Exchange's electronic market. The Exchange notes that FLEX options trade electronically on Cboe Exchange, Inc. (''CBOE''), Nasdaq PHLX LLC (''Nasdaq PHLX''), and Nasdaq ISE, LLC (''Nasdaq ISE'').[5] The proposal allows for the trading of FLEX Equity Options in electronic auctions in a substantially similar manner as both CBOE and Nasdaq ISE's electronic markets, with certain intended differences primarily to align to current System behavior (and especially current auction behavior) to provide increased consistency for Participants trading FLEX Equity Options and Non-FLEX Equity Options on BOX, as discussed in detail below. The Exchange notes further that in Nasdaq ISE's recently approved filing to adopt FLEX options and electronic FLEX options trading, Nasdaq ISE compared its proposed rules to CBOE's established rules.[6] This proposal will also compare the Exchange's proposed rules to CBOE's established rules. Accordingly, the Exchange has omitted certain CBOE rules from the proposed rules due to differences in scope and operation of FLEX trading at CBOE compared to the proposed scope and operation of FLEX trading on BOX, each as noted below. For example, the Exchange proposes only to add price improvement and solicitation auctions and will not add Electronic FLEX Auctions as defined in CBOE Rule 5.72(c). Further, BOX does not allow prices in FLEX trading to be expressed as percentages.

The Exchange proposes amendments to Rule 5055 to accommodate FLEX Equity Option trading in electronic auctions. Specifically, the Exchange proposes to include Rules 7155 (FLEX PIP) and 7275 (FLEX Solicitation Auction) as Rules that govern FLEX Equity Options trading, in proposed Rule 5055(a), along with current Rule 7605 (FOO Orders).[7] The Exchange also proposes to remove the language from Rule 5055(b)(3), which provides that FLEX Equity Options may not be traded using any other order type than FOO Orders or other trading mechanism offered by the Exchange and add new subparagraph (3) to provide that FLEX Equity Options may only be traded as provided in proposed rules 7155 (FLEX PIP) and 7275 (FLEX Solicitation Auction), and current Rule 7605 (FOO Orders).[8]

The Exchange also proposes to provide as new subparagraphs (4) and (5) in Rule 5055(f) (Fungibility of FLEX Equity Options) that:

If a Non-FLEX Equity Option series is added intra-day for a component leg(s) of a FLEX Complex Order or FLEX Multi-Leg Order, the holder or writer of a FLEX Equity Option position in the component leg(s) resulting from such FLEX Complex Order or FLEX Multi-Leg Order would be permitted to close its position(s) under the FLEX trading procedures against another closing only FLEX Equity Option position for the balance of the trading day on which the

[102] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities and Exchange Act Release No. 100156 (May 15, 2024), 89 FR 44721 (May 21, 2024) (SR–BOX–2023–20) (Notice of Filing of Amendment No. 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 3, To Adopt Rules To Govern FLEX Equity Options on the BOX Trading Floor).

[4] *See* BOX Rule 7605(b).

[5] *See* CBOE Rules 5.72–5.74, Nasdaq PHLX Rules, Options 3A, and Nasdaq ISE Rules, Options 3A.

[6] *See* Securities and Exchange Act Release No. 101720 (November 22, 2024), 89 FR 94986 (November 29, 2024) (SR–ISE–2024–12) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Adopt Rules to List and Trade FLEX Options). The Exchange notes that Nasdaq PHLX, a Nasdaq ISE affiliate, based its rules on Nasdaq ISE. *See* Securities and Exchange Act Release No. 103759 (August 21, 2025) (SR–PHLX–2025–38) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Adopt Electronic FLEX Options Rules).

[7] *See* proposed Rule 5055(a).

[8] *See* proposed Rules 5055(a)(3) and (b)(3).

Non-FLEX Equity Option series is added, and;

If a Non-FLEX Equity Option series is added for a component leg(s) of a FLEX Complex Order or FLEX Multi-Leg Order on a trading day after the FLEX Complex Order or FLEX Multi-Leg Order position is established, the holder or writer of a FLEX Equity Option position in the component leg(s) resulting from such FLEX Complex Order or FLEX Multi-Leg Order would be required to execute separate FLEX Equity Option and Non-FLEX Equity Option transactions to close its position(s), such that FLEX Equity Option component leg(s) would trade under the FLEX trading procedures and Non-FLEX Equity Option component leg(s) would trade subject to the non-FLEX trading procedures and rules.[9]

Lastly, the Exchange proposes to amend Rule 5055(l) to make the Letter of Authorization requirement for transactions in FLEX Equity Options applicable to Order Flow Providers in addition to Floor Brokers. As proposed, Rule 5055(l) will provide:

Letter of Authorization. No Floor Broker or Order Flow Provider shall effect any transaction in FLEX Equity Options unless a Letter of Authorization has been issued by a clearing member organization and filed with the Exchange specifically accepting responsibility for the clearance of FLEX Equity Option transactions of the Floor Broker or Order Flow Provider. The Letter of Authorization remains in effect until a written revocation is received by the Exchange.

The Exchange proposes to add new defined terms for ''FLEX Complex Order'' and ''FLEX Multi-Leg Order'' where the term ''FLEX Complex Order'' means an electronic Complex Order as defined in Rule 7240(a)(7) composed of FLEX Equity Options where each option leg must be for a FLEX Equity Option series authorized for FLEX trading with the same underlying security and each option leg must have the same exercise style (American or European) and the term ''FLEX Multi-Leg Order'' means an electronic Multi-Leg Order as defined in Rule 7240(a)(10) composed of FLEX Equity Options where each option leg must be for a FLEX Equity Option series authorized for FLEX trading with the same underlying security and each option leg must have the same exercise style (American or European).[10]

The Exchange proposes to establish PIP functionality for FLEX Equity Options in Rule 7155. The proposed FLEX PIP auction will be substantially similar to CBOE's FLEX AIM in CBOE Rule 5.73, except for certain intended differences as further described below. Pursuant to proposed Rule 7155, Options Participants, approved by the Exchange to trade FLEX Equity Options (''Initiating FLEX Participants'') may electronically submit for execution an order (which may be for a single FLEX Equity Option series, FLEX Complex Order, or FLEX Multi-Leg Order) it represents as agent (''FLEX PIP Order'') against principal interest or a solicited order(s) (a ''FLEX Primary Improvement Order'') provided it submits the FLEX PIP Order for electronic execution into a FLEX PIP pursuant to this Rule.[11]

Proposed Rule 7155(a) will set forth the FLEX PIP auction eligibility requirements. Specifically, the Initiating Participant may initiate a FLEX PIP auction if all of the following conditions are met:

- Class. A FLEX PIP Order must be in a FLEX Equity Option class authorized for trading by the Exchange.[12]
- FLEX Equity Option Series. The FLEX PIP Order and FLEX Primary Improvement Order must each be for a permissible FLEX Equity Option series that complies with Rule 5055. For a FLEX Complex Order or FLEX Multi-Leg Order, each leg must be in a permissible FLEX Equity Option series that complies with Rule 5055.
- Marking. The Initiating Participant must mark a FLEX PIP Order for FLEX PIP processing.
- Size. There will be no minimum size for FLEX PIP Orders. The FLEX Primary Improvement Order must be for the same size as the FLEX PIP Order.
- Minimum Increment. The price of the FLEX PIP Order and FLEX Primary Improvement Order must be in increments of one cent ($0.01) for all series. If the FLEX PIP Order and FLEX Primary Improvement Order are FLEX Complex Orders or FLEX Multi-Leg Orders, the price must be a net price for the strategy.[13]
- Time. An Initiating FLEX Participant may only submit a FLEX PIP Order to a FLEX PIP after the opening for trading of the underlying security in the primary market.

The System will reject or cancel both a FLEX PIP Order and FLEX Primary Improvement Order submitted to a FLEX PIP that do not meet the conditions in proposed paragraph (a) as described above. The proposed FLEX PIP eligibility requirements in proposed Rule 7155 are substantially similar to CBOE's FLEX AIM eligibility requirements in CBOE Rule 5.73(a), except with respect to the language related to the percentage value, as noted above.

Pursuant to proposed Rule 7155(b), the FLEX Primary Improvement Order must stop the entire FLEX PIP Order at a specified price. If the FLEX PIP Order and FLEX Primary Improvement Order are FLEX Complex Orders or FLEX Multi-Leg Orders, the price must be a net price for the strategy.[14] In particular, the Initiating Participant must specify either of the below.

- Pursuant to proposed subparagraph (b)(1), a single price at which it seeks to execute the FLEX PIP Order against the FLEX Primary Improvement Order (a ''single-price submission''), including designation of a lower amount for which it retains certain priority and trade allocation privileges upon the conclusion of the FLEX PIP (as described in proposed Rule 7155(e)(4)). This is similar to CBOE Rule 5.73(b)(1), except the Exchange is not proposing to allow Initiating Participants to elect for the FLEX Primary Improvement Order to have last priority to trade against the FLEX PIP Order, and will instead allow them to elect less than their guaranteed allocation.[15] As further discussed below, the proposed guaranteed allocation process will be based on the guaranteed allocation process available in non-FLEX PIP, and therefore the proposed rule change will provide

[9] *See* proposed Rules 5055(f)(4) and (5). The Exchange notes that these proposed rules align with current Rule 7605(d).

[10] *See* proposed Rules 7240(a)(11) and (12).

[11] *See* proposed Rule 7155, which is based on CBOE Rule 5.73. The Exchange notes the proposed rule will not incorporate the reference to FLEX SPX as this is a CBOE-specific product.

[12] Both physically settled FLEX Equity Options and those FLEX Equity Options that are permitted to have cash settlement, as provided by Rule 5050(e)(3)(i), will be permitted to trade via the FLEX PIP auction.

[13] The Exchange notes that it is not proposing order prices or minimum increments as a percentage. The Exchange notes further that one cent ($0.01) is the minimum increment for FLEX Equity Options in Rule 5055(g).

[14] *See* CBOE Rule 5.73(b) for similar provisions, except the Exchange will not allow prices to be entered as a percentage value, and therefore will not incorporate the applicable language from CBOE's rule into proposed Rule 7155(b).

[15] The Initiating FLEX Participant may designate a Surrender Quantity or lower amount for which it retains certain priority and trade allocation privileges upon the conclusion of the FLEX PIP auction than it is entitled to pursuant to the provisions of proposed Rule 7155(e)(1)(B). If the aggregate size of other FLEX Participants' responses is not equal to or greater than the Surrender Quantity, then the remaining Surrender Quantity shall be left unfilled and the FLEX Primary Improvement Order shall be allocated the remaining size of the FLEX PIP Order. CBOE's rule does not allow for the Initiating Participant to designate a specific surrender quantity rather last priority is designated. The Exchange notes that non-FLEX rules on CBOE and BOX also specify last priority and surrender quantity respectively. *See* CBOE Rule 5.37(e)(5) and BOX Rule 7150(h)(5).

further consistency across BOX's auction mechanism processes.[16]

• Pursuant to subparagraph (b)(2), an initial stop price and instruction to automatically match the price and size of all FLEX PIP responses (''auto-match'') at each price, up to a designated limit price, better than the price at which the balance of the FLEX PIP Order can be fully executed (the ''final auction price''). This is substantially similar to CBOE Rule 5.73(b)(2). The System rejects or cancels both a FLEX PIP Order and FLEX Primary Improvement Order submitted to a FLEX PIP that do not meet the conditions in this paragraph (b).

Proposed Rule 7155(c) will govern the FLEX PIP process. Specifically, upon receipt of a FLEX PIP Order that meets the conditions in paragraphs (a) and (b) as described above, the FLEX PIP process commences. Proposed subparagraph (c)(1) will provide that a FLEX PIP will not run simultaneously with another FLEX PIP in the same series, nor will FLEX PIPs interact, queue or overlap in any manner. Any request to initiate a FLEX PIP while a FLEX PIP is already in progress in the same series will be rejected.

The Exchange will accept, however, orders designated for the FLEX PIP on a single option series where a FLEX PIP on a Complex or Multi-Leg Order that includes such series may be in progress. The Exchange will also accept Complex or Multi-Leg Orders designated for the FLEX PIP where a FLEX PIP on either of the component series may be in progress. Order execution at the conclusion of such FLEX PIPs shall occur as set forth in proposed Rule 7155. The lack of concurrent FLEX PIPs is designed to align to current System behavior (and especially current auction behavior) to provide increased consistency for Participants trading FLEX Equity Options and Non-FLEX Equity Options on BOX.[17] The Exchange notes that this proposed subsection (c) differs from CBOE Rules 5.73(c)(1)(A) and (B), but again notes that the proposed functionality is consistent with BOX's current non-FLEX auction functionality.

Pursuant to proposed Rule 7155(c)(2), the System initiates the FLEX PIP process by sending a FLEX PIP notification message detailing the series or strategy, size, stop price, side of market, and when the FLEX PIP will conclude as applicable, of the FLEX PIP Order by broadcasting a message via the Exchange's data feeds. FLEX PIP notification messages are not disseminated to OPRA.[18]

Proposed Rule 7155(c)(3) will describe the ''FLEX PIP Auction period,'' and is based on CBOE Rule 5.73(c)(3). The ''FLEX PIP Auction period'' is a period of time designated by the Initiating FLEX Participant, which may be no less than three seconds and no more than five minutes.[19] The Initiating Participant will be required to identify a length of time within the specified parameters for FLEX PIP. If the Initiating Participant does not provide a length of time, the system will utilize the system default, which shall be three seconds. Further, if the designated length of the FLEX PIP Auction period exceeds the market close, then the auction will end at the market close without an execution. In doing so, the Exchange's proposal will prevent executions from occurring after the market close. Proposed Rule 7155(c)(4) will provide that an Initiating Participant may not cancel a FLEX PIP Order or FLEX Primary Improvement Order but may modify a FLEX Primary Improvement Order to improve its price after submission to a FLEX PIP. This will be similar to CBOE Rule 5.73(c)(4) except unlike CBOE, the Exchange will allow a limited exception by allowing Initiating Participants to improve the price of their FLEX Primary Improvement Orders. The Exchange notes that this will align to current non-FLEX PIP behavior, which allows entering Participants to improve their Primary Improvement Orders.[20] Similar to allowing the entering Participant of a non-FLEX PIP to improve the price of its Primary Improvement Order, the Exchange believes that it is appropriate to allow the Initiating Participant of the FLEX PIP to improve the price of its FLEX Primary Improvement Order (*i.e.,* contra-side to the FLEX PIP Order) because it would also improve the stop price of the FLEX PIP Order that came in together with the FLEX Primary Improvement Order.[21]

Proposed Rule 7155(c)(5) will govern the requirements for FLEX PIP responses.

Specifically:

• Any FLEX Participant (other than the Initiating Participant) may submit responses to a FLEX PIP that are properly marked specifying price, size, side for the FLEX PIP to which the Participant is submitting the response.[22]

• The minimum price increment for FLEX PIP responses is one-cent ($0.01) for all series. A response to a FLEX PIP of a FLEX Complex or FLEX Multi-Leg Order must have a net price. The System rejects a FLEX PIP response that is not in the applicable minimum increment or format.[23]

• A FLEX Participant may continually submit competing FLEX PIP responses for any price equal to or better than the FLEX Primary Improvement Order, and may improve the price of their response(s) at any point during the FLEX PIP. Subsequent FLEX PIP responses replace the previous response, provided that it improved the price of the previous response.[24] Responses submitted by FLEX Participants are processed by Trader

[16] *See infra* note 34 for further discussion on the guaranteed allocation process.

[17] *See* BOX IM–7150–2.

[18] *See* CBOE Rule 5.73(c)(2) for substantially similar provisions except the Exchange will not incorporate the reference to SPX as it does not list this symbol.

[19] The Exchange notes that CBOE Rule 5.73(c)(3) specifies that the designated length of the FLEX AIM Auction period may not be longer than the amount of time remaining until the market close. While this differs from BOX's proposal, BOX's System will cancel a FLEX PIP that is not over by the market close without execution.

[20] *See* BOX Rule 7150(f)(2) (providing that the Initiating Participant is not permitted to cancel or to modify the size of its Single-Priced Primary Improvement Order or the PIP Order at any time during the PIP, and may modify only the price of its Single-Priced Primary Improvement Order by improving it. The Initiating Participant is not permitted to cancel or modify the Max Improvement Primary Improvement Order, including the PIP Start Price, the designated limit price or the size). Primary Improvement Orders (*i.e.,* contra-side to the PIP Order) for PIP are functionally equivalent to FLEX Primary Improvement Orders (*i.e.,* contra-side order to the FLEX PIP Order) for FLEX PIP. *See* BOX Rule 7150(f) for a description of Primary Improvement Orders.

[21] As proposed, the Initiating Participant enters a FLEX PIP consisting of a FLEX PIP Order and a FLEX Primary Improvement Order (which is the contra-side of the FLEX PIP Order). This is identical to how non-FLEX PIP works today in that the Initiating Participant enters a paired order into non-FLEX PIP consisting of a PIP Order and a Primary Improvement Order. The Exchange notes that a PIP Improvement Order is the functional equivalent of a FLEX PIP response.

[22] *See* proposed Rule 7155(c)(5), which is based on CBOE Rule 5.73(c)(5). The Exchange notes that this proposed subsection (c)(5) differs from CBOE Rules 5.73(c)(5) because a FLEX PIP will not run simultaneously with another FLEX PIP and, therefore need not specify which response may participate in which auction. The Exchange notes further that the proposed functionality is consistent with current non-FLEX auction functionality. *See* BOX IM–7150–2.

[23] *See* proposed Rule(c)(5)(A), which is based on CBOE Rule 5.73(c)(5)(A) except the Exchange will not allow prices to be expressed as a percentage value. Further, the Exchange will not incorporate the CBOE rule portions on Index Combo Orders as the Exchange does not offer this functionality. The Exchange notes that it will not determine minimum increments on a class basis, which is consistent with established FLEX Equity Option trading on the BOX Trading Floor. *See* BOX Rule 5055(g).

[24] *See* proposed Rule 7155(c)(5)(B), which is based on CBOE Rule 5.73(c)(5)(B). The Exchange notes that it will not aggregate FLEX PIP responses from the same Participant, which aligns with current non-FLEX PIP functionality. *See* BOX Rule 7150(f).

ID.[25] If an additional FLEX PIP response is submitted for the same FLEX PIP from the same Trader ID, then that FLEX PIP response will replace the previous FLEX PIP response for that Trader ID.[26]

• Competing FLEX PIP responses may be for any size up to the size of the FLEX Primary Improvement Order.[27] The System rejects responses in excess of the size of the FLEX PIP Order when processing the FLEX PIP.

• FLEX PIP responses must be on the opposite side of the market as the FLEX PIP Order. The System rejects a FLEX PIP response on the same side of the market as the FLEX PIP Order.[28]

• FLEX PIP responses will not be visible to FLEX PIP Participants or disseminated to OPRA.[29]

• A FLEX Participant may modify or cancel its FLEX PIP responses during the FLEX PIP auction.[30]

Pursuant to proposed Rule 7155(d), a FLEX PIP concludes at the earliest to occur of the following times: (1) the end of the FLEX PIP Duration; and (2) any time the Exchange halts trading in the affected underlying, provided, however, that in such instances the FLEX PIP auction concludes without execution.[31]

Proposed Rule 7155(e) will govern how executions will occur in FLEX PIP. In particular, at the end of the FLEX PIP, the System allocates the FLEX Primary Improvement Order or FLEX PIP responses against the FLEX PIP Order at the best price(s), to the price at which the balance of the FLEX PIP Order can be fully executed (the ''final auction price''), as follows.[32] Proposed subparagraphs (e)(1)—(4) detail the FLEX PIP allocation methodology for the following scenarios:

• No Price Improvement: If the FLEX PIP results in no price improvement, the System executes the FLEX PIP Order at the stop price in the following order:

○ Public Customer responses (in time priority); [33]

○ The FLEX Primary Improvement Order for up to 50% of the FLEX PIP Order if there is a response(s) from one other Participant at the same price or up to 40% of the FLEX PIP Order if there are responses from two or more other Participants at the same price (which percentages are based on the number of contracts remaining after execution against Public Customer responses).[34] Unless there are remaining contracts after including all FLEX PIP responses, under no circumstances does the Initiating Participant receive an allocation percentage at the final auction price of more than 50% of the initial FLEX PIP Order in the event there is a response(s) from one other Participant or 40% of the initial FLEX PIP Order in the event there are responses from two or more other Participants.[35] For example, assume an Initiating Participant submitted a FLEX PIP for 20 contracts and there are 2 FLEX PIP responses (one for 3 contracts and one for 4 contracts). After the 7 FLEX PIP response contracts are allocated, the Initiating Participant would then receive the remaining 13 contracts (which is more than their 40% allocation percentage) because there are remaining contracts after all FLEX PIP responses are included.

○ All other FLEX PIP responses are allocated on a pro-rata basis. The System allocates orders proportionally according to size (*i.e.,* on a pro-rata basis). The System allocates executable quantity to the nearest whole number, with fractions rounded down. If there remains any unallocated quantity of the FLEX PIP Order, the allocation method will be to allocate one contract of the FLEX PIP Order per FLEX PIP response in sequence until each remaining response has received one contract or until the FLEX PIP Order is fully allocated. Allocation sequence among responses in this step will be in order of size with the largest remaining response allocated first. Where two or more such responses are the same size, trade allocation sequence will be by time priority; [36] and

○ The FLEX Primary Improvement Order to the extent there are any remaining contracts.[37]

• Price Improvement with Single-Price Submission: If the FLEX PIP auction results in price improvement for the FLEX PIP Order and the Initiating Participant selected a single-price submission, at each price better than the final auction price, the System executes the FLEX PIP Order in the following order:

○ Price-time priority such that responses with the lowest (highest) offer (bid) are executed in the order they are received.[38]

For example, assume a FLEX PIP Order is sent to buy 100 contracts with a price of $1.00 and the Initiating Participant selected a single-price submission. There are two FLEX PIP responses for 5 contracts each at $0.98, two FLEX PIP responses for 20 contracts each at $0.99, and two FLEX PIP responses for 40 contracts each at $1.00. The FLEX PIP responses at $0.98 and $0.99 will be executed in their entirety.[39] Then, the FLEX PIP responses at $1.00 (final auction price) will be executed on a pro-rata basis after Public Customers. At the final auction price, the System executes any remaining contracts from the FLEX PIP Order at that price in the order set forth in proposed Rule 7155(e)(1), as described above.[40] Specifically, the

[25] A Trader ID is a unique identifier created by BOX to identify each BOX Options Participant. A BOX Options Participant may be associated with multiple Trader IDs

[26] This is similar to the electronic FLEX auction functionality offered by another exchange and similar to the current PIP functionality on the Exchange. *See* ISE Options 3A, Section 11(b)(2)(D) and BOX Rule 7150, respectively.

[27] *See* proposed Rule 7155(c)(5)(C), which is based on CBOE Rule 5.73(c)(5)(C).

[28] *See* proposed Rule 7155(c)(5)(D), which is based on CBOE Rule 5.73(c)(5)(D).

[29] *See* proposed Rule 7155(c)(5)(E), which is based on CBOE Rule 5.73(c)(5)(E).

[30] *See* proposed Rule 7155(c)(5)(F), which is based on CBOE Rule 5.73(c)(5)(F).

[31] *See* CBOE Rule 5.73(d) for similar provisions, except the Exchange will make a minor clarification that this rule applies when the Exchange halts trading in the affected underlying (and not series, which is what CBOE currently has in its rule).

[32] *See* CBOE Rule 5.73(e) for similar provisions except the Exchange will not allow prices to be expressed as a percentage value.

[33] *See* proposed Rule 7155(e)(1)(A), which is based on CBOE Rule 5.73(e)(1)(A).

[34] *See* proposed Rule 7155(e)(1)(B)(ii), which is based on CBOE Rule 5.73(e)(1)(B)(ii). The Exchange notes that its proposed rules do not guarantee at least one contract. The Exchange notes further that the Initiating Participant may be allocated more than 50% of the Agency Order if there are remaining contracts after including all FLEX PIP responses.

[35] *See* proposed Rule 7155(e)(1)(B), which is based on CBOE Rule 5.73(e)(1)(B). The proposed functionality will align to current non-FLEX PIP functionality. *See* BOX Rule 7150(h)(1)–(2).

[36] *See* proposed Rule 7155(e)(1)(C), which is based on CBOE Rule 5.73(e)(1)(C).

[37] *See* proposed Rule 7155(e)(1)(D), which is based on CBOE Rule 5.73(e)(1)(D).

[38] *See* proposed Rule 7155(e)(2)(A). Unlike CBOE Rule 5.73(e)(2), which allocates contracts, at each price level better than the final auction price, Priority Customer and then pro-rata, the proposed rule allocates contracts, at each price better than the final auction price, on a price-time basis. The Exchange believes, although its proposal differs, the resulting allocations will be similar because all orders at each price level better than the final auction price will be filled. Specifically, ''at each price level better than the final auction price up to the designated limit price, the System executes the FLEX PIP Order against the FLEX Primary Improvement Order for the number of contracts equal to the aggregate size of *all* FLEX PIP responses and then executes the Agency Order against those responses . . . .'' *See* proposed Rule 7155(e)(3) (emphasis added). Because all FLEX PIP responses, at each price level better than the final auction price are executed, the application of price-time or Priority Customer and then pro-rata priority results in a similar allocation of contracts regardless of which allocation methodology is applied.

[39] The Exchange notes that, although CBOE applies Priority Customer and then pro rata priority at each price level better than the final auction price, and BOX proposes to apply price-time allocation at each price level better than the final auction price, regardless of allocation methodology, all contracts at $0.98 and $0.99 would be filled because there is sufficient FLEX PIP Order quantity.

[40] *See id.* The Exchange again notes the proposed operation of FLEX PIP is consistent with the current

FLEX Primary Improvement Order is allocated 20 contracts (40% of the remaining 50 contracts) and 15 contracts are allocated to each FLEX PIP response at $1.00 (pro rata).

• Price Improvement with Auto-Match: If the FLEX PIP results in price improvement for the FLEX PIP Order and the Initiating Participant selected auto-match, at each price better than the final auction price up to the designated limit price, the System executes the FLEX PIP Order against the FLEX Primary Improvement Order for the number of contracts equal to the aggregate size of all FLEX PIP responses and then executes the FLEX PIP Order against those responses in the order set forth in proposed Rule 7155(e)(2) described above. At the final auction price, the System executes contracts at that price in the order set forth in proposed Rule 7155(e)(1) described above.[41]

• Surrender Quantity: At its option, the Initiating FLEX Participant may designate a lower amount for which it retains certain priority and trade allocation privileges upon the conclusion of the FLEX PIP than it is entitled to pursuant to the provisions of 7155(e)(1) or 7155(e)(2), above. When starting a FLEX PIP, the Initiating FLEX Participant may designate a lower amount for which it retains certain priority and trade allocation privileges upon the conclusion of the FLEX PIP than it is entitled to pursuant to the provisions of proposed Rule 7155(e)(1)(B).[42] Upon the conclusion of the FLEX PIP, when the System determines the priority and trade allocation amounts for the Initiating FLEX Participant pursuant to proposed Rule 7155(e)(1)(B), the Trading Host will automatically adjust the trade allocations to the other FLEX PIP Participants, according to the priority set forth in proposed Rule 7155(e), up to the Surrender Quantity. The FLEX Primary Improvement Order shall be allocated the remaining size of the FLEX PIP Order above the Surrender Quantity, if any, pursuant to proposed Rule 7155(e)(1)(D). Surrender Quantity information is not available to other market participants and may not be modified after it is submitted.[43]

Pursuant to proposed Rule 7155(e)(5), the System cancels any unexecuted FLEX PIP responses (or unexecuted portions) at the conclusion of the FLEX PIP auction.[44]

The Exchange proposes a number of interpretive materials applicable to FLEX PIP. Specifically, proposed IM–7155–1 will provide that a Participant may only use a FLEX PIP where there is a genuine intention to execute a bona fide transaction.[45] Proposed IM–7155–2 will provide that it will be deemed conduct inconsistent with just and equitable principles of trade and a violation of Rule 3000 to engage in a pattern of conduct where the Initiating FLEX Participant breaks up a FLEX PIP Order into separate orders for the purpose of gaining a higher allocation percentage than the Initiating FLEX Participant would have otherwise received in accordance with the allocation procedures contained in proposed paragraph (e) above.[46] Lastly, proposed IM–7155–3 will provide that an Exchange Official may nullify a transaction following a FLEX PIP pursuant to Rule 7170.[47]

FLEX Solicitation Auction

The Exchange proposes to establish FLEX Solicitation Auction functionality for FLEX Equity Options in Rule 7275. The proposed FLEX Solicitation Auction will be substantially similar to CBOE's FLEX SAM in CBOE Rule 5.74, except for certain intended differences to align with BOX's current System functionality for Non-FLEX Equity Options, as further described below. Pursuant to proposed Rule 7275, Options Participants, approved by the Exchange to trade FLEX Equity Options (''Initiating FLEX Participants'') may electronically submit for execution an order (which may be for a single FLEX Equity Option series, FLEX Complex Order, or FLEX Multi-Leg Order) it represents as agent (''Agency Order'') against a solicited order (a ''Solicited Order'') provided it submits the Agency Order for electronic execution into a FLEX Solicitation Auction pursuant to this Rule.[48] Proposed Rules 7275(a)(1)–(6) will set forth the FLEX Solicitation Auction eligibility requirements, and will be substantially similar to CBOE Rules 5.74(a)(1)–(6) except as noted below. Specifically, Initiating FLEX Participants may initiate a FLEX Solicitation if all of the following conditions are met:

• Class. An Agency Order must be in a FLEX Equity Option class authorized for trading by the Exchange.[49]

• FLEX Option Series. The Agency Order and Solicited Order must each be for a permissible FLEX Equity Option series that complies with Rule 5055. For a FLEX Complex Order or FLEX Multi-Leg Order, each leg must be in a permissible FLEX Equity Option series that complies with Rule 5055.[50]

• Marking. The Initiating Participant must mark an Agency Order for FLEX Solicitation Auction processing.

• Size. The Agency Order must be for at least the minimum size designated by the Exchange (which may not be less than 500 contracts). The Solicited Order must be for the same size as the Agency Order. For a FLEX Complex Order or FLEX Multi-Leg Order, each leg may not be for less than 500 contracts. The System handles each of the Agency Order and the Solicited Order as all-or-none.[51]

operation of non-FLEX PIP. *See* BOX Rule 7150(g). The Exchange notes further that the proposed trade allocation at the final auction price is substantially similar to CBOE.

[41] *See* proposed Rule 7155(e)(3), which is based on CBOE Rule 5.73(e)(3).

[42] *See* proposed Rule 7155(e)(4), which is based on CBOE Rule 5.73(e)(4) except CBOE's last priority feature differs from the Exchange's surrender quantity feature that allows Participants to request a lower amount for which it retains certain priority and trade allocation privileges upon the conclusion of the FLEX PIP than it will be entitled to pursuant to the provisions of proposed Rule 7155(e). As such, the difference between CBOE's rule and BOX's rule will be that BOX Participants will be able to customize their surrender quantities for FLEX PIP (which will follow the non-FLEX PIP process in Rule 7150(h)(5)) while CBOE's rules do not appear to allow this for FLEX AIM.

[43] *See id.*

[44] *See* proposed Rule 7155(e)(5), which is based on CBOE Rule 5.73(e)(5).

[45] *See* proposed IM–7155–1, which is based on CBOE Rule 5.73 Interpretations and Policies .01.

[46] *See* proposed IM–7155–2, which is based on CBOE Rule 5.73 Interpretations and Policies .02.

[47] *See* proposed IM–7155–3, which is based on CBOE Rule 5.73 Interpretations and Policies .03.

[48] *See* CBOE Rule 5.74 for similar provisions, except the Exchange will not add CBOE's language that the Solicited Order cannot have a Capacity F (*i.e.,* Firm capacity) for the same executing firm ID (''EFID'') as the Agency Order for the following reasons. Facilitated orders cannot be entered into the FLEX Solicitation Auction (just like they cannot be entered into the non-FLEX Solicitation Auction today). Since an order with the capacity of Firm can be valid for a solicitation order, BOX will not System enforce the rejection of Firm capacity orders to avoid the rejection of contra-side orders that are entered with a Firm capacity and are, in fact, solicitations at the outset. Instead, it will monitor for compliance with the requirement that the contra-side order be a solicitation rather than a facilitation through surveillance, as it does today for non-FLEX Solicitation Auctions. The applicable rule for the foregoing requirement will be set forth in proposed IM–7275–2.

[49] Both physically settled FLEX Equity Options and those FLEX Equity Options that are permitted to have cash settlement, as provided by Rule 5050(e)(3)(i), will be permitted to trade via the FLEX Solicitation auction.

[50] *See* CBOE Rule 5.74(a)(2) for similar provisions, except the Exchange will add a provision to specify that each leg of a FLEX Complex Order or FLEX Multi-Leg Order must be in a permissible FLEX Equity Option series that complies with Rule 5055.

[51] *See* CBOE Rule 5.74(a)(4) for similar provisions except unlike CBOE, the Exchange will not allow the Solicited Order to be comprised of multiple solicited orders in the FLEX Solicitation Auction to be consistent with current non-FLEX Solicitation Auction functionality in Rule 7270. In addition, the Exchange will not incorporate CBOE's provisions relating to mini options or Micro FLEX Index

Continued

• Minimum Increment. The price of the Agency Order and Solicited Order must be in increments of one cent ($0.01) for all series. If the Agency Order and Solicited Order are FLEX Complex Orders or FLEX Multi-Leg Orders, the price must be a net price for the strategy.[52]

• Time. An Initiating FLEX Participant may only submit an Agency Order to a FLEX Solicitation after the opening for trading of the underlying security in the primary market.[53] The System rejects or cancels both an Agency Order and Solicited Order submitted to a FLEX Solicitation Auction that do not meet the conditions in this paragraph (a).

Pursuant to proposed Rule 7275(b), the Solicited Order must stop the entire Agency Order. If the Agency Order and Solicited Order are FLEX Complex or FLEX Multi-Leg Orders, the price must be a net price for the strategy. The Initiating FLEX Participant must specify a single price at which it seeks to execute the Agency Order against the Solicited Order. The System rejects or cancels both an Agency Order and Solicited Order submitted to a FLEX Solicitation Auction that does not meet this condition.[54]

Proposed Rule 7275(c) will govern the FLEX Solicitation process. Specifically, upon receipt of an Agency Order that meets the conditions in paragraphs (a) and (b) as described above, the FLEX Solicitation process commences. Pursuant to proposed subparagraph (c)(1), a FLEX Solicitation will not run simultaneously with another FLEX Solicitation in the same series, nor will FLEX Solicitations interact, queue or overlap in any manner.[55] Any request to initiate a FLEX Solicitation while a FLEX Solicitation is already in progress in the same series will be rejected. This proposal differs from CBOE Rule 5.74(c)(1) which allows concurrent auctions. The Exchange notes this is consistent with current non-FLEX Solicitation Auction functionality.

Pursuant to proposed Rule 7275(c)(2), the System initiates the FLEX Solicitation process by sending a FLEX Solicitation notification message detailing the series or strategy, size, stop price, side of market, and when the FLEX Solicitation Auction will conclude as applicable, by broadcasting a message via the Exchange's data feeds. FLEX Solicitation Auction notification messages are not disseminated to OPRA. These provisions are substantially similar to CBOE Rule 5.74(c)(2).

Proposed Rule 7275(c)(3) will describe the ''FLEX Solicitation Auction Period,'' and is based on CBOE Rule 5.74(c)(3). The FLEX Solicitation Auction Period will be defined as a period of time that must be designated by the Initiating Participant, which may be no less than three seconds and no more than five minutes, similar to the exposure interval for FLEX PIP in proposed Rule 7155 and the FOO Order announcement period in Rule 7605. The Initiating Participant will be required to identify a length of time within the specified parameters for FLEX Solicitation Auctions. If the Initiating Participant does not provide a length of time, the system will utilize the system default, which shall be three seconds. Further, if the designated length of the FLEX Solicitation Auction Period exceeds the market close, then the auction will end at the market close without an execution. The Exchange's non-FLEX auctions do not allow executions in such scenarios, so the Exchange proposes to be consistent with current System functionality in this regard.[56] In doing so, the Exchange's proposal will prevent executions in FLEX Solicitation Auctions from occurring after the market close. Proposed Rule 7275(c)(4) will provide that an Initiating FLEX Participant may cancel an Agency Order or Solicited Order after submission to a FLEX Solicitation Auction. The Initiating FLEX Participant may not modify an Agency Order or Solicited Order after submission to a FLEX Solicitation Auction. This will differ from CBOE Rule 5.74(c)(4), which does not allow cancelation or modification of the Initiating Order or Agency Order. The Exchange will allow Initiating Participants to cancel their Agency Orders and Solicited Orders upon submission into a FLEX Solicitation Auction, which will align with current non-FLEX Solicitation Auction functionality.[57] Proposed Rule 7275(c)(5) will govern the requirements for FLEX Solicitation responses. Specifically:

• Any FLEX Participant (other than the Initiating Participant) may submit responses to a FLEX Solicitation Auction that are properly marked specifying size, side, and price for the FLEX Solicitation Auction to which the FLEX Participant is submitting the response.[58]

• The minimum price increment for FLEX Solicitation Auction responses is one-cent ($0.01) for all series. A response to a FLEX Solicitation Auction of a FLEX Complex or FLEX Multi-Leg Order must have a net price. The System rejects a FLEX Solicitation Auction response that is not in the applicable minimum increment or format.[59]

• A FLEX Participant may submit FLEX Solicitation Auction responses for any price equal to or better than the stop price in paragraph (b) of proposed Rule 7275.[60] Responses submitted by FLEX Participants are processed by Trader ID. If an additional FLEX Solicitation Auction response is submitted for the same FLEX Solicitation Auction from the same Trader ID, then that FLEX Solicitation Auction response will replace the previous FLEX Solicitation Auction response for that Trader ID.[61]

• The System will cap the size of a FLEX Solicitation response at the size of

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Options into proposed Rule 7275(a)(4) as the Exchange does not list these products today. Further, the Exchange is adding a minor clarification that the minimum size requirement will apply to each leg of a FLEX Complex Order or FLEX Multi-Leg Order.

[52] The Exchange notes that unlike CBOE, it will not allow prices to be entered as a percentage value, and therefore will not incorporate the applicable language from CBOE Rule 5.74(a)(5) into proposed Rule 7275(a)(5). Additionally, the Exchange will not specify minimum increments on a per class basis and will instead specify one cent ($0.01) for all series. This is consistent with FOO Orders on the BOX Trading Floor.

[53] *See* proposed Rule 7275(a)(6), which is based on CBOE Rule 5.74(a)(6).

[54] *See* CBOE Rule 5.74(b) for similar provisions, except the Exchange will not allow prices to be entered as a percentage value, and therefore will not incorporate the applicable language from CBOE's rule into proposed Rule 7275(b).

[55] This feature is consistent with current non-FLEX Solicitation Auction functionality. The Exchange notes that it will accept orders designated for the FLEX Solicitation on a single option series where a FLEX Solicitation on a FLEX Complex or FLEX Multi-Leg Order that includes such series may be in progress. BOX will also accept FLEX Complex or FLEX Multi-Leg Orders designated for the FLEX Solicitation Auction where a FLEX Solicitation Auction on either of the component series may be in progress. Order execution at the conclusion of such FLEX Solicitations shall occur as set forth in proposed Rule 7275.

[56] The Exchange's proposal will be consistent with current non-FLEX auction functionality, including current PIP and Solicitation Auction functionality. *See* BOX Rules 7150 and 7270(b).

[57] *See* proposed Rule 7275(c)(4). *See generally* BOX Rule 7270(b).

[58] *See* proposed Rule 7275(c)(5), which is based on CBOE Rule 5.74(c)(5).

[59] *See* proposed Rule 7275(c)(5)(A), which is based on CBOE Rule 5.74(c)(5)(A) except the Exchange will not allow prices to be expressed as a percentage value.

[60] *See* proposed Rule 7275(c)(5)(B), which is based on CBOE Rule 5.74(c)(5)(B). The Exchange notes that it will not aggregate FLEX Solicitation responses from the same Participant, which aligns with current non-FLEX Solicitation Auction functionality and is similar to the electronic FLEX auction functionality offered by another exchange. *See* BOX Rule 7270(b) and ISE Options 3A, Section 13(c)(5)(B), respectively.

[61] This is similar to the electronic FLEX auction functionality offered by another exchange and similar to the current Solicitation Auction functionality on the Exchange. *See* ISE Options 3A, Section 13(c)(5)(B), and BOX Rule 7270(b), respectively.

the Agency Order (*i.e.,* the System will ignore size in excess of the size of the Agency Order when processing the FLEX Solicitation auction).[62]

• FLEX Solicitation responses must be on the opposite side of the market as the Agency Order. The System rejects a FLEX Solicitation response on the same side of the market as the Agency Order.[63]

• FLEX Solicitation responses will not be visible to FLEX Solicitation Auction participants or disseminated to OPRA.[64]

• A FLEX Participant may modify, including decrementing the price or size, or cancel its FLEX Solicitation responses during a FLEX Solicitation Auction. Subsequent FLEX Solicitation Auction responses replace the previous response.[65]

Pursuant to proposed Rule 7275(d), a FLEX Solicitation Auction concludes at the earliest to occur of the following times: (1) the end of the FLEX Solicitation Auction Period; and (2) any time the Exchange halts trading in the affected underlying, provided, however, that in such instance the FLEX Solicitation Auction concludes without execution.[66] Proposed Rule 7275(e) will govern how executions will occur in FLEX Solicitation Auctions. In particular, at the end of the FLEX Solicitation Auction, the System will execute the Agency Order against the Solicited Order or FLEX Solicitation responses at the best price(s) as follows.[67] Proposed subparagraphs (e)(1)–(3) detail the FLEX Solicitation allocation methodology for the following scenarios:

• Execution Against Solicited Order: The System executes the Agency Order against the Solicited Order at the stop price if the aggregate size of FLEX Solicitation responses at an improved price(s) is insufficient to satisfy the Agency Order.[68]

• Execution Against FLEX Solicitation Responses: The System executes the Agency Order against FLEX Solicitation Auction responses if the aggregate size of FLEX Solicitation responses at an improved price(s) is sufficient to satisfy the Agency Order. The Agency Order executes against FLEX Solicitation responses at each price level. At the price at which the balance of the Agency Order can be fully executed, responses are executed in price and time priority.[69]

Pursuant to proposed Rule 7275(e)(4), the System cancels any unexecuted FLEX Solicitation responses (or unexecuted portions) at the conclusion of a FLEX Solicitation Auction.[70]

Lastly, the Exchange proposes a number of policies applicable to FLEX Solicitation as Interpretive Materials to Rule 7275. Specifically, proposed IM–7275–1 will provide that prior to entering Agency Orders into a FLEX Solicitation Auction on behalf of customers, Initiating Participants must deliver to the customer a written notification informing the customer that its order may be executed using the FLEX Solicitation Auction. The written notification must disclose the terms and conditions contained in this Rule 7275 and be in a form approved by the Exchange.[71] Proposed IM–7275–2 will provide that under this Rule 7275, Initiating Participants may enter contra-side orders that are solicited. FLEX Solicitation provides a facility for Participants that locate liquidity for their customer orders. Participants may not use the FLEX Solicitation auction to circumvent Rule 7140 (Customer Orders and Order Flow Providers). This may include, but is not limited to, Participants entering contra-side orders that are solicited from (1) affiliated broker-dealers, or (2) broker-dealers with which the Participant has an arrangement that allows the Participant to realize similar economic benefits from the solicited transaction as it would achieve by executing the customer order in whole or in part as principal. Lastly, proposed IM–7275–3 will provide that an Exchange Official may nullify a transaction following a FLEX Solicitation Auction pursuant to Rule 7170.[72]

Risk Protections

The Exchange proposes to amend IM–7240–1(a) Debit/Credit Check and (b) Maximum Price risk protections to include FOO Orders, FLEX PIP and FLEX Solicitation Auction.[73] FOO Orders were inadvertently omitted from these rules in a prior rule change. These risk protections are mandatory for FLEX PIP and FLEX Solicitation Auction and voluntary on a per order basis for FOO Orders. The Exchange believes that applying Debit/Credit Check and Maximum Price to FLEX PIP, FLEX Solicitation Auction, Complex and Multi-Leg FOO Orders and applying Maximum Price to FLEX PIP, FLEX Solicitation Auction, and Complex FOO Orders will help Participants manage risk and be beneficial for FLEX trading.

Additionally, the Exchange notes that Rules 7330 (Activity-Based Protections) and 7340 (Global Counter) are applicable to FOO Orders and will be applicable to FLEX PIP and FLEX Solicitation Auctions.[74]

The Exchange notes that it will announce an implementation date for the proposed changes to its Participants by Regulatory Notice.

2. *Statutory Basis*

The Exchange believes that its proposal is consistent with Section 6(b)

[62] *See* proposed Rule 7275(c)(5)(C), which is based on CBOE Rule 5.74(c)(5)(C).

[63] *See* proposed Rule 7275(c)(5)(D), which is based on CBOE Rule 5.74(c)(5)(D).

[64] *See* proposed Rule 7275(c)(5)(E), which is based on CBOE Rule 5.74(c)(5)(E).

[65] *See* proposed Rule 7275(c)(5)(F), which is based on CBOE Rule 5.74(c)(5)(F).

[66] *See* CBOE Rule 5.74(d) for similar provisions, except the Exchange will make a minor clarification that this rule applies when the Exchange halts trading in the affected underlying (and not series, which is what CBOE currently has in its rule).

[67] *See* CBOE Rule 5.74(e) for similar provisions except the Exchange will not allow prices to be expressed as a percentage value.

[68] *See* proposed Rule 7275(e)(1), which is based on CBOE Rule 5.74(e)(1).

[69] *See* proposed Rule 7275(e), which differs from CBOE Rule 5.74 because responses are executed in price time priority rather than Priority Customer and then pro-rata. Additionally, CBOE cancels the Agency Order and Solicited Order with no execution if there is a Priority Customer FLEX SAM response and the aggregate size of that response and other FLEX SAM responses is insufficient to satisfy the Agency Order. BOX is not proposing a similar provision. The Exchange notes that this FLEX Solicitation proposal is based on current non-FLEX Solicitation Auction functionality. *See* BOX Rule 7270(b). The Exchange believes that consistency between FLEX and non-FLEX Solicitation Auction functionality, where applicable, will reduce opportunities for confusion and increase efficiency.

[70] *See* proposed Rule 7275(e)(4), which is based on CBOE Rule 5.74(e)(4).

[71] *See* proposed IM–7275–1, which is based on CBOE Rule 5.74, Interpretations and Policies .01.

[72] *See* proposed IM–7275–3, which is based on CBOE Rule 5.74, Interpretations and Policies .03.

[73] The Exchange will reject an eligible Complex Order or Multi-Leg Order that is a Limit Complex Order or a Limit Multi-Leg Order for a credit strategy with a net debit price, or a Limit Complex Order or a Limit Multi-Leg Order for a debit strategy with a net credit price. In addition to the debit/credit check, the system will calculate a maximum price for true butterfly spreads, vertical spreads, and box spreads. The system will reject a Complex Limit Order that is a true butterfly spread, vertical spread, or a box spread if the absolute value of the Complex Order's limit price is greater than the maximum price. The system will reject a Complex Market Order that is a true butterfly spread, vertical spread, or a box spread if the absolute value of the execution price is greater than the maximum price. The maximum price is calculated by adding a price buffer to the absolute value of a true butterfly spread, vertical spread, or box spread.

[74] For Activity-Based Protections, when the Traded Order Protection counter (Rule 7330(a)) is triggered because it exceeds the maximum permissible value, all orders for that Participant identification number in options on that class are cancelled unless such cancelation is not permitted under other rules. When the Trade Activity Protection counter (Rule 7330(b)) is triggered because it exceeds the maximum permissible value, all orders and quotes for that Participant identification number in all classes are cancelled unless such cancelation is not permitted under other rules. When the Global Counter (Rule 7340) is triggered because it has reached or exceeded the limit for the Global Counter, the system will cancel all orders and/or quotes belonging to that Participant.

of the Act [75] in general, and furthers the objectives of Section 6(b)(5) of the Act [76] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Specifically, the Exchange believes that the FLEX PIP and FLEX Solicitation Auctions as described in proposed Rules 7155 and 7275, respectively, will remove impediments to and perfect the mechanism of a free and open market, and protect investors and the public interest. The proposed FLEX PIP and FLEX Solicitation Auctions will offer market participants with electronic auctions for the execution of FLEX Equity Options at potentially improved prices that are substantially similar to CBOE's FLEX AIM and FLEX SAM set forth in CBOE Rules 5.73 and 5.74, respectively, except for certain intended differences to align to the Exchange's current PIP and Solicitation Auction functionality to allow the proposed FLEX PIP and FLEX Solicitation Auctions to fit more seamlessly into BOX's market. For instance, the Exchange will not allow prices to be expressed as percentages in FLEX PIP or FLEX Solicitation Auctions as it does not have this capability today. Furthermore, the Exchange proposes to allow but not consider the quantity of FLEX Solicitation responses in excess of the size of the Agency Order in order to align to current non-FLEX PIP and Solicitation Auction functionality.[77] The Exchange will also align to current non-FLEX PIP functionality by allowing a limited exception to the proposed restriction against modifying a FLEX Primary Improvement Order by allowing Initiating Participants to improve their FLEX Primary Improvement Orders.[78] Additionally, the Exchange will also align to current non-FLEX Solicitation Auction functionality by allowing Initiating Participants to cancel their FLEX Solicitation Agency Orders and Solicited Orders.[79]

The Exchange will further align certain aspects of the proposed FLEX PIP and FLEX Solicitation Auction functionality with its current non-FLEX PIP and non-FLEX Solicitation Auction functionality. First, the Exchange will specify a scenario where the Initiating Participant could receive an allocation percentage that is greater than the Initiating Participant's guaranteed allocation (*i.e.,* when there are remaining contracts after including all PIP responses).[80] As noted above, while CBOE does not have this exception noted in CBOE Rule 5.73(e)(1)(B), this will be consistent with current non-FLEX PIP behavior.[81] Second, the Exchange's Surrender Quantity feature allows Participants to request a lower amount than their guaranteed allocation, while CBOE allows election of last priority allocation in CBOE Rule 5.73(e)(4).[82] Third, the proposal will prohibit FLEX PIP and FLEX Solicitation Auctions from occurring concurrently with other FLEX PIP and FLEX Solicitation Auctions, respectively. Although this functionality differs from CBOE FLEX AIM and FLEX SAM behavior in CBOE Rules 5.73(c)(1) and 5.74(c)(1), the Exchange is aligning FLEX PIP and FLEX Solicitation Auction functionality with BOX's current non-FLEX PIP and Solicitation Auction functionality.[83] Fourth, unlike CBOE Rule 5.73(e)(2),[84] the proposal provides that FLEX PIP responses at prices better than the final auction price will be allocated on a price-time basis.[85] The Exchange believes, although its proposal for response allocations differs from CBOE, the resulting allocations will be similar, regardless of trade allocation methodology. Specifically, the proposal differs only for response allocations at prices better than the final auction price and all responses at prices better than the final auction price will be allocated because if there is not enough FLEX PIP Order quantity to allocate all responses at a given price level then that price level becomes the final auction price. The Exchange notes that FLEX PIP responses at the final auction price are allocated in a substantially similar manner as CBOE.[86] Fifth, the FLEX Solicitation proposal provides that responses will be executed in price-time priority, while CBOE Rule 5.74(e)(2) provides for Priority Customer FLEX SAM responses to be executed first and then others on a pro-rata basis.[87] Sixth, CBOE Rule 5.74(e)(3) provides for cancellation of a FLEX SAM Auction if there is a Priority Customer FLEX SAM response and the aggregate size of that response and other FLEX SAM responses is insufficient to satisfy the Agency Order.[88] The Exchange is not proposing a similar provision. The proposal will allow the Agency Order to execute against the Solicited Order at the stop price if the aggregate size of FLEX Solicitation Auction responses at an improved price(s) is insufficient to satisfy the Agency Order. As noted above, all of the foregoing features are consistent with BOX's current PIP and Solicitation Auction functionality for non-FLEX orders, the Exchange believes that this will promote consistency for Participants across different auctions on BOX. The Exchange believes further that the proposed priority and allocation rules for both FLEX PIP and FLEX Solicitation will ensure a fair and orderly market by maintaining the priority of orders, while still affording the opportunity for price improvement during each FLEX PIP and FLEX Solicitation Auction commenced on BOX.

Otherwise, the general frameworks of the proposed FLEX PIP and FLEX Solicitation Auctions in proposed Rules 7155 and 7275 (such as the eligibility requirements, stop price requirements, auction process and conclusion, and execution provisions) are consistent with the frameworks for CBOE's FLEX AIM and FLEX SAM in CBOE Rules 5.73 and 5.74. The clarity in how FLEX PIP and FLEX Solicitation will function and their consistency with similar auctions at other exchanges will help promote a fair and orderly national options market system. For example, the proposed range for the length of each of the FLEX PIP and FLEX Solicitation Auction periods is consistent with the range for the auction periods of the CBOE's FLEX AIM and FLEX SAM Auctions in CBOE Rules 5.73(c)(3) and 5.74(c)(3). Like CBOE, the Exchange believes it is appropriate to provide a reasonable and sufficient amount of time in which market participants may submit responses because of the unique terms of FLEX Equity Options. Therefore, the Exchange proposes that the minimum length of a FLEX PIP or FLEX Solicitation Auction be three seconds. The Exchange also proposes a maximum length of an auction period to be five minutes, as the Exchange also

[75] 15 U.S.C. 78f(b).

[76] 15 U.S.C. 78f(b)(5).

[77] *See* proposed Rule 7275(c)(5)(B).

[78] *See* proposed Rules 7155(c)(4) and (5) and proposed Rules 7275(c)(4) and (5).

[79] *See* proposed Rule 7275(c)(4). *See generally* BOX Rule 7270(b).

[80] *See* proposed Rule 7155(e)(1)(B).

[81] *See supra* note 34.

[82] *See supra* note 42.

[83] *See* BOX IM–7150–2. The Exchange notes that simultaneous Solicitation Auctions are not allowed by the System.

[84] CBOE Rule 5.73(e)(2) provides at each price better than final auction price, the System executes the Agency order first against Priority Customer responses and on a pro-rata basis for others.

[85] The Exchange notes that PIP operates in a similar manner. *See* BOX Rule 7150(g).

[86] *See* proposed Rule 7155(e)(1).

[87] The Exchange notes that Solicitation Auctions operate in a similar manner. *See* BOX Rule 7270(b)(2)(v).

[88] *See* CBOE Rule 5.74(e)(3).

believes it is appropriate to provide for efficient and timely executions so that customers do not potentially miss a market. The proposed rule change also requires the Initiating Participant to establish the length of the auction period (which will be included in the auction notification message), as the Participant is in the best position to determine a reasonable period of time to provide other Participants to respond based on the complexity of the FLEX Equity Option series that is the subject of the auction, as well as based on market conditions (for example, in a volatile market, the Participant may believe it is in the best interests of a customer to have a shorter auction period given quickly changing prices).

The Exchange believes that the defined terms added in Rule 7240 (Complex Orders) will provide increased clarity to Participants by specifying definitions for ''FLEX Complex Order'' and ''FLEX Multi-Leg Order.''

Risk Protections

The Exchange believes that specifying the risk protections in IM–7240–1 apply to FLEX trading will benefit investors with additional transparency regarding the Exchange's Debit/Credit Check and Maximum Price risk protections. The Exchange also believes that applying the foregoing risk protections to FLEX PIP and FLEX Solicitation will protect investors and the public interest, and maintain fair and orderly markets, by providing market participants with more tools to manage their risk. In addition, providing Participants with more tools for managing risk facilitates transactions in FLEX PIP and FLEX Solicitation because Participants will have more confidence that risk protections are in place. As a result, the foregoing risk protections have the potential to promote just and equitable principles of trade. The Exchange is also proposing to add references to Multi-Leg and Complex FOO Orders to the risk protections in IM–7240–1, as these references were inadvertently omitted when the Exchange initially adopted FOO Orders. The Exchange believes that adding this language will provide clarity with respect to the risk protections in IM–7240–1 and Multi-Leg and Complex FOO Orders on the Exchange.

The Exchange has analyzed its capacity and represents that it believes the Exchange and the Options Price Reporting Authority (''OPRA'') have the necessary systems capacity to handle the additional message traffic associated with the addition of FLEX PIP and FLEX Solicitation.[89]

Additionally, the Exchange believes it has an adequate surveillance program in place and intends to apply the same program procedures to FLEX PIP and FLEX Solicitation that is applied to the Exchange's other options trading, as applicable. FLEX PIP and FLEX Solicitation will be integrated into the Exchange's existing surveillance system architecture and will be subject to the relevant surveillance processes. The Exchange believes that any potential risk of manipulative activity is mitigated by these existing surveillance technologies, procedures, and reporting requirements, which allow the Exchange to properly identify disruptive and/or manipulative trading activity. Additionally, taking into consideration that FLEX PIP and FLEX Solicitation have unique characteristics, the Exchange has updated its procedures to include these unique characteristics, as applicable. The Exchange will periodically review its surveillance procedures and make any changes that the Exchange believes are necessary for FLEX PIP and FLEX Solicitation.

As a self-regulatory organization, the Exchange recognizes the importance of surveillance, among other things, to detect and deter fraudulent and manipulative trading activity as well as other violations of Exchange Rules and the federal securities laws. As discussed above, the Exchange has adequate surveillance procedures in place to monitor FLEX PIP and FLEX Solicitation.[90] The Exchange further notes that under Section 19(g) of the Act, the Exchange, as a self-regulatory organization, is required to enforce compliance by its members and persons associated with its members with the Act, the rules and regulations thereunder, and the rules of the Exchange.[91] The Exchange believes its surveillance is reasonably designed to mitigate manipulation and market disruption concerns and will permit it to enforce compliance with the proposed rules and other Exchange rules in accordance with Section 19(g) of the Act. The Exchange performs ongoing evaluations of its surveillance program to ensure its continued effectiveness and will continue to review its surveillance procedures on an ongoing basis and make any necessary enhancements and/or modifications that may be needed for FLEX PIP and FLEX Solicitation Auctions.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe that the proposed rule change will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act, as all Participants who wish to utilize FLEX PIP and FLEX Solicitation will be able to trade in the same manner. The Exchange also does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, other options exchanges currently offer electronic FLEX auctions on their respective markets.[92] The Exchange believes that its proposal will allow BOX to compete with these other exchanges and provide an additional execution venue for these transactions for market participants. Thus, the Exchange believes that its proposal will promote intermarket competition by increasing the number of exchanges where electronic FLEX auctions will be available.

The Exchange further notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues who offer similar functionality.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section

[89] The Exchange will report FLEX PIP and FLEX Solicitation trades and, if necessary, trade cancellations to OPRA.

[90] Among other things, the Exchange's regulatory program includes cross-market surveillance designed to identify manipulative and other improper trading, including spoofing, algorithm gaming, marking the close and open, as well as more general abusive behavior related to front running, wash sales, and quoting/routing, which may occur on the Exchange and other markets.

[91] 15 U.S.C. 78s(g).

[92] *See supra* notes 5 and 6.

19(b)(3)(A)(iii) of the Act[93] and subparagraph (f)(6) of Rule 19b–4 thereunder.[94]

A proposed rule change filed under Rule 19b–4(f)(6)[95] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[96] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. Other exchanges have electronic FLEX auction rules, and providing another venue for electronic FLEX auctions would help foster competition as well as the protection of investors and the public interest. The proposed rule change also raises no new or novel legal or regulatory issues. For these reasons, the Commission finds that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.[97]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2026–21 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–BOX–2026–21. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–BOX–2026–21 and should be submitted on or before November 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[98]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22756 Filed 11–6–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106823; File No. SR–Phlx–2026–68]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Introduce Conforming Changes to Nasdaq Phlx Rules in Connection With the Establishment of Fees for Nasdaq TotalView Plus and Nasdaq Basic Plus

November 4, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1], and Rule 19b–4 thereunder,[2] notice is hereby given that on October 28, 2026, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to introduce conforming changes to Phlx rules in connection with the establishment of fees for Nasdaq TotalView Plus and Nasdaq Basic Plus by the Nasdaq Stock Exchange. Specifically, the Exchange proposes to amend the Exchange's fees at (i) Equity 7, Section 3, Market Data Distributor Fees to waive the market data distributor fees for PSX TotalView for firms that consolidate it with certain other feeds for external redistribution; (ii) Equity 7, Section 3, PSX TotalView to waive the fees for firms purchasing PSX TotalView Plus; (iii) Equity 7, Section 3, PSX Last Sale and Nasdaq Last Sale Plus Data Feeds to reflect the addition of Nasdaq Basic Plus as a product offering subject to a consolidation fee; and (iv) Equity 7, Section 3, PSX BBO Feeds to clarify that firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus or both shall pay monthly administrative fees and data consolidation fees, each as described further below.[3]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rulefilings,* and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

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[93] 15 U.S.C. 78s(b)(3)(A).

[94] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[95] 17 CFR 240.19b–4(f)(6).

[96] 17 CFR 240.19b–4(f)(6)(iii).

[97] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[98] 17 CFR 200.30–3(a)(12) and (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] This filing replaces SR–Phlx–2026–55, which was withdrawn on October 28, 2026. It was previously filed as SR–Phlx–2026–54, which was withdrawn on August 31, 2026.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to introduce conforming changes to Phlx rules in connection with the establishment of fees for Nasdaq TotalView Plus and Nasdaq Basic Plus by the Nasdaq Stock Exchange. Specifically, the Exchange proposes to amend fees at (i) Equity 7, Section 3, Market Data Distributor Fees to waive the market data distributor fees for PSX TotalView for firms that consolidate it with certain other feeds for external redistribution; (ii) Equity 7, Section 3, PSX TotalView to waive the fees for firms purchasing PSX TotalView Plus; (iii) Equity 7, Section 3, PSX Last Sale and Nasdaq Last Sale Plus Data Feeds to reflect the addition of Nasdaq Basic Plus as a product offering subject to a consolidation fee; and (iv) Equity 7, Section 3, PSX BBO Feeds to clarify that firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus or both shall pay monthly administrative fees and data consolidation fees, each as described further below.

Nasdaq TotalView Plus and Nasdaq Basic Plus Fees

The Nasdaq Stock Market LLC (''Nasdaq'') recently introduced two new products, Nasdaq TotalView Plus and Nasdaq Basic Plus,[4] which consolidate Depth-of-Book [5] and Top-of-Book [6] information currently disseminated by Nasdaq, Nasdaq Texas, LLC (''Nasdaq Texas''), and the Exchange. Nasdaq has submitted to the Commission a fee filing designed to set fees for Nasdaq TotalView Plus and Nasdaq Basic Plus at or below fees currently charged for the Depth-of-Book and Top-of-Book products offered by Nasdaq, Nasdaq Texas, and Phlx. This, together with the networking and connectivity savings inherent in lowering the number of data feeds, is designed to maximize the distribution of consolidated data feeds to investors throughout the 23 hour, 5 days per week schedule set to begin in December 2026.

Nasdaq will offer Nasdaq TotalView Plus for the same Professional and Non-Professional Subscriber and enterprise license fees as Nasdaq TotalView.[7] To ensure that market data vendors will be able to offer competing consolidated data products, any firm that certifies to Nasdaq that it will consolidate Nasdaq TotalView, Nasdaq Texas TotalView and Nasdaq PSX TotalView into a data feed solely for external redistribution shall be exempt from Nasdaq Texas Market Data Distributor Fees [8] and Nasdaq PSX Market Data Distributor Fees,[9] and the Monthly External Distributor Fees for the Nasdaq Stock Market LLC at Equity 7, Section 119(b) shall be reduced by $350 per month.[10] These three discounts will ensure that vendors will be able to cover the cost of consolidating the underlying fees.

Nasdaq will offer Nasdaq Basic Plus for the same Professional and Non-Professional Subscriber, enterprise license, and Distributor fees as Nasdaq Basic. To ensure that other market data vendors will be able to offer competing consolidated data products, Nasdaq proposes to charge the same monthly administrative and data consolidation fees for Nasdaq Basic Plus as are currently charged for Nasdaq Last Sale Plus to both Internal Distributors [11] and External Distributors [12] to cover the costs of data feed consolidation to be incurred by market data vendors.

With respect to the Market Data Enterprise License for Display Usage,[13] which currently offers both Nasdaq TotalView and Nasdaq Basic in the same enterprise license, Nasdaq proposes to offer the Nasdaq TotalView Plus and Nasdaq Basic Plus feeds for the same fees currently charged for the Nasdaq TotalView and Nasdaq Basic.

As a result of the introduction of Nasdaq TotalView Plus and Nasdaq Basic Plus and their related fees, the Exchange is proposing amendments to Equity 7, Section 3, Market Data Distributor Fees, PSX TotalView, PSX Last Sale and Nasdaq Last Sale Plus Data Feeds, and PSX BBO Feeds to make conforming changes to its fee schedule to align with the fees outlined in Nasdaq's Equity 7, Sections 123, 132, 139, and 147 for these new products.

Market Data Distributor Fees

The purpose of the first fee amendment is to issue a fee waiver for External Market Data Distributor Fees of $1,620 per month, in Equity 7, Section 3, Market Data Distributor Fees for vendors that certify to Nasdaq that they will consolidate Nasdaq TotalView, Nasdaq Texas TotalView and Nasdaq PSX TotalView into a data feed solely for external redistribution. The same discount would not apply to non-vendors. Vendors would be able to apply this fee reduction, together with the waiver of Nasdaq Texas Market Data Distributor Fees, and the $350 per month reduction in Monthly External Distributor Fees for the Nasdaq Stock Market, to cover the cost of forming their own consolidated feed, thereby allowing vendors to compete with Nasdaq in the sale of consolidated data products using the depth of book data from Nasdaq affiliates.

PSX TotalView Fees

The purpose of the second fee amendment is to issue a fee waiver for PSX TotalView fees in Equity 7, Section 3, PSX TotalView, to any firm that purchases Nasdaq TotalView Plus. PSX TotalView disseminates all individual Phlx Equities System participant orders and quotes displayed in the system, the aggregate size of such orders and quotes at each price level, and the trade data for executions that occur within the Phlx Equities System.[14] This will be a fee waiver of (i) monthly Subscriber fees of $ $44.50 (operative January 1, 2026) for each Subscriber for display usage or for non-display usage not based upon Direct Access; and (ii) $1.00 per Subscriber per month for each Professional Subscriber.[15]

This is to ensure that Nasdaq can offer Nasdaq TotalView Plus for the same Subscriber fees as Nasdaq TotalView.

Administrative and Consolidation Fees

The purpose of the third and fourth fee amendments is to clarify that firms that receive Nasdaq Basic Plus, in

[4] *See* Securities Exchange Act Release No. 105997 (July 28, 2026), 91 FR 48466 (July 31, 2026) (SR–Nasdaq–2026–061) (a proposal to introduce Nasdaq TotalView Plus and Nasdaq Basic Plus, two new data feeds which will offer consolidated Top-of-Book and Depth-of-Book information currently disseminated by Nasdaq, Nasdaq Texas and Nasdaq PSX).

[5] The underlying Depth-of-Book products are Nasdaq TotalView, Nasdaq Texas TotalView, and PSX TotalView.

[6] The underlying Top-of-Book products are Nasdaq Basic (which includes both best bid and offer and last sale information), Nasdaq Texas BBO, Nasdaq Texas Last Sale, PSX BBO, and PSX Last Sale.

[7] Internal and External Distributor, as well as Direct Access fees, may apply to purchasers of Nasdaq Plus products depending on the customer's use case. *See* Nasdaq Rules, Equity 7, Section 119(b).

[8] *See* Nasdaq Texas Rules, Equity 7, Section 119(a)

[9] *See* Equity 7, Section 3 (Market Data Distributor Fees).

[10] *See* Nasdaq Stock Market Rules, Equity 7, Sections 119(b) and 119(d). There are two Monthly External Distributor Fees at Section 119(b), one for Nasdaq-listed security depth entitlements and one for Non Nasdaq-listed security depth entitlements.

[11] ''Internal Distributors'' are Distributors that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus data and then distribute that data to one or more Subscribers within the Distributor's own entity.

[12] ''External Distributors'' are Distributors that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus data and then distribute that data to one or more Subscribers outside the Distributor's own entity.

[13] *See* Nasdaq Stock Market Rules, Equity 7, Section 132.

[14] *See* Equity 7, Section 3 (PSX TotalView).

[15] *See id.*

addition to or in lieu of Nasdaq Last Sale Plus, will also pay the monthly administrative fee applicable to PSX Last Sale, and that distributors of Nasdaq Last Sale Plus or Nasdaq Basic Plus will pay a data consolidation fee of $350 per month. Currently, firms that receive Nasdaq Last Sale Plus must pay the administrative and consolidation fees,[16] and this amendment extends the same to purchasers of Nasdaq Basic Plus,[17] as both Nasdaq Last Sale Plus and Nasdaq Basic Plus contain the same PSX Last Sale feeds.[18]

This fee is designed to cover the data consolidation costs of market data vendors to ensure that they will be able to offer competing consolidated data products to the new Nasdaq Basic Plus product, which contains PSX Last Sale.

As a conforming change, the Exchange proposes to modify both Equity 7, Section 3, PSX Last Sale and Nasdaq Last Sale and PSX BBO Feeds to state that firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus or both shall pay the monthly administrative fees for PSX Last Sale and, as well as a data consolidation fee of $350 per month.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[19] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[20] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers because the proposal: (i) offers more customer choice; (ii) protects competition by covering the data consolidation costs of market data vendors; (iii) does not increase the fee for any Phlx product, but simply waives certain fees or applies consolidation costs to firms purchasing certain data feeds; (iv) conforms fees for Phlx products to the recent Nasdaq filings related to the offer of Nasdaq TotalView Plus and Nasdaq Basic Plus; and (v) offers products to all market participants on a non-discriminatory basis.

1. More Customer Choice

The proposal will expand choice by allowing customers to select whether to purchase best bid and offer information through the separate data feeds of Nasdaq Basic, Nasdaq Texas Last Sale, Nasdaq Texas BBO, and PSX Last Sale, and PSX BBO (or any combination thereof) separately or in a single feed. Purchasing Nasdaq Basic Plus or Nasdaq TotalView Plus will allow some customers to optimize consumption by ingesting information from multiple markets in a single connection, which may result in cost savings for subscribers based on a more efficient configuration of data feeds. Nothing in this proposal will change the quantity or quality of Depth-of-Book or Top-of-Book information available in the market, as the underlying feeds will remain available, and the proposed feeds are simply amalgamations of those underlying feeds.

2. No Competitive Advantage Relative To Market Data Vendors

In offering Nasdaq Basic Plus and Nasdaq TotalView Plus, Nasdaq will be acting as a redistributor of Depth-of-Book [21] and Top-of-Book [22] products from Nasdaq, Nasdaq Texas, and Phlx.[23]

Nasdaq Basic Plus and Nasdaq TotalView Plus will be compiled from the same underlying feeds from Nasdaq, Nasdaq Texas, and Phlx that are distributed to the purchasers of those feeds. With respect to speed, the path for the distribution of the information by the Exchange will not be faster than the path for distribution that would be used by a market data vendor to distribute similar, independently created products.

With respect to information, the same source of the market data to be used by the Exchange to create the two proposed products will also be available to any other market data vendor. The Nasdaq system that will create and support Nasdaq Basic Plus and Nasdaq TotalView Plus will access the underlying feeds from Nasdaq, Nasdaq Texas, and Phlx from the same point as any market data vendor.

With respect to cost, Nasdaq will ensure that market data vendors are able to compete with the proposed fees by introducing waivers of distributor fees for Nasdaq PSX and Nasdaq Texas and a reduction of $350 per month in external distributor fees for the Nasdaq Stock Market, for distributors of Nasdaq TotalView Plus and a consolidation fee for Nasdaq Basic Plus. These proposals will allow vendors to cover the costs of consolidation for Depth-of-Book and Top-of-Book feeds, respectively.[24] The Exchange is filing this proposal to implement conforming changes for a Nasdaq Stock Exchange proposal filed separately.

The proposed fee waiver for Nasdaq TotalView Plus will exempt any firm that certifies to Nasdaq that it will consolidate Nasdaq TotalView, Nasdaq Texas TotalView and PSX TotalView into a data feed solely for external redistribution from Nasdaq Texas Market Data Distributor Fees [25] and Phlx Market Data Distributor Fees,[26] and shall also receive a fee reduction of $350 per month in External Distributor fees from the Nasdaq Stock Market. This substantial savings in distributor fees offered only to external distributors—$1,620 per month for Nasdaq Texas,[27] $1,390 per month for PSX TotalView,[28] and $350 for the Nasdaq Stock Market—will allow vendors to cover the cost of consolidation of Depth-of-Book feeds and will ensure that market data vendors will be able to offer consolidated data products that compete with Nasdaq TotalView Plus.

The proposed fees for Nasdaq Basic Plus include monthly administrative fees for Nasdaq Last Sale, NTX Last Sale, and PSX Last Sale and a data consolidation fee of $350 per month for Internal Distributors and External Distributors of Nasdaq Basic Plus.[29] This is the current fee charged for Nasdaq Last Sale Plus to ensure that market data vendors will be able to offer competing feeds.

Nasdaq introduced a consolidation fee for both Nasdaq Basic Plus and Nasdaq Last Sale Plus because Nasdaq Basic Plus includes last sale information. Nasdaq expects vendors to use the same processes and servers to consolidate both best bid and offer and last sale information, and therefore the same consolidation fee should be sufficient to

[16] *See* Equity 7, Section 3 (PSX Last Sale and Nasdaq Last Sale Plus Data Feeds).

[17] Firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus would either be liable for Nasdaq Last Sale fees or Nasdaq Basic fees, but not both. SR–NASDAQ–2026–070.

[18] They also contain PSX BBO feeds, for which there is no charge.

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(4) and (5).

[21] The underlying Depth-of-Book products are Nasdaq TotalView, Nasdaq Texas TotalView, and PSX TotalView.

[22] The underlying Top-of-Book products are Nasdaq Basic (which includes both best bid and offer and last sale information), Nasdaq Texas BBO, Nasdaq Texas Last Sale, PSX BBO, and PSX Last Sale.

[23] *See* Securities Exchange Act Release No. 105997 (July 28, 2026), 91 FR 48466 (July 31, 2026) (SR–Nasdaq–2026–061); SR–NASDAQ–2026–070.

[24] There is no consolidation fee for Nasdaq TotalView because the waiver of distributor fees is sufficient to cover the costs of consolidation without any additional fee.

[25] *See* Nasdaq Texas Rules, Equity 7, Section 119.

[26] *See* Equity 7, Section 3.

[27] *See* Nasdaq Texas Rules, Equity 7, Section 119(a).

[28] *See* Equity 7, Section 3 (Market Data Distributor Fees).

[29] Firms that receive Nasdaq Last Sale Plus or Nasdaq Basic Plus would either be liable for Nasdaq Last Sale fees or Nasdaq Basic fees, but not both.

cover all data consolidation costs, enabling vendors to compete in consolidating and distributing data from multiple exchanges. The Exchange is proposing to amend its rules to permit that competition.

3. No Fee Increases

Nothing in the proposal involves an increase to the fees currently charged by Phlx for its data feeds. Any subscriber to solely a Phlx feed will continue to pay the same fees as are currently set, without any change. The subscriber fee waivers and consolidation fees proposed herein are to ensure that any purchaser of a *compiled* product, whether it is Nasdaq TotalView Plus, Nasdaq Basic Plus, or the feeds necessary to compile a competing product containing the same information as Nasdaq TotalView Plus and/or Nasdaq Basic Plus, is not at a cost disadvantage compared to other purchasers of the same information.

The proposed data consolidation fee for Nasdaq Basic Plus is exactly the same fee as currently charged for Nasdaq Last Sale Plus, and customers of Nasdaq Last Sale Plus would pay no additional consolidation fee for Nasdaq Basic Plus. These consolidation and administrative fees are not new, but are simply being expanded to Nasdaq's new product, and do not increase the fees charged to purchasers of Phlx data.

Rather, the proposed set of fee waivers for external distributor fees of Nasdaq PSX and Nasdaq Texas and $350 reduction for the Nasdaq Stock Market for data vendors lowers fees below current fees.

The proposed waiver of all subscriber fees, including both Professional and Non-Professional fees, Non-Display Usage fees, and enterprise license fees for Phlx data for Nasdaq TotalView Plus will actually lower fees further, as purchasers of Nasdaq TotalView Plus will be charged the same fees as currently charged for Nasdaq TotalView alone. The proposed Nasdaq TotalView Plus fees therefore offer customers a discount below current fees.

4. Conforming Amendments

The proposal conforms fees for Phlx products to the recent Nasdaq filings related to the offer of Nasdaq TotalView Plus and Nasdaq Basic Plus.[30] In order for Nasdaq's proposed fees to be effective, Phlx must update its rules to ensure that they do not conflict with Nasdaq's. The proposed amendments to Equity 7, Section 3 are conforming changes made to align the Exchange's rules to Nasdaq's.

5. No Unfair Discrimination

The proposal is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers because the proposed feeds are optional data fees available to all market participants on a non-discriminatory basis.

In summary, the proposal provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers because the proposal: (i) offers more customer choice; (ii) protects competition by reducing fees for market data vendors; (iii) does not increase the fee for any Phlx product, but simply waives certain fees or applies consolidation costs to firms purchasing certain data feeds; (iv) conforms fees for Phlx products to the recent Nasdaq filings related to the offer of Nasdaq TotalView Plus and Nasdaq Basic Plus; and (v) offers products to all market participants on a non-discriminatory basis.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The proposal merely implements fee waivers for certain purchasers and consolidation and administrative fees for others, which any other exchange could propose.

Nothing in the Proposal burdens intra-market competition (the competition among consumers of exchange data), because the products related to the fee changes—Nasdaq TotalView Plus and Nasdaq Basic Plus—will be offered to all market participants at the same price and any market participant that elects to purchase either Nasdaq TotalView Plus or Nasdaq Basic Plus may do so on a non-discriminatory basis.

Moreover, as explained above, the proposed fees offer no competitive advantage relative to market data vendors, and are in fact designed to promote competition. There is no change to (or advantage in) speed or information. With respect to cost, the Exchange proposes to ensure that market data vendors are able to compete with the proposed fees by introducing a set of fee waivers and a fee reduction for Nasdaq TotalView Plus that is exclusively available to market data vendors and a consolidation fee for Nasdaq Basic Plus. These Nasdaq feeds are completely voluntary products in that Nasdaq is not required by any rule or regulation to make this data available and potential subscribers may purchase it only if they voluntarily choose to do so. Information is compiled from underlying feeds from Nasdaq, Nasdaq Texas, and the Exchange, which will remain available for purchase.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[31]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–Phlx–2026–68 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

[30] *See* SR–Nasdaq–2026–091.

[31] 15 U.S.C. 78s(b)(3)(A)(ii).

All submissions should refer to file number SR–Phlx–2026–68. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–Phlx–2026–68 and should be submitted on or before November 30, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22758 Filed 11–6–26; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice 13156]

60-Day Notice of Proposed Information Collection: Shrimp Exporter's/Importer's Declaration

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *January 8, 2027.*

ADDRESSES:

You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2026–1189'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: DS2031@state.gov.*
- *Regular Mail:* Send written comments to: Office of Marine Conservation (OES/OMC), Attn: Section 609 Program, 2201 C Street NW, Room 2758, Washington, DC, 20520–2758

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Christopher Gosselin, Section 609 Program Manager, Office of Marine Conservation, Bureau of Oceans and International Environmental and Scientific Affairs, Department of State, Washington, DC 20520–2758, who may be reached on 202–647–3263 or at *DS2031@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Shrimp Exporter's/Importer's Declaration.
- *OMB Control Number:* 1405–0095.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Oceans and International Environmental and Scientific Affairs, Office of Marine Conservation (OES/OMC).
- *Form Number:* DS–2031.
- *Respondents:* Business or other for-profit organizations.
- *Estimated Number of Respondents:* 3,000.
- *Estimated Number of Responses:* 10,000.
- *Average Time per Response:* 10 minutes.
- *Total Estimated Burden Time:* 1,666 hours.
- *Frequency:* on occasion.
- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The DS–2031 form is necessary to document imports of shrimp and products from shrimp pursuant to the State Department's implementation of Section 609 of Public Law 101–162, which prohibits the entry into the United States of shrimp harvested in ways which are harmful to sea turtles. Respondents are exporters of shrimp and products from shrimp and government officials in countries that export shrimp and products from shrimp to the United States. The importer is required to present the DS–2031 form at the port of entry into the United States, to retain the DS–2031 form for a period of three years subsequent to entry, and during that time to make the DS–2031 form available to U.S. Customs and Border Protection or the Department of State upon request.

Methodology

The DS–2031 form is completed by the exporter, the importer, and under certain conditions a government official of the harvesting country. The DS–2031 form accompanies shipments of shrimp and shrimp product to the United States and must be made available to U.S. Customs and Border Protection at the time of entry and for three years after entry.

Alice M. Kottmyer,

Attorney-Adviser, Office of Management, Office of the Legal Adviser, U.S. Department of State.

[FR Doc. 2026–22786 Filed 11–6–26; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 791]

Policy Statement on Jurisdiction and Preemption Under the ICC Termination Act

AGENCY: Surface Transportation Board.

ACTION: Statement of Board Policy.

SUMMARY: The Surface Transportation Board (STB or Board) is issuing this policy statement on the scope of its jurisdiction over transportation by rail carriers and on preemption of conflicting state and federal laws under the ICC Termination Act of 1995

[32] 17 CFR 200.30–3(a)(12).

(ICCTA). The policy statement provides an overview of the Board's jurisdiction and preemption through a review of existing legal precedent, discussing many commonly occurring questions. The Board intends the policy statement to serve as a useful tool for the public to review, in one place, concise explanations from the Board about its jurisdiction and application of preemption, which the Board anticipates will reduce confusion and facilitate the efficient resolution of disputes.

DATES: This policy statement will be final on November 9, 2026.

FOR FURTHER INFORMATION CONTACT: Amanda Gorski at (202) 915–8453. If you require accommodation under the Americans with Disabilities Act, please call (202) 245–0245.

SUPPLEMENTARY INFORMATION: Congress granted the Board exclusive jurisdiction over rail transportation and preempted conflicting federal or state laws in ICCTA. *See generally* 49 U.S.C. 10501. ICCTA embodies Congress's recognition of the need to regulate railroad operations at the federal level. Broadly, it provides that the Board has jurisdiction over rail transportation that is part of the interstate rail network. In ICCTA, Congress included an expansive preemption provision, the purpose of which is to ensure the free flow of interstate commerce, including by preventing patchwork regulation and eliminating unduly burdensome state laws, and by providing a nationally uniform, efficient national rail network to meet the needs of the public and national defense. On September 19, 2025, the Board received a letter from a coalition of six railroad and shipper organizations (Coalition) [1] requesting that the Board issue guidance on the scope and application of federal preemption. Coalition Letter (Sept. 19, 2025), *https://www.stb.gov/wp-content/uploads/Coalition-Letter-on-ICCTA-Preemption_FINAL.pdf.* Board members issued a joint response letter on September 24, 2025, noting the Coalition's views and stating that the Board was considering issuing a policy statement on preemption. Letter from Board Members Fuchs, Hedlund, & Schultz (Sept. 24, 2025), *https://www.stb.gov/wp-content/uploads/Preemption-Letter-Final.pdf.*

Over the 30 years since ICCTA's enactment, the Board and the courts have issued many decisions addressing the scope of the Board's jurisdiction over transportation by rail carriers and the preemptive effect of ICCTA when presented with potentially conflicting state, local, or federal regulations. While those decisions are generally consistent, they are numerous, have not always used the same terminology or analytical approaches, and may contain technical language unfamiliar to the general public. The Board therefore views it as important to set forth its considered, longstanding view of its jurisdiction over rail transportation and the application of ICCTA preemption. This policy statement is non-exhaustive but explores a significant number of questions that are frequently presented to the Board and to courts interpreting and applying ICCTA. Although any future case that comes before the Board (or a court) will be evaluated on the specific facts, circumstances, and laws presented in that case, the Board anticipates that the policy statement will serve the public by summarizing for stakeholders existing precedent. The policy statement will promote collaboration by reducing uncertainty about the scope of the Board's jurisdiction and ICCTA preemption and describing how the Board has analyzed frequently occurring questions. The Board thus aims to proactively prevent disputes regarding the Board's jurisdiction and ICCTA preemption, and when disputes do arise, for the policy statement to serve as a useful tool for the public and courts in resolving such disputes, potentially lowering litigation costs for carriers, shippers, and state and local governments. In turn, this action would, as appropriate, potentially support economic growth by better facilitating the avoidance or removal of undue or inappropriate impediments to rail transportation serving domestic manufacturing, agriculture, and energy facilities, among other critical aspects of the economy.

By addressing key concepts and authorities in one consolidated, synthesized document, the policy statement provides benefits to stakeholders and the general public. The policy statement will lower costs by reducing the time and resources necessary to process and evaluate a breadth of topics relevant to the Board's jurisdiction and preemption. It will allow a wide array of users to quickly reference and read about their individual areas of interest. And it synthesizes precedents and provides guidance on the Board's jurisdiction and preemption—including processes for rail carrier licensing and the proper forum for adjudicating disputes—in a practical way that is not necessary, or possible, when resolving individual matters before the Board. By reducing these incremental costs, the policy statement is considered a deregulatory action under Executive Order 14192, *Unleashing Prosperity Through Deregulation.*

I. Executive Summary

This policy statement explains how the Board and state and federal courts have interpreted the Board's authority over rail transportation and the preemption of state and local laws under ICCTA.[2] Congress' framework, set forth in ICCTA, has been interpreted in ways that ensure the uniform federal regulation over interstate rail transportation, which is critical to the American economy. Individual cases must be decided based on the facts, circumstances, and applicable law in each case, and this policy statement supports that endeavor by setting forth the Board's general perspective on its jurisdiction and ICCTA preemption.

The policy statement begins with an explanation of the long-recognized need for uniform rail regulation at the federal level, including under the Commerce Clause of the U.S. Constitution, the passage of the Interstate Commerce Act in 1887, and subsequent federal legislation, culminating in the passage of ICCTA and the creation of the Board in the 1990s. In enacting the statutory provision most relevant to preemption—49 U.S.C. 10501(b)—Congress included two key, interrelated components: (1) broad, exclusive jurisdiction over transportation by rail carriers (including certain related activity), and (2) that the remedies provided under ICCTA expressly preempt the remedies provided under federal and state law. The policy statement explains and analyzes numerous elements of the statute.

Regarding jurisdiction, the Board discusses the definitions of ''transportation'' and ''rail carrier'' (with attention to both freight and passenger rail carriers), and provides an explanation of three categories of track that the Board has recognized (common carrier, ancillary, and private) and how each is viewed for jurisdictional purposes. In analyzing the preemption provision, the policy statement identifies the broad scope of

[1] The Coalition consists of American Chemistry Council, American Short Line and Regional Railroad Association (ASLRRA), Association of American Railroads, Intermodal Association of North America, National Grain and Feed Association, and National Industrial Transportation League.

[2] For demonstrative purposes, the Board cites both binding and non-binding precedents in this policy statement without necessarily adopting such precedents.

''regulations'' that may be preempted—including those from both state and local authorities and those that may take the form of less-direct methods of regulation. The policy statement also explains that preemption extends beyond economic regulation and may apply when ICCTA does not provide an alternative remedy. The Board and courts may both be proper forums for disputes regarding the Board's jurisdiction and ICCTA preemption, with courts often referring preemption issues to the Board, consistent with the Board's expertise on such matters.

The policy statement next explores the analytical preemption framework that the Board applies when considering state or local regulations. The policy statement explains that what courts often call express preemption is typically analyzed, under ICCTA, as ''categorical'' preemption, and what is often called implied preemption is typically analyzed as ''as-applied'' preemption. The policy statement then explains that the categorical analysis is employed where state or local laws attempt to regulate rail transportation matters or when regulations (such as permitting) can be used to prevent rail transportation. It further explains that the ''as-applied'' analysis is used when a regulation may unreasonably burden or interfere with rail transportation or discriminate against rail carriers. The policy statement then analyzes and synthesizes precedents on complete takings of rail property by state or local governments, as well as the indirect regulation of rail transportation through regulation of shippers in ways that may limit common carrier rail service. The policy statement then addresses a number of commonly occurring preemption questions, summarizing the preemption analysis applied and the results of Board and court decisions. The non-exhaustive list of preemption fact patterns includes: (1) abandonment of rail property interests, (2) complete taking of rail carrier property, (3) utilities and pipelines within the right-of-way, (4) blocked crossings, (5) pedestrian or road crossings of rail lines, (6) locomotive idling, (7) environmental permitting, zoning ordinances, and land use laws, (8) noise, smoke, appearance, and other nuisance-related claims, (9) design, construction, or maintenance of rail infrastructure, (10) breach of contract, and (11) routing of traffic.

The policy statement also discusses the analysis that applies in considering whether a federal law is preempted by ICCTA. The Board explains the harmonization analysis that applies to give effect to both federal laws where possible. The policy statement then discusses two illustrative federal law regimes that have been the subject of harmonization analysis in past decisions—federal rail safety laws (including the Federal Railroad Safety Act (FRSA)) and federal environmental laws (including the Clean Air Act (CAA) and Clean Water Act (CWA)).

The Board is not making any binding determinations in this policy statement. Indeed, this policy statement is not exhaustive and should not be interpreted to predetermine the outcome of any particular dispute that may come before the agency, in which the Board would consider the specific facts, circumstances, and arguments presented. Instead, it compiles principles from certain existing cases to help parties understand how the Board and courts have approached frequently occurring questions concerning the Board's jurisdiction and ICCTA preemption. Where this policy statement identifies areas in which the Board provides a refinement to its prior analysis, such as complete takings and regulations directed at rail customers, the discussion below explains the basis for the refinement. The Board intends that this policy statement will serve as a reference document that can be used to promote growth in the rail industry and collaboration between rail carriers, shippers, and communities to proactively develop solutions to rail-related concerns.

Nevertheless, railroads should not use ICCTA preemption as an excuse to be unresponsive to local public officials. Consistent with the rail transportation policy of the United States government (set forth at 49 U.S.C. 10101), railroads, as regulated entities, should seek to engage in good communication, information sharing and cooperation with the communities they serve and operate within. State and local governments may have legitimate interests in the development of, among other things, passenger rail and trails within rights of way where allowed, for the benefit of both rail carriers and local communities. Local government officials who believe that a railroad has been unresponsive may seek assistance from the Board's Office of Public Assistance, Governmental Affairs, and Compliance (OPAGAC) to facilitate improved communications.

II. Historically Recognized Need for Uniform Federal Rail Regulation

The Surface Transportation Board was created on January 1, 1996 by ICCTA, Public Law 104–88, 109 Stat. 803 (1995), as the successor to the Interstate Commerce Commission (ICC) (1887–1995). The Board is the federal agency that is responsible for the economic regulation of various modes of surface transportation, primarily freight rail. Its responsibilities include oversight of railroad rates, practices, and service issues, as well as rail restructuring transactions including mergers, line sales, line construction, and line abandonments. The Board also has jurisdiction over certain passenger rail matters, the intercity bus industry, household goods carriers' tariffs, rate regulation of non-contiguous domestic water transportation (marine freight shipping involving the mainland United States, Hawaii, Alaska, Puerto Rico, and other U.S. territories and possessions), and pipeline carriers transporting commodities other than water, gas, or oil. While questions can arise regarding the scope of the Board's authority over each of these other transportation modes, this policy statement discusses rail transportation, which is the primary focus of the Board's statutory obligations.

Congress and the courts long have recognized a need to uniformly regulate rail transportation at the federal level. As an inherently interstate mode of transportation, ''[r]ailroads have been subject to comprehensive federal regulation for [more than] a century.'' *United Transp. Union* v. *Long Island R.R.,* 455 U.S. 678, 687 (1982); *see also* Interstate Commerce Act, ch. 104, 24 Stat. 379 (1887). Even before Congress enacted the Interstate Commerce Act in 1887, the Supreme Court had established that a state's regulation of railroad rates unconstitutionally interfered with interstate commerce. *See Wabash, St. Louis & Pac. Ry.* v. *Illinois,* 118 U.S. 557, 577 (1886). In 1887, Congress created the ICC to oversee a ''comprehensive regulatory regime over the rail industry.'' Paul Stephen Dempsey, *The Rise & Fall of the Interstate Com. Comm'n,* 95 Marq. L. Rev. 1151, 1161 (2012); *see also* Interstate Commerce Act Sec. 11, 24 Stat. 383. And since that time, the Supreme Court has ''frequently invalidated attempts by the States to impose on common carriers obligations that are plainly inconsistent with the plenary authority of the [ICC] or with congressional policy as reflected in the [Interstate Commerce Act].'' *Chi. & NW Transp. Co.* v. *Kalo Brick & Tile Co.,* 450 U.S. 311, 318 (1981) (citing *Tex. & Pac. Ry.* v. *Abilene Cotton Oil Co.,* 204 U.S. 426, 446 (1907); *Transit Comm'n* v. *United States,* 289 U.S. 121, 129 (1933)). Indeed, the Interstate Commerce Act is ''among the most pervasive and comprehensive federal regulatory

schemes.'' *Chi. & NW Transp. Co.,* 450 U.S. at 318.

In response to significant financial concerns experienced by the railroad industry in the 1970s, Congress substantially amended the Interstate Commerce Act by enacting ''two major pieces of legislation of a generally deregulatory thrust'': the Railroad Revitalization and Regulatory Reform Act of 1976, Public Law 94–210, and the Staggers Rail Act of 1980 (Staggers Act), Public Law 96–448. *Balt. Gas & Elec. Co.* v. *United States,* 817 F.2d 108, 112–13 (D.C. Cir. 1987). Together, these laws were intended to reduce unnecessary regulation and help restore the financial stability of the railroad industry.

Congress carried that deregulatory thrust forward in 1995, when it enacted ICCTA as a means of ''extending exclusive Federal jurisdiction'' over rail transportation. H.R. Rep. No. 104–311, at 82, 95 (1995), *as reprinted in* 1995 U.S.C.C.A.N. 793, 793–94, 807 (''There is a long history behind the termination of the [ICC] beginning with [the Staggers Act], which began the substantial economic deregulation of the surface transportation industry . . . .''). And through ICCTA, Congress further expanded federal uniformity by preempting certain areas of state authority over rail activity that previously existed. *See Fla. E. Coast Ry.* v. *City of W. Palm Beach,* 266 F.3d 1324, 1337–38 (11th Cir. 2001) (explaining that ''[t]he pre-ICCTA statute expressly authorized regulation of certain railroad activities to be undertaken concurrently by the federal and state governments, while still other regulation would be the exclusive province of state law.''). At the same time, in further deregulating the rail industry, Congress did not intend for states and local governments to replace federal regulation with a patchwork of differing state and local rail regulations. *See* S. Rep. No. 104–176, at 6 (1995) (noting that nothing in ICCTA ''should be construed to authorize States to regulate railroads in areas where Federal regulation has been repealed . . . .'').

Indeed, in ICCTA, Congress reaffirmed that ''the direct and complete pre-emption of State economic regulation of railroads'' was necessary to preserve ''the uniformity of Federal standards'' and prevent ''the balkanization and subversion of the Federal scheme of minimal regulation for this intrinsically interstate form of transportation.'' H.R. Rep. No. 104–311, at 95–96. Subjecting the interstate rail network to varying state regulations ''would greatly undermine the industry's ability to provide the 'seamless' service that is essential to its shippers,'' and would weaken the rail industry's ''efficiency and competitive viability.'' S. Rep. No. 104–176, at 6. In this way, preemption is consistent with the national rail transportation policy to promote a ''safe and efficient rail transportation system,'' 49 U.S.C. 10101(3), and ''ensure the development and continuation of a sound rail transportation system with effective competition among rail carriers and with other modes, to meet the needs of the public and the national defense,'' 49 U.S.C. 10101(4).

III. The Jurisdiction and Preemption Provisions of 49 U.S.C. 10501(b)

The scope of the Board's exclusive jurisdiction over transportation by rail carriers is set forth in 49 U.S.C. 10501(b). The statute also contains an express preemption provision. Taken together, the statutory provisions governing jurisdiction and preemption establish the framework for the Board's analysis.

The statute provides that the ''jurisdiction of the Board over (1) transportation by rail carriers, and the remedies provided in [Part A of Subtitle IV of Title 49] with respect to rates, classifications, rules (including car service, interchange, and other operating rules), practices, routes, services, and facilities of such carriers; and (2) the construction, acquisition, operation, abandonment, or discontinuance of spur, industrial, team, switching, or side tracks, or facilities, even if the tracks are located, or intended to be located, entirely in one State, is exclusive.'' 49 U.S.C. 10501(b). Furthermore, ''[e]xcept as otherwise provided in [Part A of Subtitle IV of Title 49], the remedies provided under this part with respect to regulation of rail transportation are exclusive and preempt the remedies provided under Federal or State law.'' *Id.*

These provisions of section 10501 work together to ensure the free flow of interstate commerce by preventing a patchwork of different state and local regulations. *E.g., Tenth Ave. Neighbors—Pet. for Declaratory Ord.,* FD 36654, slip op. at 3–4 (STB served May 8, 2024) (citing *Tubbs—Pet. for Declaratory Ord.,* FD 35792, slip op. at 5 (STB served Oct. 31, 2014), *aff'd sub nom. Tubbs* v. *STB,* 812 F.3d 1141 (8th Cir. 2015)); *see also Elam* v. *Kan. City S. Ry.,* 635 F.3d 796, 804 (5th Cir. 2011) (recognizing that a purpose of ICCTA was to create a ''[f]ederal scheme of minimal regulation for this intrinsically interstate form of transportation''); *Fayus Enters.* v. *BNSF Ry.,* 602 F.3d 444, 452 (D.C. Cir. 2010) (ICCTA reflected a Congressional effort to prevent the ''balkanization'' of railroad-related laws); *U.S. Env't Prot. Agency—Pet. for Declaratory Ord.* (*EPA Declaratory Ord.*), FD 35803, slip op. at 7 (STB served Dec. 30, 2014) (''The courts and the Board have emphasized the importance of national uniformity in laws governing rail transportation when interpreting [section] 10501(b).''). Since ICCTA was enacted, it has been observed that ''[i]t is difficult to imagine a broader statement of Congress' intent to preempt state regulatory authority over railroad operations.'' *City of Auburn* v. *United States,* 154 F.3d 1025, 1030 (9th Cir. 1998) (quoting *CSX Transp. Inc.* v. *Ga. Pub. Serv. Comm'n,* 944 F. Supp. 1573, 1581 (N.D. Ga. 1996)).

From this established statutory structure, disputes have arisen about both the jurisdictional and preemption aspects of ICCTA. Two preliminary jurisdictional questions have guided the analysis of whether regulation under local, state, or another federal law may be subject to ICCTA preemption. First, is the activity at issue ''transportation by rail carrier'' as part of the interstate rail network or related to the construction, acquisition, operation, abandonment or discontinuance of spur, industrial, team, switching, or side tracks (collectively, commonly referred to as ''ancillary track'' or ''excepted track''), or facilities? And second, does the local, state, or federal action constitute regulation of such activity? If the answer to both questions is yes, then the Board and courts apply a preemption analysis to determine whether ICCTA preempts such regulation.[3]

Though the steps are straightforward, the case-specific analysis required to determine preemption is often fact-intensive and detailed. Questions can arise in each stage of the inquiry: what activities constitute ''transportation''; is the actor a ''rail carrier,'' or operating on behalf of a rail carrier; are the railroad tracks or facilities part of the interstate rail network or a shipper's private facilities; what types of actions by local and state governments (or other actors) are considered ''regulation''; when does a state or local regulation ''unreasonably interfere'' with rail transportation; to what extent does preemption cover lawsuits for damages allegedly caused by rail carrier operations? The analysis below addresses these and other related questions and summarizes existing precedent on the Board's jurisdiction and ICCTA preemption.

[3] As discussed below, the test applied varies depending on whether the regulation is based on state (or local) law or federal law, and the content of the regulation.

A. Transportation by Rail Carrier or Related to Ancillary/Excepted Track or Facilities

The threshold question in any preemption analysis is whether the activity at issue falls within the Board's jurisdiction. As specified, under 49 U.S.C. 10501(b), the Board has jurisdiction over ''transportation by rail carriers.'' Whether a particular activity constitutes ''transportation by rail carrier'' is a case-by-case, fact-specific determination. *E.g., Town of Smithtown—Pet. for Declaratory Ord.,* FD 36575 (Sub-No. 1), slip op. at 3 (STB served Feb. 23, 2024) (citing *Padgett* v. *STB,* 804 F.3d 103, 108 (1st Cir. 2015); *Town of Milford—Pet. for Declaratory Ord.,* FD 34444, slip op. at 2 (STB served Aug. 12, 2004)). The same is true for determining whether railroad tracks and facilities are subject to the Board's jurisdiction. *See, e.g., Ne. La. Multimodal Dist.—Pet. for Declaratory Ord.,* FD 36809, slip op. at 5–6 (STB served Sept. 15, 2025) (describing factors considered in distinguishing between common carrier/mainline (10901) and ancillary/excepted (10906) track)); *Tri-City R.R.—Pet. for Declaratory Ord.,* FD 36037, slip op. at 5 (STB served June 1, 2017) (describing hallmarks of private track).

To determine whether a particular activity is subject to the Board's jurisdiction and, potentially, preemption under 49 U.S.C. 10501, both the ''transportation'' and ''by rail carrier'' prongs of the standard must be satisfied. The Board has held that preemption does not apply to non-transportation activities by rail carriers. *See, e.g., Grafton & Upton R.R.—Pet. for Declaratory Ord.,* FD 36696, slip op. at 10 (STB served Nov. 15, 2023) (stating that ''the taking of the [rail carrier's property] via eminent domain would likely not be preempted if it is developed for purposes unrelated to rail transportation.''). Likewise, transportation activities by non-rail carriers generally are not preempted. *See, e.g., Smithtown,* FD 36575 (Sub-No. 1), slip op. at 4–5 (holding that application of state and local regulations to transloading facility would not be preempted where the facility was owned by a non-carrier that was not affiliated with the carrier; not acting as the carrier's agent; and not subject to the carrier's exertion of control over operations).

1. Transportation

The Board has jurisdiction over transportation in the United States, including, but not limited to,[4] (1) between a place in a state and a place in another state, and (2) between a place in a state and another place in the same state, as long as that intrastate transportation is ''part of the interstate rail network.'' 49 U.S.C. 10501(a)(2). Rail carriers that operate exclusively in one state—as many short line railroads [5] often do—are thus generally subject to the Board's jurisdiction if they connect to the interstate rail network. *See Great Redwood Trail Agency—Adverse Aban.—Mendocino Ry. in Mendocino Cnty., Cal.,* AB 1305 (Sub-No. 1), slip op. at 9–10 (STB served Feb. 19, 2026) (acknowledging that a rail carrier solely transporting shipments between points within the same state could be subject to the Board's jurisdiction). As used in ICCTA, ''transportation'' includes not just the act of moving freight or passengers by rail but also broadly encompasses equipment, facilities, and services related to that movement. Specifically, transportation ''includes a locomotive, car, vehicle, vessel, warehouse, wharf, pier, dock, yard, property, facility, instrumentality, or equipment of any kind related to the movement of passengers or property, or both, by rail, regardless of ownership or an agreement concerning use; and services related to that movement, including receipt, delivery, elevation, transfer in transit, refrigeration, icing, ventilation, storage, handling, and interchange of passengers and property.'' 49 U.S.C. 10102(9). This list is non-exhaustive, as ''use of the word 'include' indicates the list is illustrative rather than comprehensive.'' *Del Grosso* v. *STB,* 898 F.3d 139, 142 (1st Cir. 2018).

Proceedings before the Board and courts have made clear that the broad definition of ''transportation'' includes transloading and related operations when performed or operated by, or under the auspices of, a rail carrier. *See, e.g., Smithtown,* FD 36575 (Sub-No. 1), slip op. at 4–5 (stating that ''the Board's jurisdiction extends to rail-related activities that take place at transload facilities if the activities are offered by a rail carrier, either directly or through its agent, or if a rail carrier exerts control over a third-party's operations''). Additionally, conducting activities such as making repairs to rail equipment and the construction and operation of excepted track constitute ''transportation'' because they involve facilities, instrumentalities, and equipment related to the movement of property (tracks and rail equipment) and services related to that movement (repairs and operation of tracks and rail equipment). *See Grafton & Upton,* FD 36696, slip op. at 10–11.

Though expansive, the definition of ''transportation'' has its limits. *Emerson* v. *Kan. City S. Ry.,* 503 F.3d 1126, 1129 (10th Cir. 2007); *see also Del Grosso* v. *STB,* 804 F.3d 110, 119 (1st Cir. 2015) (stating that courts and the Board have rejected interpretations of ''transportation'' that extend beyond activities relating to the movement of ''passengers or property'' by rail). As the courts have recognized, ''regulation of activities that occur before or after 'transportation' and are incidental to such transportation may not be preempted.'' *Delaware* v. *STB,* 859 F.3d 16, 21–22 (D.C. Cir. 2017); *see also Emerson,* 503 F.3d at 1130–32 (holding that a railroad's disposal of railway ties into a wastewater drainage ditch adjacent to its tracks was not ''transportation,'' and thus state tort claims related to the disposal were not preempted).

As one example, ''manufacturing and commercial transactions that occur on property owned by a railroad that are not part of or integral to the provision of rail service are not embraced within the term 'transportation.' '' *Del Grosso,* 898 F.3d at 142 (quoting *New England Transrail, LLC—Constr., Aquis. & Operation Exemption—in Wilmington & Woburn, Mass.* (*New England Transrail*), FD 34797, slip op. at 10 (STB served July 10, 2007)); *see also Fla. E. Coast Ry.,* 266 F.3d at 1327, 1336 (a third party's aggregate distribution business operating in a rail yard was not ''transportation''); *New England Transrail,* FD 34797, slip op. at 14–15 (shredding of construction debris at a transloading facility before loading the material onto railcars was not ''transportation''); *Town of Milford,* FD 34444, slip op. at 1–2 (cutting and welding steel in a rail yard after rail transportation had occurred but before the steel was loaded onto trucks was not ''transportation'').

[4] In full, section 10501(a)(2) provides: Jurisdiction under paragraph (1) applies only to transportation in the United States between a place in—

(A) a State and a place in the same or another State as part of the interstate rail network;

(B) a State and a place in a territory or possession of the United States;

(C) a territory or possession of the United States and a place in another such territory or possession;

(D) a territory or possession of the United States and another place in the same territory or possession;

(E) the United States and another place in the United States through a foreign country; or

(F) the United States and a place in a foreign country.

[5] Class II and III carriers are commonly referred to as ''regional'' or ''short line'' railroads. In this policy statement, the Board uses the term ''short line railroads'' to refer to these rail carriers.

2. Rail Carrier

Under ICCTA, a ''rail carrier,'' is defined as ''a person providing common carrier railroad transportation for compensation, but does not include street, suburban, or interurban electric railways not operated as part of the general system of rail transportation.'' 49 U.S.C. 10102(5). The term ''railroad'' includes ''a bridge, car float, lighter, ferry, and intermodal equipment used by or in connection with a railroad; the road used by a rail carrier and owned by it or operated under an agreement; and a switch, spur, track, terminal, terminal facility, and a freight depot, yard, and ground, used or necessary for transportation.'' 49 U.S.C. 10102(6). The common carrier obligation requires that rail carriers ''providing transportation or service subject to the jurisdiction of the Board under [Part A of Subtitle IV of Title 49] shall provide the transportation or service on reasonable request.'' 49 U.S.C. 11101(a). Thus, as the Supreme Court has recognized, rail carriers are required to provide transportation ''to any person or commodity,'' and ''cannot decline to provide [such] transport based on the product or commodity to be carried.'' *Seven Cnty. Infrastructure Coal.* v. *Eagle Cnty.,* 605 U.S. 168, 191 n.6 (2025). This includes products ranging from crude oil, *id.,* to hazardous substances, *Riffin* v. *STB,* 733 F.3d 340, 346–47 (D.C. Cir. 2013), to agricultural products, construction materials, and retail goods.

The Board and courts have also interpreted the term ''rail carrier'' broadly, such that activities do not necessarily need to be conducted directly by the rail carrier in order for preemption to apply. Rather, the transportation must be performed ''by, or under the auspices of, a rail carrier.'' *Del Grosso—Pet. for Declaratory Ord.,* FD 35652, slip op. at 2 & n.4 (STB served July 31, 2017) (collecting cases); *City of Alexandria—Pet. for Declaratory Ord.,* FD 35157, slip op. at 2 (STB served Feb. 17, 2009). The Board has stated that, for example, at transload facilities, ''the Board's jurisdiction extends to rail-related activities that take place at transload facilities if the activities are offered by a rail carrier, either directly or through its agent, or if a rail carrier exerts control over a third-party's operations.'' *Smithtown,* FD 36575 (Sub-No. 1), slip op. at 4. As discussed in more detail below, certain cases have held that indirect regulation that burdens common carrier rail service implicates preemption.

a. Freight Rail Carriers

The Board has jurisdiction over freight rail carriers engaged in interstate transportation, as well as intrastate transportation that is ''part of the interstate rail network.'' 49 U.S.C. 10501(a)(2). The Board classifies freight rail carriers into three categories based on annual operating revenues, with Class I carriers being the largest, Class II in the middle, and Class III the smallest. *See* 49 CFR 1201. Class II and III carriers are commonly referred to as short line railroads. Short line railroads frequently operate within the Board's jurisdiction because, even when they operate only within one state, they often connect with Class I carriers and serve as part of the interstate rail network by handling the first or last segment (sometimes referred to as ''first mile/last mile service'') as part of a longer journey.

Whether a freight operator is considered a rail carrier within the Board's jurisdiction is not always immediately clear. The Board (as did the ICC before it) issues decisions authorizing transactions that, if consummated, confer rail carrier status. Typically, the Board-issued document is a decision approving the potential rail carrier's authority for construction,[6] acquisition, and/or operation (under 49 U.S.C. 10901 or 10502), often in the form of a notice of exemption in the case of acquisition and operation transactions (under 49 CFR 1150.31).[7] Although these decisions are maintained in agency records, they may not be readily accessible, particularly when the agency's approval was issued decades ago. Moreover, the Board's licensing structure is permissive. Only when the entity consummates a Board-authorized acquisition or operation does it become a ''rail carrier'' under the Board's jurisdiction. *See Mendocino Ry.—Pet. for Declaratory Ord.,* FD 36868, slip op. at 3–4 (STB served Sept. 26, 2025) (citing *Middletown & N.J. R.R.—Lease & Operation Exemption—Norfolk S. Ry.,* FD 35412, slip op. at 4–5 (STB served Mar. 27, 2013)). And once the transaction is consummated, no separate notice of consummation is required to be filed with the Board. At this time, the Board does not maintain a registry, list, or website of licensed rail carriers, nor does it provide a physical or digital license document.[8]

Additionally, a rail carrier does not automatically lose its common carrier status by stopping its rail service over a line. By statute, Board authorization is needed to terminate the common carrier obligation generally through a line sale, abandonment, or discontinuance. *See, e.g., Middletown,* FD 35412, slip op. at 4; *see also Strohmeyer—Acquis. & Operation Exemption—Valstir Indus. Track in Middlesex & Union Cntys., N.J.,* FD 35527, slip op. at 2 & n.5 (STB served Oct. 20, 2011) (discussing the mechanisms a railroad may employ to excuse itself, permanently or temporarily, from its common carrier obligations) (citing *Pejepscot Indus. Park, Inc.—Pet. for Declaratory Ord.,* 6 S.T.B. 886, 898 (2003)). Therefore, regardless of how much time has passed since a shipper last requested common carrier service, a rail carrier remains within the Board's jurisdiction until the Board, in its sole authority, authorizes its removal and that authorization is consummated.

When questions concerning a rail carrier's status cannot be resolved through the review of public decisions, parties often seek assistance from the Board.[9] The Board's Rail Customer and Public Assistance (RCPA) program can assist in resolving disputes, explain the Board's jurisdiction and procedures, and informally answer questions based on the Staff's knowledge and experience.[10] Additionally, the Board has discretionary authority under 5 U.S.C. 554(e) and 49 U.S.C. 1321 to

[6] Construction authority, once consummated, confers on the constructing entity a common carrier obligation, even in cases where ''fulfillment [of that obligation] may be undertaken by operating railroads under trackage rights, leases, or similar arrangements.'' *Midwest Generation, LLC—Exemption from 49 U.S.C. 10901—for Constr. in Will Cnty., Ill.,* FD 34060 et al., slip op. at 7 n.15 (STB served Mar. 21, 2002) (quoting *Big Stone-Grant Ind. Dev. & Transp., L.L.C.—Constr. Exemption—Ortonville, Minn. & Big Stone City, S.D.,* FD 32645, slip op at 2 (ICC served Sept. 26, 1995)).

[7] As recently explained by the ASLRRA in a proceeding before the Board, ''non-carrier companies often enter the rail transportation system, and become common carriers subject to [Board] jurisdiction, through the acquisition of either a part or of the entirety of a rail line segment that is currently within the jurisdiction of the Board or otherwise would be the entirety of the line of railroad to be operated by that soon-to-be carrier.'' ASLRRA Comment 6, July 7, 2025, *Mendocino Ry.—Pet. for Declaratory Ord.,* FD 36868.

[8] Some of the Board's licensing provisions—for example, 49 U.S.C. 10901 and 10902—refer to the Board's issuance of a ''certificate'' authorizing the proposed activity. In practice, such certificates consist of a Board decision granting the authority or, in the case of class exemptions, a Board-issued notice of exemption served and published in the **Federal Register**.

[9] The Board is aware that other agencies or organizations, such as the U.S. Railroad Retirement Board, at times also make their own determinations about whether an entity is a rail carrier. The Board does not address those circumstances here and focuses solely on the Board's (and courts') determinations of the Board's jurisdiction for purposes of regulation under ICCTA.

[10] Additional information about RCPA, including contact information, can be found on the Board's website.

issue a declaratory order to eliminate controversy or remove uncertainty. *See, e.g., Bos. & Me. Corp.* v. *Town of Ayer,* 330 F.3d 12, 14 n.2 (1st Cir. 2003); *Delegation of Auth.—Declaratory Ord. Procs.,* 5 I.C.C.2d 675 (1989). For example, the Board recently received a request from a rail carrier to confirm its status as a common carrier subject to the Board's jurisdiction, which was disputed during legal challenges by local municipalities and state agencies. *See Mendocino Ry.,* FD 36868, slip op. at 1. The Board reviewed prior decisions related to the requesting rail carrier—including past Board decisions granting a common carrier obligation to the rail carrier's predecessor, and subsequently granting the rail carrier authority to purchase the line—and determined that the rail carrier was a common carrier subject to the Board's jurisdiction and therefore, if applicable, entitled to the benefits of federal preemption for its transportation activities under 49 U.S.C. 10501(b). *See id.* at 1–4.

b. Passenger Rail Carriers

The Board also has jurisdiction over certain passenger rail operations. While the Board generally has jurisdiction over ''transportation''—including equipment or services related to the movement of passengers as well as property, *see* 49 U.S.C. 10102(9)—by a ''rail carrier,'' not all passenger rail operations fall within the Board's jurisdiction. The definition of ''rail carrier'' specifically excludes ''street, suburban, or interurban electric railways not operated as part of the general system of rail transportation.'' 49 U.S.C. 10102(5). Additionally, except in limited circumstances,[11] the Board ''does not have jurisdiction under this part over . . . public transportation provided by a local government authority.'' 49 U.S.C. 10501(c)(2)(A). This exclusion generally applies to ''regular, continuing shared-ride surface transportation services that are open to the general public or open to a segment of the general public defined by age, disability, or low income,'' with certain exceptions, when provided by a local governmental authority.[12] 49 U.S.C. 5302(15). Additionally, the National Railroad Passenger Corporation (Amtrak) is treated separately under ICCTA. Although Amtrak is part of the interstate rail network, Congress limited the Board's jurisdiction over Amtrak to specific statutory provisions, including to address directed service (49 U.S.C. 11123), equipment trusts (*id.* 11301), pooling (*id.* 11322(a)), withholding taxes (*id.* 11502), and liability (*id.* 11706). *See* 49 U.S.C. 24301(c).[13]

Whether a passenger rail service solely within one state is part of the interstate rail network is a fact-specific determination based on the totality of the circumstances. *Tex. Cent. R.R. & Infrastructure, Inc.—Pet. for Exemption—Passenger Rail Line Between Dallas & Houston, Tex.,* FD 36025, slip op. at 7 (STB served July 16, 2020); *Cal. High-Speed Rail Auth.—Constr. Exemption—in Merced, Madera & Fresno Cntys., Cal.,* FD 35724, slip op. at 11–15 (STB served June 13, 2013). It has also long been the agency's position that it does not have jurisdiction over purely intrastate passenger service, even if that service is performed by a licensed rail carrier. *See, e.g., Napa Valley Wine Train, Inc.—Pet. for Declaratory Ord.,* 7 I.C.C.2d 954, 969 (1991). However, questions can arise when an intrastate passenger line connects to the interstate rail network, as such service may indeed be subject to the Board's jurisdiction. *See, e.g., Tex. Cent. R.R.,* FD 36025, slip op. at 12 (finding that a proposed intrastate passenger rail line would be subject to the Board's jurisdiction because it was connected to the interstate rail system via through-ticketing arrangements and transfer service). The Board examines multiple factors in determining whether a particular passenger service is under its jurisdiction, such as whether the proposed service has a through-ticketing arrangement or whether it shares a station with an interstate carrier, although no single factor is dispositive. *See, e.g., id.,* slip op. at 7; *Cal. High-Speed Rail Auth.,* FD 35724, slip op. at 11–15.

3. Classifications of Rail Track

Whether an activity falls within the definition of ''transportation by rail carrier'' will sometimes depend, in whole or in part, on the legal status of the rail line or track on which service is being provided. Again, the Board recognizes three categories of track: common carrier (or mainline),[14] ancillary (or excepted),[15] and private. The first two (common carrier and ancillary) are subject to the Board's jurisdiction, whereas private track is not.

a. Common Carrier/Mainline Rail Lines

The Board has exclusive jurisdiction over rail lines over which a rail carrier provides ''common carrier'' service to shippers. 49 U.S.C. 10501(a)–(b); *id.* 11101; *see Allied Erecting & Dismantling Co.* v. *STB,* 835 F.3d 548, 550 (6th Cir. 2016). No one may build an extension to a common carrier rail line, build additional lines, provide transportation over an extended or additional line, or abandon a line without Board authorization. 49 U.S.C. 10901(a), 10903; *see Allied Erecting & Dismantling Co.,* 835 F.3d at 550.[16]

b. Ancillary/Excepted Tracks

The Board often refers to spur, industrial, team, switching, or side tracks, or facilities interchangeably as ''ancillary'' or ''excepted'' tracks. ''Ancillary'' because such tracks and facilities are used for loading cars, track switching, and other activities that are incidental, or *ancillary,* to the provision of common carrier service, *see Nicholson* v. *ICC,* 711 F.2d 365, 367–68 & n.11 (D.C. Cir. 1983); ''excepted'' because under 49 U.S.C. 10906, the construction, acquisition, operation, abandonment, or discontinuance of such tracks and related facilities is *excepted* from the Board's licensing authority. Thus, while spur, industrial, team, switching, or side tracks, or facilities, are within the Board's exclusive jurisdiction, they can be added to or removed from the interstate rail network without authorization from the Board. *See N.Y.C. Econ. Dev. Corp.—Pet. for Declaratory Ord.,* FD 36467, slip op. at 5 (STB served June 11, 2021); *Tri-City R.R.,* FD 36037, slip op.

[11] These include the use of terminal facilities (49 U.S.C. 11102) and switch connections/tracks (49 U.S.C. 11103) in limited circumstances. *See* 49 U.S.C. 10501(c)(3)(B).

[12] The term ''local governmental authority'' includes ''(A) a political subdivision of a State; (B) an authority of at least 1 State or political subdivision of a State; (C) an Indian tribe; and (D) a public corporation, board, or commission established under the laws of a State.'' 49 U.S.C. 5302(11).

[13] The Board also has certain regulatory responsibilities relating to Amtrak under other statutes not relevant for purposes of this policy statement. The Board also notes that, under separate statutes, Amtrak itself may be able to invoke its own form of preemption in certain circumstances. *See* 49 U.S.C. 24902(j), 24301(g).

[14] The Board and courts regularly refer to these lines as ''mainline'' or ''main line'' track for purposes of the Board's jurisdiction under ICCTA, which is the focus of this policy statement. The Board is not herein equating, or taking any position on, these terms as they may pertain to FRA's definition of ''main line'' under 49 CFR 236.1003, or FRA's use of the term ''general railroad system of transportation'' as described in 49 CFR part 209, Appendix A.

[15] The term ''excepted track'' derives from 49 U.S.C. 10906, titled ''Exception''. The use of the term ''excepted track'' as it pertains to ICCTA is not the same as FRA's definition of ''excepted track'' under 49 CFR 213.4.

[16] When Board authorization is required for certain projects, the Board must consider, among other things, the potential environmental and historic impacts of the construction and operation of a proposed rail line pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321–4370m–11, Section 106 of the National Historic Preservation Act, 54 U.S.C. 300101 *et seq.,* the Board's environmental rules at 49 CFR part 1105, and related environmental laws.

at 4. Even though the Board does not license ancillary track (as it does common carrier rail lines), such track is under the Board's exclusive jurisdiction and therefore is subject to federal preemption. *See* 49 U.S.C. 10501(b)(2). There is no bright-line test to distinguish between common carrier rail lines and ancillary tracks. Instead, the Board considers various indicia when determining whether a track is excepted under section 10906, including a track's relationship to the rail system, intended use, physical characteristics, and history. *See, e.g., Oakland Glob. Rail Enter.—Pet. for Declaratory Ord.,* FD 36168, slip op. at 8 & n.8 (STB served Mar. 15, 2019).[17] A track segment that constitutes a carrier's entire rail system cannot be considered ancillary track (because it is not ''ancillary'' to other track of the carrier), and therefore is not excepted under 49 U.S.C. 10906. *Effingham R.R.—Pet. for Declaratory Ord.—Constr. at Effingham, Ill.,* FD 33468, slip op. at 5 (STB served Sept. 18, 1998).

c. Private Track

Private track is track typically built and maintained by a shipper (or for a shipper at the shipper's expense), and operated by the shipper or its contractor to serve its own operations and move its own goods. *E.g., B. Willis, C.P.A., Inc.—Pet. for Declaratory Ord.,* 6 S.T.B. 280, 281 (2002), *aff'd sub nom. B. Willis, C.P.A., Inc.* v. *STB,* 51 Fed. App'x 321 (D.C. Cir. 2002). Where the shipper does not hold out to provide common carrier railroad service over the line to other shippers for compensation, neither the construction of the track nor the operations require Board approval. *See B. Willis, C.P.A., Inc.,* 6 S.T.B. at 285; *see also Devens Recycling Ctr.—Pet. for Declaratory Ord.,* FD 34952, slip op. at 3 (STB served Jan. 10, 2007) (finding no jurisdiction over operations conducted on private track used exclusively to serve the track owner pursuant to a contractual arrangement with the owner). When track is constructed and operated in a manner that does not constitute common carriage, the agency has held that it is not subject to the Board's jurisdiction. *See B. Willis, C.P.A., Inc.,* 6 S.T.B. at 285. The agency has stated that private track need not serve only one shipper and can include private service to numerous shippers within a single location—such as an industrial park—as long as the carrier is not providing common carrier service. *Cf. TGS Cedar Port R.R.—Operation Exemption—in Chambers Cnty., Tex.,* FD 36627, slip op. at 1 (STB served Apr. 1, 2024) (noting that carrier previously operated 1.28 miles of private track within an industrial park without needing Board authority until conversion to common carrier service). Because such track is not subject to the Board's jurisdiction, construction and removal of such track is not covered by federal preemption. However, as discussed in further detail below, the Board is providing in this policy statement clarification regarding instances where state or local regulation of construction of or operations over private track may be considered to interfere with ''transportation by rail carrier'' and thus could be subject to preemption.

B. Regulation of Rail Transportation and the Preemption of Remedies

ICCTA contains an express preemption provision, providing that ''[e]xcept as otherwise provided in [Part A of Subtitle IV of Title 49], the remedies provided under this part with respect to regulation of rail transportation are exclusive and preempt the remedies provided under Federal or State law.'' 49 U.S.C. 10501(b). The plain meaning of ''regulation'' is ''managing or governing,'' *Fla. E. Coast Ry.,* 266 F.3d at 1331 (citing Black's Law Dictionary 1286 (6th ed. 1990)) (citation modified), or ''controlling by rule or restriction,'' *Union Pac. R.R.* v. *Chi. Transit Auth.,* 647 F.3d 675, 679 n.2 (7th Cir. 2011). ICCTA thus bars states from ''exercising control . . . over rail transportation as it is defined in 49 U.S.C. 10102(9).'' *Id.* (citation modified).

ICCTA's use of ''State'' encompasses both state and local law, and it is well established that ICCTA preempts local as well as state regulation. *Padgett,* 804 F.3d at 107 (citation modified). This can include, among other things, certain state or local building permits, zoning ordinances, and environmental and land use permitting requirements. *See, e.g., Wash. & Idaho Ry.—Pet. for Declaratory Ord.,* FD 36017, slip op. at 4 (STB served Mar. 17, 2017) (noting that state or local permitting or preclearance requirements, including building permits, zoning ordinances, and environmental and land use permitting requirements may be subject to preemption).

''Regulation'' does not simply mean laws passed by a legislature or rules enacted by a regulatory agency, and can, in appropriate circumstances, include common-law tort claims that similarly regulate rail transportation and certain related activity. Legal actions asserting eminent domain, adverse possession, easements, and other property rights have, as appropriate, been deemed ''regulation'' for purposes of analyzing ICCTA preemption. *See, e.g., Tri-City R.R.—Pet. for Declaratory Ord.,* FD 35915, slip op. at 7 (STB served Sept. 14, 2016) (collecting cases); *see also Edwards* v. *CSX Transp., Inc.,* 983 F.3d 112, 121 (4th Cir. 2020) (holding that ''regulation'' need not ''be by way of public rule''). Tort actions may also be considered ''regulation'' for purposes of ICCTA in certain circumstances ''because damages awarded under state tort laws can manage or regulate a railroad as effectively as the application of any other type of state statute or regulation.'' *Tubbs,* FD 35792, slip op. at 4. Thus, ICCTA's ''preemptive reach can encompass common-law tort actions, in addition to statutes and ordinances.'' *Edwards,* 983 F.3d at 121–22 (collecting cases) (recognizing that ICCTA's preemption clause ''in no way distinguishes between statutory prohibitions and common-law duties''). Indeed, the statute's ''all-encompassing language'' does not ''permit the federal statute to be circumvented by allowing liability to accrue under state common law.'' *Ezell* v. *Kan. City S. Ry.,* 866 F.3d 294, 299–300 (5th Cir. 2017). It has been noted that ''[o]f course, not *all* common-law claims against railroads are preempted.'' *Edwards,* 983 F.3d at 122. Rather, common law claims are subject to the same preemption analyses as are other forms of ''regulation,'' such as state and local laws.

While ''the core of ICCTA preemption is 'economic regulation,'' *Fayus Enters.,* 602 F.3d at 451, such as state laws governing the setting of rates and rules and practices related to rail transportation or service, ''ICCTA 'does not preempt only explicit economic regulation.'' *Id.* (quoting *N.Y. Susquehanna & W. Ry.* v. *Jackson,* 500 F.3d 238, 252 (3d Cir. 2007)); *accord City of Auburn,* 154 F.3d at 1030. And as the Board has recognized, any such limitation would be ''contrary to the statutory text and unworkable in practice.'' *Friends of the Aquifer,* 5 S.T.B. 880, 884 n.8 (2001). Additionally, given the broad language of section 10501(b)(2) (granting the Board exclusive jurisdiction over construction, acquisition, operation, abandonment, or discontinuance of rail lines), the distinction between ''economic'' and ''environmental'' regulation begins to blur. *See City of Auburn,* 154 F.3d at 1031. ''For if local authorities have the ability to impose 'environmental'

[17] Parties that are uncertain whether a particular track is considered a common carrier rail line or ancillary track (or private track) often request a determination from the Board. *See, e.g., Ne. La. Multimodal Dist.,* FD 36809; *N.Y.C. Econ. Dev. Corp.,* FD 36467.

permitting regulations on the railroad, such power will in fact amount to 'economic regulation' if the carrier is prevented from constructing, acquiring, operating, abandoning, or discontinuing a line.'' *City of Auburn,* 154 F.3d at 1031.

The remedies that the Board may impose are set forth throughout the Board's governing statute, covering issues such as competition and access (49 U.S.C. 11102), rates (*id.* 10702(1)), licensing (*id.* 10901–10910), and the economic relationship between shippers and carriers (*id.* 10702(2)). Section 10501(b) expressly states that ''the remedies provided under [49 U.S.C. 10101–11908] with respect to regulation of rail transportation are exclusive and preempt the remedies provided under Federal or State law.'' And so ICCTA preemption may apply even though a remedy may not exist under the Interstate Commerce Act for all instances where a state or local law is preempted. *14500 Ltd. LLC—Pet. for Declaratory Ord.,* FD 35788, slip op. at 5 (STB served June 5, 2014) (''Although [section] 10501(b) states that 'the remedies provided under this part with respect to rail transportation are exclusive,' that does not mean that a remedy must exist under the Interstate Commerce Act for all instances where a state or local law is preempted under [section] 10501(b)''.); *Norfolk S. Ry.—Pet. for Declaratory Ord.,* FD 35701, slip op. at 6 (STB served Nov. 4, 2013).

A notable instance where the Board does not have regulatory authority (but still has jurisdiction) is with respect to ancillary or excepted track. As noted above, Congress provided the Board with exclusive jurisdiction over the ''construction, acquisition, operation, abandonment, or discontinuance of spur, industrial, team, switching, or side tracks,'' 49 U.S.C. 10501(b)(2), while simultaneously stating that ''[t]he Board does not have authority'' over the licensing of these activities, 49 U.S.C. 10906. *See also Pace* v. *CSX Transp., Inc.,* 613 F.3d 1066, 1068–69 (11th Cir. 2010) (finding state law claims relating to side track preempted even though Board does not actively regulate such track); *Port City Props.* v. *Union Pac. R.R.,* 518 F.3d 1186, 1188 (10th Cir. 2008) (stating that Congress intended to remove Board authority over the construction, operation, and abandonment of side tracks ''while still preempting state jurisdiction over them''). Accordingly, even though the Board does not authorize construction or abandonment of ancillary track, state and local governments are prohibited from regulating such activities. *See* 49 U.S.C. 10906. For example, this means that states and localities are barred from requiring an environmental permit for construction of ancillary track, despite no environmental review being conducted by the Board.

The principle applies to other ''transportation'' activities that the Board does not directly regulate. *See Del Grosso,* 804 F.3d at 114 (''Whether or not the Board is exercising its regulatory authority over the transportation, state and local laws governing such transportation are generally preempted.''). ICCTA preemption can apply ''without regard to whether or not the Board actively regulates the particular activity involved.'' *Tubbs,* FD 35792, slip op. at 4 (holding that a state law damages claim alleging improper design, construction, and maintenance of a rail carrier's main line track was preempted even though the Board does not directly regulate these issues).[18] For example, although the Board does not regulate how long carriers may idle locomotives, a state or local law seeking to impose its own regulation on how long locomotives may idle would nonetheless be preempted. *See Pet. of Norfolk S. Ry. for Expedited Declaratory Ord.,* FD 35949, slip op. at 4–5 (STB served Feb. 25, 2016), *aff'd sub nom. Delaware,* 859 F.3d at 21–22.

ICCTA preempts not only direct regulation but may also preempt indirect regulation that affects a rail carrier's ability to provide common carrier operations to its customers. *See Smithtown,* FD 36575 (Sub-No. 1), slip op. at 4 n.7 (collecting cases); *City of Alexandria,* FD 35157, slip op. at 2 (holding that ICCTA preempted local regulation of trucks serving a transloading facility operated by rail carrier's contractor). Such laws conflict with Congress's purpose in codifying the common carrier obligation because a rail carrier's ability to provide service and a shipper's right to receive service on reasonable request are two sides of the same coin.

C. Proper Forum for Disputes Concerning Board Jurisdiction and ICCTA Preemption

The Board's exclusive ''jurisdiction'' should not be confused with traditional subject-matter jurisdiction to hear and resolve a dispute. The Board's ''jurisdiction'' essentially confers a broad and exclusive ''authority to regulate'' (except where specifically stated otherwise, *e.g.,* ancillary track). But the Board does not have exclusive ''subject-matter jurisdiction'' to resolve disputes about whether a particular activity is preempted. It is well-established that the Board and courts have concurrent jurisdiction to resolve preemption questions. *E.g., Ne. La. Multimodal Dist.,* FD 36809, slip op. at 4; *see also Adrian & Blissfield R.R.* v. *Vill. of Blissfield,* 550 F.3d 533, 539 n.4 (6th Cir. 2008). Actions implicating ICCTA preemption therefore may be originated either at the Board or in court.[19] Because jurisdiction is concurrent, the Board often has exercised its discretion not to address questions that have already been litigated by the parties and decided by a court. *See, e.g., City of N. Chi.,* FD 36619, slip op. at 4 n.3 (declining to issue declaratory order where ''the preemption question posed by [the petition for declaratory order] has already been decided by the [referring] court'').

In addition to resolving disputes filed directly with the Board, the Board generally accepts referrals from courts grappling with questions regarding the extent of the Board's jurisdiction and preemption under ICCTA. Courts have sought the Board's input in a variety of ways, including dismissing a judicial proceeding without prejudice while the Board resolves an issue, *e.g., Tri-City R.R.,* FD 35915, slip op. at 4 n.4; staying a judicial proceeding while the parties seek a determination from the Board, *e.g., Tubbs,* FD 35792, slip op. at 1; or referring a question to the Board for resolution, *e.g., Grafton & Upton,* FD 36696, slip op. at 5. And some courts have retained jurisdiction while referring a preemption determination to the Board, despite retaining concurrent jurisdiction to resolve the issue. *See, e.g., Grafton & Upton,* FD 36696, slip op. at 5. Particularly when the threshold question is whether the Board has jurisdiction at all—such as where the parties dispute whether an entity qualifies as a ''rail carrier'' under ICCTA, or whether a segment of track is excepted (jurisdictional) or private (non-jurisdictional), or whether a

[18] Although the Board's statute has a provision on ''rights and remedies of persons injured by rail carriers,'' 49 U.S.C. 11704, this provision ''only applies to claims for violations of the Interstate Commerce Act,'' and does not create a general cause of action. *See City of N. Chi.—Pet. for Declaratory Ord.,* FD 36619, slip op. at 4 n.3 (STB served May 18, 2023); *see also 14500 Ltd. LLC,* FD 35788, slip op. at 5 (explaining that section 11704 and the Interstate Commerce Act do not address or provide any remedies for state law property issues).

[19] The Board takes no position regarding whether a preemption related claim may be initiated originally in state or federal court, or whether a claim can be removed to federal court. As the Board has acknowledged, ''[t]he Board is not the proper forum for deciding the extent of a court's jurisdiction.'' *Waneck—Pet. for Declaratory Ord.,* FD 36167, slip op. at 4 (STB served May 25, 2018) (citing *Lopez-Elias* v. *Reno,* 209 F.3d 788, 791 (5th Cir. 2000) (noting that the determination of a court's jurisdiction is exclusively for the court to decide)).

jurisdictional track has been abandoned and therefore is no longer subject to the Board's jurisdiction as a matter of federal law—the Board's expertise and unique responsibility for ensuring uniform national rail standards may be utilized. *Cf. In re Metro. Transp. Auth.,* 32 A.D.3d 943, 946 (N.Y. App. Div. 2006) (When ''questions exist with regard to whether the track at issue is a spur and, if so, whether its apparent nonuse is sufficient to result in an abandonment, . . . [s]uch matters are properly addressed to the [Board]''). For example, some courts have directed the parties, during litigation, to seek guidance from the Board on the jurisdictional status of track. *See, e.g., Brookhaven Rail Terminal—Pet. for Declaratory Ord.,* FD 35819, slip op. at 4 (STB served Aug. 30, 2016) (determining Board's jurisdiction over track subject to litigation); *Pinelawn Cemetery—Pet. for Declaratory Ord.,* FD 35468, slip op. at 8 (STB served Apr. 21, 2015) (same).

IV. ICCTA Preemption Analysis for State and Local Laws

There is a well-settled framework, grounded in Supreme Court precedent, that guides the analysis of whether a federal law preempts state (or local) law. In relevant part, federal preemption of state law can either be express or implied.[20] Although courts (particularly the federal courts) regularly describe the Board's preemption framework using these established terms, the Board historically has not, electing instead to use the terms ''categorical'' and ''as-applied.'' The Board takes this opportunity to clarify where these concepts overlap: Express preemption is generally analyzed as ''categorical'' ICCTA preemption,[21] and implied preemption is generally [22] analyzed as ''as-applied'' ICCTA preemption. As described in more detail below, ''categorical'' preemption addresses state or local action that, by its nature, manages or governs rail transportation, whereas ''as-applied'' preemption addresses action that does so in its particular operation or effect. Each term is defined in more depth below.

A. Constitutional Framework for Preemption Analysis

Under our constitutional structure, the federal government is responsible for regulating interstate commerce. *See King Cnty.—Pet. for Declaratory Ord.,* 1 S.T.B. 731, 735 (1996) (citing Supreme Court precedent and stating that ''under the Commerce and Supremacy Clauses of the United States Constitution, direct regulation of interstate commerce by the states is prohibited''); *see also Mo. Pac. R.R.* v. *Stroud,* 267 U.S. 404, 408 (1925) (''It is elementary and well settled that there can be no divided authority over interstate commerce, and that the acts of Congress on that subject are supreme and exclusive.''). Federal preemption flows from the United States Constitution's Supremacy Clause, which makes federal law ''the supreme Law of the Land.'' U.S. Const., art. VI, cl. 2. The Supremacy Clause empowers Congress to enact federal laws that supersede state law by means of an express provision in a federal statute or by implication. *See id.; see also Arizona,* 567 U.S. at 398–99. Congress can show preemptive intent either expressly through the statute's language or impliedly through its purpose and structure. *Altria Grp., Inc.* v. *Good,* 555 U.S. 70, 76 (2008); *Franks Inv. Co.* v. *Union Pac. R.R.,* 593 F.3d 404, 407 (5th Cir. 2010) (en banc). Congress established a uniform federal regulatory framework governing the regulation of rail transportation through ICCTA, which both expressly and impliedly preempts state regulation. *E.g., Edwards,* 983 F.3d at 121 (recognizing that ICCTA's provisions ''produce both express and implied preemptive effects'').

ICCTA contains an express preemption provision, stating that ''[e]xcept as otherwise provided in [Part A of Subtitle IV of Title 49], the remedies provided under this part with respect to regulation of rail transportation are exclusive and preempt the remedies provided under Federal or State law.'' 49 U.S.C. 10501(b). When a ''statute contains an express pre-emption clause, [courts] do not invoke any presumption against pre-emption,'' instead following the statute's ''plain wording.'' *See Puerto Rico* v. *Franklin Cal. Tax-Free Tr.,* 579 U.S. 115, 125 (2016) (citation modified); *CSX Transp., Inc.* v. *Easterwood,* 507 U.S. 658, 664 (1993); *see also Arizona,* 567 U.S. at 399 (''There is no doubt that Congress may withdraw specified powers from the States by enacting a statute containing an express preemption provision.''). As relevant to interstate commerce, ''States are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance.'' *Id.* ''A principal purpose of this express federal preemption is to prevent a patchwork of local and state regulations from unreasonably interfering with interstate commerce.'' *Tenth Ave. Neighbors,* FD 36654, slip op. at 3–4. In the Board's parlance, such state laws are categorically preempted. *See, e.g., Wichita Terminal Ass'n—Pet. for Declaratory Ord.,* FD 35765, slip op. at 6 (STB served June 23, 2015) (stating that certain actions are ''expressly or categorically preempted under [section] 10501(b)'').

The breadth of this grant of exclusive jurisdiction, in conjunction with the preemption provision, also forms a basis for implied preemption. Congress stated its intent to ''reflect the direct and complete pre-emption of State economic regulation of railroads,'' and ''extend[ ] exclusive Federal jurisdiction'' to areas where state jurisdiction was previously reserved. H.R. Rep. No. 104–311, at 95. And through ICCTA, Congress affirmed that ''the Federal policy of occupying the entire field of economic regulation of the interstate rail transportation system'' was ''intended to address and encompass all such regulation and to be completely exclusive.'' *Id.* The Board considers contrary state law to be preempted on an as-applied basis. *See, e.g., Franks Inv. Co.,* 593 F.3d at 414 (''We adopt the [Board's] as-applied preemption analysis as appropriate for implied preemption under the ICCTA.''). This rule also follows longstanding precedent, predating ICCTA, holding that the Interstate Commerce Act ''preempts state laws that could operate to unreasonably burden interstate commerce.'' *Tex. Dep't of Transp.—Pet. for Declaratory Ord. Regarding Highway Constr. In Tarrant Cnty, Tex.,* FD 32589, slip op. at 4 (ICC served Feb. 7, 1995); *see also Reguls. Governing Fees for Servs. Performed in Connection with Licensing & Related Servs.,* 1 I.C.C.2d 60, 81 (1984) (evaluating whether state regulatory actions were ''an unreasonable burden on interstate commerce'').

[20] The Board recognizes that federal preemption analysis involves many nuances beyond whether preemption is express or implied. For example, implied preemption can be broken down into ''field preemption'' and ''conflict preemption.'' *See Arizona* v. *United States,* 567 U.S. 387, 399 (2012). For purposes of this policy statement, the Board believes it is sufficient to analogize ''as-applied'' preemption to implied preemption without further elaboration on whether field preemption, conflict preemption, or both are the basis for the analysis.

[21] Categorical preemption is also sometimes referred to as ''per se'' or ''facial'' preemption. *See, e.g., Soo Line R.R.* v. *City of St. Paul,* 827 F. Supp. 2d 1017, 1020 (D. Minn. 2010); *CSX Transp., Inc.—Pet. for Declaratory Ord.,* FD 34662, slip op. at 4–5 (STB served May 3, 2005).

[22] It should be noted that at least one circuit court has determined that ''as-applied'' preemption is a form of express, rather than implied, preemption. *See City of Ozark,* v. *Union Pac. R.R.,* 843 F.3d 1167, 1171 (8th Cir. 2016). Numerous other circuit court cases have interpreted the Board's ''as-applied'' analysis as a form of implied preemption. *E.g., Edwards,* 983 F.3d at 121; *Ezell,* 866 F.3d at 299.

B. ICCTA Preemption Framework

When faced with a question about whether ICCTA preempts a state or local law, the Board and courts first determine whether to apply a categorical preemption analysis or an as-applied preemption analysis based on the nature of the regulation. Whether preemption is categorical or as-applied does not turn merely on whether the potentially preempted regulation is directed at rail carrier transportation specifically (such as limiting railroad operating hours) or instead is of general applicability (like zoning ordinances). Both sorts of regulations may be preempted either categorically or as-applied, depending on whether the regulation intrudes on a matter directly regulated by the Board—for example, reasonable rail rates and practices—and not on the entity subject to the regulation.[23]

It is the Board's long-established policy to analyze preemption in a way that seeks to prevent a patchwork of state and local regulation from interfering with rail transportation within the Board's jurisdiction. *See Tenth Ave. Neighbors,* FD 36654, slip op. at 3–4 (recognizing that ''[a] principal purpose of this express federal preemption is to prevent a patchwork of local and state regulations from unreasonably interfering with interstate commerce''); *CSX Transp., Inc.—Pet. for Declaratory Ord.,* FD 34662, slip op. at 11 (STB served March 14, 2005) (stating that ''[s]ection 10501(b) is intended to prevent a patchwork of local regulation from unreasonably interfering with interstate commerce,'' and that the regulation at issue ''would unreasonably interfere with interstate commerce, and if permitted to exist, would likely lead to further piecemeal attempts by other localities to regulate rail shipments'').

1. Categorical Preemption Analysis

State or local laws are preempted categorically if they may reasonably be understood to manage or govern transportation by a rail carrier or certain related activities, including by foreclosing or restricting the railroad's ability to conduct its own operations. *See Delaware,* 859 F.3d at 18 (ICCTA preempts ''all state laws that may reasonably be said to have the effect of managing or governing rail transportation.''); *Wichita Terminal Ass'n,* FD 35765, slip op. at 6. Categorical preemption typically applies to: (1) laws that directly regulate transportation by rail carriers, and (2) generally applicable permitting or preclearance laws when imposed on rail transportation.

ICCTA ''prevent[s] states or localities from intruding into matters that are directly regulated by the Board (*e.g.,* railroad rates, services, construction, and abandonment).'' *14500 Ltd. LLC,* FD 35788, slip op. at 3; *see also Ass'n of Am. R.Rs.* v. *S. Coast Air Quality Mgmt. Dist.,* No. 06–CV–1416, 2007 WL 2439499, at *7 (C.D. Cal. Apr. 30, 2007) (holding that rules directly regulating rail operations, such as idling, are preempted regardless of whether they are considered undue or unreasonable), *aff'd,* 622 F.3d 1094 (9th Cir. 2010). Categorical preemption ''also prevents states or localities from imposing requirements that, by their nature, could be used to deny a railroad's ability to conduct rail operations or proceed with activities that the Board has authorized, such as a construction or abandonment,'' or to maintain its facilities. *14500 Ltd. LLC,* FD 35788, slip op. at 3–4 & n.5. Therefore, ''state law preclearance or permitting requirements that could be used to deny or unreasonably delay a rail carrier's ability to conduct rail operations typically are categorically preempted.'' *Grafton & Upton,* FD 36696, slip op. at 7 (collecting cases). Some examples include building permits, zoning ordinances, and environmental and land use permitting requirements. *E.g., Jie Ao—Pet. for Declaratory Ord.,* FD 35539, slip op. at 5 (STB served June 6, 2012). The Board and courts have long recognized that ''[i]f local authorities have the ability to impose 'environmental' permitting regulations on the railroad, such power will in fact amount to 'economic regulation' if the carrier is prevented from constructing, acquiring, operating, abandoning, or discontinuing a line.'' *City of Auburn,* 154 F.3d at 1031 (affirming Board finding of preemption of state and local environmental permitting laws as applied to rail construction project).

Additionally, categorical preemption applies regardless of the stated purpose of the law. *See Borough of Riverdale—Pet. for Declaratory Ord.—N.Y. Susquehanna & W. Ry.,* 4 S.T.B. 380, 388 n.16 (1999) (noting that ''even health and safety regulation is preempted where Congress intended to preempt all state and local law''). Moreover, it ''does not depend on whether the practical application of the statute or regulation is narrowly tailored.'' *Delaware,* 859 F.3d at 22. The categorical ''preemption analysis is addressed not to the reasonableness of the particular state or local action, but rather to the act of regulation itself.'' *CSX Transp., Inc.,* FD 34662, slip op. at 3 (STB served May 3, 2005); *see also Green Mountain R.R.* v. *Vermont,* 404 F.3d 638, 644 (2d Cir. 2005) (stating that ''the focus is the act of regulation itself, not the effect of the state regulation in a specific factual situation'') (citation modified). Some limited fact-finding may be needed to determine ''whether the state or local action falls within a category subject to categorical preemption.'' *CSX Transp., Inc.,* FD 35832, slip op. at 5. But if it does, a regulation that has the effect of managing or governing transportation by rail carrier is preempted ''regardless of its practical effect.'' *Delaware,* 859 F.3d at 19. And state permitting or preclearance requirements are categorically preempted ''without requiring a factual analysis of their effect on transportation.'' *See, e.g., Grafton & Upton,* FD 36696, slip op. at 7 (collecting cases); *see also Green Mountain R.R.,* 404 F.3d at 644 (''[W]hat is preempted here is the permitting process itself, not the length or outcome of that process in particular cases.'').

2. As-Applied Preemption Analysis

Even when a state or local law is not categorically preempted, it may be preempted under the ''as-applied'' analysis if it either: (1) unreasonably burdens or interferes with transportation by rail carriers, or (2) discriminates against rail carriers.

a. Unreasonable Burden or Interference

State and local laws are preempted ''as applied'' if they unreasonably burden or interfere with current—or future—rail transportation. This is ''a fact-specific determination based on the circumstances of each case.'' *See, e.g., Wichita Terminal Ass'n,* FD 35765, slip op. at 6 (citation omitted). An as-applied analysis includes a comprehensive analysis of the likely impact of the proposed law's application to current rail operations. *See, e.g., Tri-City R.R.,* FD 35915, slip op. at 8 (analyzing length, location, and configuration of track, its uses, and potential alternative locations for operations). The Board and courts also consider interference with planned or potential future rail operations. Certain state actions may be preempted even when no current rail operations exist on tracks within the Board's jurisdiction, based on potential future use (for example, when a line is

[23] Moreover, a Board or court holding that a state law of general applicability is preempted, either categorically or as-applied, does not invalidate the state law. Instead, the ICCTA preemption determination means that the law is preempted only in its application to activities within the Board's exclusive jurisdiction under 49 U.S.C. 10501(b). Thus, a zoning ordinance that is categorically preempted when used to manage jurisdictional rail carrier transportation may still be applied generally to other industries.

railbanked or when a rail carrier intends to develop a property for rail use). *See, e.g., id.* (analyzing future operations and effects of increases in rail traffic); *Jie Ao,* FD 35539, slip op. at 5 (analyzing effects on future reactivation of railbanked line, even though ''there are currently no specific plans to reactivate this property,'' including impacts on potential rail-related construction, track bed stabilization, drainage, and maintenance).

Because ICCTA was established to prevent a patchwork of differing state and local regulations, the unreasonable-burden analysis also requires consideration of ripple effects across the broader interstate rail network. Accordingly, the analysis considers not only the facts of a single case, but also the potential impact on the interstate rail network as a whole, guarding against a ''patchwork'' of ''potentially differing standards'' as trains travel across the network. *See Wichita Terminal Ass'n,* FD 35765, slip op. at 10; *see also Norfolk S. Ry.,* FD 35701, slip op. at 4–6 (finding that state inverse condemnation claims based on dust, vibration, and noise were preempted and explaining that absent preemption ''all railroads on the interstate rail network could be subject to inverse condemnation actions from adjacent landowners throughout the country based on the effects of normal railroad operations''). ''The interstate rail network could not function properly if states and localities could impose their own potentially differing standards for'' rail operations, nor if state regulations could ''interfer[e] with the railroad's ability to uniformly design, construct, maintain, and repair its railroad line.'' *Tubbs,* FD 35792, slip op. at 5.

Again, ICCTA preemption has its limits. Federal law does not preempt local and state application of laws having a ''more remote or incidental effect on rail transportation.'' *N.Y. Susquehanna & W. Ry.,* 500 F.3d at 252. Therefore, ICCTA's ''preemption provision does not prevent state and local governments from imposing appropriate health and safety regulations and exercising their police powers'' in appropriate circumstances. *Smithtown,* FD 36575 (Sub-No. 1), slip op. at 4. In addition, the Board has held that condemnations of railroad property, under generally applicable state eminent domain law for ''routine non-conflicting uses, such as non-exclusive easements for at-grade road crossings . . . are not preempted so long as they would not impede rail operations or pose undue safety risks.'' *Wichita Terminal Ass'n,* FD 35765, slip op. at 6. Additionally, the enforcement of ''generally applicable, non-discriminatory regulations'' like ''[e]lectrical, plumbing and fire codes'' that have only an ''incidental'' effect on rail transportation may be permissible. *See Green Mountain R.R.,* 404 F.3d at 643, 645; *Smithtown,* FD 36575 (Sub-No. 1), slip op. at 4. And again, ICCTA preemption reaches ''transportation'' by ''rail carrier.''

But states ''cannot use their police powers to indirectly regulate matters reserved to the Board . . . .'' *Soo Line R.R.—Pet. for Declaratory Ord.,* FD 35850, slip op. at 5 (STB served Dec. 23, 2014). Although pre-ICCTA, the Interstate Commerce Act explicitly preserved the states' ''police power'' to impose ''reasonable intrastate transportation'' requirements, 49 U.S.C. 10501(c) (1994), this ''disclaimer regarding residual State police powers [was] eliminated as unnecessary [in ICCTA], in view of the Federal policy of occupying the entire field,'' H.R. Rep. No. 104–311, at 95–96. ''Although States retain the police powers reserved by the Constitution, the Federal scheme of economic regulation and deregulation is intended to address and encompass all such regulation and to be completely exclusive.'' *Id.* at 96. Thus, ''states are not free to impose any requirements they wish in the name of their police power.'' *CSX Transp., Inc.,* FD 34662, slip op. at 4–5 (STB served May 3, 2005). Although certain decisions have referred to a ''police power exception'' to ICCTA preemption, *see Grafton & Upton R.R.—Pet. for Declaratory Ord.,* FD 35752, slip op. at 9 (STB served Sept. 19, 2014), what matters is not that the state or locality is exercising ''police powers'' as such, but that it is enforcing ''generally applicable, non-discriminatory regulations'' like ''[e]lectrical, plumbing and fire codes'' that have only an ''incidental'' effect on rail transportation—and even then, such regulations ''must not have the effect of foreclosing or restricting the railroad's ability to conduct its operations or otherwise unreasonably burdening interstate commerce,'' or they may be preempted. *See Green Mountain R.R.,* 404 F.3d at 643, 645; *Smithtown,* FD 36575 (Sub-No. 1), slip op. at 4 (ICCTA ''does not prevent state and local governments from . . . exercising their police powers so long as'' they do not regulate, unreasonably burden, or discriminate against rail carriers).

b. Discrimination Against Rail Transportation.

State laws and regulations that discriminate against rail transportation may also be preempted on an as-applied basis. The ICC long held that, ''in areas not governed by [f]ederal legislation, [s]tates and their subdivisions may make reasonable regulations affecting commerce under our jurisdiction so long as they are uniformly applied and do not discriminate against or constitute an undue burden on or an obstruction of commerce, in accordance with standard preemption principles.'' *Appls. for Operating Auth.—Motor Passenger Carriers,* 133 M.C.C. 62, 86–87 (I.C.C. 1982) (discussing motor carriers); *see also City of Auburn,* 154 F.3d at 1029 n.6 (''Before 1980, the ICC was empowered to preempt state regulation of intrastate lines only when an intrastate rate set by the state unjustly discriminated against or imposed an undue burden on interstate commerce.''). Thus ''state and local entities can enforce in a non-discriminatory manner'' local laws passed under their police powers. *Riverdale,* 4 S.T.B. at 389; *see also Green Mountain R.R.,* 404 F.3d at 643 (noting that certain ''non-discriminatory regulations'' would not be preempted); *Delaware,* 859 F.3d at 18–19 (same, after conducting extensive survey of precedent); *City of Milwaukie—Pet. for Declaratory Ord.,* FD 35625, slip op. at 4 (STB served Mar. 25, 2013) (noting that such regulations can apply to rail carrier transportation ''if they are applied without discrimination'').

Courts have recognized that ''[t]he non-discriminatory prong is particularly useful in determining whether a state is regulating principally to discriminate against a specific industry.'' *N.Y. Susquehanna & W. Ry.,* 500 F.3d at 254. ''[F]or a state regulation to pass muster, it must address state concerns generally, without targeting the railroad industry.'' *Id.; see also BNSF Ry.* v. *Cal. Dep't of Tax & Fee Admin.,* 904 F.3d 755, 761, 768 (9th Cir. 2018) (concluding that ICCTA would preempt use of traditional state police powers to impose a fee on shipment of hazardous materials in California, where the fee would apply only to shipments ''by rail''). But even so, a regulation addressing state concerns generally—which may include a fee or other charge on rail carriers or transportation by rail—cannot be used ''as pretext for interfering with or curtailing rail service.'' *N.Y. Susquehanna & W. Ry.,* 500 F.3d at 254; *see also BNSF Ry.* v. *Town of Cicero, Ill.,* 592 F. Supp. 3d 716, 729 (N.D. Ill. 2022) (finding that the rail carrier adequately showed that a local sewer ordinance regulated railroad transportation because it singled out and targeted railroads for a rate higher than the rate paid by other commercial and industrial

properties).[24] To assess preemption in this context, the Board and courts look to whether the law ''is being applied in a discriminatory manner, or being used as a pretext for frustrating or preventing a particular activity.'' *Joint Pet. for Declaratory Ord.—Bos. & Me. Corp.,* 5 S.T.B. 500, 509 (2001). Though not all state regulations that apply specifically to railroads are impermissibly discriminatory, such regulations may be preempted in at least two circumstances: (1) when the regulation requires something of the railroad that it does not require of other modes of transportation or similarly situated entities, or (2) when the regulation could be used to target railroads in order to cause indefinite delays to railroad operations. *See Adrian & Blissfield R.R.,* 550 F.3d at 541–42.

As in other forms of preemption analysis, laws can be discriminatory whether or not they specifically mention rail carriers. For example, a law of general applicability passed to protect health and safety by imposing quantity, duration, and location restrictions on the storage of certain substances was found discriminatory as applied to a rail carrier's transloading facility. *See Vt. Ry.* v. *Town of Shelburne,* 287 F. Supp. 3d 493, 494 (D. Vt. 2017), *aff'd,* 918 F.3d 82 (2d Cir. 2019). In that instance, the court held that the timing of the passage of the ordinance (during litigation between the town and rail carrier), threshold limits, and commodities affected would, in practice, uniquely apply to the transload facility and not others who may be similarly situated, and as such, ''these provisions clearly target and discriminate against the [rail carrier]'s facility.'' *Id.* at 500–01. For these reasons (as well as unreasonable burden), the ordinance was preempted. *Id.* at 505. Conversely, in *Adrian & Blissfield R.R.,* an ordinance requiring rail carriers to construct, or pay for the construction of sidewalk crossings over their tracks was found non-discriminatory. *See Adrian & Blissfield R.R.,* 550 F.3d at 539. In that case, the court first held that the ordinance did not regulate rail transportation. *See id.* at 540 & n.6. It went on to ''apply the as-applied-preemption analysis,'' including the prohibition on laws that ''discriminate against railroads.'' *Id.* at 541 (citation omitted). The court deemed the ordinance was non-discriminatory because (1) it ''addresse[d] a general state concern''; (2) there was ''no evidence'' that the ordinance could be used pretextually to interfere with rail operations; and (3) the state was not ''requir[ing] something of the Railroad that it does not require of similarly situated entities.'' *Id.* at 541–42.

3. Complete Takings—Refocused Categorical Approach

When state or local law is used in an attempt to entirely dispossess a rail carrier of its property rights—such as through a private claim for adverse possession, or a state's use of eminent domain—the Board and court precedents have been unclear about whether categorical or as-applied analysis should govern.[25] *See, e.g., Jie Ao,* FD 35539, slip op. at 1 (holding that ''state law adverse possession claim is federally preempted, regardless of whether this case is analyzed as 'categorical' preemption [or] as 'as applied' preemption''). And as courts have recognized, ''[t]he more a property action excludes a rail carrier and takes a property for a conflicting use, the more likely the action will be preempted.'' *Norfolk S. Ry.* v. *Dille Rd. Recycling, LLC,* 94 F.4th 517, 524, 527 (6th Cir. 2024) (discussing a ''spectrum'' of easement claims where ''routine, nonexclusive easements . . . are generally not preempted,'' but those ''that are exclusive or deemed adverse possession by another name are often preempted''). While this policy statement is not adopting a definitive approach that resolves all cases, there are strong policy arguments that state and local law claims seeking to take exclusive possession of any portion of a validly held railroad right-of-way, or to take rail carrier property that the rail carrier uses—or plans to use—to support rail transportation (*i.e.,* property falling within the definition of ''transportation'' under 49 U.S.C. 10102(9)) would be better reviewed under the categorical preemption analysis.[26] And there are also strong policy arguments that claims involving more routine, non-conflicting uses—such as non-exclusive easements for at-grade road crossings, subterranean water or sewer lines, and related claims—are best assessed using an as-applied analysis as the Board does currently.

State or local regulation that seeks to take exclusive control of rail carrier rights-of-way or other property can take many different forms, including but not limited to claims for eminent domain, condemnation, or adverse possession, among others. ''The agency's broad and exclusive jurisdiction over railroad operations and activities prevents application of state law claims that would take rail property for another, conflicting use, including adverse possession claims that would interfere with rail use, present or future.'' *14500 Ltd. LLC,* FD 35788, slip op. at 4. Using state law for these purposes ''is exercising control—the most extreme type of control—over rail transportation as it is defined in section 10102(9).'' *Wis. Cent. Ltd.* v. *City of Marshfield,* 160 F. Supp. 2d 1009, 1013 (W.D. Wis. 2000). This type of taking ''is a permanent action, and 'it can never be stated with certainty at what time any particular part of a right of way may become necessary for railroad uses.''' *City of Lincoln* v. *STB,* 414 F.3d 858, 862 (8th Cir. 2005) (quoting *Midland Valley R.R.* v. *Jarvis,* 29 F.2d 539, 541 (8th Cir. 1928)). Further, such actions ''would foreclose [the rail carrier]'s development of the property for rail 'transportation' purposes.'' *Grafton & Upton,* FD 36696, slip op. at 11.

For rail carrier property within the Board's jurisdiction, only upon abandonment does the underlying property become ''ordinary property'' subject to the application of state law. *See, e.g., Hayfield N. R.R.* v. *Chi. & NW*

[24] In general, a fee is discriminatory if it treats railroads differently than other modes without sufficient justification. *Cf. Ala. Dept. of Revenue* v. *CSX Transp., Inc.,* 575 U.S. 21, 27, 30 (2015) (discussing discriminatory taxes under the Railroad Revitalization and Regulation Reform Act of 1976 (4R Act), 49 U.S.C. 11501(b)(4)); *Union Pac. R.R.* v. *Wis. Dep't. of Revenue,* 940 F.3d 336, 337 (7th Cir. 2019) (finding a tax ''singl[ing] out railroads as part of an isolated and targeted group'' unlawful under the 4R Act).

[25] State laws governing the acquisition of property by a rail carrier generally are not preempted. *See, e.g., Grafton & Upton R.R.* v. *STB,* 177 F.4th 1234, 1240 (D.C. Cir. 2026) (''ICCTA does not preempt generally applicable state property laws that 'do not unreasonably interfere with railroad operations or the Board's regulatory programs.'") (quoting *CSX Transp.,* FD 35832, slip op. at 4); *Great Walton R.R.—Pet. for Declaratory Ord.,* AB 1242 (Sub-No. 1), slip op. at 7, 11 (STB served June 9, 2020) (leaving it to rail carrier to establish its interest in the underlying real property under state law); *see also Allegheny Valley R.R.—Pet. for Declaratory Ord.—William Fiore,* FD 35388, slip op. at 4 & n.4 (STB served Apr. 25, 2011) (explaining that disputes over the ''size, location, and nature of property rights'' are most appropriately decided by courts applying state law and that ''[p]roof of ownership . . . cannot be inferred from our approval to acquire and operate the rail line''); *Tongue River R.R.—Constr.& Operation—W. Alignment,* FD 30186 (Sub-No. 3) et al., slip op at 16 n.50 (STB served Oct 9, 2007) (''The applicant [in rail construction cases] is responsible for acquiring the land necessary to build the line.''). Relatedly, the Board's jurisdiction generally does not preempt rail carrier efforts to acquire property under state eminent domain law, including where a state denies a carrier condemnation request. *See Great Walton R.R.,* AB 1242 (Sub-No. 1), slip op. at 7 (STB served June 9, 2020); *see also Great Redwood Trail Agency,* AB 1305 (Sub-No. 1), slip op. at 14 (''[R]ail carriers are generally responsible for acquiring the land necessary to support their operations, including to the extent permitted by condemnation.'').

[26] As noted above, limited fact-finding may be needed to determine ''whether the state or local action falls within a category subject to categorical preemption.'' *CSX Transp., Inc.,* FD 35832, slip op. at 5.

Transp. Co., 467 U.S. 622, 633–34 (1984). Rail lines under the Board's jurisdiction remain available for common carrier service upon reasonable request. 49 U.S.C. 11101(a). Even where the Board has authorized discontinuance of service over a rail line, such that there is no extant common carrier obligation, the line remains available for the reinstitution of service in the future. *See, e.g., Preseault* v. *ICC,* 494 U.S. 1, 5 n.3 (1990) (stating that ''discontinuance'' authority allows a railroad to cease operating a line for an indefinite period while preserving the rail corridor for possible reactivation of service in the future). The common carrier obligation is not permanently extinguished until the line has been removed from Board jurisdiction via Board-authorized abandonment. *See id.*

Permitting the use of state law for acquiring exclusive control of rail carrier property would contravene this statutory scheme. As the Board has explained, it would allow for the taking of ''railroad [right-of-way] all over the country for non-rail use, even though the Board has not authorized the [right-of-way] to be permanently removed from the nation's rail system under Title 49.'' *Jie Ao,* FD 35539, slip op. at 7. This is an ''untenable result [that] would undermine interstate commerce and the strong federal policy in favor of retaining rail property in the national rail network, where possible.'' *Id.* (citing 49 U.S.C. 10904, 10907 & 16 U.S.C. 1247(d)). Subjecting Board-jurisdictional rail line or excepted track to adverse possession, eminent domain, or condemnation claims under state law would thus ''have the effect of managing or governing rail transportation,'' *Skidmore* v. *Norfolk S. Ry.,* 1 F.4th 206, 215 (4th Cir. 2021), and ''would amount to regulation of rail transportation because [they] would confer exclusive control to [someone other than the rail carrier] over property that is part of the national rail network.'' *Jie Ao,* FD 35539, slip op. at 3. With this backdrop, the Board has previously observed that ''[n]either the Board nor the courts . . . have found that cities can entirely take from a railroad land the railroad has slated for present or future rail use.'' *Norfolk S. Ry.—Pet. for Declaratory Ord.* (*Ala. Great S.*), FD 35196, slip op. at 5 (STB served Mar. 1, 2010).[27] And the Board has held that ICCTA ''preempts state law eminent domain and adverse possession claims for exclusive possession of part of a railroad right-of-way or other railroad property that could affect present or future rail transportation.'' *Ohio Rail Dev. Comm'n—Pet. for Declaratory Ord.,* FD 36822, slip op. at 7 (STB served Mar. 30, 2026). As summarized by the Fourth Circuit:

> Indeed, allowing an individual landowner to wrest exclusive control of land within the national rail corridor away from a railroad could expose a rail carrier to death by a thousand cuts. Rail carriers would either have to be hyper-vigilant about fending off adverse possession claims along countless miles of tracks, or risk losing ownership interests in land that is (or might be) necessary to conduct business and comply with federal regulations. Because maintaining a unified federal mechanism for governing the national rail network is an issue of overwhelming national importance, federal law must preempt [state or local] quiet title claims.

Skidmore, 1 F.4th at 217.

One critical aspect of the Board's categorical preemption analysis is that such regulations are preempted without requiring a factual analysis of their effect on transportation and whether any interference may be unreasonable. With respect to claims for possession of rights-of-way subject to the Board's jurisdiction, once the threshold determination is made that the scope of the sought-after property right would exclude rail use, there are strong arguments that the analysis should be at its end. Such claims may be categorically preempted without a detailed inquiry into their effect on present or future operations and whether interference is unreasonable. *Cf. Green Mountain R.R.,* 404 F.3d at 644 (applying categorical preemption to permitting of transloading construction and stating that ''what is preempted here is the permitting process itself, not the length or outcome of that process in particular cases''); *see also Wis. Cent. Ltd.,* 160 F. Supp. at 1013–14 (holding that condemnation was preempted without an inquiry as to interference). The Board recognizes that condemnation claims, including those involving non-exclusive easements, have often been analyzed under the as-applied framework. *See e.g., City of Lincoln,* 414 F.3d at 860. In the Board's view, there are compelling policy considerations that the as-applied framework is ill-suited to address condemnation or similar claims that would foreclose rail use of rail property and rights-of-way (or portions thereof) that are subject to the Board's jurisdiction and must remain available for common carrier service. These types of takings are arguably more severe incursions on activities within the Board's exclusive jurisdiction than others that have been long recognized as categorically preempted. If a state entity is categorically prohibited from enforcing a zoning law or other preclearance requirement to prevent the construction of a rail carrier's facility on its property, it makes little sense to find that the state entity would be subject to a less rigorous as-applied framework if it were instead to seek to take the property outright through condemnation. Moreover, consideration of such exclusive takings under the as-applied preemption framework may result in patchwork regulation of standards concerning present and future rail service, contrary to the uniform licensing framework established in ICCTA. Parties contending that such rights-of-way no longer serve any bona fide rail purpose have historically directed that contention to the Board through an adverse abandonment proceeding.[28] In prior cases, rail carriers defending against actions to take their property have been required to set forth extensive analysis of the current and potential future uses of the property for rail operations. *See, e.g., Grafton & Upton,* FD 36696 (STB served Nov. 15, 2023); *14500 Ltd. LLC,* FD 35788 (STB served June 5, 2014); *Ala. Great S.,* FD 35196 (STB served Mar. 1, 2010). Where an action to take rail property would exclude rail use on a portion of the rail property or rights-of-way subject to the Board's jurisdiction, that consequence is ascertainable at the outset and therefore may warrant categorical treatment without further inquiry. *See Jie Ao,* FD 35539, slip op. at 5–7*; see also Wis. Cent. Ltd.,* 160 F. Supp. 2d at 1013–14 (categorically preempting condemnation of rail property and stating that ''the nature of the preempted state regulation is irrelevant''); *Soo Line R.R.,* 827 F. Supp. 2d at 1022 (same and noting that ''factual 'as applied' arguments concerning whether the proposed easement would unreasonably interfere with [the rail carrier]'s activities are not relevant'').

It may be reasonable to conclude that certain other takings claims would not be appropriate for a categorical analysis.

[27] *But see Girard* v. *Youngstown Belt Ry.,* 979 NE2d 1273, 1287 (Ohio 2012) (subsequently holding that eminent domain claim was not preempted).

[28] Although the Board has granted adverse abandonment of rail carrier property in certain limited circumstances, applicants bear a heavy burden. *See Colo. Landowners—Adverse Aban.—Great W. Ry. of Colo. in Weld Cnty, Colo.,* AB 857 (Sub-No. 2), slip op. at 5 (STB served July 30, 2025). The Board considers matters such as whether active shippers would lose service, whether there is any potential for continued rail service, whether the carrier has taken reasonable steps to attract traffic or rehabilitate or utilize an inoperable line, and the carrier's judgment about the need for, and usefulness of, the line. *See id.* at 6–7 (summarizing the state of the Board's precedent on adverse abandonments).

As noted above, there are strong arguments that non-exclusive easements, such as for crossings, warrant an as-applied preemption analysis that looks to the degree of interference with rail operations. Similarly, claims to take land under a right-of-way or under other rail property, such as for laying subterranean utility or broadband lines or similar facilities, may be analyzed under the as-applied framework. Subject to the facts and circumstances in particular cases, such non-exclusive uses may be permissible, or may unreasonably interfere with interstate rail transportation if, for example, they are placed in locations that undermine the integrity of the rail right-of-way, or are installed in a manner, or for a duration, that prevents or materially interferes with rail operations.

4. Shipper and Receiver Rights to Common Carrier Rail Service

The Board recognizes that private investment in rail infrastructure—by carriers and customers alike—is critical to maintaining and improving the expansive interstate rail network for existing customers, extending its reach to new customers, and ensuring its competitiveness with other modes of transportation. Rail transportation—unlike modes such as trucking and water carriage, which rely heavily on public infrastructure maintained by public entities (such as roads, waterways, and ports)—operates almost exclusively on privately owned and developed infrastructure. Such projects are time and labor intensive, and require high levels of coordination—and, frequently, co-investment—between rail carriers and potential customers seeking common carrier rail service.

Although the Board's jurisdiction extends only to ''transportation'' by, or under the auspices of, a ''rail carrier,'' the application of state and local regulations nominally to rail customers implicates ICCTA in certain situations.

It has been long recognized that ''ICCTA preempts both direct and indirect regulation that affects a railroad's ability to conduct common carrier operations.'' *Smithtown,* FD 36575 (Sub-No. 1), slip op. at 4 n.7 (collecting cases). Thus, for example, a local ordinance and permit restricting truck transportation ''regulate[d] 'transportation by a rail carrier,' as defined by the ICCTA,'' because they ''directly impact[ed] [the rail carrier]'s ability to move goods shipped by rail.'' *Norfolk S. Ry.* v. *City of Alexandria,* 608 F.3d 150, 158–59 (4th Cir. 2010). Preemption applied even though the ordinance and permit ''regulate[d] only the trucks leaving the [railroad's transloading] Facility, not the transloading process itself,'' and did not directly ''regulate any aspect of the movement of trains [or] the unloading or transloading of trains.'' *Id.* at 159. Likewise, ICCTA does not permit ''regulation of the interstate freight rail network under the guise of local regulations directed at the shippers who would use the network,'' which would ''create the patchwork of conflicting local regulations that Congress sought to avoid in the Interstate Commerce Act.'' *Bos. & Me. Corp.—Pet. for Declaratory Ord.,* FD 35749, slip op. at 5 (STB served July 19, 2013). Shippers have ''rights provided by federal law to ask for and receive common carrier rail service from'' rail carriers under the Board's jurisdiction, and so even regulations ''directed solely at'' a shipper would create a ''fundamental conflict between'' the shipper's right to request, and a rail carrier's right to provide, common carrier rail service under ICCTA. *Id.* at 4. Such state and local regulations conflict with Congress's purpose in codifying the common carrier obligation, because rail carriers' ability to provide service and shippers' right to receive service on reasonable request are two sides of the same coin. *Cf. Engine Mfrs. Ass'n* v. *S. Coast Air Quality Mgmt. Dist.,* 541 U.S. 246, 255 (2004) (''[T]reating sales restrictions and purchase restrictions differently for pre-emption purposes would make no sense,'' because the ''right to sell . . . is meaningless in the absence of a purchaser's right to buy . . . .'').

The point at which activities no longer constitute ''transportation by rail carrier'' and certain related activities, and thus fall outside the Board's jurisdiction, can be difficult to discern in some situations—particularly for activities involving the loading and unloading of rail cars on shipper-owned track—and the Board's precedents in this area have not always been entirely consistent. In *Boston & Maine,* FD 35749, slip op. at 4–5, the Board suggested that state regulation of a customer's private, non-jurisdictional track would be preempted if it impacted common carrier service. On the other hand, in *SEA–3, Inc.—Petition for Declaratory Order* (*SEA–3*), FD 35853, slip op. at 6–7 (STB served Mar. 17, 2015), the Board determined that a city's challenge to a zoning decision allowing an existing rail customer to increase its use of rail common carrier service by constructing additional rail berths at its transloading facility was not preempted. And, in *Valero Refining Co.—Petition for Declaratory Order* (*Valero*), FD 36036, slip op. at 2, 6 (STB served Sept. 20, 2016), the Board held that it did not have jurisdiction over an existing rail customer's construction of an off-loading facility designed to receive common carrier unit train service. In *Valero,* state and local authorities denied a permit for construction of the project, based at least in part on the impacts of increased common carrier service, as well as impacts of the commodity likely to be carried in that service. *See id.* at 2.[29]

Thus, the Board provides here a modified analytical framework that, subject to the arguments and facts presented in particular proceedings, may inform an evaluation of whether regulations nominally directed at rail customers are, in practice and in legal effect, regulations of transportation by rail carriers that are preempted by ICCTA. The potential framework begins with a fact-specific threshold inquiry consisting of two questions. First, is the facility or project at issue developed or used to receive or tender common carrier rail service—a transload, off-loading, or similar facility whose function is the interchange of traffic with a rail carrier? Second, does the state or local action restrict, condition, or dictate common carrier service to that facility, such as the volume, frequency, timing, configuration, or commodity mix of common carrier service? Where the answer to both is yes, the action may regulate transportation by rail carrier in practical effect, and the categorical or as-applied framework, as appropriate, would apply depending on the nature of the regulation. A regulation that, for

[29] The Board has been made aware that Valero abandoned the rail transload terminal project following the Board's decision and announced its intent to cease refining operations at the facility in 2026, *see* Valero, *Valero Announces Notice to the California Energy Commission Regarding its Benicia, California, Refinery* (Apr. 16, 2025), *https://investorvalero.com/news/news-details/2025/Valero-Announces-Notice-to-the-California-Energy-Commission-Regarding-its-Benicia-California-Refinery/default.aspx,* and Valero's website indicates that full idling of all processing units at this facility was completed in April 2026, *see* Valero, *Benicia Refinery, https://www.valero.com/about/locations/benicia-refinery* (last visited Sept. 30, 2026). Additionally, although the Board has not revisited *Valero* in the decade since its issuance, the Board is aware that state and local restrictions on rail-served facilities have been promulgated and upheld as beyond the Board's jurisdiction in numerous circumstances. *See, e.g., Montana* v. *City of Portland,* No. 3:23–cc–00219–YY, 2024 WL 1007865, at *1, 12 (D. Or. Feb. 26, 2024) (finding local ordinance restricting the construction of bulk fossil fuel terminals was, among other things, not preempted because plaintiffs did not allege they were rail carriers or performing activities on behalf of or under the auspices of a rail carrier), *rep. & recommendation adopted in part, rejected in part,* No. 3:23–CV–00219–YY, 2024 WL 3326230 (D. Or. July 5, 2024).

example, caps the rail traffic a facility may receive binds the carrier as surely as one addressed to the carrier by name: the carrier cannot lawfully tender the service, the shipper cannot lawfully receive it, and the common carrier obligation of 49 U.S.C. 11101(a)—and the shipper's correlative right to service on reasonable request—is displaced by local command. *See Boston & Maine,* FD 35749, slip op. at 4–5; *cf. Engine Mfrs. Ass'n,* 541 U.S. at 255. Where either answer is no—such as where the object of the regulation is the facility's non-rail activities, not the receipt or tender of rail service—section 10501(b) is not implicated (unless the action discriminates against rail transportation, which is an independent basis for analyzing preemption).

This potential framework would refine the principle recognized in *Boston & Maine*—state or local action directed at a rail customer implicates section 10501(b) where it operates, in practical effect, on the common carrier service the customer receives. *See Bos. & Me.,* FD 35749, slip op. at 4–5. The threshold inquiry clarifies the limit and scope of this principle, and its rationale is evident from the examples of *SEA–3* and *Valero.* In *SEA–3,* a city sought to use state and local regulations to prevent an already rail-served customer from increasing its facility from three to eight rail berths. If the construction was not allowed to occur, the result from the local regulation would be no different than a locality limiting or directing a rail carrier's execution of its common carrier obligations. In practice, it would dictate that only three, and not eight, cars could be sent to the customer at any given time. And to provide the same amount of product, the common carrier must make three trips, rather than one, to the customer facility, and must also change its operational schedule, yard storage, and any number of other operational decisions accordingly. Similarly, in *Valero,* the refusal by state and local officials to grant permission for construction not only dictated the number of cars and type of service (unit train vs. manifest) that the carrier could provide, but also imposed restrictions on the types of commodities that the rail carrier could tender to its customer, thus preventing the rail carrier from being able to fulfill its common carrier obligation. These types of decisions are ordinarily within the decision-making control of rail carriers in providing service to their customers, but were implicated by local regulation of rail customers in both cases. *SEA–3* and *Valero* read ''transportation by rail carrier'' to ask what is the stated object of the regulation, whereas a better reading might ask what was regulated in effect. The Board recognizes that rail service provided by a common carrier remains transportation by rail carrier even when the restriction on such service is addressed to the customer and takes this opportunity to reemphasize that principle.

To be sure, rail customers are not directly under the Board's jurisdiction. And the Board expects that much regulation of rail customers' facilities is, and should remain, beyond the Board's jurisdiction. For example, a zoning ordinance would likely be preempted if it prevented a rail carrier from developing a transload facility. By contrast, ICCTA would not prevent enforcement of that same ordinance against a private business developing a manufacturing facility with an incidental rail component, or against the portions of the facility unrelated to the receipt or tender of common carrier rail service, unless there was evidence that the ordinance was being applied in a discriminatory manner against rail transportation. Likewise, if the construction projects in *SEA–3* and *Valero* implicated local zoning or environmental ordinances, the ordinances' application to these customers would not implicate ICCTA to the extent that they apply to portions of the project unrelated to receiving common carrier rail service. And, in any event, many local ordinances—such as electrical, fire, plumbing, and others—would still apply, just as they do to rail carrier facilities.

C. Commonly Arising State and Local Preemption Issues

There are numerous types of state laws or regulations that frequently result in litigation about preemption. Below is a list of common situations, and a summary of how such issues have been analyzed for preemption purposes. It should be noted that the list is not exhaustive, and that there are additional precedents on many of the issues discussed below, that at times come to differing conclusions based on the facts of the particular case. Moreover, the Board here does not take a position on how any potential future case that may come to the Board (or a court analyzing preemption) will, or should be, resolved. Rather, this list is meant to inform the public about relevant existing precedents on certain topics, in the hopes that this information will help parties proactively resolve disputes at an early stage.

1. Abandonment of Rail Property Interests

As long as the Board retains jurisdiction over rail rights-of-way, only the Board can grant abandonment authority, and state law abandonment claims are preempted. *Grantwood Vill.* v. *Mo. Pac. R.R.,* 95 F.3d 654, 658 (8th Cir. 1996). For example, state laws providing that an easement used for rail purposes can be abandoned simply through non-use, or where the rail carrier has removed track and ties, have been found to be federally preempted. *Great Walton R.R.,* AB 1242 (Sub-No. 1), slip op. at 6–8, 13 (STB served Feb. 27, 2026) (finding that ancillary track was not abandoned and remained subject to the Board's jurisdiction and that, therefore, a prior state court ruling that the easement for the track had been abandoned under state law was preempted); *see also Ala. R.R.—Aban. Exemption—in Escambia, Conecuh, & Monroe Cntys., Ala.,* AB 1324X, slip op. at 2 n.4 (STB served Oct. 24, 2022) (stating that a state court's ''assertion of jurisdiction'' to find that railroad abandoned a rail line right-of-way as a matter of ''state law'' is ''flatly inconsistent with the Board's exclusive and plenary authority over the abandonment of rail lines''); *Jackson Cnty.—Acquis. & Operation Exemption—Union Pac. R.R.,* FD 35982, slip op. at 5, 7 (STB served July 31, 2019) (rejecting argument that rail line was ''abandoned under Missouri law when the tracks and ties were removed'' because it is ''well settled'' that the Board has exclusive jurisdiction over abandonment). Federal preemption of state abandonment laws applies both to common carrier/mainline track and ancillary/excepted track. *Great Walton R.R.,* AB 1242 (Sub-No. 1), slip op. at 6–7 (STB served Feb. 27, 2026).[30] It should be noted that preemption may apply to forestall eviction or removal of the rail carrier from rail property even in situations where a rail carrier voluntarily agreed to a time-limited property interest. *See Fillmore & W. Freight Serv., LLC—Emergency Pet. for Declaratory Ord.,* FD 35813, slip op. at 3 (STB served Mar. 12, 2015) (''It is well settled that, without abandonment or

[30] A Board determination that a state court ruling finding a rail line has been abandoned under state law is preempted does not affect the state court's ruling on who has title to the property. The Board has acknowledged that it is ''well settled that the interpretation of deeds and the determination of who owns good title to property are issues of state law'' that are most appropriately decided by state courts. *Great Walton R.R.,* AB 1242 (Sub-No. 1), slip op. at 6 n.8 (STB served Feb. 27, 2026) (citing *Cent. Kan. Ry.—Aban. Exemption—in Marion & McPherson Cntys., Kan.,* AB 406 (Sub-No. 6X), slip op. at 2 (STB served May 8, 2001)).

discontinuance authority from the Board, the enforcement of a state or local order that would prevent operation over a railroad line is precluded.''); *see also Pinelawn Cemetery,* FD 35468, slip op. at 9–11 (''[E]ven if the state court were to find that the 1904 Lease was not renewed, Pinelawn could not use that ruling to evict the Railroads from the property.'').

2. Complete Takings of Rail Carrier Property

Takings of rail property can come in many different forms, including but not limited to claims for eminent domain, condemnation, adverse possession, prescriptive easement, or quiet title, among others. The Board and courts have recognized that state law actions which ''would remove the land at issue from the national railway system and deprive [a common carrier] of the ability to use the land to support its rail transportation operations'' are typically preempted. *Skidmore,* 1 F.4th at 214–15 (holding that state actions for quiet title and an exclusive prescriptive easement were preempted); *see also City of Lincoln,* 414 F.3d at 862 (same for eminent domain claim); *Grafton & Upton,* FD 36696, slip op. at 1 (same for eminent domain claim); *14500 Ltd. LLC,* FD 35788, slip op. at 4–5 (same for claims of adverse possession and exclusive prescriptive easement); *Jie Ao,* FD 35539, slip op. at 6–7 (same for adverse possession claim). *But see Girard,* 979 N.E.2d at 1287 (holding that an eminent domain claim was not preempted where the carrier claimed a speculative future need for rail service, but the railroad property had remained vacant for 15 years, and the carrier appeared to undermine its own claim by entering into an agreement to sell the property for purposes unrelated to rail transportation).[31] Although Board and court decisions have at times reviewed such exclusive takings under the ''as-applied'' standard, others have found preemption ''regardless of whether th[e] case is analyzed as 'categorical' preemption [or] as 'as applied' preemption . . . .'' *Jie Ao,* FD 35539, slip op. at 1. Synthesizing these analyses, takings of exclusive control of rail property and rights-of-way are best understood as categorically preempted, whereas non-exclusive takings may be reviewed under an as-applied approach.

The Board and courts have recognized that removal of part of the right-of-way or a railroad's property, including of currently unused property, could foreclose or unduly restrict present or future transportation by the rail carrier. *E.g., Grafton & Upton,* FD 36696, slip op. at 7. Rail carriers defending such cases have elaborated on the operational issues that may be raised by the removal of rail property, even when it is not being used directly. For example, rail carriers have expressed the importance of the property and rail yard to their overall network (*14500 Ltd. LLC*); the necessity to conduct maintenance or handle derailments (*City of Lincoln*); maintenance of retaining walls; and the placement of signal towers (*Ala. Great S.*). Carriers have also highlighted the potential of future use, such as for the planned construction of a transload facility (*Grafton & Upton,* Docket No. FD 36696); available capacity to accommodate future traffic growth (*14500 Ltd. LLC, Ala. Great S.*); and the ability to conduct maintenance including slope stabilization (*Jie Ao*). Accordingly, a broad array of present or future transportation-related uses could support a finding that attempts to take rail property are categorically preempted.

Such cases can sometimes present complex policy issues. For example, in *Wisconsin Central Ltd.,* a city and state department of transportation sought to condemn rail property in order to realign a highway in an effort to reduce traffic accidents. 160 F. Supp. 2d at 1011. And in *City of Lincoln,* the town sought to take a strip of rail property to improve its storm drainage system and complete a commuter trail for pedestrians and bicyclists that would connect campuses at a state university. 414 F.3d at 859; *see also Ala. Great S.,* FD 35196, slip op. at 4 (condemnation for creation of a public park with amphitheater, children's playground, and other features). Notwithstanding these worthy public purposes, both actions were held to be preempted by ICCTA.

3. Utilities and Pipelines Within the Right-of-Way

The Board and courts typically view actions seeking condemnation for the purposes of constructing overhead or underground utilities, such as water or sewer lines or wire crossings, under the as-applied framework. The Board has determined that ''routine, non-conflicting uses such as non-exclusive easements for at-grade road crossings, wire crossings, sewer crossings, etc., are not preempted so long as they would not impede rail operations or pose undue safety risks.'' *Maumee & W. R.R.—Pet. for Declaratory Ord.,* FD 34354, slip op. at 2 (STB served Mar. 3, 2004); *see also City of Lincoln,* 414 F.3d at 863 (addressing storm sewer project and noting that ''it is well established that nonconflicting, nonexclusive easements across railroad property are not preempted if they do not hinder rail operations or pose safety risks''). Relevant considerations include whether the facility will be placed in a location that would impair the railroad's use of the right-of-way (such as by undermining the integrity of underlying real property) or whether the timing and duration of the activity would hinder the rail carrier's operations. The Board has also focused on whether the crossings would be on the surface level or underground, and the amount of access to the right-of-way that would be conferred. *See, e.g., City of N. Chi.,* FD 36619, slip op. at 3–4 (acknowledging that a state court had already determined that a condemnation action for a water main easement crossing under rail property was preempted but providing guidance explaining that in cases where preemption is found the state court may be able to craft a remedy that avoids unreasonable interference with rail operations and would thus not be preempted); *E. Ala. Ry.—Pet. for Declaratory Ord.,* FD 35583, slip op. at 6–7 (STB served Mar. 9, 2012) (holding that condemnation for construction of underground water and sewage lines was not preempted).

4. Blocked Crossings

State and local laws that limit a rail carrier's ability to block at-grade road crossings have been found to be preempted in the courts, regardless of whether the regulations apply to moving or stationary trains. These laws generally attempt to regulate the amount of time that a train may block a road crossing and contain a variety of terms related to the amount of time the train may block a crossing; whether the train is moving or stopped; the permissible reasons for doing so; and various penalties. Although the Board itself has not had occasion to rule on any blocked crossings law outside of the permitting process—and thus has never resolved the issue of whether ICCTA preemption or FRSA preemption should apply as it pertains to blocked crossings—courts that have applied ICCTA preemption have regularly found such laws preempted. Anti-blocking laws have been found to be preempted by ICCTA because they ''purport[ ] to regulate rail transportation by dictating how railroads conduct their operations at crossings,'' *CSX Transp., Inc.* v. *Williams,* No. 3:16CV2242, 2017 WL 1544958, at *2 (N.D. Ohio Apr. 28,

[31] In *Grafton & Upton,* FD 36696, the Board analyzed *Girard,* distinguished it on the facts presented, and for that reason, determined that ''[t]he Board need not decide whether to endorse the court's analysis in *Girard*.'' *Grafton & Upton,* FD 36696, slip op. at 8.

2017), including train speed and length, scheduling, the performance of federally mandated air brake tests, the coupling and uncoupling of cars, switching, repairs, safety checks, and waiting for tracks to clear. *See BNSF Ry.* v. *Hiett,* 22 F.4th 1190, 1194 (10th Cir. 2022) (''[M]any factors determine the time that a train will block a grade crossing, including the train's speed and length, whether the side track intersects the grade crossing, when a railroad schedules a train to pass, and the time required to comply with federally mandated tests and procedures.''), *cert. denied sub nom. City of Edmond* v. *BNSF Ry.,* 142 S. Ct. 2835 (2022); *Elam,* 635 F.3d at 807. Because such regulations dictate rail operations directly, courts have uniformly found them preempted, and their reasoning aligns with the Board's categorical framework. *See, e.g., Hiett,* 22 F.4th at 1194 (finding a blocked crossing statute preempted, explaining that ''it too effectively regulates rail operations—a task the ICCTA reserves for the STB''); *Elam,* 635 F.3d at 807 (finding a blocked crossing statute completely preempted because the statute directly attempted to manage the carrier's switching operations, including the carrier's decisions as to train speed, length, and scheduling); *Williams,* 2017 WL 1544958, at *2 (finding a blocked crossing statute categorically preempted because it purported ''to regulate rail transportation by dictating how railroads conduct their operations at crossings'').

In 2022, and again in 2024, the United States Supreme Court declined to review, respectively, a federal circuit court and a state supreme court decision invalidating state blocked-crossing laws as federally preempted, leaving those decisions in place. *See City of Edmond,* 142 S. Ct. 2835 (2022); *Ohio* v. *CSX Transp., Inc.,* 144 S. Ct. 545 (2024).

5. Pedestrian or Road Crossings of Rail Lines

State or local laws that dictate where track crossings must be constructed or closed are evaluated for preemption on an as-applied basis. Non-exclusive easements for at-grade road crossings may be considered routine, non-conflicting uses of rail carrier property. *See Wichita Terminal Ass'n,* FD 35765, slip op. at 6 (citation omitted). State actions related to such crossings are therefore permissible if the actions do not unreasonably burden or interfere with rail transportation. *Id.* at 7. Because the Board utilizes an as-applied preemption analysis, such cases require a factual analysis of the specific crossing at issue. *E.g., Franks Inv. Co.,* 593 F.3d at 415 (requiring evidence about specific crossings at issue, rather than general evidence about crossings, in denying as-applied preemption challenge to crossing case). Such evidence can include the location of the crossing, present or future operational impacts on the rail carrier, and potential alternatives. *See, e.g., Wichita Terminal Ass'n,* FD 35765, slip op. at 9 (analyzing proposed crossing's potential impacts on traffic, capacity, and operations); *Tri-City R.R.,* FD 35915, slip op. at 8–9 (same, including switching and storage operations, as well as present and future impacts). For example, in *Wichita Terminal Association,* FD 35765, the Board found that a state court order requiring construction of a road crossing over tracks at a specific location was preempted. At the same time, however, the Board noted that it did ''not conclude that any crossing . . . necessarily would be preempted,'' suggesting that an alternative location for a crossing may not impose the same burden or interference with rail transportation. *Id.* at 10–11; *see also City of Ozark—Pet. for Declaratory Ord.,* FD 36104, slip op. at 5–6 (STB served July 28, 2017) (holding that, based on facts presented, the city's effort to force reinstallation of a removed at-grade crossing would unreasonably interfere with present and future railroad operations and cause undue safety risks under an as-applied preemption analysis). And a court has found that a state statute requiring pedestrian crossings over rail tracks was not preempted where operational impacts were limited by giving the railroads discretion as to the manner of construction. *See Adrian & Blissfield R.R.,* 550 F.3d at 542.

6. Locomotive Idling

State or local laws that regulate idling trains have been found to be categorically preempted. These regulations may include restrictions on the amount of time, hours, reasons for, or location of idling, including record-keeping requirements. Unlike generally applicable building codes, such regulations specifically target railroads and directly regulate rail operations. *E.g., Ass'n of Am. R.Rs.,* 2007 WL 2439499, at *7 (holding that rules related to railroad idling were categorically preempted). These laws place the state or local regulator, rather than the railroad, in the position to ''mak[e] operational decisions about when, where, and how long locomotives could idle.'' *Delaware,* 859 F.3d at 22. Therefore, regardless of the purpose of the state or local law, and regardless of whether the state or locality has attempted to narrowly tailor the law or provide exceptions, idling-related laws have been found to be categorically preempted. For example, in *Delaware,* a state statute generally prohibiting idling in residential neighborhoods at night was categorically preempted, even though the statute only prohibited ''non-essential'' idling and contained exemptions for certain enumerated purposes, because the statute directly managed railroad operations regardless of its practical effect. *See id.*

7. Environmental Permitting, Zoning Ordinances, and Land Use Laws

State or local permitting or preclearance requirements, including building permits, zoning ordinances, and environmental and land use permitting requirements, have been found to be categorically preempted as to rail carrier transportation and related infrastructure because ICCTA ''prevents states and localities from imposing requirements that, by their nature, could be used to deny a rail carrier the ability to conduct rail operations.'' *Soo Line R.R.—Pet. for Declaratory Ord.,* FD 35850, slip op. at 4 (STB served Dec. 23, 2014). Otherwise, states or localities could interfere with interstate commerce by denying, or indefinitely delaying, approval of rail projects or operations approved by the Board and subject to its exclusive jurisdiction. *See Green Mountain R.R.,* 404 F.3d at 643; *Grafton & Upton,* FD 36696, slip op. at 7 (collecting cases); *CSX Transp., Inc.,* FD 35832, slip op. at 4 (recognizing that state or local authority to ''deny or unreasonably delay'' construction and maintenance ''would irreconcilably conflict with the Board's authorization of those facilities and operations''). For example, the Board has held that a local conservation commission's order seeking to impose environmental permitting requirements on the construction of a rail carrier's transload facility was categorically preempted. *Grafton & Upton,* FD 36696, slip op. at 12. However, state and local regulations that have a ''more remote or incidental effect on rail transportation,'' have been found not to be preempted. *N.Y. Susquehanna & W. Ry.,* 500 F.3d at 252 (internal citation omitted). Resolution of issues regarding such remote or incidental effects may require discussion and cooperation between communities and rail carriers. *See Joint Pet. for Declaratory Ord.,* 5 S.T.B. at 508 (noting that some environmental requirements, such as requiring carriers to share their plans with the community or to submit environmental monitoring or testing information for an appropriate

period of time after operations begin, may not be preempted).

8. Noise, Smoke, Appearance, and Other Nuisance-Related Claims

State or local regulation of nuisance-related issues, such as noise caused by rail operations,[32] smoke, appearance of rail property, and other related matters have been found to be categorically preempted when related to activities under the Board's jurisdiction. These issues may also arise in litigation raising state or common law claims for nuisances caused by rail operations. *See, e.g., Pace,* 613 F.3d at 1068–69 (holding that a lawsuit alleging that construction and operation of side track caused an increase in noise and smoke that made land unusable was preempted). Such state or local actions can directly regulate, and potentially provide remedies for, rail carrier operations under the Board's exclusive jurisdiction and thus may be preempted by ICCTA, even though ICCTA provides no remedy. *See, e.g., Friberg* v. *Kan. City S. Ry.,* 267 F.3d 439, 443 (5th Cir. 2001) (holding that state tort claims related to trains on a railroad's side tracks blocking access to plaintiff's property were preempted, explaining that ''it is beyond peradventure that regulation of [the railroad's] train operations, as well as the construction and operation of the [railroad's] side tracks, is under the exclusive jurisdiction of the STB . . . .''); *Lange—Pet. for Declaratory Ord.,* FD 35037, slip op. at 4 (STB served Jan. 28, 2008) (stating that remedies for nuisance claims are preempted); *Joint Pet. for Declaratory Ord.* 5 S.T.B. at 510 (holding that a local ordinance declaring an automobile unloading facility to be a ''noisome trade'' was preempted) However, such claims may not be preempted if they do not directly implicate subject matter within the Board's jurisdiction. *See Emerson,* 503 F.3d at 1130–32 (holding that a railroad's disposal of railway ties into a wastewater drainage ditch adjacent to its tracks was not ''transportation'' under ICCTA and thus state tort claims related to flooding of adjoining property were not preempted).

9. Design, Construction, or Maintenance of Rail Infrastructure

State law regulations, including tort claims, that dictate the design, construction or maintenance of rail lines and rail transportation facilities under the Board's jurisdiction have been found to be categorically preempted. *See CSX Transp. Inc.,* FD 35832, slip op. at 4–5 (collecting cases). Common cases include claims for damages caused by flooding or other events that claimants assert were caused by rail carrier infrastructure decisions, such as the design of bridges or embankments, materials used in construction, maintenance of culverts, and related operational decisions. *E.g., Edwards,* 983 F.3d at 122 (preempting flooding damage claims). *But see Emerson,* 503 F.3d at 1130–32 (holding that state tort claim related to flooding on plaintiffs' property allegedly caused by a railroad's disposal of railway ties into a wastewater drainage ditch adjacent to its tracks was not preempted because the railroad's disposal did not qualify as ''transportation'' under ICCTA); *Hatcher—Pet. for Declaratory Ord.,* FD 35581, slip op. at 5–8 (STB served Sept. 21, 2012) (holding that state tort claims related to flooding and damage to plaintiffs' property allegedly caused by defendant railroads' blocking drainage infrastructure near the rail line during salvage operations following Board-authorized abandonment of the rail line were not preempted). As the Board has recognized, such claims can ''unduly burden interstate commerce and amount to impermissible state regulation of [a rail carrier]'s operations by interfering with the railroad's ability to uniformly design, construct, maintain, and repair its railroad line. The interstate rail network could not function properly if states and localities could impose their own potentially differing standards for these important activities, which are an integral part of, and directly affect, rail transportation.'' *Tubbs—Pet. for Declaratory Ord.,* FD 35792, slip op. at 5 (STB served Oct. 31, 2014), *aff'd,* 812 F.3d 1141 (8th Cir. 2015).[33] However, claims based on violation of FRA's regulations and standards would be subject to the federal harmonization analysis. *See Tubbs,* FD 35792, slip op. at 7 (declining to preempt, under ICCTA, claims based on uniform federal regulations under the FRSA).

10. Breach of Contract

Under 49 U.S.C. 10709, Congress has expressly provided that contracts between rail carriers and purchasers of rail services to provide such services are not subject to the rail provisions of 49 U.S.C. subtitle IV (Part A). Because Part A of subtitle IV includes the preemption provision at 49 U.S.C. 10501(b), enforcement of such contracts in court is not preempted. Additionally, actions under state law for breach of a contract between a rail carrier and other parties are generally not preempted. As the Fourth Circuit has explained, ''[v]oluntary agreements between private parties,'' and the ''enforcement'' of such contracts, ''are not presumptively regulatory acts.'' *PCS Phosphate Co.* v. *Norfolk S. Corp.,* 559 F.3d 212, 218–19 (4th Cir. 2009) (explaining how the ''history and purpose of ICCTA . . . suggest that such agreements do not fall into the core of economic regulation that the ICCTA was intended to preempt.''). The Board has stated that ''voluntary agreements must be seen as reflecting the carrier's own determination and admission that the agreements would not unreasonably interfere with interstate commerce.'' *Twp. of Woodbridge, N.J.* v. *Consol. Rail Corp.,* 5 S.T.B. 336, 340 (2000); *see also Joint Pet. for Declaratory Ord.,* 5 S.T.B. at 508 (''[P]reemption provisions should not be used to shield a carrier from its own commitments . . . .''). However, depending on the facts and circumstances of a specific case and the degree to which a voluntary agreement unreasonably interferes with interstate rail operations, certain agreements may be subject to an as-applied preemption analysis. *See Woodbridge,* 5 S.T.B. at 340 (declining to find enforceable agreement preempted where, among other things, there was not evidence that enforcement of the agreement would unreasonably interfere with the railroad's operations); *see also PCS Phosphate,* 559 F.3d at 221 (''This is not to say that a voluntary agreement could never constitute an 'unreasonable interference' with rail transportation, but the facts of this case indicate that any interference is not unreasonable . . . .'').

11. Routing of Traffic

The Board and courts have found that ICCTA categorically preempts state and local laws that seek to regulate when and where particular commodities can be carried by rail. *See, e.g., CSX Transp., Inc.,* FD 34662, slip op. at 5 (STB served May 3, 2005). In one example, the District of Columbia passed a law banning transportation of certain classes of hazardous commodities within an area of the District without a permit from the DC. Department of Transportation. *CSX Transp., Inc.—Pet. for Declaratory Ord.,* FD 34662, slip op. at 2 (STB served Mar. 14, 2005). The Board found that such regulation ''plainly'' fell within the

[32] Although not enforced by the Board, the Board notes that under the Noise Control Act of 1972, other federal agencies have established and enforce standards related to railroad noise which preempt state or local standards. *See* 42 U.S.C. 4916; 40 CFR part 201; 49 CFR part 210.

[33] The Board determined in *Tubbs* that the state law claims were preempted regardless of whether they were analyzed as ''categorical'' or ''as-applied,'' *Tubbs,* FD 35792, slip op. at 4, though on appeal, the Eighth Circuit utilized the as-applied framework, *see generally Tubbs,* 812 F.3d. 1141.

types of actions categorically preempted under section 10501(b), explaining that to the extent the DC law ''would require a permit to move certain rail traffic through protected parts of the City, it is directly covered by the categorical preemption against state and local permitting processes.'' *CSX Transp., Inc.,* FD 34662, slip op. at 5 (STB served May 3, 2005). ''And to the extent that the D.C. Act would otherwise ban the specified movements, it would directly conflict with the Board's authority over rail operations, including matters such as routing over which any state action is expressly preempted by section 10501(b).'' *Id.* (noting that other federal regulatory regimes may also apply in a complementary fashion).

V. ICCTA Harmonization Analysis for Federal Law

By its terms, ICCTA's express preemption provision applies to federal, as well as state, law. 49 U.S.C. 10501(b). When, however, the question presented is the interaction between ICCTA and another federal law, the express or implied preemption framework flowing from the Supremacy Clause is inapplicable. The Board therefore does not utilize its categorical/as-applied framework in such cases, and instead follows the tests set forth in the federal courts to analyze whether the laws can be harmonized and, if not, whether the later-enacted law repealed the other by implication. These federal-federal conflicts have mostly arisen in the realms of rail safety and environmental regulation, but the Board would apply similar principles to other potentially conflicting federal laws.

A. Constitutional Framework for Harmonization Analysis

''When confronted with two Acts of Congress allegedly touching on the same topic,'' the Board [34] and courts are ''not at liberty to pick and choose among congressional enactments and must instead strive to give effect to both.'' *Epic Sys. Corp.* v. *Lewis,* 584 U.S. 497, 510 (2018) (citation modified). When there is an apparent conflict between ICCTA and another federal law, the Board or a court ''must strive to harmonize the two laws, giving effect to both laws if possible.'' *Ass'n of Am. R.R.s* v. *S. Coast Air Quality Mgmt. Dist.,* 622 F.3d 1094, 1097 (9th Cir. 2010). However, if there is a ''positive repugnancy'' or an ''irreconcilable conflict'' between the laws, the question becomes whether the later-enacted statute repealed the earlier-enacted statute to the extent of the conflict. *Matsushita Elec. Indus. Co.* v. *Epstein,* 516 U.S. 367, 381 (1996); *Radzanower* v. *Touche Ross & Co.,* 426 U.S. 148, 155 (1976); *see also Joint Pet. for Declaratory Ord.,* 5 S.T.B. at 509 n.28. Whether one law ''displaces the other'' requires ''a clearly expressed congressional intention.'' *Epic Sys. Corp.,* 584 U.S. at 510. And where ''there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment.'' *Crawford Fitting Co.* v. *J.T. Gibbons, Inc.,* 482 U.S. 437, 445 (1987) (citation modified). Thus, the statutes are harmonized by giving effect to the more specific statute. *See generally Patten* v. *District of Columbia,* 9 F. 4th 921, 926 (D.C. Cir. 2021) (''In seeking to harmonize [disparate] statutes . . . [w]e are guided by the 'old and familiar rule' that 'the specific governs the general,' which is 'particularly true' where 'Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions.''') (quoting *RadLAX Gateway Hotel, LLC* v. *Amalgamated Bank,* 566 U.S. 639, 645–46 (2012)).

The Board conducts this analysis against the backdrop of the expansive, exclusive, and specific jurisdiction that ICCTA grants over transportation by rail carriers, which is the manifestation of Congress's intent to ensure uniform federal regulation. *Ass'n of Am. R.R.s,* FD 36369, slip op. at 14 (''Congress clearly intended that [section] 10501(b) preempt laws that create an irreconcilable conflict with the free flow of interstate commerce by imposing a patchwork of regulation on interstate rail transportation.''). ICCTA will often be the more specific statute insofar as it applies specifically to the rail industry, although there are numerous other federal laws related to the rail industry, and the Board would accord appropriate weight to the specificity of those laws in any harmonization analysis.[35] *See Pittsburgh & Lake Erie R.R.* v. *Ry. Lab. Executives' Ass'n,* 491 U.S. 490, 511 (1989) (discussing harmonization of the Railway Labor Act and Interstate Commerce Act).

B. Examples of Harmonization of ICCTA and Other Federal Laws

The analytical framework for harmonization described above would apply in any Board analysis of another federal law for a determination of ICCTA preemption. There are two illustrative examples of federal laws that the Board has previously addressed—related to rail safety and environmental laws—that are discussed in more detail below. The Board could apply a similar analysis when presented with questions about the preemptive effect of ICCTA when harmonization with another federal law is required.

1. Harmonization With FRSA

Congress enacted the FRSA in 1970 ''to promote safety in every area of railroad operations.'' 49 U.S.C. 20101. FRSA instructed the Secretary of Transportation, who has delegated this power to the FRA, to ''prescribe regulations and issue orders for every area of railroad safety.'' *Id.* 20103(a); 49 CFR 1.89(a). Under the FRSA preemption provision, Congress provided that ''[l]aws, regulations, and orders related to railroad safety . . . shall be nationally uniform to the extent practicable.'' 49 U.S.C. 20106(a)(1). To ensure ''[n]ational uniformity of regulation'' in this area, FRSA preempts state law obligations aimed at a ''subject matter'' addressed in regulations issued thereunder. *Id.* 20106(a)(2); *see also Duluth, Winnipeg & Pac. Ry.* v. *City of Orr,* 529 F.3d 794, 796 (8th Cir. 2008) (FRSA ''generally preempt[s] state laws covering the same subject matter'' as Department of Transportation (DOT) or Department of Homeland Security (DHS) standards).

Nonetheless, in some limited situations, FRSA might lead to the patchwork of rail regulations that ICCTA is designed to avoid, because FRSA contains a narrow savings clause permitting states to regulate where FRA has not yet issued rail safety [36] regulations covering ''the subject matter of the State requirement.'' 49 U.S.C.

[34] The Board has previously affirmed that it, as well as the courts, can engage in this federal-federal harmonization and implied repeal analysis. *Ass'n of Am. R.R.s—Pet. for Declaratory Ord.* (*AAR Declaratory Ord.*), FD 36369, slip op. at 9, 12 (STB served Dec. 30, 2020). This is because ''[t]he statute requires, in certain circumstances, the preemption of other federal laws and does not prohibit the Board from opining on its interpretation of the other federal laws to determine where ICCTA preemption applies.'' *Id.* at 9.

[35] At the time of this writing, these include, but are not limited to, the Railroad Retirement Act of 1974 (45 U.S.C. 231 *et seq.*); the Railway Labor Act (45 U.S.C. 151 *et seq.*); the Railroad Unemployment Insurance Act (45 U.S.C. 351 *et seq.*); and the Federal Employers' Liability Act (45 U.S.C. 51 *et seq.*).

[36] Certain state and local regulations that impact rail carriers may in reality be related to public safety, rather than rail safety, which could impact the Board's analysis of its jurisdiction and harmonization with FRSA. *See* Br. for United States as Amicus Curiae, *Ohio* v. *CSX Transp., Inc.,* No. 22–459, OSG Amicus Brief, 2023 WL 8112708, at *14 (U.S. Nov. 21, 2023) [hereinafter OSG Amicus Brief] (''It is debatable whether a blocked-crossing statute . . . is 'related to *railroad* safety,' 49 U.S.C. 20106(a)(1) (emphasis added), given that [the] safety-related concerns principally involve the safety of emergency-services users and other members of the public—not the safety of railroads and railroad operations.'').

20106(a)(2); *Duluth, Winnipeg & Pac. Ry.,* 529 F.3d at 796 (stating that FRSA ''creates a narrow exception to preemption through its savings clause''). FRSA also allows states to ''adopt or continue in force an additional or more stringent'' rail safety law or regulation, but only if it ''(A) is necessary to eliminate or reduce an essentially local safety or security hazard; (B) is not incompatible with a law, regulation, or order of the United States Government; and (C) does not unreasonably burden interstate commerce.'' 49 U.S.C. 20106(a)(2). Courts have interpreted the ''essentially local'' safety hazard requirement narrowly to address ''local situations which are not statewide in character and not capable of being adequately encompassed within national uniform standards.'' *Nat'l Ass'n of Regul. Util. Comm'rs* v. *Coleman,* 542 F.2d 11, 14–15 (3d Cir. 1976); *see also Duluth, Winnipeg & Pac. Ry.,* 529 F.3d at 798 (collecting cases). And notably, the exception directly requires that such regulations must be ''not incompatible'' with federal laws.

In 2007, Congress enacted an amendment clarifying the savings clause in section 20106. *See* 49 U.S.C. 20106(b); *see also Bates* v. *Mo. & N. Ark. R.R.,* 548 F.3d 634, 637 (8th Cir. 2008). The amendment specifically provided that nothing within section 20106 ''shall be construed to preempt an action under State law seeking damages for personal injury, death, or property damage'' alleging that a party: (A) failed to comply with an applicable Federal standard of care established by DOT or DHS; (B) failed to comply with its own plan, rule, or standard that it created pursuant to an applicable DOT or DHS regulation or order; or (C) failed to comply with a State law, regulation, or order that is not incompatible with the provisions of section 20106(a)(2) described above. 49 U.S.C. 20106(b).

By contrast, ICCTA expressly overrides ''remedies provided under [other] Federal . . . law[s]'' to the extent of a conflict. 49 U.S.C. 10501(b). ICCTA was enacted more recently (1995) than the authority at section 20103 and the savings clause at section 20106(a)(2). *See In re Fed.-Mogul Global Inc.,* 684 F.3d 355, 374 (3d Cir. 2012) (citation omitted) (declining ''to limit the preemptive scope'' of a statute based on the existence of an older, narrower provision covering a closely related topic). And if there is a potential conflict with the tort law clarification to the FRSA savings clause, enacted in 2007 at section 20106(b), the Board could take note of the timing. *See Lundeen* v. *Can. Pac. R.R.,* 532 F.3d 682, 688 (8th Cir. 2008) (''This 'clarifying' amendment reflected Congress's disagreement with the manner in which the courts . . . had interpreted [section] 20106 to preempt state law causes of action whenever a federal regulation covered the same subject matter as the allegations of negligence in a state court lawsuit.'').

The Board has said that ICCTA and FRSA should be harmonized to give effect to both. *See, e.g., Tubbs,* FD 35792, slip op. at 7. ICCTA primarily applies to rail transportation and operations, and FRSA primarily applies to rail safety. Although ''the ICCTA preemption provision can be read to cover virtually everything related to rail transportation and . . . rail safety-related claims will almost always touch on rail transportation and operations,'' *Waneck—Pet. for Declaratory Ord.,* FD 36167, slip op. at 5 (STB served Oct. 31, 2018),[37] the Board has long recognized that ICCTA ''does not preempt valid safety regulation under [FRSA].'' *Green Mountain R.R.—Pet. for Declaratory Ord.,* FD 34052, slip op. at 6 n.8 (STB served May 28, 2002). The agencies have exercised their authority in complementary fashion, and when their responsibilities overlap, they have ''coordinate[d] and cooperate[d] with each other as appropriate.'' *CSX Transp., Inc.,* FD 34662, slip op. at 10 (STB served Mar. 14, 2005); *see also Tyrrell* v. *Norfolk S. Ry.,* 248 F.3d 517, 523 (6th Cir. 2001) (stating that the Board's and FRA's ''complementary exercise of their statutory authority accurately reflects Congress's intent for the ICCTA and FRSA to be construed *in pari materia*''). And the Board ''does not usurp or interfere with the role of other federal agencies in regulating railroad safety and security and hazardous materials transportation under other federal regulatory statutes.'' *CSXT Transp., Inc.,* FD 34662, slip op. at 7 (STB served May 3, 2005).

Applying these principles, the Board has determined that ICCTA applies to operation and construction-related claims, including state-law tort claims alleging that a rail line was designed, constructed, and maintained in a way that caused flooding-related property damage. *See Tubbs,* FD 35792, slip op. at 6–7. Conversely, FRSA applies to primarily safety-related claims, including state-law tort claims related to a collision between a train and a tour bus at a railroad crossing, *see Waneck,* FD 36167, slip op. at 4 (STB served May 25, 2018), and state regulation of the clearance distance between tracks, *see Tyrrell,* 248 F.3d at 522–24. The Board has stated that ''the states' ability to act with respect to railroad/highway crossings (including grade separations) remains undisturbed so long as their action does not unreasonably interfere with railroad operations or interstate commerce, and does not constitute regulation of the railroad's operations.'' Br. of Surface Transp. Bd. as Amicus Curiae, *Iowa, Chi. & E. R.R.* v. *Wash. Cnty.,* 384 F.3d 557 (8th Cir. 2004) (No. 03–3136), 2004 WL 6395939, at *21–23 (discussing whether law about redesign and replacement of bridges at crossing for safety reasons was subject to ICCTA preemption). And, as discussed above, the Board found that both ICCTA and FRSA applied to a local safety-related regulation limiting the shipment of hazardous materials because it affected both safety and the railroad's ability to carry certain commodities. *CSX Transp., Inc.,* FD 34662, slip op. at 5–7 (STB served May 3, 2005).

Thus, ICCTA and FRSA can typically be harmonized. However, issues may arise when a state or local safety-related law which may not be preempted under FRSA may still be preempted under ICCTA because such laws effectively manage or govern rail transportation and thus directly conflict with the Board's exclusive jurisdiction. Some courts have suggested that only FRSA preemption can apply to at least some safety-related issues. *See, e.g., Island Park, LLC* v. *CSX Transp.,* 559 F.3d 96, 107 (2d Cir. 2009) (stating that the ''federal statutory scheme places principal federal regulatory authority for rail safety with the FRA, not the [Board],'' and so ''FRSA provides the appropriate basis for analyzing whether a state law, regulation or order affecting rail safety is pre-empted by federal law''); *Tyrrell,* 248 F.3d at 522–23. And the Board has partially endorsed the same view in non-binding guidance. *See Waneck,* FD 36167, slip op. at 5 (STB served Oct. 31, 2018). However, as the Office of the Solicitor General recently argued to the Supreme Court in a case about whether states could regulate blocked crossings, ''FRSA cannot be read to create a loophole in the ICCTA that would permit a patchwork of state and local regulation over rail transportation simply because the regulations also happen to touch on 'safety-related' matters.'' OSG Amicus Brief, 2023 WL 8112708, at *13; *see also Ohio* v. *CSX Transp., Inc.,* 144 S. Ct. 545 (2024) (denying Ohio's certiorari petition). This is also consistent with the savings clause's requirement that state regulations that are in addition to or more stringent than DOT or DHS

[37] Note, however, that the *Waneck* opinion described itself as ''purely advisory guidance.'' *Id.* at 4.

rules governing the same subject matter must relate to an ''essentially local'' hazard, be ''not incompatible with'' other federal laws, and ''not unreasonably burden interstate commerce.'' *See* 49 U.S.C. 20106(a)(2)(B). Thus, even if FRSA alone does not preempt a state or local railroad safety regulation, ICCTA preemption may still apply if upholding the state or local regulation addresses a generally-applicable concern, would be inconsistent with ICCTA, or would otherwise unreasonably burden rail transportation.

2. Harmonization With Federal Environmental Laws

The Board has stated that ICCTA preemption is implicated when the relevant state activity was undertaken pursuant to regulations passed under the auspices of federal environmental statutes. This dynamic has arisen in two situations. First, ICCTA preemption may apply to the extent the state regulations would cause a ''patchwork of regulations'' burdening interstate commerce. *See EPA Declaratory Ord.,* FD 35803, slip op. at 8. In *EPA Declaratory Ord.,* the Board concluded that ICCTA would likely preempt a California air quality district's rules related to railroad locomotive idling and recordkeeping—even if those rules were approved by EPA under the CAA as part of California's state implementation plan ''because of the potential patchwork of regulations that could result.'' *Id.* The Board noted that it must consider ''not only the impact of the District's rules . . . but the fact that other states and local districts throughout the country could follow suit and adopt their own emission rules . . . leading to the lack of uniformity of regulation that Congress intended to preclude in [section] 10501(b).'' *EPA Declaratory Ord.,* FD 35803, slip op. at 8; *see also id.* at 10 (''[A]llowing states and localities to create a variety of complex regulations governing how an instrument of interstate commerce is operated, equipped, or kept track of (even if federalized under the CAA) would directly conflict with the goal of uniform national regulation of rail transportation.'').

The Board applied the same principle in *AAR Declaratory Order* to conclude that the CWA's National Pollutant Discharge Elimination System (NPDES) permitting program and discharge prohibition ''would likely be preempted by [ICCTA] if applied to discharges incidental to the operation of rail cars in transit.'' *AAR Declaratory Ord.,* FD 36369, slip op. at 1. Because the program was ''based on state-specific permitting requirements'' and ''individual permit writers . . . have discretion to impose [standards] more stringent than EPA guidelines,'' applying the program would be ''likely to result in a patchwork of differing regulations'' that would ''be incompatible with [ICCTA's] purpose of ensuring uniform regulation of rail transportation.'' *Id.* at 11–12; *see also id.* at 13–14 (stating that ICCTA was ''arguably the more specific statutory provision,'' and that, to the extent the NPDES permitting program was ''incompatible with the purpose'' of ICCTA, the later-enacted statute (ICCTA) should ''be given effect'').

Thus, similar to the unreasonable-burden prong of as-applied preemption, the analysis is cumulative: if applying another federal law or allowing claims thereunder would, in the aggregate, interfere with Congress's uniform regulatory scheme, ICCTA preemption is implicated. This suggests two important distinctions: between federal laws with one uniform federal standard and those that permit a patchwork of state-promulgated requirements; and between state laws passed under color of federal law that apply to instrumentalities of interstate commerce in motion [38] versus those applying to stationary structures. In *AAR Declaratory Order,* the Board asserted that ''[t]o the extent that EPA could issue a nationwide general permit for incidental discharges from rail cars in transit that includes uniform requirements for the states, such a nationwide general permit would not create a patchwork of differing regulations and could therefore potentially be harmonized with [section] 10501(b).'' *AAR Declaratory Ord.,* FD 36369, slip op. at 16. The Board also focused on the fact that ''rail cars in transit are inherently instrumentalities of interstate commerce.'' *Id.* at 15. Although ''subjecting them to differing regulatory requirements as they pass from one state to the next is likely to be incompatible with the free flow of interstate commerce that Congress envisioned when enacting [section] 10501(b)[,] . . . non-discriminatory application to . . . stationary facilities owned or operated by railroads'' may not be. *Id.* Instead, such stationary facility applications under the color of federal law ''are generally not preempted because, although they may differ from state to state, they do not typically conflict with [section] 10501(b)'s goal of preventing differing regulations from interfering with the free flow of interstate commerce.'' *Id.*

Additionally, ICCTA preemption is implicated if a federal ''statute or regulation is being applied in a discriminatory manner, or being used as a pretext for frustrating or preventing a particular activity.'' *Joint Pet. for Declaratory Ord.,* 5 S.T.B. at 509. In *Joint Petition for Declaratory Order,* the Board concluded that the local governments were ''simply using [federal environmental law] as a pretext to do what Congress expressly precluded: interfere with interstate commerce by imposing a local permitting or environmental process as a prerequisite to the railroad's ability to conduct its operations.'' *Id.* The local concerns appeared unfounded because neither EPA nor the state environmental regulator had expressed any concerns, and the record showed that substantial pollution was ''unlikely.'' *Id.* at 509–10.

This is necessarily a ''fact-bound'' analysis in which the regulator's stated concerns ''need to be reviewed individually'' to determine whether they have a reasonable basis. *Id.* at 508–09. As in the preemption context, this aspect of the analysis furthers the congressional scheme by ensuring that seemingly neutral regulatory measures are not being used to target or obstruct rail operations.

VI. Conclusion

This policy statement sets forth the Board's perspective on the state of the law as of the time of its issuance, acknowledging that new precedents from the Board and courts will further develop the law on STB jurisdiction and preemption. Although forthcoming cases will be evaluated based on their facts, circumstances, and proffered arguments, the Board intends for this policy statement to be beneficial and informative to the public about the Board's jurisdiction and ICCTA preemption, and to encourage the smooth flow of interstate commerce via the nation's rail network.

Executive Order 12866 (Regulatory Planning and Review) and Executive Order 14192 (Unleasing Prosperity Through Deregulation)

Executive Order 12866, as modified by Executive Order 14215, provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant

[38] The Board notes that a significant percentage of rail cars are owned by separate leasing companies or directly by shippers, rather than the rail carriers themselves. *See* Pet. 5–7, July 26, 2021, *Pet. for Rulemaking to Adopt Rules Governing Priv. Railcar Use by R.Rs.,* EP 768. This disparate ownership structure may amplify the effects of patchwork regulation as compliance costs are imposed on many different entities, ranging from large rail carriers and manufacturers to small shippers that own their own small fleets.

regulatory actions. OIRA has determined that this policy statement is significant under section 3(f) of Executive Order 12866. For the reasons discussed above, this policy statement is considered an Executive Order 14192 deregulatory action.

Decided: November 2, 2026.

By the Board, Board Members Fuchs, Hedlund, Kloster, and Schultz.

Andrea Pope-Matheson,

Clearance Clerk.

[FR Doc. 2026–22811 Filed 11–6–26; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Compatibility Program for Seattle-Tacoma International Airport, King County, Washington

AGENCY: Federal Aviation Administration, DOT.

ACTION: Acceptance of Seattle-Tacoma International Airport noise exposure map.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by the Port of Seattle for Seattle-Tacoma International Airport are compliant with applicable statutory and regulatory requirements.

DATES: The effective date of the FAA's determination on the noise exposure map is October 26, 2026.

FOR FURTHER INFORMATION CONTACT: Sky M. Laron, Community Engagement Officer, Northwest Mountain Region, Airports Division, Federal Aviation Administration, 2200 S. 216th Street, Des Moines, WA 98198, (206) 231–4136.

SUPPLEMENTARY INFORMATION: The FAA determined the noise exposure map submitted by the Port of Seattle for Seattle-Tacoma International Airport, is in compliance with applicable statutory and regulatory requirements, effective October 26, 2026 Under title 49, United States Code (U.S.C.) section 47503, an airport operator may submit to the FAA, noise exposure maps depicting non-compatible uses as of the date such map is submitted, a description of estimated aircraft operations during a forecast period that is at least five years in the future and how those operations will affect the map. A noise exposure map must be prepared in accordance with title 14, Code of Federal Regulations (CFR) part 150, the regulations promulgated pursuant to 49 U.S.C. 47502, and developed in consultation with public agencies and planning authorities in the area surrounding the airport, state and Federal agencies, interested and affected parties in the local community, and aeronautical users of the airport. In addition, an airport operator that submitted a noise exposure map, which the FAA determined is compliant with statutory and regulatory requirements, may submit a noise compatibility program for FAA approval that sets forth measures the operator has taken or proposes to take to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The FAA completed its review of the noise exposure map and supporting documentation submitted by the Port of Seattle and determined the noise exposure map and accompanying documentation are compliant with applicable requirements. The documentation that constitutes the noise exposure map includes the current and forecast noise exposure map graphics, the 2022 Existing Condition Noise Exposure Map and 2032 Future Condition Noise Exposure Map, and other narrative, graphic or tabular representations of the data required by 14 CFR A150.101 and 49 U.S.C. 47503. This determination is effective on October 26, 2026. FAA's determination on an airport's noise exposure map is limited to a finding that the noise exposure map was developed in accordance with the 49 U.S.C. 47503 and procedures contained in 14 CFR A150.101. FAA's acceptance of an NEM does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program. If questions arise concerning the precise relationship of specific properties within noise exposure contours depicted on a noise exposure map, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of 49 U.S.C. 47506. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under 14 CFR part 150 or through FAA review and acceptance of a noise exposure map. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted a noise exposure map or with those public agencies and planning authorities with which consultation is required under 49 U.S.C 47503. The FAA relied on the certification by the airport operator that the consultations and opportunity for public review required under 14 CFR 150.21 has been accomplished during the development of the noise exposure maps. Copies of the noise exposure map and supporting documentation and the FAA's evaluation of the noise exposure maps are available for examination at the following locations:

Federal Aviation Administration, Northwest Mountain Region, Airports Division, 2200 S. 216th Street, Des Moines, WA 98198.

Seattle-Tacoma International Airport, Port of Seattle, 17801 International Blvd., SeaTac, WA, 98158.

Questions may be directed to the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Issued in Des Moines, Washington, on October 26, 2026.

Jason Ritchie,

Director (Acting), ANM Airports Division, ANM–600, Northwest Mountain Region Airports Division.

[FR Doc. 2026–22729 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2026–1255]

Agency Information Collection Activities: Notice of Request for Extension of a Currently Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for extension of currently approved information collection.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for extension of an existing information collection that is summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by January 8, 2027.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 1255by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Wendy McAbee, (202) 366–5658, Office of Administration, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 7 a.m. to 3:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Highway Bridge and National Bridge Inspection Programs (National Bridge Inspection Standards).

OMB Control: 2125–0501.

Background: This collection is necessary to meet legislative requirements of Title 23 United States Code section 144, and the Code of Federal Regulations, 23 Highways Part 650, Subpart C—National Bridge Inspection Standards which require States, Federal Agencies, and Tribal Governments to: (1) perform, and report inventory data from, initial, routine, non-redundant steel tension member, underwater, damage, in-depth, and special inspections as appropriate for all highway bridges on public roads, and element level inspections for highway bridges on the National Highway System; (2) report costs associated with the replacement of highway bridges; and (3) report critical findings on highway bridges. The bridge replacement unit cost information that is provided to the FHWA is on an annual basis. The critical findings information is periodically provided to the FHWA. The bridge information is used for multiple purposes, including: (1) the determination of the condition of the Nation's bridges which is included in a biennial report to Congress on the Status of the Nation's Bridges; (2) for various additional reports to Congress on Bridge Safety; (3) the data source for executing various sections of the Federal-aid program which involve highway bridges; (4) the data source for assessing the bridge penalty provisions of Title 23 United States Code section 119; (5) the data source for the evaluation of bridge performance measures established in Title 23 United States Code section 150; (6) for conducting oversight of the National Bridge Inspection Program at the State, Federal, and Tribal government level; and (7) for strategic national defense needs.

Respondents: 52 State highway agencies including the District of Columbia and Puerto Rico, Federal Agencies, Tribal Governments, and transportation departments of United States Territories of U.S Virgin Islands and Guam. The number of inspections per respondent varies in accordance with the National Bridge Inspection Standards.

Frequency: Annually.

Estimated Average Burden per Response: The estimated average burden for each routine bridge inspection on the National Highway System is 10 hours. The estimated average burden for each routine bridge inspection that is not on the National Highway System is 9 hours. The estimated average burden for each Non-redundant Steel Tension Member, Underwater, and Special inspection is 9 hours. The estimated average burden for each cost collection report is 16 hours. The estimated average burden for reporting critical findings is 40 hours.

Estimated Total Annual Burden Hours: The annual burden hours associated with this renewal are 3,179,366 hours. This estimated figure is based on 76,557 annual instances for bridge inspections on the National Highway System multiplied by 10 hours (765,570 hours); plus 73,492 annual instances for routine bridge inspection that are not on the National Highway System multiplied by 9 hours (2,235,339 hours); plus annual instances for non-redundant steel tension member, underwater, and special inspections multiplied by 9 hours (175,545 hours); plus 16 hours for each unit cost report multiplied by 52 reports (832 hours); plus 40 hours for follow up on critical findings multiplied by 52 respondents (2,080 hours) for a combined annual burden of 3,179,366 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued on: November 4, 2026.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2026–22738 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Maryland

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by FHWA.

SUMMARY: This notice announces action taken by FHWA that are final. The actions relate to the proposed improvements along U.S. 50/301 and proposed replacement of the Chesapeake Bay Bridges (Bay Bridge) across the Chesapeake Bay. Those actions grant licenses, permits, or approvals for the Project. The Tier 2 Combined Final Environmental Impact Statement (FEIS) and Record of Decision (ROD) under the National Environmental Policy Act (NEPA) and other documents in the Project file provide details on the Project and FHWA's actions.

DATES: By this notice, FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before April 8, 2027. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA: Valeriya Remezova, Division Administrator, Federal Highway Administration, 31 Hopkins Plaza, Suite 1520, Baltimore, MD 21201, Telephone (410) 962–4440, *valerirya.remezova@dot.gov.* The FHWA Maryland Division's normal business hours are 8:00 a.m. to 4:30 p.m. (EST).

For MDTA: Bruce Gartner, Executive Director, Maryland Transportation Authority, 2310 Broening Highway Baltimore, MD 21224, Telephone (410) 537–1001, *bgartner@mdta.state.md.us.*

The MDTA's normal business hours are 8:00 a.m. to 5:00 p.m. (EST).

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA has taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing approvals and initiating consultation for the proposed improvements along U.S. 50/301, the proposed replacement of the Bay Bridge, and the proposed demolition of the current Bay Bridge in Maryland.

FHWA's actions and the laws under which such actions were taken, are described in the Tier 2 Combined FEIS and ROD and other documents in the project records. The FEIS, ROD, supporting technical reports and other project records are available by contacting FHWA at the address provided above and can also be viewed and downloaded from the project website at: *https://baycrossingstudy.com/.*

This notice applies to all Federal agency decisions that are final as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321 *et. seq.*]; Federal-Aid Act (FAHA) [23 U.S.C. 109, 139, and 128].

2. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q)].

3. *Noise:* Noise Control Act of 1972 [42 U.S.C. 4901 *et seq.*].

4. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303; 23 U.S.C. 138]; Land and Water Conservation Fund Act of 1965 [16 U.S.C. 4601–4604].

5. *Wildlife:* Endangered Species Act (ESA) [16 U.S.C. 1531–1544 and 1536]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act [16 U.S.C. 703–712]; Bald and Golden Eagle Protection Act [16 U.S.C. 668–668c].

6. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 306108].

7. *Social and Economic:* Farmland Protection Policy Act [7 U.S.C. 4201–4209]; Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 [42 U.S.C. 4601 *et seq.*]; Americans with Disabilities Act of 1990, as amended (ADA) [42 U.S.C. 12101].

8. *Wetlands and Water Resources:* Clean Water Act (Section 404, Section 401, Section 402, Section 319) [33 U.S.C. 1251–1387]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j)(26)].

9. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9601 et. seq.]; Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

10. *Executive Orders:* The analysis pertaining to any applicable Executive Order considered during the environmental review process to the extent such analysis may be challenged in court. Such Executive Orders may include: Executive Order 11990 Protection of Wetlands; Executive Order 11988 Floodplain Management; Executive Order 11593 Protection and Enhancement of the Cultural Environment; Executive Order 13007 Indian Sacred Sites; Executive Order 13287 Preserve America; Executive Order 13175 Consultation and Coordination with Indian Tribal Governments; Executive Order 13112 Invasive Species, as amended by Executive Order 13751 Safeguarding the Nation from the Impacts of Invasive Species.

(Authority: 23 U.S.C. 139(*l*)(1))

Valeriya Remezova,

Division Administrator, Maryland Division, Federal Highway Administration.

[FR Doc. 2026–22771 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2026–0036]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of denials.

SUMMARY: FMCSA announces its decision to deny applications from 16 individuals who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting persons with a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to operate a commercial motor vehicle (CMV) from operating CMVs in interstate commerce.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–4001; *fmcsamedical@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments, go to *www.regulations.gov.* Insert the docket number, (FMCSA–2026–0036) in the keyword box and click ''Search.'' Next, choose the only notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W58–213 of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. DOT posts these comments, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice DOT/ALL–14 FDMS (Federal Docket Management System), which can be reviewed under the ''Department Wide System of Records Notices'' link at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices.* The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the FMCSRs. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level of safety that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision from which the applicant will be exempt, the effective period, and all terms and conditions of

the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

III. Background

The physical qualification standard for drivers regarding seizures and loss of consciousness provides that a person is physically qualified to drive a CMV if that person has ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control'' a CMV (49 CFR 391.41(b)(8)). To assist in applying this standard, FMCSA publishes guidance for medical examiners (MEs) in the form of medical advisory criteria in Appendix A to 49 CFR part 391.[1] In 2007, FMCSA published recommendations from a Medical Expert Panel (MEP) that FMCSA tasked to review the existing seizure disorder guidelines for MEs.[2] The MEP performed a comprehensive, systematic literature review, including evidence available at the time. The MEP issued recommended criteria to evaluate whether an individual with a history of epilepsy, a single unprovoked seizure, or a provoked seizure should be allowed to drive a CMV.

On January 15, 2013, FMCSA began granting exemptions, on a case-by-case basis, to individual drivers from the physical qualification standard regarding seizures and loss of consciousness in 49 CFR 391.41(b)(8) (78 FR 3069). The Agency considers the medical advisory criteria, the 2007 MEP recommendations, and each individual's medical information and driving record in deciding whether to grant the exemption.

On March 17, 2026, FMCSA published a notice announcing receipt of applications from 17 individuals requesting an exemption from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) and requested comments from the public (91 FR 12893). The public comment period ended on April 16, 2026, and five comments were received.

IV. Discussion of Comments

FMCSA received five comments on these exemption applications. One commenter advocated balanced and individualized regulations that prioritize both public safety and the equal opportunity for individuals to drive when their seizures are well-managed. In response to this comment, FMCSA finds that its seizure exemption process adequately balances the Agency's mission of improving public safety on the nation's roadways with the opportunity for otherwise ineligible individuals to present evidence of why they should nonetheless be permitted to drive CMVs.

Two comments were in support of granting an exemption to Mr. Sparkman and one comment was in support of granting an exemption to Donte Watkins, both listed in this notice. Although FMCSA received comments in support of Mr. Sparkman's and Mr. Watkins' Federal seizure exemption applications, FMCSA evaluates each application considering the medical advisory criteria, the 2007 MEP recommendations, and each individual's medical information and driving record in deciding whether to grant the exemption as stated above. In both cases, the information provided in the comments did not alter FMCSA's evaluation of the medical evidence the individuals submitted with their applications.

The last comment was out of scope for this notice.

V. Basis for Exemption Determination

The Agency conducted an individualized assessment of each applicant's medical information, including the root cause of the respective seizure(s) and medical information about the applicant's seizure history, the length of time that has elapsed since the individual's last seizure, the stability of each individual's treatment regimen, and the duration of time on or off of anti-seizure medication. In addition, the Agency reviewed the treating clinician's medical opinion related to the ability of the driver to safely operate a CMV with a seizure history and each applicant's certified driving record from their State Driver Licensing Agency (SDLA). The information obtained from each applicant's driving record provides the Agency with details regarding any moving violations or reported crash data, which demonstrates whether the driver has a safe driving history and is an indicator of future driving performance. If the driving record revealed a crash, FMCSA requested and reviewed the related police reports and other relevant documents, such as the citation and conviction information. A summary of each applicant's seizure history was discussed in the March 17, 2026, **Federal Register** notice (91 FR 12893) and will not be repeated in this notice.

VI. Conclusion

Based upon its evaluation of the 17 exemption applications, FMCSA has determined that the following 16 applicants do not satisfy the eligibility criteria or meet the terms and conditions of the Federal exemption and granting these exemptions would not provide a level of safety that would be equivalent to, or greater than, the level of safety that would be obtained by complying with 49 CFR 391.41(b)(8). Therefore, the 16 applicants in this notice have been denied exemptions from the physical qualification standards in 49 CFR 391.41(b)(8).

Each applicant has, prior to this notice, received a letter of final disposition regarding his or her exemption request. Those decision letters fully outlined the basis for the denial and constitute final action by the Agency. This notice summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(6)(c) by publishing names and reasons for denial.

The following 16 applicants do not meet the minimum time requirement for being seizure-free, either on or off anti-seizure medication:

Andrew Barker (NC)
Kyle Benner (PA)
Devin Brockington (MD)
Wendy Cook (OR)
Caedmon Cunningham (KS)
Steven Ernest (ME)
Chauncy Gibson (GA)
Matthew Heller (NY)
Michael S. Miller (CA)
Michael George Murray (NY)
Brandon Petruzzi (MA)
Scott Pontious (OH)
Anthony Sanders (MO)
Ryen Seyfried (NY)
Jeffrey Sparkman (KY)
Donte Watkins (NC)

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2026–22829 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–EX–P

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[1] Appendix A to Part 391, Title 49, available at *https://www.ecfr.gov/current/title-49/part-391/appendix-Appendix* A to Part 391.

[2] ''Expert Panel Recommendations, Seizure Disorders and Commercial Motor Vehicle Driver Safety,'' Medical Expert Panel (Oct. 15, 2007), available at *https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/2020-04/Seizure-Disorders-MEP-Recommendations-v2-prot%2010152007.pdf.*

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for New Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before December 9, 2026.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Director, Office of Hazardous Materials Safety Special Permits Program, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–6, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: (1) Motor vehicle, (2) Rail freight, (3) Cargo vessel, (4) Cargo aircraft only, (5) Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH–6, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 2, 2026.

Donald P. Burger,

Director, Special Permits Program.

SPECIAL PERMITS DATA

Application No.	Applicant	Regulation(s) Affected	Nature of the special permits thereof
22420–N	Eastman Chemical Company	172.203(a), 172.302(c), 173.31(d)(1)(ii).	To authorize the transportation in commerce of tank cars in which the manway cover gasket has been subjected to the leak detection method(s) in lieu of a visual inspection. (mode 2)
22422–N	Busek Co., Inc	173.301(f)(1), 178.35(e)	To authorize the transportation in commerce of non-DOT specification cylinders containing xenon, compressed within the Hall Effect Thruster propulsion system (satellite component). (modes 1, 2, 3, 4, 5)
22424–N	EVE Energy Malaysia Sdn. Bhd.	173.185(b)(3)(i), 173.185(b)(6).	To authorize the transportation in commerce by motor vehicle, rail freight, and cargo vessel of lithium ion cells packaged within a UN50G fiberboard Large Packaging. (modes 1, 2, 3)
22425–N	The Battery Network, Inc	173.185(f)(1)	To authorize the manufacture, mark, sale and use of UN1A2 PGI drums containing granular thermal suppressant material for the transportation in commerce of damaged, defective, or recalled cells and batteries including those contained in or packed in equipment. (mode 1 and 2)
22428–N	Xona Space Systems Inc	171.23(a)(1), 171.23(a)(3), 172.101(j)(1), 173.301(f), 173.302a(a)(1), 173.304a(a)(2).	To authorize the transportation in commerce of spacecraft (satellite) or components of spacecraft containing toxic gas (anhydrous ammonia) in non-DOT specification containers (heat pipes), non-flammable, non-toxic gas (xenon) in non-DOT specification aluminum lined composite overwrapped pressure vessels and low production lithium ion batteries transported in a Satellite Transport Container (STC). (modes 1, 3, 4)
22429–N	LDJ Manufacturing, Inc	177.834(h), 178.705(d)	To authorize the manufacture, mark, sale and use of non-specification IBCs having a capacity less than 119 gallons which may be discharged without being removed from the vehicle. (mode 1)
22430–N	U.S. Bureau of Customs and Border Protection.	172.200, 172.300, 172.400, 173.25, 175.75(b).	To authorize the transportation in commerce of certain radiation survey devices containing Division 2.2 gases aboard commercial passenger aircraft. (mode 5)
22438–N	BIC Indiana	173.185(a)(1)	To authorize the transportation in commerce of prototype lithium ion batteries for lab testing. (mode 4)
22439–N	DGM Italia Srl	172.101(j)	To authorize the transportation in commerce of lithium ion batteries packed with equipment that exceed 35 kg net weight aboard cargo-only aircraft. (mode 4)
22443–N	Hawkeye Helicopter LLC	172.101(j), 172.101(j)(1), 172.200, 172.204(c)(3), 172.301(c), 173.27(b)(2), 175.30, 175.30(a)(1), 175.75.	To authorize the transportation in commerce of hazardous materials by rotorcraft external load in amounts that exceed the maximum net quantity in the HMR with additional hazard communication, specification packaging, and stowage exceptions. (mode 4)
22447–N	Max Wagner GmbH	107.807, 173.301(f), 173.302a(a)(1), 173.304a(a)(1), 178.35.	To authorize the manufacture, mark, sale and use of non-DOT specification composite overwrapped pressure vessels (COPV) for the transportation in commerce of compressed gases. (modes 1, 2, 3, 4, 5)

Application No.	Applicant	Regulation(s) Affected	Nature of the special permits thereof
22448–N	Luoyang Sunrui Special Equipment Co., Ltd.	180.205(g)(1)	To authorize the requalification of DOT 3AA, 3AAX, 3T cylinder or UN/ISO 11120 cylinders by utilizing 100% Ultrasonic Examination (UE) in lieu of the internal visual inspection and the hydrostatic pressure test. (modes 1, 2, 3)

[FR Doc. 2026–22777 Filed 11–6–26; 8:45 am]
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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Actions on Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has granted or denied the application described herein.

DATES: Comments must be received on or before December 9, 2026.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Director, Office of Hazardous Materials Safety Special Permits Program, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–6, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH–6, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 2, 2026.

Donald P. Burger,

Director, Special Permits Program.

Application No.	Applicant	Regulation(s) affected	Nature of the special ermits thereof
SPECIAL PERMITS DATA—Granted			
7573–M	Department of Defense (Military Surface Deployment & Distribution Command).	49 CFR Parts 172, 175	To modify the special permit to add a safety control measure to the special permit.
12532–M	Mission Systems Orchard Park Inc.	173.302a(a)	To modify the special permit to clarify the proof testing pressure when a cylinder is inspected and to update the heat treatment call out to reflect the drawing from H1025 to H1000.
15493–M	Mission Systems Orchard Park Inc.	173.302a	To modify the special permit to update the heat treatment used on the drawing from H1025 to H1000.
15493–M	Mission Systems Orchard Park Inc.	173.302a	To modify the special permit to update a drawing and to authorize each cylinder to be refilled up to five times.
21706–M	The Battery Network, Inc	172.102(c)(1), 172.303(a), 172.401(a), 173.159(f), 173.159a(c)(2), 173.159a(d)(1).	To modify the special permit to authorize cargo and ferry vessels as additional modes of transportation.
22203–N	Toyota Motor Engineering & Manufacturing North America, Inc.	173.301(a)(1), 173.302(a)(1), 178.70.	To authorize the manufacture, mark, sale and use of non-DOT specification cylinders designed, manufactured, tested and type approved in accordance with the UN Global Technical Regulation (GTR) No. 13 and UN Regulation No. 134 that are installed in a hydrogen storage module for transportation.
22206–N	Versum Materials US, LLC	171.23(a)(3), 171.23(b)(10)(ii)	To authorize the transportation in commerce of non-DOT specification pressure drums (aka: Tonners) containing anhydrous hydrogen chloride.
22246–N	Western Digital Technologies, Inc.	172.101(b)(4), 173.232(g)(3)	To authorize the transportation in commerce of certain hazardous materials in non-DOT specification packaging aboard motor vehicle, cargo vessel and cargo-only aircraft.
22290–N	Ningbo ZhengXin Fire-Fighting Equipment Co., Ltd.	173.309(c)(2), 173.309(c)(4)	To authorize the transportation in commerce of non-specification fire extinguishers that do not meet the requirements of 49 CFR 173.309(c)(2) and (4).
22319–N	Mission Systems Orchard Park Inc.	173.302(a)	To authorize the manufacture, mark, sale and use of non-DOT specification cylinders.

Application No.	Applicant	Regulation(s) affected	Nature of the special ermits thereof
22332–N	Network Access Associates Limited.	171.23(a)(1), 171.23(a)(3), 172.101(j)(1), 173.185(a)(1), 173.301(f), 173.302a(a)(1), 173.304a(a)(2).	To authorize the transportation in commerce of spacecraft (satellite) or components of spacecraft containing toxic gas (anhydrous ammonia) in non-DOT specification containers (heat pipes), non-flammable, non-toxic gas (xenon) in non-DOT specification aluminum-lined composite-overwrapped pressure vessels, and low production lithium ion batteries transported in a Satellite Transport Container (STC).
22346–N	Eve Power Co., Ltd	173.185(a)(1), 173.185(b)(3)(i), 173.185(b)(6).	To authorize the transportation in commerce by motor vehicle, rail freight, and cargo vessel of lithium cells packaged within a UN50G fiberboard Large Packaging.
22349–N	Astroforge, Inc	173.301(g)(1), 173.302(a)(1)	To authorize the transportation in commerce of xenon, compressed in non-DOT specification cylinders without pressure relief devices.
22360–N	Geogas American Samo Inc ..	180.407(c), 180.407(e)	To authorize the transportation in commerce of a DOT specification cargo tank motor vehicle with an extension of the internal visual inspection and pressure test interval periods.
22392–N	Saildrone, Inc	172.101(j)	To authorize the transportation in commerce of lithium ion batteries exceeding the 35 kg net weight per package aboard cargo-only aircraft.
22409–N	Clean Harbors Environmental Services, Inc.	173.3(d)(9)	To authorize the transportation of leaking DOT3A480 cylinder containing chlorine which has been overcharged in a salvage cylinder that has not been requalified within the period specified in 49 CFR 173.3(d)(9).
22416–N	Energy Security Agency, Inc	173.185(f)(3)	To authorize the transportation in commerce of certain damaged, defective, or recalled lithium ion batteries in alternative packaging.
22418–N	North Carolina Department of Transportation.	172.101(k)(5)	To authorize the transportation in commerce of cargo tanks containing residual amounts of gasoline on ferry vessels where the limiting number of passengers is exceeded.
22434–N	Guidance Air Service, LLC	172.101(j), 172.200, 172.301(c), 173.1, 175.75.	To authorize the transportation in commerce of certain hazardous materials only in remote areas of the U.S. by 14 CFR Part 133 cargo-only aircraft (rotorcraft external load operations) in which hazardous materials are attached to or suspended from the aircraft, and Part 135, as applicable, without being subject to certain hazard communication requirements, quantity limitations and certain loading and stowage requirements.
SPECIAL PERMITS DATA—Denied			
15343–M	Desert Air Transport, Inc	173.242	To modify the special permit to add an authorized packaging.
22170–N	Thales Alenia Space	172.300(a), 172.400(a), 173.21, 173.185(a)(1), 173.301(f)(1), 173.302a(a)(1), 173.304a(a)(2).	To authorize the transportation in commerce of certain non-DOT specification cylinders containing Division 2.2 and 2.3 compressed gases and other hazardous materials identified in the special permit for use in specialty cooling and propulsion applications for a satellite.
22340–N	EUROTRE S.r.l. Italy	172.203(a), 172.315(a)(2), 173.301b(d), 173.301b(d)(1), 173.306(a)(1).	To authorize the transportation in commerce of certain Division 2.2 gases as limited quantities when contained in a cylinder with a capacity exceeding 4 fluid ounces.
SPECIAL PERMITS DATA—Withdrawn			
16279–M	Daniels Sharpsmart, Inc	173.196(a)	To modify the special permit to authorize the transportation in commerce of an additional medical waste for disposal.
22322–N	Mission Systems Orchard Park Inc.	173.302(a)	To authorize the manufacture, mark, sale and use of non-DOT specification cylinders conforming with all regulations applicable to a DOT 39 specification cylinder for the transportation in commerce of helium, compressed.
22412–N	American Lithium Energy Corp.	173.185(a), 173.185(e)	To authorize the transportation in commerce of prototype lithium ion battery packs which have not been tested in accordance with UN Manual of Tests and Criteria, Section III, Subsection 38.3.

[FR Doc. 2026–22779 Filed 11–6–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Modification to Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before November 24, 2026.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comment(s) is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Director, Office of Hazardous Materials Safety Special Permits Program, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–6, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: (1) Motor vehicle, (2) Rail freight, (3) Cargo vessel, (4) Cargo aircraft only, (5) Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH–6, 1200 New Jersey Avenue Southeast, Washington, DC or at *http://regulations.gov.*

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 2, 2026.

Donald P. Burger,

Director, Special Permits Program.

SPECIAL PERMITS DATA

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
9758–M	The Coleman Company Inc	173.304a(d)	To modify the special permit to update drawings and add additional packaging designs. (modes 1, 2, 3)
13112–M	Mission Systems Orchard Park Inc.	173.302a(a)(1)	To modify the special permit to update the drawing of the packaging. (modes 1, 2, 3, 4, 5)
16624–M	Framatome Inc	173.301(a)(1), 173.302(a)(1)	To modify the special permit to authorize additional packaging. (mode 1)
21463–M	Mission Systems Orchard Park Inc.	173.302(a)(1)	To modify the special permit to authorize additional packagings. (modes 1, 2, 3, 4, 5)
22231–M	Benelux Imaging B.V	172.101(j), 172.301(c), 173.232(h)(2).	To modify the special permit to authorize the transportation of an additional magnetic resonance imaging (MRI) machine. (mode 4)
22240–M	Atlas Chemical Corp	173.56(b)	To modify the special permit to authorize additional packaging. (modes 1, 2, 3)

[FR Doc. 2026–22778 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2026–4192]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection(s): Procedures for Transportation Workplace Drug and Alcohol Testing Programs (ICR 2105–0529)

AGENCY: Office of the Secretary (OST), DOT.

ACTION: Notice and request for comments.

SUMMARY: The Department of Transportation (DOT) invites public comments about our intention to request Office of Management and Budget (OMB) approval to renew the information collection approved under OMB Control No. 2105–0529, Procedures for Transportation Drug and Alcohol Testing Program. The information to be collected will be used to document tests conducted and actions taken to ensure safety in the workplace or is otherwise necessary to collect under the Omnibus Transportation Employee Testing Act of 1991, which requires DOT to implement a drug and alcohol testing program in various transportation-related industries. DOT is required to publish this notice in the **Federal Register** in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments to this notice must be received by January 8, 2027.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building, W58–213, Washington, DC 20590–0001;
- *Hand Delivery:* West Building, W58–213, 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9826;

Instructions: You must include the agency name and docket number [DOT–OST–2026–4192] of this notice at the beginning of your comment. Note that all comments received will be posted without change to *http://www.regulations.gov* including any personal information provided. Please see the Privacy Act section of this document.

Docket: You may view the public docket through the internet at *http://www.regulations.gov* or in person at the

Docket Management System office at the above address.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Bohdan Baczara, Office of Drug and Alcohol Policy and Compliance, Office of the Secretary, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590; *ODAPCWebmail@dot.gov* (email).

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2105–0529.

Title: Procedures for Transportation Workplace Drug and Alcohol Testing Programs.

Form Numbers: DOT F 1385; DOT F 1380.

Type of Review: Clearance of a renewal of an information collection.

Background: Under the Omnibus Transportation Employee Testing Act of 1991, DOT is required to implement a drug and alcohol testing program in various transportation related industries. This specific requirement is elaborated in 49 CFR part 40, Procedures for Transportation Workplace Drug and Alcohol Testing Programs (Part 40). This request for a renewal of the information collection for the program includes 45 burden items related to the overall program and two official DOT forms: the U.S. Department of Transportation Alcohol Testing Form (ATF) [DOT F 1380] and the DOT Drug and Alcohol Testing Management Information System (MIS) Data Collection Form [DOT F 1385].

The ATF includes the employee's name, the type of test taken, the date of the test, and the name of the employer. Data on each test conducted, including test results, is necessary to document that the tests were conducted and is used to take action, when required, to ensure safety in the workplace.

The MIS form includes employer specific drug and alcohol testing information such as the reason for the test and the cumulative number of test results for the negative, positive, and refusal tests. No employee specific data is collected. The form has fields for data related to urine and oral fluid drug testing. The MIS data is used by each of the affected DOT Agencies (*i.e.,* Federal Aviation Administration, Federal Transit Administration, Federal Railroad Administration, Federal Motor Carrier Safety Administration, and the Pipeline and Hazardous Materials Safety Administration) and the United States Coast Guard when calculating their industry's annual random drug and/or alcohol testing rate.

DOT will request OMB approval to revise the MIS Data Collection Form. Specifically, in Section I of the form, ''Employer'', in the line for PHMSA—Pipeline, DOT will remove the text '': (Check) Gas Gathering__ Gas Transmission__ Gas Distribution__ Transport Hazardous Liquids__ Transport Carbon Dioxide__''. Because pipeline operators submit other reports to PHMSA, PHMSA already knows the types of pipelines they operate; therefore, collecting this data element on the MIS form is unnecessary. Furthermore, contractors to pipeline operators who must submit an MIS form are not operators and are confused by the options because the 'type of pipeline' does not apply to them. Removing this data element will not hinder the data collection effort or alter the form's burden estimate. In the Paperwork Reduction Act Notice section of the form, DOT will replace the text 'Suite W62–300' with 'Rm W75–211' to reflect the new office location.

Respondents: The information will be collected from transportation employers, Department representatives, and a variety of service agents. Estimated total number of respondents is 2,383,126.

Frequency: The information will be collected annually.

Estimated Total Number Burden Hours; 723,484.

PRA item	Number of respondents	Number of responses	Burden per response (min)	Total burden hours	Total salary costs ($)
Exemptions from Regulation Provisions Requests [40.7(a)]	700	700	180	2,100	$97,860
Employer Stand-down Waiver Requests [40.21(b)]	1	1	480	8	373
Employee Testing Records from Previous Employers [40.25(a)]	24,477	668,581	8	89,144	4,154,110
Employee Release of Information [40.25(f)]	24,447	668,581	4	44,572	2,077,055
MIS Form Submission [40.26]	27,680	27,680	90	41,520	1,934,832
Urine Collector (Qualification and Refresher) Training Documentation (40.33(b) & (e)]	5,000	5,000	4	333	15,518
Urine Collector Error Correction Training Documentation [40.33(f)]	5,000	39,770	4	2,651	123,537
Oral Fluid Collector (Qualification and Refresher) Training Documentation (40.35(b) & (e)]	5,000	5,000	4	333	15,518
Oral Fluid Collector Error Correction Training Documentation [40.35(f)]	5,000	2,993	4	199	9,273
Laboratory Reports to DOT Regarding Unlisted Adulterant [40.87(e)]	.....	.....	30	.....	.....
Semi-Annual Laboratory Reports to Employers [40.111(a)]	14	365,951	4	24,396	1,136,854
Semi-Annual Laboratory Reports to DOT [40.111(d)]	14	336	4	22	1,025
Medical Review Officer (MRO) (Qualifications and Continuing Education) Training Documentation [40.121(c) & (d)]	1,000	1,000	4	67	3,122
MRO Review of Negative Results Documentation [[40.127(b)(2)(ii)]	1,708	345,636	4	23,042	1,073,757
MRO Failure to Contact Donor Documentation [40.131(c)(1)]	1,708	46,899	4	3,127	145,718
MRO Effort to Contact DER Documentation [40.131(c)(2)(iii)]	1,708	46,899	4	3,127	145,718
DER Successful Contact Employee Documentation [40.131(d)]	549,477	37,519	4	2,501	116,547
DER Failure to Contact Employee Documentation [40.131(d)(2)(i)]	549,477	9,379	4	625	29,125
MRO Verification of Positive Result Without Interview Documentation [40.133]	1,708	9,379	4	625	29,125
Adulterant/Substitution Evaluation Physician Statements [40.145(g)(2)(ii)(d)]	0	0	30	0	0
MRO Cancellation of Adulterant/Substitution for Legitimate Reason Reports [40.145(g)(5)]	0	0	30	0	0
Employee Admission of Adulterating/Substituting Specimen MRO Determination [40.159(c)]	40	40	4	3	124

PRA item	Number of respondents	Number of responses	Burden per response (min)	Total burden hours	Total salary costs ($)
Split Specimen Requests by MRO [40.171(c)]	1,708	10,943	4	730	34,018
Split Failure to Reconfirm for Drugs Reports by MRO [40.187(b)]	1,708	91	4	6	280
Split Failure to Reconfirm for Adulterant/Substitution Reports by MRO [40.187(c)]	7	7	5	1	47
Shy Bladder Physician Statements [40.193(f)]	1,708	701	5	58	2,703
MRO Statements Regarding Physical Evidence of Drug Use [40.195(b) & (c)]	.....	.....	.....	.....	.....
Drug Test Correction Statements [40.205 (b)(1) & (2)]	25,000	142,028	8	18,937	882,464
Breath Alcohol Technician (BAT)/Screening Test Technician (STT) (Qualification and Refresher) Training Documentation [40.213(b)(c)&(e)]	2,000	2,000	4	133	6,213
BAT/STT Error Correction Training Documentation [40.213(f)]	10,000	167	4	12	559
Complete DOT Alcohol Testing Forms [40.225(a)]	10,000	3,357,739	8	447,699	20,862,773
Evidential Breath Testing Device Quality Assurance/Calibration Records [40.233(c)(4)]	10,000	10,000	4	667	31,082
Shy Lung Physician Statements [40.265(c)(2)]	144	144	4	10	466
Alcohol Test Correction Statements [40.271(b)(1)&(2)]	10,000	336	4	22	1,025
Substance Abuse Professional (SAP) (Qualification and Continuing Education) Training Documentation [40.281(c)&(d)]	5,998	3,334	4	222	10,345
Employer SAP Lists to Employees [40.287]	549,477	107,008	4	7,134	332,444
SAP Reports to Employers [40.311(c),(d) & (e)]	549,477	138,928	4	9,262	431,609
Correction Notices to Service Agents [40.373(a)]	25	25	60	25	1,660
Notice of Proposed Exclusion (NOPE) to Service Agents [40.375(a)]	1	1	600	10	664
Service Agent Requests to Contest Public Interest Exclusions (PIE) [40.379(b)]	1	1	1	1	66
Service Agent Information to Argue PIE [40.379(b)(2)]	1	1	240	4	266
Service Agent Information to Contest PIE [40.381(a) & (b)]	1	1	240	4	186
Notices of PIE to Service Agents [40.399]	1	1	60	1	66
Notices of PIE to Employer and Public [40.401 (b) & (d)]	1	1	60	1	66
Service Agent PIE Notices to Employers [40.403 (a)]	1	300	30	150	6,990
Total New	2,383,126	6,055,101	2,270	723,484	33,715,186

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for DOT's performance; (b) The accuracy of the estimated burden that the collection would impose on respondents; (c) Ways for the DOT to enhance the quality, utility and clarity of the information to be collected; and (d) Ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1:48.

Issued in Washington, DC, on November 5, 2026.

Authority and Issuance.

Bohdan Baczara,

Deputy Director, DOT, Office of Drug and Alcohol Policy and Compliance.

[FR Doc. 2026–22814 Filed 11–6–26; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing updates to the identifying information of one or more entries currently included on one or more of OFAC's sanctions lists.

DATES: See **SUPPLEMENTARY INFORMATION** for relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for the Office of Sanctions Support and Operations, 202–622–6943; Associate Director for Global Targeting, 202–622–2420; or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Electronic Availability

OFAC's sanctions lists and additional information concerning OFAC sanctions programs are available on OFAC's website: *https://ofac.treasury.gov.*

Notice of OFAC Action

On November 4, 2026, OFAC updated the following names to apply secondary sanctions information to names associated with the IRAN–EO13902 program. The updated names and relevant sanctions authorities are available at the below URL: *https://ofac.treasury.gov/recent-actions/20261104_33.*

(Authority: 31 CFR chapter V.)

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2026–22802 Filed 11–6–26; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List

(SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: This action was issued on November 4, 2026. See **SUPPLEMENTARY INFORMATION** for relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, 202–622–2420; Assistant Director for Licensing, 202–622–2480; Assistant Director for Sanctions Compliance, 202–622–2490; or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website: *https://ofac.treasury.gov.*

Notice of OFAC Actions

On November 4, 2026, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals

1. DHIMAN, Ashwani Kumar, Chandigarh, India; DOB 01 Mar 1980; nationality India; Gender Male; Secondary sanctions risk: See Section 2 of E.O. 13902; Registration Number 08188219 (India) (individual) [IRAN–EO13902] (Linked To: ARYAVART SHIP MANAGEMENT PRIVATE LIMITED).

Designated pursuant to section 1(a)(iv) of Executive Order 13902 of January 10, 2020, ''Imposing Sanctions With Respect to Additional Sectors of Iran,'' 85 FR 2003, 3 CFR, 2020 Comp., p. 299 (E.O. 13902), for having acted or purported to act for or on behalf of, directly or indirectly, ARYAVART SHIP MANAGEMENT PRIVATE LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 13902.

2. SHAHID, Jaspreet Preeti (a.k.a. KAUR, Jaspreet), Chandigarh, India; DOB 22 Aug 1980; POB Chandigarh, India; nationality India; Gender Female; Secondary sanctions risk: See Section 2 of E.O. 13902; Registration Number 03563403 (India) (individual) [IRAN–EO13902] (Linked To: SHARMA, Suniel Kumar).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, SUNIEL KUMAR SHARMA, a person whose property and interests in property are blocked pursuant to E.O. 13902.

3. SHARMA, Suniel Kumar (a.k.a. SHARMA, Suniel; a.k.a. ''KUMAR, Suniel''), Chandigarh, India; DOB 07 Oct 1979; POB Lucknow, Uttar Pradesh, India; nationality India; website *https://amaocr.org/;* alt. Website *https://epnicaragua.org;* alt. Website *ema.org.sz;* alt. Website *msta-registry.com;* alt. Website *mstaregistry.com;* alt. Website *https://imsagregistry.wordpress.com/;* alt. Website *https://smmrm.com;* alt. Website *https://www.timorleste-registry.org;* Gender Male; Secondary sanctions risk: See Section 2 of E.O. 13902; Passport Z5925452 (India) expires 27 Jul 2030 (individual) [IRAN–EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the petroleum sector of the Iranian economy.

4. SINGH, Ishwinder, Chandigarh, India; DOB 01 Apr 1992; nationality India; Gender Male; Secondary sanctions risk: See Section 2 of E.O. 13902; Registration Number 08409602 (India) (individual) [IRAN–EO13902] (Linked To: ARYAVART SHIP MANAGEMENT PRIVATE LIMITED).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for having acted or purported to act for or on behalf of, directly or indirectly, ARYAVART SHIP MANAGEMENT PRIVATE LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 13902.

Entities

1. OCEANIEK TECHNOLOGIES INDIA, S.C.O. 86, Sector 44C, Chandigarh 160047, India; Plot No. C–205, SM Heights, Mohali, Punjab 160055, India; Secondary sanctions risk: See Section 2 of E.O. 13902; Organization Established Date 16 Dec 2022; Tax ID No. AAIFO2899P (India); Registration Number UDYAM–CH–01–0023384 (India) [IRAN–EO13902] (Linked To: SHARMA, Suniel Kumar).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, SUNIEL KUMAR SHARMA, a person whose property and interests in property are blocked pursuant to E.O. 13902.

2. ALEXARYA FINSERV PRIVATE LIMITED, SCO–318, 2nd Floor Sector 38D, Chandigarh 160036, India; Secondary sanctions risk: See Section 2 of E.O. 13902; Organization Established Date 27 Sep 2018; Tax ID No. AARCA3945Q (India); Registration Number U67100CH2018PTC042186 (India) [IRAN–EO13902] (Linked To: SHAHID, Jaspreet Preeti).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JASPREET PREETI SHAHID, a person whose property and interests in property are blocked pursuant to E.O. 13902.

3. ALEXARYA MEDIA AND ENTERTAINMENT PRIVATE LIMITED, SCO–318, Sector 38–D, Chandigarh 160036, India; Secondary sanctions risk: See Section 2 of E.O. 13902; Organization Established Date 16 Jan 2018; Tax ID No. AAQCA4372G (India); Registration Number U93000CH2018PTC041837 (India) [IRAN–EO13902] (Linked To: SHAHID, Jaspreet Preeti).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JASPREET PREETI SHAHID, a person whose property and interests in property are blocked pursuant to E.O. 13902.

4. ARYAVART MARITIME AND EDUCATIONAL TRUST, SCO 373, Sector 37 D, Chandigarh, India; Secondary sanctions risk: See Section 2 of E.O. 13902; Organization Established Date 21 Jul 2016; Registration Number CH/2024/0406033 (India) [IRAN–EO13902] (Linked To: SHAHID, Jaspreet Preeti).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JASPREET PREETI SHAHID, a person whose property and interests in property are blocked pursuant to E.O. 13902.

5. ARYAVART SHIP MANAGEMENT PRIVATE LIMITED, SCO–318, 1st Floor Sector 38–D, Chandigarh 160036, India; Secondary sanctions risk: See Section 2 of E.O. 13902; Organization Established Date 27 Jul 2011; Tax ID No. AAJCA7074N (India); Registration Number U74900CH2011PTC033139 (India) [IRAN–EO13902] (Linked To: SHAHID, Jaspreet Preeti).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JASPREET PREETI SHAHID, a person whose property and interests in property are blocked pursuant to E.O. 13902.

6. ESWATINI MARITIME AFFAIRS AND INTERNATIONAL SHIP REGISTRY PTE. LTD., 10 Jalan Besar, #07–06 Sim Lim Tower, 208787, Singapore; Secondary sanctions risk: See Section 2 of E.O. 13902; Organization Established Date 25 Sep 2023; Registration Number 202338388W (Singapore) [IRAN–EO13902] (Linked To: SHAHID, Jaspreet Preeti).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JASPREET PREETI SHAHID, a person whose property and interests in property are blocked pursuant to E.O. 13902.

7. POLYNESIA MARITIME PRIVATE LIMITED, H No 3335 CHD Police Society, Sector 51 D, Chandigarh 160047, India; Secondary sanctions risk: See Section 2 of E.O. 13902; Organization Established Date 27 Jan 2015; Tax ID No. AAICP0398K (India); Registration Number U74900CH2015PTC035391 (India) [IRAN–EO13902] (Linked To: SHAHID, Jaspreet Preeti).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JASPREET PREETI SHAHID, a person whose property and interests in property are blocked pursuant to E.O. 13902.

8. PRECEPT TRENDS PRIVATE LIMITED, S.C.O. 86 First Floor, Sector 44C, Chandigarh 160047, India; Secondary sanctions risk: See Section 2 of E.O. 13902; Organization Established Date 12 Apr 2022; Tax ID No. AAMCP8147L (India); Registration Number U18100CH2022PTC044314 (India) [IRAN–EO13902] (Linked To: SHAHID, Jaspreet Preeti).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JASPREET PREETI SHAHID, a person whose property and interests in property are blocked pursuant to E.O. 13902.

9. VIHARABOATING PRIVATE LIMITED, Building No 4, Pallippuram P O, Pallippuram, Cherthala, Alappuzha, Kerala 688541, India; Secondary sanctions risk: See Section 2 of E.O. 13902; Organization Established Date 12 Feb 2026; Registration Number U55101KL2026PTC100900 (India) [IRAN–EO13902] (Linked To: SHAHID, Jaspreet Preeti).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, JASPREET PREETI SHAHID, a person whose property and interests in property are blocked pursuant to E.O. 13902.

10. FUGO GROUND SERVICES INC (Latin: FUGO YER HİZMETLERİ ANONİM ŞİRKETİ) (a.k.a. FUGO AVIATION), Gayrettepe Mh. Vefabey Sk. No: 16 Inner Door No: 4, Besiktas, Istanbul, Turkey; website *https://www.fugoaviation.com;* Secondary sanctions risk: See Section 2 of E.O. 13902; Organization Established Date 28 Nov 2019; Tax ID No. 3881357595 (Turkey); Chamber of Commerce Number 1210423 (Turkey); Registration Number 220631–5 (Turkey); Central Registration System Number 0388135759500001 (Turkey) [IRAN–EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the aviation sector of the Iranian economy.

(Authority: E.O. 13902.)

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2026–22766 Filed 11–6–26; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request on Form 15254

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before January 8, 2027 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Include ''OMB Control No. 1545–2297'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to LaNita Van Dyke, 202–317–6009.

SUPPLEMENTARY INFORMATION: The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Title: Request for Section 754 Revocation (Form 15254).

OMB Control Number: 1545–2297.

Form Number: 15254.

Abstract: Form 15254 is a public use form which will be submitted by partnerships to request a Section 754 Revocation. Partnerships, partners, and their representatives will need to access the form from *IRS.gov* to complete and submit the form along with the required documents.

Current Actions: There is no change to the previously approved information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 50.

Estimated Time per Response: 5 hours, 7 minutes.

Estimated Total Annual Burden Hours: 256.

Dated: November 5, 2026.

LaNita Van Dyke,

Tax Analyst.

[FR Doc. 2026–22806 Filed 11–6–26; 8:45 am]

BILLING CODE 4831–GV–P

DEPARTMENT OF THE TREASURY

United States Mint

Establish Price for 2026 Semiquincentennial President Donald J. Trump $1 Coin—1,000-Coin Bags

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint is announcing the price of $1,350.00 for the 2026 Semiquincentennial President Donald J. Trump $1 Coin—1,000-Coin Bag. This product is limited to 15,100 units.

FOR FURTHER INFORMATION CONTACT: Ann Bailey, Product Management, United States Mint, 801 9th Street NW, Washington, DC 20220; or call 202–354–7601.

Authority: 31 U.S.C. 5112(y)(1)(C).

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2026–22797 Filed 11–6–26; 8:45 am]

BILLING CODE 4810–37–P



FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 405, et al.

Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 405, 406, 407, 410, 414, 415, 417, 422, 423, 424, 425, 427, 428, and 512

[CMS–1848–F]

RIN 0938–AV82

Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; codification of establishment of new policies for: the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act of 2022; limiting Medicare coverage of certain individuals; the Ambulatory Specialty Model; updates to drugs and biological products paid under Part B; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; updates to policies for Rural Health Clinics and Federally Qualified Health Centers; update to the Ambulance Fee Schedule regulations; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2026 provisions; updates to Clinical Laboratory Fee Schedule regulations; updates to the Medicare Promoting Interoperability Program.

DATES: These regulations are effective on January 1, 2027.

FOR FURTHER INFORMATION CONTACT:

MedicarePhysicianFeeSchedule@cms.hhs.gov, for any issues not identified below. Please indicate the specific issue in the subject line of the email. For all questions related to reporting a service on a claim, please contact your Medicare Administrative Contractor.

Michael Soracoe, Morgan Kitzmiller, or *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Hannah Ahn, Allison Bramlett, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to potentially misvalued services under the PFS.

Mikayla Murphy, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to E/M overlap between stand-alone visits and global periods, and E/M visit complexity add-on code (B1 and B2).

Terry Simananda, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to smoking and tobacco use cessation, screening, brief intervention, and referral to treatment, psychiatric collaborative care model, and shared medical appointments.

Sarah Leipnik, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to global surgery payment accuracy.

Pamela West, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to comprehensive outpatient rehabilitation facility (CORF) services and KX modifier thresholds.

Zehra Hussain, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment of skin substitutes.

Laura Kennedy, (410) 786–3377, Rebecca Ray, (667) 414–0879, and Jae Ryu, (667) 414–0765 for issues related to Drugs and Biological Products Paid Under Medicare Part B.

Lisa Parker, (410) 786–4949, or *FQHC–PPS@cms.hhs.gov*, Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov*, and Patrick Sartini, (410) 786–9252 for issues related to FQHC and RHC payments.

Patrick Sartini, (410) 786–9252, or *CLFS_Inquiries@cms.hhs.gov* for issues related to the Clinical Laboratory Fee Schedule.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Medicare Shared Savings Program (Shared Savings Program) quality performance standard and other quality reporting requirements.

Kimberly Spalding Bush, (410) 786–3232, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Shared Savings Program certified electronic health record technology (CEHRT) use requirements.

Janae James, (410) 786–0801, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program beneficiary assignment and financial methodology.

Lucy Bertocci, (443) 681–0762, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to reducing or eliminating Part B cost sharing, prepaid shared savings, beneficiary notifications, advance investment payments or identifying ACOs experienced with performance-based risk.

Elisabeth Daniel, (667) 290–8793, for issues related to the Medicare Prescription Drug Inflation Rebate Program.

Benjamin Picillo or Genevieve Kehoe, *AmbulatorySpecialtyModel@cms.hhs.gov*, or 1–844–711–2664 (Option 4) for issues related to the Ambulatory Specialty Model.

Amy Gruber, (410) 786–1542, for issues related to Ambulance Fee Schedule.

Kati Moore, (410) 786–5471, for inquiries related to the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program (QPP).

Trevey Davis, (410) 786–6600, for inquiries related to the Advanced Alternative Payment Models (APMs) track of QPP.

Jessica Warren, (410) 786–7519, and Lisa Marie Gomez, (410) 786–1175, for inquiries related to the Medicare Promoting Interoperability Program.

Steve Manning, (410) 786–1691, for inquiries related to limiting Medicare coverage of certain individuals.

SUPPLEMENTARY INFORMATION:

Addenda Available Only Through the Internet on the CMS Website: The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2027 PFS final rule, refer to item CMS—1848–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov*.

CPT (Current Procedural Terminology) Copyright Notice: Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT

codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major final rule revises payment policies under the Medicare PFS and makes other policy changes, including to the implementation of certain provisions of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4, March 15, 2025), Further Continuing Appropriations and Other Extensions Act of 2024 (Pub. L. 118–22, November 17, 2023), Consolidated Appropriations Act, 2023 (Pub. L. 117–328, December 29, 2022), Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022), Consolidated Appropriations Act, 2022 (Pub. L. 117–103, March 15, 2022), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018), the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018) and Consolidated Appropriations Act, 2026 (Pub. L. 119–75, February 3, 2026), related to Medicare Part B payment. In addition, this final rule includes other Medicare payment and eligibility provisions described in sections III. and IV.

This final rule updates policies for the Medicare Prescription Drug Inflation Rebate Program codified at 42 CFR parts 427 and 428 consistent with sections 1847A(i) and 1860D—14B of the Social Security Act (the Act). For the Medicare Part B Drug Inflation Rebate Program, this rule describes the identification of the Consumer Price Index for all Urban Consumers (CPI–U) for the payment amount benchmark quarter and the rebate period in certain instances when CPI–U survey data are unavailable and the calculation of the Part B rebate amount in such instances; clarifies the definition of ''first marketed date''; and clarifies that certain skin substitutes would not be excluded from the definition of a Part B rebatable drug. For the Medicare Part D Drug Inflation Rebate Program, this rule describes the identification of the CPI–U for the payment amount benchmark period and applicable period in certain instances when CPI–U survey data are unavailable and the calculation of the Part D rebate amount in such instances; modifies the methodology finalized in the CY 2026 PFS final rule to account for 340B-eligible units for AIDS Drug Assistance Program (ADAP) clients for the applicable period beginning October 1, 2025; and requires Medicare providers and suppliers that are 340B covered entities to submit Part D 340B claims data to the Medicare Part D Claims Data 340B Repository beginning in 2027.

This final rule modifies policies for the Shared Savings Program, which is a voluntary program that started in 2012. The program allows groups of providers and suppliers to form or participate in Accountable Care Organizations (ACOs), and to be held accountable for the quality and total cost of care for an assigned population of Medicare fee-for-service (FFS) beneficiaries.

B. Summary of the Key Provisions

Section 1848 of the Act requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major final rule, we are finalizing RVUs for CY 2027 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes discussions and provisions regarding several other Medicare Part B payment policies, and other policies regarding programs administered by CMS.

Specifically, this final rule addresses:

- Background (section II.A.)
- Determination of PE RVUs (section II.B.)
- Payment for Medicare Telehealth Services (section II.C.)
- Valuation of Specific Codes, Including Potentially Misvalued Codes (PMVC) (section II.D.)
- Redesigning Primary Care to Make America Healthy Again (section II.E.)
- Comprehensive Outpatient Rehabilitation Facility (CORF) Services and KX Modifier Threshold, and Medical Review Threshold (section II.F.)
- Supporting Beneficiaries Planning for Future Medical Decisions (section II.G.)
- Current Procedural Terminology (CPT) Request for Information (RFI) (section II.H.)
- Drugs and Biological Products Paid Under Medicare Part B: Discarded Drugs (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Clinical Laboratory Fee Schedule (CLFS): CAA, 2026 (section III.C.)
- Changes to the Ambulatory Specialty Model (ASM) (section III.D.)
- Limiting Medicare Coverage of Certain Individuals (section III.E.)
- Medicare Prescription Drug Inflation Rebate Program (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Changes to the Regulations Associated with the Ambulance Fee Schedule (section III.H.)
- Request for Information (RFI) on Duplicate Laboratory Testing, Imaging, and Result Sharing and Interoperability (section III.I)
- CY2027 Modifications to the Quality Payment Program Reporting and Data Submission (section IV.)
- Collection of Information Requirements (section V.)
- Regulatory Impact Analysis (section VI.)

C. Summary of Costs and Benefits

Based on our estimates, the Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this final rule is economically significant under section 3(f)(1) of Executive Order 12866. As required by section 1848(d)(1)(A) of the Act, beginning in 2026, there are two separate conversion factors (CFs): one for items and services furnished by a qualifying APM participant (QP) as defined in section 1833(z)(2) of the Act and 42 CFR 414.1305 (referred to as the qualifying APM conversion factor) and another for items and services furnished by clinicians who are not QPs (referred to as the nonqualifying APM conversion factor), equal to the respective conversion factor for the previous year multiplied by the update established under section 1848(d)(20) of the Act for such respective conversion factor for such year. Under these provisions, the 2027 qualifying APM conversion factor represents a projected decrease of $0.62 (−1.83 percent) from the current conversion factor of $33.5675. Similarly, the 2027 nonqualifying APM conversion factor represents a projected decrease of $0.77 (−2.31 percent) from the current conversion factor of $33.4009.

For a detailed discussion of the economic impacts, see section VI., Regulatory Impact Analysis, of this final rule.

D. Public Comments in Response on the CY 2027 PFS Proposed Rule

We received approximately 43,100 timely pieces of correspondence on the CY 2027 PFS proposed rule that appeared in the **Federal Register** on July 14, 2026 (91 FR 43842 through 44557). We received comments from individuals, providers and suppliers, practitioners, and advocacy groups. We provide summaries of the public comments, and our responses are set forth in the various sections of this final rule under the appropriate headings. We note that we received some public comments that were outside the scope of the CY 2027 PFS proposed rule.

II. Provisions of the Rule for the PFS

A. Background

In accordance with section 1848 of the Social Security Act (the Act), CMS has paid for physicians' services under the Medicare physician fee schedule (PFS) since January 1, 1992. The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for Medicare payment for physicians' services.

We note that throughout this final rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expenses, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We refer readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC) and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and changes to the PE methodology in the CY 2007 PFS proposed rule (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour (PE/HR) worked to develop the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty obtained from the AMA's Socioeconomic Monitoring System (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We have stated that we believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology or how the PE/HR data are used. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs nor independent labs participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties are not separately recognized by Medicare, nor

do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2027 PFS Final Rule PE/HR'' on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Under current policy, we allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, under current policy, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

In the CY 2007 PFS final rule with comment period, we implemented the ''bottom up'' methodology for the development of PE RVUs (71 FR 69630–69643). We finalized the use of the work RVU or the clinical labor portion of the direct PE RVU, whichever is greater, to allocate indirect costs. We also finalized a modified formula for a global service (that is, a service with a professional component (PC) and a technical component (TC)) to utilize both the work RVU and the clinical labor PE RVU to allocate indirect costs. As noted in the CY 2007 PFS final rule with comment period, we do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVU and the clinical labor PE RVU. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.

In recent years, as we have conducted analyses aimed at improving the accuracy of payment under the PFS, we have re-examined this longstanding policy that effectively allocates a larger share of indirect PE RVUs to services that can be reported using technical, professional, and global components than to those that cannot. We refer the reader to a report by RAND Corporation, under contract with CMS, which addresses several approaches to improving the accuracy of other PFS services relative to services that have a professional and technical component. This report is available at *https://www.rand.org/pubs/research_reports/RRA4720-2.html*.

This longstanding policy inadvertently advantages services that can be reported using technical, professional, and global components, referred to as ''triplet services'' in the report by RAND Corporation, because indirect PE RVUs are allocated on the sum, whereas services that can only be reported as a global service, referred to as ''non-triplet services'' in the report, depend on the maximum (rather than sum) of clinical labor PE RVUs and physician work RVUs. This is an unintended advantage of the arithmetic required for the global component RVUs to equal the sum of the PC and TC RVUs. As we stated in the proposed rule, we believe it would be more accurate than the current PE methodology to use the same allocation methodology for all PFS services. Therefore, we proposed to allocate indirect PE using both the work RVU and the clinical labor RVU for all services, with the exception of codes with 10- and 90-day global periods, instead of just applying that methodology to those services that can be reported using technical, professional, and global components (typically diagnostic and imaging services). In the description of the calculation of the PE methodology noted later in the section, we indicate the portion of the methodology that would be calculated differently under this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that CMS did not provide a rationale for excluding 10- and 90-day global codes from the proposed revised indirect PE

allocation in the proposed rule. Some commenters stated that the RAND analysis published alongside the proposed rule did not exclude these global codes, disagreed with CMS' exclusion of 10- and 90-day global codes and requested that we finalize their inclusion in the proposal to allocate indirect PE using both the work RVU and the clinical labor RVU for all services. Some commenters supported the exclusion of the 10- and 90-day global period codes from the proposal. They reiterated our ongoing questions and concerns about the current valuation of work and clinical labor RVUs for 10- and 90-day global period codes noted elsewhere in section II.B. of this final rule, and said that the proposed change should not be extended to those codes until the other questions and concerns are addressed. Another commenter requested that the exclusion of the 10- and 90-day global period codes does not further delay the separate work needed to correct documented misvaluation within global surgical payments.

Response: We appreciate the commenters' feedback and note that we inadvertently omitted a specific rationale for their exclusion in the proposed rule. We discussed difficulties and concerns with the global period codes elsewhere in section II.B. of the proposed rule (91 FR 43861) and similarly excluded 10- and 90-day global surgery services from the new ''CY 2027 PFS Proposed Rule Display Only TC PE RVUs'' public use file discussed in the proposed rule. Specifically, the use of bundled payments for the 10- and 90-day global surgery services results in aggregated valuation for all pre-operative, intra-operative, and post-operative services furnished over a defined period (10-, or 90-day global periods), including services by both physician and clinical staff and practice expense without clear visibility into how each component contributes to the total bundled valuation. This is the rationale referenced previously that was inadvertently omitted from the proposed rule.

This unintended advantage of the arithmetic required for the global component RVUs to equal the sum of the PC and TC RVUs has led to concerns of incorrect relativities between PFS services. While the RAND report recommends allocating indirect PE using the sum of work and clinical labor as a default for all services (that is, not just those with TC/PC splits), the report also notes that strategies CMS might pursue to mitigate these concerns could interact with other aspects of Medicare payment policy, leading to unintentional or undesired effects or the need for special adjustments or other consideration for certain PFS services.

Additionally, other RAND reports [1] [2] [3] [4] and recent OIG reports [5] [6] have consistently found that substantially fewer post-operative visits are typically provided to Medicare beneficiaries as part of 10- and 90-day global periods compared to the number of assumed post-operative visits considered in surgical procedure valuation. Including the 10- and 90-day global surgery services in the proposed revised indirect PE allocation would have significantly increased the indirect PE allocated to these services and amplified the payment distortions that result from including too many post-operative visits in global packages because there is work and clinical labor bundled into the valuation associated with the post-operative visits. Similar to how we do not believe codes with technical, professional, and global components should be advantaged over other services by the indirect PE allocation using both the work RVU and clinical labor RVU, we do not believe global period services should be advantaged by the proposal because they have additional work & clinical labor RVUs bundled into their post-operative periods.

Comment: A commenter expressed concern with the proposal, stating that the proposal was aimed at addressing the assertion in RAND's report that the current indirect PE methodology may contribute to overutilization of imaging services. The commenter stated that, absent evidence demonstrating that indirect PE allocation directly affects ordering behavior or utilization patterns, they believe we should proceed cautiously before implementing significant redistributions of RVUs based on assumptions regarding imaging utilization.

Response: We appreciate the commenter's feedback. We note that, as discussed in the proposed rule, this longstanding policy inadvertently advantages services that can be reported using technical, professional, and global components, and is an unintended advantage of the arithmetic required for the global component RVUs to equal the sum of the PC and TC RVUs. We note that we did not propose this change to address any utilization patterns discussed in RAND's report, but rather, to address the longstanding and unintended advantage because we believe it would be more accurate than the current PE methodology to use the same allocation methodology for all PFS services.

Comment: A commenter stated they could not determine whether CMS incorporated this proposed modification into the calculation of PE RVUs for the proposed rule. They stated that, in the separately published Sample Calculation of PE RVUs under Methodology for Selected Codes public use file, CMS indicated that the second component of the indirect PE allocator for CPT code 99213 is based on the work RVU and does not appear to incorporate the clinical labor as proposed.

Response: We appreciate the commenter's feedback and acknowledge the concern. Because this was a proposed change, our methodology public use files, such as the Sample Calculation of PE RVUs under Methodology for Selected Codes and CY 2027 PFS Proposed Rule Practice Expense Algorithm Technical Memo, displayed information regarding the methodology in its current state for the proposed rule, so as to not presume finalization of a proposal without notice and comment rulemaking. We provided the public with Addendum B and CY 2027 PFS Proposed Rule Fully Implemented PE RVUs for full transparency into implementation of these proposals. We also acknowledge that the formula displayed in step (20) of the published Sample Calculation of PE RVUs under Methodology for Selected Codes public use file indicated that the second part of the indirect PE allocator for CPT code 99213 is based on the work RVU but we note that the calculated value displayed in step (21) of the published file is correct. For the final rule, we note that our methodology public use files reflect all finalized proposals.

After consideration of the public comments, we are finalizing our proposal to allocate indirect PE using both the work RVU and the clinical labor RVU for all services, with the exception of codes with 10- and 90-day global periods, instead of just applying that methodology to those services that can be reported using technical, professional, and global components.

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[1] *https://www.rand.org/pubs/research_reports/RRA203-1.html.*

[2] *https://www.rand.org/pubs/research_reports/RRA4720-1.html.*

[3] *https://www.rand.org/pubs/research_reports/RRA203-2.html.*

[4] *https://www.rand.org/pubs/research_reports/RR2941.html.*

[5] *https://oig.hhs.gov/reports/all/2025/cms-should-improve-its-methodology-for-collecting-medicare-postoperative-visit-data-on-global-surgeries/.*

[6] *https://oig.hhs.gov/reports/all/2025/cms-should-confirm-it-is-receiving-medicare-postoperative-visit-data-on-global-surgeries-when-reporting-is-required/.*

(3) Facility and Non-Facility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and non-facility. The methodology for calculating PE RVUs is generally the same for both the facility and non-facility RVUs but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the non-facility PE RVUs. In the CY 2026 PFS final rule (90 FR 49292 through 49296), we finalized a modification in the allocation of indirect PE to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs beginning in CY 2026.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different healthcare providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global direct PE RVUs.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we direct readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.* This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/non-facility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 52983) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning a specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list annually. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

In prior years, we reviewed information submitted during the proposed rule comment period regarding potential additions to the list of expected specialty assignments, to determine whether the specialty assignments commenters recommended were appropriate for the services in question. Our review process has been based on determining if the recommended specialty matched the dominant specialty in the claims data. However, we have long held reservations on whether this was the most accurate method for implementing updates to the expected specialty assignments list. Since these updates to the list were never formally proposed in the proposed rule of each calendar year, there was never an opportunity for interested parties to comment and provide feedback before the assignments were finalized in the final rule. We believe that it would provide greater transparency and more opportunities for public comment if additions to the expected specialty assignments list were instead proposed in each year's proposed rule.

Therefore, we did not finalize any additions to the expected specialty assignments list in the CY 2026 PFS final rule (90 FR 49270). We stated that we would instead review the list of approximately 75 low volume HCPCS codes submitted by commenters and propose additions to the list in this year's CY 2027 PFS proposed rule. We will also review any submissions for inclusion to the expected specialty assignments list by the same February 10th deadline that we have finalized in the past for consideration of RUC recommendations and invoice-based updates to supply and equipment pricing. We believe that synchronizing submissions to the expected specialty assignments list for low volume services with the same annual date used for RUC recommendations and invoice submissions will help standardize the process, while also providing more opportunities for feedback from interested parties by going through the annual comment process.

During the comment period for the CY 2026 PFS rule, several commenters stated that they had performed an analysis to identify all codes that meet the criteria to receive a specialty override under this CMS policy and drafted updated recommendations for codes that meet these criteria. Commenters stated that the purpose of assigning a specialty to these codes was to avoid the significant adverse impact on MP RVUs that results from errors in specialty utilization data magnified in representation (percentage) by small sample size. These commenters submitted a list of approximately 75 low volume HCPCS codes with recommended expected specialty assignments.

After reviewing the information provided by the commenters to determine whether the specialty assignments they recommended were appropriate for the services in question, based on determining if the recommended specialty matches the dominant specialty in the claims data, we proposed the additions to the list of expected specialty assignments for low volume services identified in Table A–B1. We agree with the commenters that, based on claims data, CPT codes 33277 through 33281 and 33287 through 33288 should be crosswalked to the Cardiac Electrophysiology specialty and that CPT codes 93584 through 93588 should be crosswalked to the Interventional Cardiology specialty. We also agree with commenters that CPT code 23077 should be crosswalked to the Surgical Oncology specialty. However, we do not have PE/HR data for these specialties as they were not part of the PPIS when it was conducted in 2007; therefore, we are crosswalking these CPT codes to the closest available specialties (Cardiology for the first two groups of codes and All Physicians for CPT code 23077), as listed on Table A–B1.

We disagree with the commenters on a series of additional suggested assigned specialties. In each case, there was another specialty which was reported more than twice as often in the claims data as the specialty suggested by commenters and in some cases reported as much as five times as often. Therefore, we proposed to crosswalk CPT codes 15135 and 41000 to the Otolaryngology specialty, CPT codes 26118 and 26650 to the Orthopedic Surgery specialty, CPT codes 93025 and 93150 to the Cardiology specialty, and CPT codes 93152 and 93153 to the Pulmonary Disease specialty as these were the dominant specialties in the claims data. These crosswalks are included in Table A–B1.

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TABLE A-B1: PROPOSED NEW ADDITIONS TO THE EXPECTED SPECIALTY ASSIGNMENT LIST

HCPCS	Short Descriptor	Expected Specialty Assignment
0596T	Temp fml iu vlv-pmp 1st insj	UROLOGY
0597T	Temp fml iu valve-pmp rplcmt	UROLOGY
11463	Exc skn hdrdnt ing complex	PLASTIC AND RECONSTRUCTIVE SURGERY
15135*	Drm agrft f/s/n/h/f/g/m 1st	OTOLARYNGOLOGY
20979	Us bone stimulation	PODIATRY
21407	Opn tx orbit fx w/implant	PLASTIC AND RECONSTRUCTIVE SURGERY
22836	Ant thrc vrt body tethrg <7	ORTHOPEDIC SURGERY
22837	Ant thrc vrt body tethrg 8+	ORTHOPEDIC SURGERY
22838	Rev rplc/rmv thrc vrt tethrg	ORTHOPEDIC SURGERY
22860	Tot disc arthrp 2ntrspc lmbr	NEUROSURGERY
23077*	Resect shoulder tumor < 5 cm	ALL PHYSICIANS
23675	Cltx sho dislc neck fx mnpj	ORTHOPEDIC SURGERY
25440	Repair nonu scphd carpl b1	HAND SURGERY
26118*	Rad resect hand tumor 3 cm/>	ORTHOPEDIC SURGERY
26650*	Treat thumb fracture	ORTHOPEDIC SURGERY
27087	Remove hip foreign body	ORTHOPEDIC SURGERY
27393	Lengthening of thigh tendon	ORTHOPEDIC SURGERY
28055	Neurectomy foot	PODIATRY
31032	Explore sinus remove polyps	OTOLARYNGOLOGY
31292	Nsl/sins ndsc med/inf dcmprn	OTOLARYNGOLOGY
32096	Open wedge/bx lung infiltr	THORACIC SURGERY
32141	Remove/treat lung lesions	THORACIC SURGERY
33277*	Insj phrnc nrv stim transvns	CARDIOLOGY
33278*	Rmvl phrnc nrv stim sys	CARDIOLOGY
33279*	Rmvl phrnc nrv stim transvns	CARDIOLOGY
33280*	Rmvl phrnc nrv stim pg only	CARDIOLOGY
33281*	Reposg phrnc nrv stim trnsvn	CARDIOLOGY
33287*	Rmv&rplcmt phrnc nrv stim pg	CARDIOLOGY
33288*	Rmv&rplcmt phrnc nrv stim ld	CARDIOLOGY
33875	Thoracic aortic graft	THORACIC SURGERY
34813	Femoral endovas graft add-on	VASCULAR SURGERY

HCPCS	Short Descriptor	Expected Specialty Assignment
35682	Composite byp grft 2 veins	VASCULAR SURGERY
35881	Revise graft w/vein	VASCULAR SURGERY
36474	Endovenous mchnchem add-on	VASCULAR SURGERY
41000*	Drainage of mouth lesion	OTOLARYNGOLOGY
41530	Tongue base vol reduction	OTOLARYNGOLOGY
42815	Excision of neck cyst	OTOLARYNGOLOGY
43501	Surgical repair of stomach	GENERAL SURGERY
44850	Repair of mesentery	GENERAL SURGERY
45550	Repair rectum/remove sigmoid	COLORECTAL SURGERY
50542	Laparo ablate renal mass	UROLOGY
50951	Endoscopy of ureter	UROLOGY
51570	Removal of bladder	UROLOGY
51880	Repair of bladder opening	UROLOGY
53260	Treatment of urethra lesion	UROLOGY
58580	Transcrv abltj utrn fibrd rf	OBSTETRICS/GYNECOLOGY
61055	Injection into brain canal	DIAGNOSTIC RADIOLOGY
61516	Crnec treph exc cyst sttl	NEUROSURGERY
61889	Ins sk-mnt crnl nstm pg/rcvr	NEUROSURGERY
61891	Rev/rplcmt sk-mnt crnl nstm	NEUROSURGERY
61892	Rmv sk-mnt crnl nstm pg/rcvr	NEUROSURGERY
62281	Treat spinal cord lesion	PHYSICAL MEDICINE AND REHABILITATION
63200	Release spinal cord lumbar	NEUROSURGERY
67550	Insert eye socket implant	OPHTHALMOLOGY
74415	Urography nfs drip&/bls w/nf	DIAGNOSTIC RADIOLOGY
76145	Med physic dos eval rad exps	INTERVENTIONAL RADIOLOGY
76812	Ob us detailed addl fetus	OBSTETRICS/GYNECOLOGY
92583	Select picture audiometry	AUDIOLOGIST
93025*	Microvolt t-wave assess	CARDIOLOGY
93150*	Therapy activation ipnss	CARDIOLOGY
93152*	Interrog&prgrmg ipnss polysm	PULMONARY DISEASE
93153*	Interrog w/o prgrmg ipnss	PULMONARY DISEASE
93584*	Vngrph chd anom/persist svc	CARDIOLOGY
93585*	Vngrph chd azygs/hemiazygs	CARDIOLOGY
93586*	Vngrph chd coronary sinus	CARDIOLOGY
93587*	Vngrph chd vnvn cltrl at/abv	CARDIOLOGY
93588*	Vngrph chd vnvn cltrl below	CARDIOLOGY
95866	Needle emg hemidiaphragm	NEUROLOGY
96203	Mlt fam grp bhv train ea add	PSYCHIATRY
96933	Rcm celulr subcelulr img skn	DERMATOLOGY
G0017	Crisis psychotherapy 60m	PSYCHIATRY
G0018	Crisis psychotherapy add 30m	PSYCHIATRY

* Recommended specialty assignment crosswalked.

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Comment: Several commenters stated that they concurred with CMS that synchronizing submissions to the expected specialty assignments list for low volume services with the same annual date used for RUC recommendations and invoice submissions will help standardize the process, while also providing additional opportunities for feedback through annual rulemaking. Commenters stated that they would submit additional recommendations for CY 2028 rulemaking before the February 10, 2027 deadline.

Response: We appreciate the support for our proposed policy from the commenters.

Comment: Several commenters disagreed with the CMS proposed specialty assignment for the 21 codes where CMS diverged from the RUC's recommended specialty. For CPT codes 15135, 26118, 26650, 93152, and 93153,

commenters stated that, based on the description of work, the list of specialty societies that participated in the RUC survey process, and with respect to the whole population of patients who might receive this service, CMS should use the RUC's recommended specialty assignments even though they were not the top reported specialty in 2024 Medicare claims data.

Response: We disagree with the commenters and continue to believe that the proposed specialty assignments are the more accurate choice for these CPT codes. As we stated in the CY 2018 PFS final rule, we agree that the use of service-level overrides for low volume services would help mitigate annual fluctuations and provide greater stability in the valuation of these services (82 FR 52982). We finalized the creation of this list of assigned specialty for low volume services at this time with the intention of minimizing these annual fluctuations in valuation, not with the goal of matching each CPT code to its idealized specialty. We believe that it is more accurate to assign specialties based on the actual billing practices for each CPT code as reflected in the claims data, not what might have been intended by the CPT Editorial Panel at the time of the code's creation. All five of the CPT codes listed by commenters were reported twice as often by the assigned specialty that we proposed as compared with the RUC's recommended specialty; in the case of CPT code 93152, Pulmonary Disease was reported roughly five times more often than the recommended Cardiac Electrophysiology. We therefore continue to believe that the proposed specialty assignments are the most accurate choices for these codes.

Comment: Several commenters stated that for the approximately 15 CPT codes in Table A–B1 that did not have PE/HR data, CMS should use the available MP premium data and crosswalk the assigned specialty for these codes as recommended by the RUC for MP purposes. The commenters stated that the proposed CMS crosswalks could still be used for PE purposes due to the lack of PE/HR data. Commenters made this request for CPT codes 23077, 33277–33281, 33287, 33288, 93025, 93150, and 93584–93588.

Response: We disagree with the commenters that CMS should establish separate PE and MP crosswalks for the specialty assignment in these cases where there is no PE/HR data available. We specifically finalized this policy in the CY 2018 PFS final rule that we would apply these service-level overrides for both PE and MP, rather than one or the other category. We provided rationale at that time, stating that this would simplify the implementation of service-level overrides for PE and MP, and would continue to address stakeholder concerns about the year-to-year variability for low volume services (82 FR 52982–52983). Our rationale from the CY 2018 PFS final rule continues to apply, but we will continue to address stakeholder concerns as they arise.

Comment: A commenter asked CMS to confirm that low-volume echocardiographic services are assigned to cardiology or pediatric cardiology rather than to a specialty with a materially different cost structure. The commenter requested that CMS provide the underlying utilization crosswalk for these assignments so societies can verify them.

Response: As we noted in the proposed rule, the CPT codes associated with the Cardiac Electrophysiology specialty were all crosswalked to the Cardiology specialty due to a lack of PE/HR data. All of the proposed and finalized expected specialty assignments are included in the CY 2027 public use files associated with the PFS proposed and final rules as detailed previously.

Comment: A commenter requested that CMS add several codes to the expected specialty assignment for low volume services list as part of CY 2028 rulemaking and assign thoracic surgery as their expected specialty.

Response: We appreciate the feedback from the commenter, however we will consider these additional codes for inclusion to the expected specialty assignment list in next year's CY 2028 PFS proposed rule to allow for public comment.

After consideration of the comments, we are finalizing the new additions to the expected specialty assignment list as proposed in Table A–B1.

As noted in the proposed rule, the full list of expected specialty assignments is included in the CY 2027 public use files, which are available on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.*

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

Under current policy, for most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* Under current policy, for global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- Under current policy, the second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

We note that for CY 2026, we finalized a change to the methodology so that when work RVUs are used to allocate indirect PE to the facility RVUs, they are assigned at one-half the amount allocated to the non-facility PE RVUs for that same service. These PE methodology changes are discussed in greater detail in the CY 2026 PFS final rule (90 FR 49292 through 49296).

Proposed Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

The proposed indirect allocator is: indirect PE percentage *(direct PE RVUs/direct percentage) + work RVUs + clinical labor RVUs. The proposed change, as detailed in the proposed rule (91 FR 43842 through 44557), is to include both the work RVUs and clinical labor RVUs in the indirect allocator for all services, except for

codes with 10- and 90-day global periods, as opposed to including the work RVUs and clinical labor RVUs only for global services.

We stated that, if this proposed policy were to be finalized, this Proposed Step 8 would replace the Step 8 listed in the proposed rule (91 FR 43842 through 44557). We note that step was also listed earlier in this final rule. For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes,'' the formulas were divided into two parts for each service.

- The first part is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is the sum of the work RVU and the clinical labor PE RVU, including the methodology change finalized in CY 2026 for services performed in the facility setting (when work RVUs are used to allocate indirect PE to the facility RVUs, they are assigned at one-half the amount allocated to the non-facility PE RVUs for that same service).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Under current policy, calculate the indirect practice cost index (IPCI). We refer readers to the CY 2007 PFS final rule with comment period (71 FR 69633) for more information about the establishment of the IPCI.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 as the denominator and Step 13 as the numerator, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

Proposal regarding Steps 12 through 17: We develop the indirect practice expense (PE) RVUs under the PFS to reflect the relative resources involved in furnishing the services. Since the implementation of the resource-based PE RVUs, we have assumed that aggregate specialty level practice costs derived primarily from the 2007 PE/HR survey data are a reasonable way to help establish the resource-based indirect PE RVUs. We have historically used that data both to allocate indirect costs to each code and to re-scale the resulting PE RVUs for each code at the end of the established methodology to ensure that the overall allocation of PE RVUs for each specialty across the PFS approximates those expected based on the index derived from the PE/HR survey data. Over time, however, we have identified various limitations of the survey data, especially as the data we use has become increasingly dated and are intrinsically limited to small, selective samples based on pre-determined assumptions about where costs are likely to differ, and, as we addressed in CY 2026 PFS rulemaking, have not been adequately updated. (We refer readers to an extended discussion of our concerns with and decision not to update this data in the CY 2026 PFS final rule at 90 FR 49286 through 49292.) This has resulted in a PE methodology that privileges the historic survey data over incorporation of more recent data about specific services and produces unpredictable and counterintuitive results that are not transparent to the public.

Because we have taken various steps to improve the data used in the pricing inputs and the indirect allocation methodologies, we are proposing to remove the steps of the current methodology that rely on the indirect practice cost index (IPCI) from the calculation of the PE RVUs. We proposed this change because the steps of the current methodology that rely on the IPCI calculation effectively favor the aggregate specialty-level survey data over the code level inputs and allocators and consequently limit the influence of improvements to inputs and allocation methodologies. We proposed to implement this change over a 2-year transition period. Specifically, in the first year, only half of the measured variation in the IPCI will be applied to the indirect allocator. In the second year, CY 2028, the IPCI will no longer be applied.

The steps of the current methodology that rely on the IPCI calculation are steps 12 through 17. Thus, under this proposal, steps 12 through 17 would no longer be a part of the calculation, starting for CY 2028, and the total PE RVU, prior to the calculation of final PE RVUs described at Step 18, would be the sum of step 5 (Direct Cost PE RVUs) and step 11 (Indirect Cost PE RVUs).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported removing the IPCI from the PE methodology and agreed with CMS that the underlying data are nearly two decades old and no longer representative of current practice costs. Several commenters agreed that eliminating the IPCI reduces unintended and opaque effects on PE RVUs, and supported the 2-year transition as an appropriate way to mitigate disruption while implementing a more accurate methodology. Multiple commenters strongly supported removal, explaining that the IPCI has historically amplified payment advantages for specialties with higher aggregate indirect costs, such as those tied to expensive equipment, while disadvantaging specialties whose costs are driven primarily by clinical labor activities. A commenter cited its own analysis of the CY 2026 facility-based payment change, finding that specialties with very low facility utilization saw an average 12.4 percent decrease in their IPCI values while specialties with very high facility utilization saw an average 32.2 percent increase. The commenter stated that some specialties experienced PE RVU decreases as a result of how facility-based services were paid that were

opposite of CMS's stated policy intentions and highlighted that the counterintuitive and seemingly unintended decrease in PE RVUs for some specialties as a result of the CY 2026 rule demonstrates that the IPCI can create winners and losers based on unrelated policy changes, rather than actual practice expenses. Other commenters expressed disappointment that CMS did not instead update the underlying PPI Survey data using more recent survey efforts, but supported removing the IPCI in the absence of adoption of the updated survey data because the current methodology privileges antiquated, aggregate specialty-level survey data over code-level inputs and limits the influence of improvements to those inputs.

The Medicare Payment Advisory Commission (MedPAC) also supported eliminating the IPCI, citing its June 2025 report to Congress recommending that CMS improve the accuracy of Medicare's relative payment rates by using timely data that reflect the costs of delivering care, and noting that the IPCI is calculated using PE/HR survey data collected nearly two decades ago. MedPAC further encouraged CMS to seek additional ways to reduce reliance on that survey data, observing that even after IPCI removal, direct PE RVUs would still be multiplied by a ratio of indirect-to-direct PE costs drawn from the specialties billing a service, meaning indirect PE RVUs would remain adjusted based on decades-old, specialty-reported data. MedPAC stated that forgoing specialty-specific practice expense data has the potential to improve payment accuracy and make routine updates more practicable, and cited the AMA's updated PPI and CPI Survey efforts as examples of the difficulty of collecting representative specialty-level data: low response rates led to data based on a small number of practices for some specialties, acceptance of practices that volunteered or were recruited to report data, and inconsistent consolidation of specialty categories. MedPAC stated that these concerns led them to support CMS's decision not to incorporate that updated survey data into the ratesetting process.

Response: We appreciate the commenters' support and feedback on the proposal. We agree with the commenters that the CY 2026 facility indirect PE example illustrates precisely the type of unexpected effect that motivated CMS's proposal to remove the IPCI and believe that this is one of many examples that support removing the IPCI rather than preserving it. We also acknowledge that, while an updated survey may be preferable in principle, the data quality concerns with the available updated survey data support proceeding with removal of the IPCI now . We thank MedPAC for its support and its analysis of the continued role of PE/HR survey data in the indirect PE allocation. We agree with MedPAC that removing the IPCI does not fully eliminate CMS's reliance on this outdated survey data, as discussed further in the section. We may consider, in future rulemaking, additional approaches to reduce reliance on specialty-specific PE/HR data, consistent with the direction of the policies we are finalizing this year.

Comment: Some commenters stated the belief that the IPCI was used to allocate indirect PE and expressed concern that the specialty-specific differences in indirect costs continue to exist, but noted that CMS proposed to eliminate the IPCI without offering a reasonable, empirically supported alternative. Some commenters stated that CMS should not assume indirect costs are similar or equal across specialties without supporting data, citing certain specialties that have indirect costs exceeding what would be expected under a code-level-only approach, and recommended that CMS instead conduct its own updated survey of indirect costs rather than eliminate the IPCI.

Response: Some commenters seem to be confused that we proposed to remove all specialty-specific PE/HR data and we want to clarify that is not the case. As described previously, we still use the specialty-specific data to allocate indirect PE, but removing the IPCI means we would no longer re-scale the resulting PE RVUs to an index derived from the outdated survey data. The IPCI functions to force changes that would otherwise occur in indirect PE (that is payments for office overhead such as administrative staff and rent that cannot be directly attributed to individual services) back to the status quo, which is currently based on the physician overhead contained in the 2007 AMA Physician Practice Information (PPI) Survey. However, the continued use of the IPCI has resulted in a PE methodology that privileges the historic survey data over incorporation of more recent data about specific services, limits the influence of improvements to inputs and allocation methodologies, and produces unpredictable and counterintuitive results that are not transparent to the public. We proposed to remove the IPCI from our methodology for CY 2027 over a 2-year transition period, though for now we would retain the use of the survey data in other places in the methodology, as discussed previously. We continue to believe this proposed change will improve the transparency and stability of PE RVUs over time and better position us to make necessary refinements to the PE methodology to improve the accuracy of valuation of the PE portion of services paid under the PFS.

In the proposed rule, we acknowledged that the IPCI, because it is rooted in static PE/HR data, effectively resulted in stabilizing year-to-year changes in PE RVUs, especially due to changes in input valuations and changes to allocation methodologies, which is why we proposed the PE stabilization adjustment to further improve predictability and reduce volatility within the PE RVUs. We note that our proposal to eliminate the IPCI was not solely based on the age of the survey data, but also based on the fact that the IPCI can result in counter-intuitive payment outcomes and is a barrier to broader payment changes.

We do not agree that CMS should instead conduct a new survey of specialty-level indirect costs before removing the IPCI. As discussed previously in connection with MedPAC's comment, recent efforts to collect updated, representative specialty-level practice expense data encountered low response rates, relied on practices that volunteered or were recruited rather than being randomly sampled, and inconsistently consolidated specialty categories. We do not believe commissioning another specialty-level survey would resolve these structural difficulties, and we do not believe it is appropriate to delay improvements to the current methodology. We also do not agree that removing the IPCI assumes indirect costs are identical across specialties. Rather, our proposal reflects the conclusion that the IPCI is not a reliable means of capturing any genuine specialty specific variation in indirect costs that may exist, because it re-scales a code's indirect PE based on the mix of specialties that happen to bill it in claims data, not based on a direct measurement or acceptable proxy for the indirect costs those specialties incur in furnishing that specific service. We continue to believe that removing the IPCI results in PE RVUs that more accurately reflect the indirect resources a service requires.

Comment: Many commenters opposed removal of the IPCI or asked CMS to delay finalizing the proposal. Several commenters asked CMS to explain why a 2-year transition is sufficient given the scale of redistribution among specialties, and asked CMS to compare

payment trajectories under 2-year and 4-year transitions, noting that CMS has historically used four-year transitions for significant PE methodology changes, including the CY 2007 transition to the bottom-up PE methodology and the CY 2010 incorporation of Physician Practice Information Survey data. A commenter, while not opposing removal of the IPCI outright, stated that CMS should publish detailed impact analyses and supporting data before finalizing the proposal, and that if CMS proceeds, a stabilization mechanism is essential to prevent disruptions in PE that could jeopardize practice stability and patient access to care. Other commenters stated that CMS has not published code- and specialty-level impact analyses of the IPCI removal in isolation from the other proposed PE changes, making it difficult for stakeholders to evaluate the proposal's actual effects, and requested that CMS delay finalization until it demonstrates, through empirical validation and transparent impact analyses, that removing the IPCI produces more accurate resource-based relativity rather than assuming that eliminating an older data source necessarily improves accuracy.

Response: We recognize that the aggregate specialty impact tables published with the proposed rule do not isolate the effect of IPCI removal from our other PE proposals because all three policies affect PE RVUs concurrently. We agree with commenters that these proposals are interconnected and interact with one another, and therefore, we could not publish disaggregated specialty impact tables of each proposal individually without misconstruing their combined impact when they are implemented together. We note that, in the past, we have published impact tables for different alternatives considered, but we do not typically publish disaggregated policy impacts because of how these policies may interact.

We note that we published code-level impacts in the CY 2027 PFS Proposed Rule Fully Implemented PE RVUs public use file. While we have used 4-year transitions in the past to temper impacts over time, the proposed 5% PE stabilization adjustment proposed for CY 2027 already functions to phase in the changes to the PE RVUs and temper impacts over time. For example, for codes that experience large increases or decreases as a result of our PE methodology proposals, and are not the result of a revaluation, the PE stabilization adjustment effectively serves to phase in those changes over many years, often exceeding the 4-year transition we have used in the past. We acknowledge that this may not be the desired implementation for specialties that benefit from the proposed PE methodology changes, but we believe this results in a reasonable balance between safeguarding against significant, unintended payment volatility while still allowing meaningful progress toward more accurate PE valuations within a reasonable timeframe. We note that this 2-year transition, which phases in the removal of steps 12 through 17, is a distinct mechanism from the PE stabilization adjustment discussed later in the section, which separately caps the year-to-year change in any code's PE RVU. The two mechanisms work together: the 2-year transition sets the pace at which the IPCI's influence is phased out of the methodology, while the PE stabilization adjustment independently moderates how quickly any resulting change reaches a given code's final PE RVU.

Comment: A commenter requested that CMS detail how we would treat Non-Physician Practitioners (NPPs) under this new methodology. They stated that NPPs' specialty is obscured in the claims data because they are not able to be associated with their specialty when they enroll.

Response: As stated later in the section, to calculate the PE and MP RVUs, we exclude certain specialties, such as NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. However, these specialties are still included to calculate the BN adjustment.

After consideration of public comments, we are finalizing the proposal to remove steps 12 through 17 that rely on the IPCI from the calculation of the PE RVUs over a 2-year transition period, as proposed.

(d) Calculate the Final PE RVUs

Step 18: Under current policy, add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this final rule). Under the proposed policy, add the direct cost PE RVUs from Step 5 to the indirect cost PE RVUs from Step 11 and apply the final PE BN adjustment.

Proposed Step 19: Calculate and apply the PE stabilization adjustment for each PE RVU by comparing the result of step 18 with the results of the prior year's PE RVUs from step 18. As described in the proposed rule, we proposed to remove the IPCI from the PE methodology, which we believe will improve the transparency and stability of PE RVUs over time. However, we recognize that the IPCI, because it is rooted in static PE/HR data, effectively resulted in stabilizing year-to-year changes in PE RVUs, especially due to changes in input valuations and changes to allocation methodologies. We have long noted that extreme volatility in PE RVUs can have unintended consequences and distortions. To mitigate volatility that could otherwise occur, we proposed a PE stabilization adjustment to further improve predictability and reduce volatility within the PE RVUs. Specifically, we proposed that the PE RVU calculated after the application of the cognitive services floor and any adjustments that occur outside of the PE methodology will be subject to a cap and will not increase or decrease by more than 5 percent each year. In the proposed Step 19 we would compare the PE RVU after the application of the cognitive services floor and any code-level adjustments in the current ratesetting year to the allocation methodology from the prior year and then apply the 5 percent cap. We note that the proposed PE stabilization adjustment in Proposed Step 19 will be applied prior to the statutory phase-in of significant RVU reductions required by Section 1848(c)(7) of the Act, discussed in more detail later in this section, which limits all codes that are not new or revised to a 19 percent decrease in total RVU in an individual calendar year. Therefore, a code may be impacted by both the PE stabilization adjustment and the statutory phase-in, meaning a code's PE RVU may ultimately differ by greater than the PE stabilization adjustment detailed in proposed Step 19.

This proposed adjustment would not apply to new and revised codes or codes formerly contractor priced that are newly nationally priced, because it is not clear what the comparison PE RVU would be for those codes. Because we believe the benefits of the PE stabilization adjustment would ideally apply to new and revised codes and newly nationally priced codes, we sought comment on an approach that would allow us to expand the PE stabilization adjustment to these categories of codes.

Additionally, the proposed PE stabilization adjustment would not

apply to revalued codes because we believe the statutory phase-in sufficiently limits large reductions to individual codes undergoing review and/or revaluation, and limits the amount of time a revalued code would remain under or overvalued by being significantly constrained from reductions found to be appropriate through revaluation.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that CMS should identify the codes subject to the PE stabilization adjustment and the codes' final PE RVUs, similar to our published public use file of codes subject to the statutory phase-in of significant RVU reductions.

Response: We appreciate commenters' feedback and note that we are publishing this list as a public use file with this final rule, which can be found under the Downloads section for this rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

Comment: A commenter stated that they support the idea of adding a PE stabilization adjustment to the PE RVU methodology to mitigate volatility in PE RVUs and avoid unintended consequences. The commenter requested further explanation of how the proposed adjustment would operate and its relationship to the existing phase-in of significant RVU reductions. Multiple commenters requested that we exempt increases to direct PE inputs from the PE stabilization adjustment when supported by higher supply or equipment prices validated through the invoice submission process to ensure that direct PE resource costs are fully reflected in PE RVUs. Another commenter supported the proposal to establish a PE stabilization adjustment to safeguard against unintended payment swings while allowing CMS to continue modernizing the PE methodology, but stated that a 2 to 3 percent adjustment would be more appropriate, particularly for CY 2027 because CMS proposed multiple changes to the PE methodology. The commenter also supported CMS' consideration of extending the PE stabilization adjustment to new and revised codes and codes that are newly nationally priced and encouraged CMS to develop an appropriate methodology for providing comparable protection to newly established services without compromising the accuracy of their initial valuations. Another commenter requested that CMS extend the proposed PE stabilization adjustment to revalued codes, or at a minimum, to codes revalued on a single direct PE input cost change rather than a full RUC survey, and stated that the statutory phase-in of significant RVU reductions is not a sufficient cushion. Another commenter stated that we should modify the PE stabilization adjustment to either have a fixed duration or larger percentage because, as proposed, limiting annual changes to 5 percent would mean that, for the commenter's most commonly billed codes, it would take nearly a decade of phase-in before the RVUs fully reflected their current, updated valuation. The commenter recommends a 4-year, 5 percent PE stabilization adjustment that allows providers to prepare for the updated code values.

Response: We agree with the commenters that changes due to revaluation, such as changes to a code's direct PE prices, should be exempt from the PE stabilization adjustment. As noted previously, the PE stabilization adjustment will not apply to revalued codes, such as the commenter's example of PE input changes, because we believe the statutory phase-in sufficiently limits large reductions in total RVUs to individual codes undergoing review and/or revaluation. This exemption also limits the amount of time a revalued code would remain under- or overvalued by being significantly constrained from increases or reductions found to be appropriate through revaluation. Although revalued codes are excluded from the PE stabilization adjustment, significant decreases in total RVUs are statutorily phased-in for codes that are not new or revised. As the commenter mentioned, for CY 2027, we proposed changes to the supply code SA119's price, which decreased the PE RVU for CPT code 97610 (*Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day*). Because this reduction was the result of revaluation of the code's supply input, CPT code 97610 is exempt from the PE stabilization adjustment, but the statutory phase-in of significant total RVU decreases does apply because it is an existing code, not new or revised, whose total RVU decrease is greater than 19 percent. We do not agree with the commenter that we should apply the PE stabilization adjustment in these instances because it would extend the amount of time that a code would remain constrained from increases or reductions found to be appropriate through revaluation. Conversely, the PE RVU for CPT code 99285 (*Emergency department visit for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making*) will increase as the result of our proposed PE methodology changes (that is, removal of IPCI). It is not subject to the 19 percent statutory phase-in of significant RVU decreases because it is an increase, but it is subject to the 5 percent PE stabilization adjustment and the increase will be effectively phased-in by that policy. We encourage interested parties to review the additional public use file provided with this final rule that details the codes subject to the PE stabilization adjustment.

We appreciate the commenters' request for further explanation of how the PE stabilization adjustment interacts with the existing statutory phase-in of significant RVU reductions. As illustrated by the examples noted previously, the two policies operate independently and apply to different sources of RVU change: the statutory phase-in applies to a code's total RVU decrease, and is implemented on the PE RVU, while the PE stabilization adjustment applies specifically to changes in PE RVUs, typically resulting from methodological changes rather than code-by-code changes (that is, the sum-based indirect PE allocation and removal of the IPCI proposed for CY 2027), and does not apply when the change results from revaluation. A code may therefore be subject to one, both, or neither policy depending on the source and magnitude of its RVU changes for a given year, although we note that it is unlikely for a code to be subject to both since revalued codes are exempt from the PE stabilization adjustment, which is the most likely source of significant decreases in total RVUs greater than 19 percent. The PE stabilization adjustment is primarily intended to mitigate volatility and improve predictability of the PE RVUs that result from changes to the PE methodology.

We appreciate the commenters' feedback about considering alternative higher and lower percentages and a fixed duration of the PE stabilization adjustment. However, as discussed previously, we believe 5 percent is a reasonable balance between safeguarding against significant, unintended payment volatility while still allowing meaningful progress toward more accurate PE valuations within a reasonable timeframe, and we are finalizing the PE stabilization adjustment at 5 percent as proposed. We are not extending the PE stabilization adjustment to new, revised, or newly nationally priced codes at this time

because it is not clear what the comparison PE RVU would be for those codes. However, we remain interested in a methodology that would extend the PE stabilization adjustment to these services and invite stakeholders to share methodological approaches for us to consider in future rulemaking.

After consideration of public comments, we are finalizing the proposals to remove steps 12 through 17 that rely on the IPCI from the calculation of the PE RVUs over a 2-year transition period, and to add a new step to the PE methodology to apply a 5 percent PE stabilization adjustment to the PE RVUs, as proposed.

Step 20: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs must be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year 1 reduction for the service to the maximum allowed amount (that is, 19 percent) and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

In summary, for CY 2027, we proposed, and have now finalized our proposals to:

- Modify step 8 to calculate indirect PE based on both work RVUs and clinical labor RVUs for all services except 10- and 90-day global period codes;
- Remove steps 12 through 17 that rely on the IPCI from the calculation of the PE RVUs over a 2-year transition period, and;
- Add a new step to apply a PE stabilization adjustment to the PE RVUs (new step 19).

(e) Setup File Information

- Specialties excluded from ratesetting calculation: To calculate the PE and MP RVUs, we exclude certain specialties, such as NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included to calculate the BN adjustment. They are displayed in Table A–B2.

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TABLE A-B2: SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, for example, private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (for example, drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	Skilled nursing facility
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

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- *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual technical component (TC) and professional component (PC or 26) modifiers:* Flag the services that are PC and TC services but do not use TC and PC/26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- *Payment modifiers:* In the CY 2013 PFS final rule with comment period (77 FR 68901), we introduced a more detailed methodology for adjusting volume and time to account for payment modifiers and other special payment rules, such as multiple procedure payment reductions, in the utilization data. We proposed that, beginning in CY 2027, we would utilize a new approach to account for payment modifiers and other special payment rules. For each paid claim line, we would calculate the ratio of allowed charges to the national PFS payment amount. This would account for differences resulting from payment modifiers and other special payment rules, as well as differences in geography. We proposed to use the same ratio to adjust time, rather than a separate calculation under our current methodology, with the exception of anesthesia, for which we calculate time using only procedures with modifiers indicating they are personally

performed. These proposed changes will allow us to more accurately capture any combination of modifiers and special payment rules and automatically account for updates in modifiers and/or special payment rules in future years. These proposed changes have a very minimal impact on the resulting PE RVUs but will produce a more accurate result. As under our current methodology, the adjusted volume will be displayed in the utilization public use file that is posted in conjunction with each PFS rule.

Comment: Several commenters identified large declines in the total allowed charges displayed for certain specialties, such as Pathology Independent Laboratories, and Physical and Occupational Therapy, in Table D–B5 ''Estimated Impact on Total Allowed Charges by Specialty'' of the CY 2027 PFS proposed rule (91 FR 44244–44248). Commenters stated that nothing in the PFS proposed rule appeared to explain declines of this scale and the figures seemed inconsistent with the considerably smaller percentage payment effects reported elsewhere in the table. Commenters asked whether these estimates arose from a reporting error or resulted from a change in data or methodology in the proposed rule.

Response: We appreciate commenters raising this issue. We identified and corrected a minor technical error that impacted the adjusted utilization of codes that are frequently furnished in multiple MTUS (miles, time, units), such as codes reported in time or square centimeter increments. This technical error in the adjusted utilization resulted in erroneous decreased allowed charges in Table D–B5 of the proposed rule for specialties that bill these types of codes like the specialties that commenters raised concerns about. We appreciate the feedback from interested parties in identifying this error, which has been corrected in the adjusted utilization for the final rule.

Comment: Some commenters noted that CMS has published detailed modifier-specific utilization data in the public use files with each proposed and final PFS rule for decades. Commenters expressed concern that CMS excluded all modifiers except for -26, -TC, and -53 in the utilization data public use file for this proposed rule, which commenters say is particularly challenging when CMS proposed changes to modifier 25 and for HCPCS code G2211 to instead be reported with modifiers. Commenters recommend that CMS change the ''CY 2027 2025 Utilization Data Crosswalked to 2027'' to include all modifiers to maintain a sufficient level of transparency for interested parties. Several commenters requested that CMS consider providing additional supporting materials such as utilization crosswalk files between the current and previous years. The commenters also requested the restoration of utilization file fields (such as undiscounted allowed services, PE, MP, and work discounted allowed services, and complete modifier columns).

Response: We no longer display the work, PE, and MP adjusted allowed services columns in the Utilization Data file because of our proposed changes to the adjusted utilization process, described previously. The proposed approach to calculate the ratio of allowed charges to the national PFS payment amount to adjust utilization means that all current payment modifiers, special payment rules, and geographic adjustments are accounted for in column G of the utilization data public use file. Additionally, the new columns H and I are discussed in the proposed rule at 91 FR 44248. Because the modifier -25 (column H) and modifier B1 (referred to as MOD1 in the proposed rule) and modifier B2 (referred to as MOD2 in the proposed rule) (column I) proposals impact adjusted utilization, they are also accounted for in the utilization data public use file, but we believed it would be best to publish these new columns separately to help commenters understand the impact of the proposals. As a result, Column J is the cumulative adjusted utilization of columns G, H, and I that was used in CY 2027 PFS ratesetting, effectively accounting for our proposed new approach to adjust utilization for current payment modifiers, geographic adjustments, and special payment rules, plus our proposed changes to modifier 25, modifier B1 (referred to as MOD1 in the proposed rule) and modifier B2 (referred to as MOD2 in the proposed rule). As the commenter mentioned, modifiers -26, -TC, and -53 (for select services) remain in the utilization data file because codes with these modifiers are listed with separate base RVUs in the payment files (that is, Addendum B) before any modifiers are applied, which distinguishes them from all other payment modifiers and geographic adjustments which typically impact payment for a claim at the time of processing.

We appreciate the commenters' feedback about the additional supporting materials that would be helpful for interested parties and may consider for future rulemaking. In an effort to improve transparency, we are including both allowed services and MTUS in the file for the final rule. We note that, for the proposed rule, the unadjusted and adjusted allowed services columns were inadvertently mislabeled and actually represented unadjusted and adjusted MTUS. For the purposes of ratesetting, for non-anesthesia services, MTUS represent the unit for which PFS rates are established and are the correct measure of service utilization. For the final rule, we have added allowed services to the file for reference since it reflects the number of times the service was provided, regardless of the number of units reported for each service, although it is not used in ratesetting. Anesthesia services do not have RVUs or payment amounts listed in our payment files but are included in the total RVU pool used to establish budget neutrality. To accomplish this, we use allowed services and calculate RVUs based on average allowed charges by service to capture anesthesia spending within the ratesetting process. Therefore, the file does not report MTUS for anesthesia services, only allowed services, which are reflected in the value in Column J of adjusted utilization file, which is used in ratesetting.

Comment: A commenter did not support the proposed new approach to account for payment modifiers and other special payment rules and requested that CMS eliminate all geographic adjustments from the PFS except for those designed to achieve a specific public policy goal (for example, to encourage physicians to practice in underserved areas). To the extent the proposed new approach to accounting for payment modifiers and other special payment rules also accounts for and potentially adjusts RVUs based on geography, the commenter opposed the proposal and would, instead, recommend that CMS continue to use its current approach or otherwise find an approach that does not further geographically adjust Medicare payments.

Response: Section 1848(e)(1)(A) of the Act requires us to develop Geographic Practice Cost Indices (GPCIs) to measure relative cost differences among localities compared to the national average for each of the three fee schedule components (that is, work, practice expense (PE), and malpractice (MP)), therefore, we do not have the statutory authority to eliminate all geographic adjustments from the PFS. Additionally, utilization at the geographic level has always been used in PFS ratesetting, but the new proposed approach allows us to more accurately capture any combination of modifiers, geographic adjustments, and special payment rules in the claims data that underpins PFS ratesetting.

Comment: A commenter stated that, when CMS transitioned to the PE methodology in CY 2007, utilization was assigned exclusively to physical therapy, not to the previously combined ''physical and occupational therapy practice expense pool.'' All prior crosswalks had been to PT and OT, and no policy rationale was given for dropping OT from the crosswalk in 2007. The commenter stated that this methodology resulted in all therapy treatment codes where OT or speech language pathology (SLP) account for the majority of billing volume, receiving PT's IPCI, which is the lowest of the three therapy disciplines. The commenter stated that even under the CY 2027 proposal to remove the IPCI over 2 years, the crosswalk continues to matter during the transition year as half the IPCI will still be applied, and the utilization crosswalk ensures that it will be applied at PT's lower index rather than the actual specialty blend, and requested for CMS to remove the following step when establishing the final CY 2027 setup file: ''Physical therapy utilization: Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy''.

Response: We did not propose to change how utilization is assigned to the therapy specialties for IPCI purposes, a policy which was finalized in CY 2007 rulemaking (71 FR 69635), and we are not finalizing a change since CY 2027 will be the only transition year before the elimination of the IPCI for CY 2028. We believe that this issue identified by the commenter provides an example of the public confusion and counterintuitive results associated with the IPCI which is why we proposed to transition away from its use.

After consideration of the comments, we are finalizing the new approach to account for payment modifiers and other special payment rules, as proposed, with the minor technical error identified corrected for the final rule.

- *Work RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 − (1/((1 + interest rate) − life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally, 150,000 minutes.
usage = variable, see discussion later in this final rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion later in this proposed rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, (85 FR 84482 through 84483) we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding data sources containing equipment maintenance rates, commenters could not identify an auditable, robust data source that CMS could use on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, in the proposed rule, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted in the CY 2026 PFS proposed rule (90 FR 32593) that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table A–B3.

TABLE A-B3: SBA MAXIMUM INTEREST RATES

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We did not propose and we are not finalizing any changes to the equipment interest rates for CY 2027.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

We have long stated that we believe that the MEI is the best measure available to determine the relative weights of the three components in payments under the PFS—work, practice expense (PE), and malpractice (MP). Accordingly, we believe that to ensure that the PFS payments reflect the relative resources in each of these PFS components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the cost share weights in the Medicare Economic Index (MEI). Accordingly, we have finalized to accomplish this (78 FR 74241 through 74242) by holding the work RVUs constant and adjusting the PE RVUs, MP RVUs, and conversion factor (CF) to produce the appropriate balance in RVUs among the three PFS components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. Historically, as the MEI cost shares are updated, we have proposed to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the MEI cost share weights, and to recalibrate the relativity adjustment that we apply in step 18 as described in the CY 2023 PFS final rule (87 FR 69414 and 69415) and CY 2014 PFS final rule (78 FR 74236 and 74237). The most recent recalibration was done for the CY 2014 RVUs.

However, due to overarching concerns with the data as described in the CY 2026 PFS final rule (90 FR 49287 through 49293) and our previously described policy goal to balance PFS payment stability and predictability with incorporating new data through routine updates to the MEI, we finalized our proposal to maintain the current PE/HR and 2006-based MEI cost shares (rather than transitioning to the 2017-based MEI cost shares). Additionally, for CY 2027, we proposed to continue to use the current PE/HR and 2006-based MEI cost shares for CY 2027 PFS ratesetting. We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Few commenters requested that we implement the 2024 PPI and CPI Survey PE/HR data and cost shares in PFS ratesetting for CY 2027. Several commenters requested that we update the cost shares to the most currently available MEI. Several commenters supported our proposal to continue using the current PE/HR and 2006-based MEI cost shares for CY 2027 PFS ratesetting, or until the 2024 PPI Survey data may be considered. Some commenters stated that we should not implement the PPI and CPI Survey data until the issues discussed in the CY 2026 final rule have been addressed.

Response: We agree with commenters that we should continue using the current PE/HR and 2006-based MEI cost shares for CY 2027 PFS ratesetting, and may consider the commenters' feedback in future rulemaking as we consider data to update the cost shares.

After consideration of the public comments, we are finalizing our proposal to continue to use the current PE/HR and 2006-based MEI cost shares for CY 2027 PFS ratesetting.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2027 direct PE input public use files, which are available on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve the relativity of values among codes. For example, as medical practice and technologies change over time, standards could be updated simultaneously for all codes with the applicable clinical labor tasks instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and

exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on the number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we believe that the three total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. We direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 through 59464) for additional details.

Following the publication of the CY 2020 PFS proposed rule, a commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. We direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584) for additional details.

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time, and among the medical specialties developing the recommendations. These variations have made it difficult for the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC mandated the use of a new PE worksheet for its recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations helps us simplify and standardize the hundreds of clinical labor tasks currently listed in our direct PE database. To facilitate rulemaking for CY 2027, we are displaying the Labor Task Detail public use file that contains the current listing of clinical labor activity codes. This file is available on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update using information developed by our contractor which updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule, we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY PFS 2019), 50/50 percent (CY PFS 2020), 75/25 percent (CY PFS 2021), and 100/0 percent (CY PFS 2022) split between new and old pricing. We believe that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy while maintaining stability and allowing interested parties to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule

with comment period (83 FR 59473 through 59480).

For CY 2027, we proposed to update the price of nine supplies and two equipment items in response to the public submission of invoices following the publication of the CY 2026 PFS final rule. These supply and equipment items with updated prices are listed in the valuation of specific codes section of the final rule under Table A–D9, CY 2027 Invoices Received for Existing Direct PE Inputs.

These proposed pricing updates included a request from the RUC to update the pricing of the moderate sedation pack (SA044) to more accurately reflect its components. The RUC determined that a sterile gown is not needed as part of the moderate sedation pack, however, a regular staff gown should be included to protect the sedation provider from all body fluids, substance, and excretions. The RUC also requested that a mask would be an appropriate addition in the sedation pack, resulting in a price change from the current $19.20, minus the $5.13 sterile gown, plus the $1.19 staff gown and $0.43 mask, for a new total price of $15.69. We proposed this $15.69 price for the SA044 moderate sedation pack which is reflected in Table A–D9, CY 2027 Invoices Received for Existing Direct PE Inputs.

Additionally, we received a potentially misvalued code (PMVC) nomination for SA119 kit, low frequency ultrasound wound therapy (MIST) and proposed an updated supply cost from $320.18 to $100 for SA119. We refer readers to section II.D. of this final rule for more information about this proposal.

Comment: Many commenters stated that they approved of the proposed pricing changes included in the CY 2027 PFS proposed rule. Different commenters stated their approval for the proposed change in pricing for the aquatic therapy pool (EQ050), the liposorber system (EQ174), the Universal Detection Kit (SA117), the Varithena admin pack (SA125), the Varithena (foam) (SD324), the Dorsal SI Joint Arthrodesis Implant (SD356), and the Esketamine (56 mg vial) (SH109) and Esketamine (84 mg vial) (SH110) supplies.

Response: We appreciate the support for our proposed pricing from the commenters.

Comment: A commenter stated that the existing supply cost for the purified protein derivative (SH059) supply falls short of covering the cost of the product, leading many pediatric practices to stop purchasing the product and potentially reducing patient access to tuberculosis skin testing. The commenter requested that CMS increase the supply cost for the SH059 purified protein derivative supply to better reflect the actual cost paid by practices and align payment with current market pricing; to this effect, the commenter submitted five invoices with updated pricing information.

Response: We appreciate the submission of these invoices from the commenter to assist in updating the price of the SH059 supply. In reviewing these invoices, we determined that they averaged out to a price of $138.60 by selling 10 doses in 1 mL vials, a substantial increase over the current $26.11 price for the SH059 supply. We were able to find unit prices of $36.70 and $51.44 when the product was sold in 50 doses of 5 mL vials which average together for a price of $44.07. Since we believe it would be more typical to purchase the SH059 in larger batch sizes given the considerable cost savings, we are finalizing an update in the price at the averaged $44.07 rate, which we note still constitutes a pricing increase of roughly 70% for the SH059 supply.

Comment: A commenter submitted invoices reflecting the costs associated with furnishing the SleepioRx product, together with a request to create a new direct PE supply code that refers to validated pricing for SleepioRx. The commenter stated that there was a lack of consistent contractor pricing for HCPCS code G0552 (*Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan*) which uses this supply item and therefore creates an access barrier to Medicare beneficiaries with insomnia. The commenter urged CMS to establish a direct PE input supply code for SleepioRx, based on the submitted invoices and provide billing guidance to the Medicare Administrative Contractors (MACs).

Response: We appreciate the submission of these invoices from the commenter. We note that a supply code for this product was finalized last year in the CY 2026 PFS final rule, using the name ''Digital mental health device (insomnia)'' and using the supply code SD386 (90 FR 49460). This supply is currently not assigned to any CPT codes since HCPCS code G0552 is contractor priced and therefore cannot include any direct PE inputs; we did not propose to establish national pricing for HCPCS code G0552 and we are not finalizing a change in its contractor priced status at this time. However, we will update the price of the SD386 supply based on the invoices submitted by the commenters at a new price of $400.00. The SD386 supply is listed along with the other updated supply and equipment prices under Table A–D9, CY 2027 Invoices Received for Existing Direct PE Inputs.

Comment: A commenter requested that CMS establish new direct PE supply and equipment codes for the TearCare System, a technology that is used to perform the interventional procedure reported with CPT code 0563T (*Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral*) to treat dry eye disease (DED) due to meibomian gland dysfunction (MGD). The commenter specified that they were not requesting that CMS establish national pricing for CPT code 0563T, instead stating that establishing supply and equipment codes for these devices would provide greater transparency and consistency in valuation, support more uniform reimbursement policies nationwide, and better align payment with the resources associated with performing the procedure among the Medicare Administrative Contractors (MACs). The commenter submitted 16 invoices to support the establishment of these new supply and equipment codes associated with the resources used to furnish CPT code 0563T.

Response: We appreciate the submission of these invoices from the commenter with additional pricing information. After reviewing the invoices, we are finalizing the establishment of a new supply code for Smart Lids (SD397) at a price of $1000 and a new equipment code for a Smart Hub (EQ423) at a price of $6583.33 based on an average of the submitted invoices. As the commenter noted, these new direct PE inputs are currently not assigned to any CPT codes since CPT code 0563T is contractor priced and therefore cannot include any direct PE inputs. However, we have added them to the ratesetting database as requested by the commenter and they will appear in Table A–D10: CY 2027 Invoices Received for New Direct PE Inputs.

Comment: Several commenters submitted a series of invoices in support of establishing nonfacility pricing for CPT code 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation*) along with related CPT codes 65820, 66174, 66982, 66989, and 66991. Commenters stated that these invoices substantiated the direct PE costs of

performing cataract surgery and requested that CMS use them to develop nonfacility pricing for these codes.

Response: Although we appreciate the submission of these invoices from the commenters, we did not propose to establish nonfacility pricing for CPT code 66984 or any of the other related codes listed by the commenters. The submitted invoices included pricing for several dozen supply and equipment items, including some costs which are considered to be indirect under the current PE methodology such as building construction costs and service/licensing fees. It is unclear whether these invoices were intended to update the pricing for current supply and equipment items or establish new supply/equipment codes, as well as which items were intended to be associated with cataract surgery. We are not finalizing the creation of nonfacility pricing for CPT code 66984 or any of the other related codes listed by the commenters at this time; we remind interested parties that if they have reason to believe that individually services are inaccurately priced, we encourage them to submit a request under the potentially misvalued code initiative discussed elsewhere in this rule.

(1) Invoice Submission

We remind readers that we routinely accept public submissions of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often, these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, as noted in the proposed rule we considered invoices submitted as public comments during the comment period following the publication of the CY 2027 PFS proposed rule and will consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

(2) Supply Pack Pricing Update

Interested parties previously notified CMS that they identified numerous discrepancies between the aggregated cost of some supply packs and the individual item components contained within. The interested parties indicated that CMS should rectify these mathematical errors as soon as possible to ensure that the sum correctly matches the totals from the individual items, and they recommended that we resolve these pricing discrepancies in the supply packs during CY 2024 rule. The AMA RUC convened a workgroup on this subject and submitted recommendations to update pricing for a series of supply packs along with the RUC's comment letter for the CY 2024 rule cycle.

We appreciated the additional information and RUC workgroup recommendations regarding discrepancies in the aggregated cost of some supply packs. However, due to the projected significant cost revisions in the pricing of supply packs and because we did not propose to address supply pack pricing in the CY 2024 proposed rule, we stated in the CY 2024 final rule that this issue would be better addressed in future rulemaking. For example, the cleaning and disinfecting endoscope pack (SA042) is included as a supply input in more than 300 HCPCS codes, which could have a sizable impact on the overall valuation of these services, and which was not incorporated into the proposed RVUs published for the CY 2024 proposed rule. We stated that interested parties would be better served if we comprehensively addressed this topic during future rulemaking in which commenters could provide feedback in response to proposed pricing updates (88 FR 78833 through 78834).

For CY 2025, we proposed implementing the supply pack pricing update and associated revisions as recommended by the RUC's workgroup (89 FR 97726 through 97727). We proposed to update the pricing of the ''pack, cleaning and disinfecting, endoscope'' (SA042) supply from $19.43 to $31.29, to update the pricing of the ''pack, drapes, cystoscopy'' (SA045) supply from $17.33 to $14.99, to update the pricing of the ''pack, ocular photodynamic therapy'' (SA049) supply from $16.35 to $26.35, to update the pricing of the ''pack, urology cystoscopy visit'' (SA058) supply from $113.70 to $37.63, and to update the pricing of the ''pack, ophthalmology visit (w-dilation)'' (SA082) supply from $3.91 to $2.33. As recommended by the RUC workgroup, we also proposed to delete the ''pack, drapes, laparotomy (chest-abdomen)'' (SA046) supply entirely. The updated prices for these supply packs were listed in the valuation of specific codes section of this rule under Table A–B5, CY 2025 Invoices Received for Existing Direct PE Inputs (89 FR 97852).

In accordance with the RUC workgroup's recommendations, we also proposed to create eight new supply codes, including components contained within previously existing supply packs. Aside from the SB056 supply, which is a replacement in several HCPCS codes for the deleted SA046 supply pack, all of these new supplies are not included as standalone direct PE inputs in any current HCPCS codes, as they are, again, components contained within previously existing supply packs. We proposed to add:

- The kit, ocular photodynamic therapy (PDT) (SA137) supply at a price of $26.00 as a component of the SA049 supply pack;
- The Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply at a price of $8.049 as a replacement for the SA046 supply pack;
- The drape, surgical, legging (SB057) supply at a price of $3.284 as a component of the SA045 supply pack;
- The drape, surgical, split, impervious, absorbent (SB058) supply at a price of $8.424 as a component of the SA045 supply pack;
- The post-mydriatic spectacles (SB059) supply at a price of $0.328 as a component of the SA082 supply pack;
- The y-adapter cap (SD367) supply at a price of $0.352 as a component of the SA049 supply pack;
- The ortho-phthalaldehyde 0.55 percent (for example, Cidex OPA) (SM030) supply at a price of $0.554 as a component of the SA042 supply pack; and
- The ortho-phthalaldehyde test strips (SM031) supply at a price of $1.556 as a component of the SA042 supply pack.

The new supply pack component items were listed in the valuation of specific codes section of the rule under Table A–B8, CY 2025 PFS (89 FR 97722) New Invoices (89 FR 97853).

We also proposed the following additional supply substitutions based on the recommendations of the RUC workgroup. We proposed to remove the deleted SA046 supply pack and replace it with the drape, sterile, fenestrated 16in x 29in (SB011) supply for CPT codes 19020, 19101, 19110, 19112, 20101, and 20102. We proposed to remove the deleted SA046 supply pack and replace it with two supplies—the drape, sterile, three-quarter sheet (SB014) and the drape, towel, sterile 18in x 26in (SB019)—for CPT codes 19000 and 60300. We proposed to remove the deleted SA046 supply pack

and replace it with 2 supplies—the drape, towel, sterile 18in x 26in (SB019) and the newly created Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply—for CPT codes 22510, 22511, 22513, and 22514. We proposed to remove the deleted SA046 supply pack without replacing it with anything for CPT code 22526; the RUC workgroup did not make a recommendation on what to do with CPT code 27278, which also previously contained the SA046 supply pack. Therefore, we also proposed not to replace the SA046 supply pack with any supplies for this code. The RUC workgroup also recommended removing the SA046 supply pack from CPT code 64595 with no replacement; however, this code was recently reviewed at the April 2022 RUC meeting and it no longer includes the SA046 supply.

In the comments on the CY 2025 PFS proposed rule (89 FR 97727), several commenters supported the proposed supply pack pricing update as recommended by the RUC workgroup, however they indicated concern over the proposed decrease in the price of the urology cystoscopy visit pack (SA058) from $113.70 to $37.63. The commenters stated that the proposed pricing reduction in the SA058 supply could result in drastic payment rate cuts for physicians performing cystoscopy services in the office setting. The commenters requested that CMS either delay the pricing update or phase-in the supply pack changes over a 4-year period like it has done for other PE changes with significant redistributive effects, allowing independent urology practices to better prepare for the negative financial impact this change will have.

After considering these comments, we agreed that the use of a phased-in transition period would be appropriate to allow practitioners to adjust to the updated pricing of these supplies. During our previous supply and equipment pricing update in the CY 2019 PFS final rule (83 FR 59475), we finalized a policy to phase in any updated pricing that we established during the 4-year transition period for very commonly used supplies and equipment, such as sterile gloves (SB024) or exam tables (EF023), even if invoices were provided as part of the formal review of a code family. Based on this previously established policy, we finalized the use of a pricing transition for three supply packs in Table A–B4.

TABLE A-B4: CY 2025 SUPPLY PACK PRICING TRANSITION

CMS_ CODE	HCPCS Codes	CMS_2024 Price	Recommended Price	Year 1 (CY 2025) Price	Year 2 (CY 2026) Price	Year 3 (CY 2027) Price	Final (CY 2028) Price
SA042	306	$19.43	$31.29	$22.40	$25.36	$28.33	$31.29
SA058	38	$113.70	$37.63	$94.68	$75.67	$56.65	$37.63
SA082	145	$3.91	$2.33	$3.52	$3.12	$2.73	$2.33

Following the same pattern as our previous supply/equipment and clinical labor pricing updates, we finalized the implementation of this pricing transition over 4 years such that one-quarter of the difference between the current price and the fully phased-in price is implemented for CY 2025 PFS (89 FR 97722), one-third of the difference between the CY 2025 PFS (89 FR 97722) price and the final price is implemented for CY 2026 PFS, and one-half of the difference between the CY 2026 price and the final price is implemented for CY 2027, with the new direct PE prices fully implemented for CY 2028. For the other proposed supply packs, the cystoscopy drapes pack (SA045) is only included in seven HCPCS codes and the ocular photodynamic therapy pack (SA049) is only included in a single HCPCS code which do not meet these criteria established in previous rulemaking and described previously in this section. Therefore, we finalized each of them at their updated pricing for CY 2025 PFS (89 FR 97722) as proposed in the proposed rule. We believe that the use of this pricing transition will minimize any potential disruptive effects during the 4-year transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply packs.

Several commenters also stated that although five incomplete packs would have their pricing updated in the proposed rule, mathematical errors still remained for a number of additional supply packs. Commenters stated that only 3 of the 18 affirmed packs were priced correctly to match their components and provided tables showing the pricing of an additional 15 packs that needed mathematical correction by deconstructing the packs to determine the correct price through summing their individual components. Commenters requested that CMS initiate a correction of the packs pricing such that the sum of the individual components match the price of the corresponding pack as detailed in Table A–B5.

TABLE A-B5: SUPPLY PACK PRICING REQUESTED BY CY 2025 COMMENTERS

HCPCS Codes	Item Name	CMS Code	Current Price	New Price	% Change
111 codes	pack, basic injection	SA041	$10.45	$17.28	65%
560 codes	pack, cleaning, surgical instruments	SA043	$12.61	$11.09	-12%
3 codes	pack, moderate sedation	SA044	$18.55	$19.20	4%
4568 codes	pack, minimum multi-specialty visit	SA048	$5.02	$1.98	-61%
168 codes	pack, ophthalmology visit (no dilation)	SA050	$2.72	$1.35	-50%
239 codes	pack, pelvic exam	SA051	$20.16	$2.81	-86%
1079 codes	pack, post-op incision care (staple)	SA052	$4.80	$9.90	106%
469 codes	pack, post-op incision care (suture & staple)	SA053	$5.47	$11.54	111%
1708 codes	pack, post-op incision care (suture)	SA054	$4.62	$10.34	124%
12 codes	pack, post-op incision care, craniotomy	SA055	$7.30	$18.18	149%
24 codes	pack, post-op incision care, neurosurgical	SA056	$6.20	$16.05	159%
120 codes	pack, drapes, ortho, large	SA080	$37.30	$25.38	-32%
29 codes	pack, drapes, ortho, small	SA081	$2.25	$1.88	-16%
119 codes	pack, protective, ortho, large	SA083	$10.86	$14.75	36%
27 codes	pack, protective, ortho, small	SA084	$5.99	$8.15	36%

While we shared the concerns of the commenters regarding the need for accuracy in the pricing of these supply packs, we had reservations about their potential for pricing disruptions. Ten of these supply packs are included in the direct PE inputs for at least 100 HCPCS codes, and three of the packs are included in more than 1000 HCPCS codes. Many of these pricing updates would lead to drastic changes in pricing for these supply packs which are included in hundreds of HCPCS codes, such as the SA051 pelvic exam pack decreasing in price from $20.16 to $2.81 (−86 percent) and the SA048 minimum multi-specialty visit pack decreasing in price from $5.02 to $1.98 (−61 percent). We were particularly concerned that these changes in supply pack pricing could lead to significant shifts in the overall PE RVU for affected HCPCS codes, without these proposed rates appearing in the proposed rule or allowing any opportunity for public comment.

Therefore, we did not finalize pricing updates for these additional 15 supply packs as requested by commenters. We anticipated returning to this subject in future rulemaking to allow any changes in associated pricing for HCPCS codes to appear in the proposed rule and provide an opportunity for the public to comment. Should these supply pack pricing updates be proposed in future rulemaking, we anticipated that we might propose the same pricing transition described previously due to the number of potentially affected HCPCS codes. We finalized all of the other supply pack pricing changes as proposed, with the exception of the 4—year pricing transition for three supply packs as described previously in this section.

For CY 2026, we proposed to continue implementing the supply pack pricing update and associated revisions as previously recommended by the RUC's workgroup. We proposed to update the price of the 15 supply packs detailed in Table A–B5 which were received too late in CY 2025 PFS (89 FR 97722) to allow for proposed pricing or public comment. In the case of the surgical instruments cleaning pack (SA043), the moderate sedation pack (SA044) and the small ortho drapes pack (SA081), the proposed pricing update is modest enough that we proposed these supplies move immediately to their final prices for CY 2026.

For the 12 other supply packs, we proposed that they be incorporated into the muti-year supply pack pricing transition finalized in CY 2025 rulemaking. Rather than having two separate 4-year pricing transitions associated with supply packs, we proposed that these 12 additional supply packs fold into the previous pricing transition using the same methodology, such that one-third of the difference between the CY 2025 PFS (89 FR 97722) price and the final price is implemented for CY 2026, and one-half of the difference between the CY 2026 price and the final price is implemented for CY 2027, with the new direct PE prices fully implemented for CY 2028 (89 FR 97728). With the inclusion of the SA042, SA058, and SA082 supply packs which began their pricing transition for CY 2025, we proposed the total supply pack pricing update detailed in Table A–B6.

TABLE A-B6: SUPPLY PACK PRICING TRANSITION

CMS_ CODE	HCPCS Codes	CMS_2024 Price	Recommended Price	Year 1 (CY 2025) Price	Year 2 (CY 2026) Price	Year 3 (CY 2027) Price	Final (CY 2028) Price
SA042	306	$19.43	$31.29	$22.40	$25.36	$28.33	$31.29
SA058	38	$113.70	$37.63	$94.68	$75.67	$56.65	$37.63
SA082	145	$3.91	$2.33	$3.52	$3.12	$2.73	$2.33
SA041	111	$10.45	$17.28	-	$12.73	$15.00	$17.28
SA048	4568	$5.02	$1.98	-	$4.01	$2.99	$1.98
SA050	168	$2.72	$1.35	-	$2.26	$1.81	$1.35
SA051	239	$20.16	$2.81	-	$14.38	$8.59	$2.81
SA052	1079	$4.80	$9.90	-	$6.50	$8.20	$9.90
SA053	469	$5.47	$11.54	-	$7.49	$9.52	$11.54
SA054	1708	$4.62	$10.34	-	$6.53	$8.43	$10.34
SA055	12	$7.30	$18.18	-	$10.93	$14.55	$18.18
SA056	24	$6.20	$16.05	-	$9.48	$12.77	$16.05
SA080	120	$37.30	$25.38	-	$33.33	$29.35	$25.38
SA083	119	$10.86	$14.75	-	$12.16	$13.45	$14.75
SA084	27	$5.99	$8.15	-	$6.71	$7.43	$8.15
SD089	100	$20.56	$41.15	-	$27.42	$34.29	$41.15

Table A–B6 also includes the hydrophilic guidewire (SD089) supply which we proposed to transition in pricing over 3 years given its inclusion in approximately 100 HCPCS codes. We continue to believe that the use of this pricing transition will minimize any potential disruptive effects during the transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply items. After consideration of the public comments, we finalized our supply pack pricing policies as proposed in the CY 2026 PFS final rule (90 FR 49284).

For CY 2027, as stated in the proposed rule, these supply packs will continue with the third year of the previously finalized 4-year transition process as detailed in Table A–B6. In the proposed rule we noted that as is the case with other supply and equipment pricing, we would consider invoices associated with these supply packs which were submitted as public comments during the comment period following the publication of the CY 2027 PFS proposed rule as part of our established annual process for requests to update supply and equipment prices. We also encouraged interested parties to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

Comment: A commenter stated that they supported the continuing phase-in transition of supply pack pricing, specifically mentioning the SA041, SA042, SA048, SA052, SA053, and SA054 supply packs.

Response: We appreciate the support for our previously finalized policy from the commenter.

Comment: Several commenters stated that CMS should stop the continued pricing transition for the pelvic exam supply pack (SA051) and the cystoscopy visit supply pack (SA058). Commenters stated that these supply reductions were disconnected from actual practice costs and reductions in payment could create access barriers and push procedures into hospital outpatient departments where Medicare and patients generally pay more. Commenters requested that CMS freeze the price for these supply packs at their CY 2026 values and reconsider documentation of invoice pricing for these supplies.

Response: We share the concerns of the commenters regarding the large decreases in pricing associated with the SA051 and SA058 supply packs, which is why we finalized the use of a phased-in transition period in the CY 2025 PFS final rule (89 FR 97722). We note that the pricing of these supply packs was already finalized in the CY 2025 PFS final rule, with the four-year implementation continuing to take place in CY 2027. However, we also believe in the importance of valuing supply items at the most accurate market-based pricing available, and therefore we cannot continue to price these supply packs at rates much higher than the cost of the individual components that make up the total packs. We welcome the submission of updated invoices and other cost data associated with these supply packs for potential inclusion in future rulemaking; we note that we did not receive any invoices from commenters supporting different pricing for the SA051 and SA058 supply packs.

c. Technical Corrections to Direct PE Input Database and Supporting Files

Following the publication of the CY 2026 PFS final rule, the RUC submitted a potential technical correction issue related to global period assignment for approximately three dozen codes. The RUC stated that these codes had long descriptors which indicated that they were add-on codes ''(List separately in addition to code for primary procedure)''; however, these codes were assigned the XXX global period instead of the ZZZ global period. The RUC requested that CMS consider assigning the ZZZ global period for these codes as a technical correction.

We reviewed the list of codes submitted by the RUC and we agree that there appears to be a technical error in the global period assignment for these codes. Most of the affected codes have non-payable status codes and no RVUs, while the handful of affected HCPCS codes that do have RVUs specifically state in their descriptors that they were intended to be add-on codes, such as CPT code 88332 (Pathology consultation during surgery; each additional tissue block with frozen section(s)). We therefore proposed to change the following codes to the ZZZ global period:

TABLE A-B7: PROPOSED ZZZ GLOBAL PERIOD CODES

HCPCS	Short Descriptor
20930	Sp bone algrft morsel add-on
20936	Sp bone agrft local add-on
22841	Insert spine fixation device
81266	Str markers spec anal addl
81416	Exome sequence analysis
81426	Genome sequence analysis
81536	Oncology gynecologic
82952	Gtt-added samples
87187	Sc std microdil/agar mlc
87503	Influenza dna amp prob addl
87904	Phenotype dna hiv w/clt add
88314	Histochemical stains add-on
88332	Path consltj surg ea add blk
94645	Cont inhlj tx each addl hour
95940	Ionm in operatng room 15 min
95941	Ionm remote/>1 pt or per hr
99486	Suprv interfac trnsport addl
99602	Home nfs visit each addl hr
0054T	Bone srgry cmptr fluor image
0055T	Bone srgry cmptr ct/mri imag
0076T	S&i stent/chest vert art
0095T	Rmvl artific disc addl crvcl
0098T	Rev artific disc addl
0174T	Cad cxr with interp
0397T	Ercp w/optical endomicroscpy
G1028	Take home supply 8mg per 0.1
G2078	Take-home meth
G2079	Take-hom buprenorphine
G2080	Add 30 mins counsel
G2215	Home supply nasal naloxone
G2216	Home supply inject naloxon
S2351	Diskectomy, anterior, with d
S2900	Robotic surgical system

The RUC also requested assigning the ZZZ global period to three anesthesia codes: CPT codes 01953, 01968, and 01969. However, currently all anesthesia codes use the XXX global period, and it is unclear whether the concept of an add-on global period would apply to anesthesia coding given that they are valued using base units and time units, unlike all other PFS services. As noted in the proposed rule, we did not propose the ZZZ global period for these three codes at this time. We solicited comments from interested parties regarding the global period assignment for these three anesthesia codes, as well as the other codes listed in Table A–B7.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they did not support assigning a ZZZ global period to CPT codes 01953, 01968, and 01969 and questioned the necessity and potential negative consequences of doing so. The commenters stated that although they understood the RUC's rationale for requesting a ZZZ global period assignment for CPT codes 01953, 01968, and 01969, they believed this would be an inappropriate policy change that could have unintended negative consequences. The commenters stated that the anesthesia code set does not currently utilize global periods beyond the perceived global period defined by the anesthesia start and stop times of an anesthesia service and establishing any structure that would appear to assign an anesthesia global period could lay the groundwork to establishing a defined generic or average global period that could impact the unique recognition and utilization of an actual case's unique start and stop times. The commenters stated that the administrative burden of ensuring that these downstream impacts would not occur would far outweigh any perceived benefit of unnecessarily assigning a ZZZ global period to these codes.

Response: We appreciate the feedback from the commenters; we agree that there are unique aspects to the anesthesia codes and therefore continue to believe that CPT codes 01953, 01968, and 01969 should retain the same XXX global period used by all other anesthesia codes.

After consideration of public comments, we are finalizing the change to a ZZZ global period for the codes listed in Table A–B7 as proposed. We are not finalizing a change in the global period for anesthesia CPT codes 01953, 01968, and 01969.

Comment: Several commenters, including the RUC, requested that CMS separately identify and pay for high-cost

disposable supplies. Commenters highlighted the outsized impact that high-cost disposable supplies have within the current practice expense RVU methodology, which not only accounts for a large amount of direct practice expense for these supplies but also allocates a large amount of indirect practice expense into the PE RVU for the procedure codes that include these supplies. Commenters stated that if high-cost supplies were paid separately with appropriate HCPCS codes, the disproportionate indirect expense would no longer be associated with that service, with the result that indirect PE RVUs would be redistributed throughout the specialty practice expense pool and the practice expense for all other services. Commenters requested that CMS separately identify and pay for high-cost disposable supplies priced more than $500 using appropriate HCPCS codes. Commenters stated that they had anticipated a response from CMS on this issue and argued that the pricing of these supplies should be based on a transparent process whereby items are reviewed and updated on an annual basis.

Response: We have received a number of prior requests from interested parties, including the RUC, to implement these separately billable alpha-numeric Level II HCPCS codes to allow practitioners to be paid the cost of high cost disposable supplies per patient encounter instead of per CPT code. We stated at the time, and we continue to believe, that this option presents a series of potential problems that we have addressed previously in the context of the broader challenges regarding our ability to price high cost disposable supply items. We did not propose and are not finalizing the implementation of standalone Level II HCPCS codes for high cost disposable supplies at this time. For further discussion of this issue, we direct the reader to our discussion in the CY 2011 PFS final rule with comment period (75 FR 73251).

This is a subject that we may consider for future rulemaking alongside other updates to the PE methodology. We appreciate the continued feedback from commenters as we consider potential approaches to this complicated topic.

d. Updates to Practice Expense (PE) Methodology—Site of Service Payment Differential

We proposed a significant refinement to our PE methodology to better reflect trends in physician practice settings in the CY 2026 PFS final rule (90 FR 49292 through 49297). Under the finalized policy, we allocate half the amount of indirect PE RVUs per work RVU for services furnished in the facility setting compared to those allocated to services furnished in the non-facility setting. We noted in the CY 2026 PFS proposed rule (90 FR 32374) that this change to the indirect cost allocation methodology was intended to better recognize the relative resources involved in furnishing services paid under the PFS in facility and non-facility settings. We compared this change to our current methodology prior to CY 2026, which functionally presumed approximately equal indirect costs incurred by physicians across sites of service. This presumption was initially made in the context of most practitioners maintaining office practices independent of the facilities in which they provided care, and as we discussed in the CY 2026 PFS proposed and final rules, appears to be inconsistent with contemporary trends in physician practice where some significant portion of services furnished in facility settings are performed by medical practitioners who do not maintain fully independent practices and are less likely to incur a comparable amount of indirect costs.

Since finalizing the proposal in the CY 2026 PFS final rule, we have heard from interested parties that the implementation of this policy resulted in an unintended, but significant, site of service differential for physician visits in nursing facility settings based solely on whether the beneficiary's stay is covered under Part A. For purposes of PFS payment, a service furnished to a patient in a skilled nursing facility during a Part A hospital stay (place of service 31) is considered to be in the ''facility'' setting, while a service furnished to a patient in a Part B stay (place of service 32) is considered to be in the ''non-facility'' setting, per the Medicare Claims Processing Manual (MCPM), Chapter 12, Section 20.4.2 at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*. Prior to CY 2026, the payment rate for these E/M services furnished in a skilled nursing facility (''facility'') and a nursing facility (''non-facility'') were equal. As intended, the 50 percent reduction to the allocation of indirect PE based on work RVUs that we finalized for CY 2026 shifted PE RVUs from the facility setting to the non-facility setting. However, for nursing facility and skilled nursing facility visits, the current site of service differential is determined based on the status of the beneficiary (that is, a Part A versus Part B stay) in that setting, rather than in the setting of care itself. Given that the resource costs for the professional involved in furnishing an E/M service would not be expected to differ based on whether the patient is in a Part A stay or not, we believe it is more accurate for these E/M services to be paid the same amount without regard to the beneficiary's Part A status.

Therefore, we proposed to address this anomaly for CY 2027 by equalizing the rate for nursing facility visits without regard to the beneficiary's status by setting the facility PE RVU equal to the non-facility PE RVU for CPT codes 99304 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*), 99305 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*), 99306 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*), 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*), 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.*), 99309 *(Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*), 99310 *(Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision*

making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.), 99315 *(Nursing facility discharge management; 30 minutes or less total time on the date of the encounter*), and 99316 *(Nursing facility discharge management; more than 30 minutes total time on the date of the encounter*).

This particular situation illuminates ongoing concerns regarding the current site of service differential. For example, interested parties have suggested that the current binary of facility and non-facility does not account for the range of employment models associated with physician services that drive significant differences in actual practice expenses. Interested parties have encouraged us to refine our previously finalized policy to ensure it is more empirically grounded and narrowly tailored to independent physicians, consistent with the policy's original intent. Interested parties have also stated that the facility PE reductions have had a disparate effect on hospital medicine groups and hospitalists, particularly those that operate independently from their hospital or health systems. Interested parties have stated that independent hospital medicine groups account for approximately one-third to one-half of the hospital medicine groups nationwide, and they are unable to cut administrative and overhead costs enough to absorb our CY 2026 facility PE reductions. As a result, some interested parties have stated that the reductions are accelerating the insolvency of independent physician practices and leading to an increase in hospital consolidation. We note that we have heard no general consensus among interested parties to this effect, and we have received feedback that this policy supports independent practices.

In the CY 2026 PFS proposed rule, we sought comments on whether our proposal to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs was an appropriate reduction or whether we should consider a different percentage reduction for CY 2026 or in future years. In finalizing the proposal, we noted that, while our change to the methodology for CY 2026 represented a starting point to correcting historic distortions in the allocation of indirect PE costs across settings of care, we intended to further examine our methodology and consider additional refinements based upon feedback received and any studies or data sources identified.

For CY 2027, we remained open to more specific data that addresses the variability, as well as feedback on how to update the valuation and payment methodologies to better reflect the relative resources involved in furnishing the services, both across settings of care, and within the context of an evolving ecosystem of care models and business arrangements. Historically, we have relied extensively on specialty-specific PE/HR survey data and the binary site of service differential to best reflect variable PE costs.

To better inform our consideration of how to account for practice expenses under the PFS methodologies, including the current differentials that are effectuated based on the binary facility/non-facility settings of care, we sought comment on how PE costs vary for physicians and other professionals, not only based on whether they practice in part or exclusively in a facility setting but also based on how their costs vary when they are employed by health systems, hospitals, or other entities. We noted in the CY 2026 PFS final rule that (90 FR 49292) that the AMA has stated that physician practices maintain some indirect PE costs for physicians who are solely facility-based such as coding, billing, and scheduling. That being said, we generally agree with the concerns presented by MedPAC on the growth of exclusively facility-based physicians and agree that potential overpayments for indirect practice expense costs could be a driver of clinician movement to higher cost settings without creating commensurate clinical value. This is why we lowered indirect PE for facility-based physician to 50 percent in the CY 2026 PFS final rule.

Moving forward, we remain interested in ensuring indirect PE RVUs are appropriately accounting for indirect PE costs. As such, we sought information that will help illuminate to what extent these costs are truly incurred when the professionals are employed by the hospital and/or practice primarily in the hospital and are not already accounted for in the existing OPPS payments. For example, when a physician is employed by and practicing in a hospital, what portion of the indirect PE is associated with the PFS service, versus costs that are associated with the payment to the hospital, such as those paid under the OPPS?

We sought comment on the amount of indirect PE hospital-employed physicians incur when they furnish care within a facility. For these physicians, is the 50 percent indirect PE allocation accurate or could it possibly be less than 50 percent, such as 0 percent? In the case that there are little to no indirect costs incurred by the physician or other professionals, and these costs are borne by the hospital, we believe that these costs are not appropriately accounted for under the PFS and we may well be overestimating the relative resource costs compared to other PFS services. In consideration of the accuracy of the current 50 percent indirect PE allocation for services furnished in the facility setting, we are also seeking comment on whether and how we might, alternatively or additionally, define and identify physicians and professionals who are employed by hospitals, health systems, or other entities to ensure the services they furnish are not inappropriately consuming PE RVUs that would be more appropriately assigned to services furnished by professionals incurring comparatively greater practice expenses. Specifically, we sought comment on whether a new HCPCS modifier for employed physicians would be a reasonable way to identify and reduce facility PE from the services they perform in the facility setting, or whether there are other methods we could consider.

We sought comment on what are the primary variables we should consider to continue to improve our data sources, allocation methodologies, and payment rates across settings of care, to best reflect the resources involved in furnishing PFS services by professionals and suppliers operating in a complex marketplace, across settings of care. We remain interested in objective data regarding payment arrangements between hospitals, health systems, other employers and physicians, including which costs are incurred and whether the full range of costs are truly incurred by physicians and other professionals in these kinds of employment relationships. This would help us understand and improve how PE is allocated across settings of care, both in general and for specific kinds of services.

We received public comments on this proposal and comment solicitation. The following is a summary of the comments we received and our responses.

Comment: Commenters were unanimously supportive of our proposal to set the facility PE RVU equal to the non-facility PE RVU for nursing facility E/M codes (CPT codes 99304 through 99310, 99315 and 99316). We also received feedback in response to our comment solicitation on the current site of service differential finalized in the CY 2026 PFS final rule.

Response: We appreciate the commenters' support on our proposal. We received many comments on our comment solicitation regarding the site of service differential. Commenters agreed that using facility place-of-

service as a proxy for physician employment is imprecise, though they were divided on how to structure the differential going forward, with some supporting refinements such as additional specialty-specific adjustments and more detailed impact data. Most recommended replacing or supplementing this proxy with a more direct method of identifying hospital-employed physicians, with several suggesting independent practices self-identify given their incentive to do so. However, many commenters cautioned that employment status alone is not a reliable indicator of who bears indirect costs, noting that practices often continue to incur substantial administrative costs regardless of employment or site of service, and that the variety of employment arrangements makes any binary classification difficult to administer and prone to disputes. Commenters broadly urged CMS to take a more data-driven approach, including easing the impact on independent practices and reconsidering the reduction until better evidence is available. They also raised specialty-specific concerns and warned the policy could accelerate practice consolidation into hospital employment or acquisition by other entities. After consideration of public comments, we are finalizing to set the facility PE RVU equal to the non-facility PE RVU for nursing facility E/M codes (CPT codes 99304 through 99310, 99315 and 99316), as proposed. We may consider comments about the site-of-service differential in future rulemaking.

6. Strategies To Improve Payment Transparency, Accuracy, and Congruency Across Payment Systems

a. Professional and Technical Components

Because PFS services are paid across settings of care, and are the primary way that Medicare pays medical professionals, understanding the structure of PFS payment is a critical part of price transparency for Medicare, other payers, and consumers. Likewise, misunderstanding or confusion about what relative resources are incorporated in specific PFS payment rates can be a significant obstacle for payers and consumers navigating the health care market. For example, approximately 4,100 services paid as ''global surgical packages,'' (herein 'globals') are valued as bundled payments that aggregate multiple components of care into a single payment amount, including post-operative visits that are presumed to occur in particular settings (for example, inpatient hospital, outpatient hospital, office) regardless of where the services actually take place. Most PFS services are valued with a site of service binary, where the non-facility setting is the aggregation of all relative resources involved in furnishing the professional and technical aspects of the service, and the facility setting, where the rate generally excludes the facility costs involved in the service since those costs are addressed through separately reported facility fees. In contrast to these two constructs, there are other codes (mainly describing diagnostic and imaging services) that may be billed with professional component (PC, or modifier 26) and technical component (TC) modifiers, or without modifiers (global codes) that are paid for the complete global service. These differences in how payments are constructed and displayed can make it difficult for interested parties and CMS to evaluate relative payment rates, underlying resource costs, and value across settings of care.

These challenges are further compounded by differences across Medicare payment systems in how similar services are defined, bundled, and paid. For example, some payment systems incorporate technical inputs and facility resources into a single payment. This variation can obscure meaningful comparisons across sites of care and may complicate efforts to advance site-neutral payment policies aimed at reducing incentives for hospitals to acquire physician practices and limit site-of-care decisions based on financial considerations. As CMS continues to consider approaches that remove obstacles from market competition across settings of care, especially by improving transparency, comparability of PFS payments is an important foundational step.

We noted in the proposed rule, to facilitate more consistent comparisons across services and settings, we have developed a public use file that displays, for services that are not currently billable with TC/26 modifiers, RVUs amounts that reflect the relative resources involved in furnishing professional and technical aspects of the services, which is available on the CMS website under downloads for the CY 2027 PFS proposed rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*. This file is intended to improve transparency regarding how PFS payments may be conceptually divided between physician professional and technical components of the services, especially to illuminate the differences in fees between technical aspects of PFS services compared to facility fees across settings of care. We believe that making these components more visible, where feasible, may help interested parties better understand the structure of PFS payments and support more informed comparisons across settings of care. We noted that we have excluded 10- and 90-day global surgery services from display in this public use file since there are numerous ways to consider how the structure of payment for those codes may be best understood. The use of bundled payments for the 10- and 90-day global surgery services results in aggregated valuation for all pre-operative, intra-operative, and post-operative services furnished over a defined period (0-, 10-, or 90-day global periods), including services by both physician and clinical staff and practice expense without clear visibility into how each component contributes to the total bundled valuation. While we noted that the current structure of global surgery services has effectively obscured how the components of care are individually valued and limited our ability to disaggregate them for purposes of this public use file, we sought comment on how to address this problem, either in possible improvements to the global surgery packages or, at least, in the best way to make their component pieces transparent.

Additionally, we noted that there is a subset of additional exclusions from this public use file, such as codes subject to the cognitive services floor and the statutory phase-in of significant RVU reductions, due to technical challenges with how these policies are implemented that hinder the disaggregation of their component parts.

We emphasized in the proposed rule that we did not propose any changes to existing payment or billing policies, including the use of the 10- and 90-day globals. Rather, this effort is intended to improve transparency and provide a foundation for future rulemaking. We believe that greater visibility into how the professional and technical aspects of PFS services are valued and paid, where feasible, may enhance the ability of consumers, and payers (including CMS) to assess relativity across services, may enhance CMS's efforts to improve valuation over time, and support broader efforts to align payments across settings of care. We sought comment on several aspects of this approach. First, we sought comment on the utility of displaying RVUs associated with professional and technical aspects of services that are not currently billable with TC/26 modifiers, including how we may use this information to assess payment differences across settings. Again, we also sought comment on

potential approaches CMS could consider in future rulemaking to improve transparency for services currently paid as globals. Specifically, we were interested in feedback on how CMS could develop methodologies to more clearly identify and, where appropriate, disaggregate the underlying components of these services. We were also interested in comments on how CMS could ''right-size'' payments for the globals over time to ensure they remain aligned with current clinical practice and resource costs, are more readily updated based on empirical data, and do not obscure differences in cost and value across settings of care.

We received public comments on this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: Some commenters were supportive of the CMS goal of improving transparency and developing more consistent information about the resources used to furnish services across different settings, but disagreed with our methodology of developing component-level values for services that the commenters say were not designed or valued as separately billable professional and technical components. Commenters stated that the display-only file raises significant methodological and policy questions, and that these values should not be treated as directly comparable, or used to support future payment changes, until CMS has completed further analysis and engaged affected interested parties. Another commenter stated that the proposed approach to create the file appears to be arbitrary and does not reflect allocations based on a thorough review of each service, and discouraged us from advancing future payment policy that relies on the public use file. The commenter stated that there are often justifiable reasons for cost variation between different sites of care and expressed concern that we intend to use the file in future years to equalize rates across sites of care that could result in hospitals being underpaid for care.

Response: We appreciate the commenters' support of our efforts to make available transparent information about the resources required to furnish services across settings. With respect to commenters who stated that the file's methodology was arbitrary or lacked utility, we note that estimating component-level resource use for display purposes does not require that those components be separately billable, and we believe such estimates can serve the transparency goals described in the proposed rule. We are open to alternative approaches to advancing comparisons across sites of care and may take any such suggestions into account in future rulemaking. We did not propose to use the file for payment comparisons in this rule. The display is intended only to begin building a transparency foundation, as described in the comment solicitation. We will consider commenters' methodological concerns before any future proposal that relies on cross-setting comparisons.

Comment: Some commenters stated that the re-presentation is more understandable to interested parties, but it would be more useful if CMS confirmed the systemic approach used or explained in greater detail how CMS developed the resource with sample calculations. Another commenter stated that they strongly support the establishment of this public use file because the AMA has historically been the gatekeeper of the relevant information utilized when determining RVU amounts. The commenter stated that the process is secretive and monetized access to databases has prevented interested parties from accessing and understanding the structure of PFS payments. Another commenter requested the addition of the code descriptors to the file to improve the readability and data analytics of the public use file.

Response: We appreciate the feedback from interested parties and may consider expanding the scope of the file in future rulemaking.

Comment: A commenter suggested that this file allows the opportunity for TC services under the MPFS to use the OPPS relativity data (excluding the packaged services) to assess the PE RVUs, rather than survey data. The commenter said that this would be similar to what CMS proposed for radiation oncology and proton beam treatment delivery services. They stated that they believe the public use file would provide greater accuracy to tie the RVUs to the audited hospital cost report data for the PE component, rather than survey data. The commenter also requested that we consider publishing the direct and indirect PE RVUs for facility and non-facility for all codes, and stated that this information available across services would provide valuable information and would increase transparency associated with RVUs and the PFS.

Response: We appreciate the feedback from interested parties. We may consider publishing the direct and indirect PE RVUs in future rulemaking.

b. Global Surgical Packages

We finalized a policy in the CY 2015 PFS final rule (79 FR 67582 through 67591) to transition all 10-day and 90-day globals to 0-day globals, allowing any post-operative visits furnished after the day of the procedure to be billed as a standalone visit. CMS was prohibited from implementing this policy through section 523(a) of the Medicare Access and CHIP Reauthorization Act (MACRA) and was required to collect data on how to best value globals. CMS did so through a research contract with RAND and a data-collection process over several years to develop data to improve the payment rates for these services. Data collection has been based on reporting of CPT code 99024 (*Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure*), which is limited to practices with 10 practitioners or more, limited to nine States, and is used solely for data collection so it has no associated payment with reporting the code. In the CY 2019 PFS final rule (83 FR 59503), we released findings that only 4 percent of reviewed 10-day globals and 67 percent of reviewed 90-day globals had one or more post-operative visit which occurred during the global period and sought comment on potential approaches for revaluing the globals based on these findings (83 FR 59504). In the CY 2023 PFS proposed rule (87 FR 45877 through 45880), CMS reviewed the prior work and conversations around global valuations, solicited feedback from the public, and has continued to explore ways over the years to address valuation of the globals that would be minimally disruptive to the PFS.

Over the past several years, CMS has taken several iterative steps to improve payment accuracy for the globals. In the CY 2025 PFS final rule (89 FR 97964 through 97968), CMS expanded the applicability of the transfer of care modifiers to address instances where separate practitioners are billing for standalone E/M visits during the global period more directly with mandatory reporting of payment modifiers in clinical cases when there is both a formal or informal transfer of care between practitioners furnishing distinct portions of a global service. CMS also created a post-operative care services add-on code to more appropriately reflect the time and resources involved for practitioners who were not involved in furnishing the surgical procedure. CMS is continuing to explore further steps to improve accountability and more accurate

payment and what additional next steps CMS could take to improve the payment rates for global services.

In keeping with the administration priorities and aligning spending and value, we proposed to pause the data collection required by MACRA based on RAND's findings over the past several years. We remain interested in how best to use and collect this data going forward and ways we might consider improving this data collection. We currently have several years of data that have continued to illustrate what we believe is the issue with the post-operative visits during the global period and how these visits are not occurring, yet providers are still being paid for these visits under the current global payment policy. Additionally, we believe that the current data collection may be causing undo burden to providers and we believe that pausing the data collection will aid in burden reduction for practitioners. We do however question whether a more robust data collection would be appropriate and if we should have all providers report CPT code 99024.

We also sought comment on the question, as to whether CMS should have all providers report CPT code 99024, and also other data sources we might consider to more accurately value the globals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally in support of the CMS proposal to pause the data collection required by MACRA to report CPT code 99024. Most commenters were not in support of CMS using that data for the revaluation process. Commenters were overall in agreement that expanding the data collection would pose undo administrative burden to providers and urged CMS to not expand the reporting. Commenters were not in support of using the information presented in the Public Use File (PUF), in particular the purely ''arithmetic approach'' to understand the valuation of the services based on the data that was analyzed. Many commenters were opposed to CMS using the reported data in the process of revaluation. Commenters stated that the underreporting of CPT code 99024 does not indicate or capture the post-operative work that was furnished even though a visit was not actually reported. Commenters noted that pausing the data collection allows for opportunity to evaluate the data limitations and develop a more accurate approach. Several commenters suggested CMS spend time understanding post operative care, how it is organized, as well as non-visit post-operative work that takes place even when a visit is not furnished as care extends beyond the post-operative visits.

Response: We appreciate the commenters' feedback and support of pausing the data collection of CPT code 99024. We understand the commenters' concerns that data collection may impose administrative burden and understand this concern with expanding the data collection beyond the sample that was required. We believe that a pause in the data collection allows CMS an opportunity to evaluate the data limitations and further refine our approach to data collection on the global surgical packages.

After consideration of public comments on our proposal, we are finalizing pausing the data collection as proposed. CMS remains interested in how to best capture post operative data to better inform valuation of post-operative services under the PFS.

As noted in the proposed rule, we posted a public use file with the proposed rule to display the imputed RVUs associated with both the 10- and 90-day post-operative visits based on a purely arithmetic approach to understand the valuation of the services based on the data that was analyzed. The public use file shows the current work RVUs, the number of post-operative visits that are reported to CMS using no-pay HCPCS code 99024, and the work RVUs remaining if all post-operative visits are removed. The public use file is available on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*. We solicited comments on potential revaluation strategies that we may consider through future rulemaking. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: As stated previously, many commenters were not in support of using the information in the public use file to help inform revaluation of the global surgical packages. Other commenters thought it was a good first step toward the revaluation process. A few commenters supported aligning payment for global surgical services with services actually furnished, while others noted the reporting of CPT code 99024 did not specify the visit level or level of physician work. Other commenters supported the publication of the imputed post-operative visit RVU public use file while other commenters did not think CMS should use missing postoperative visit claims as proof that postoperative care is not being furnished.

Response: We thank the commenters for their feedback.

After consideration of public comments, we express appreciation for the feedback from commenters and will take the comments into consideration for possible future rulemaking.

C. Payment for Medicare Telehealth Services

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006), the CY 2021 PFS final rule (85 FR 84502), the CY 2024 PFS final rule (88 FR 78861 through 78866), the CY 2026 PFS final rule (90 FR 49316 through 49320), and in 42 CFR 410.78 and 414.65. Our current 3-step review process reflects the stepwise method by which we consider requests to add services to or remove services from the Medicare Telehealth Services List, beginning with the CY 2026 Medicare Telehealth Services List:

Step 1. Determine whether the service is separately payable under the PFS.

Step 2. Determine whether the service is subject to the provisions of section 1834(m) of the Act.

Step 3. Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3).

1. Changes to the Medicare Telehealth Services List

a. Requests To Add Services to the Medicare Telehealth Services List for CY 2027

We did not receive any requests to add or remove services from the Medicare Telehealth Services List for CY 2027.

Consistent with the deadline for our receipt of code valuation recommendations from the American Medical Association's Relative Value Scale Update Committee (AMA RUC) and other interested parties established in the CY 2019 PFS final rule (83 FR 59491) and with the process set forth in prior calendar years, for CY 2027, requests to add services to the Medicare Telehealth Services List must have been submitted to and received by CMS by February 10, 2026. Consistent with the deadline for our receipt of code

valuation recommendations from the AMA RUC and other interested parties established in the CY 2019 PFS final rule (83 FR 59491) and with the process set forth in prior calendar years, for CY 2028, requests to add services to the Medicare Telehealth Services List must be submitted to and received by CMS by February 10, 2027. Each request submitted by the deadline to add a service to the Medicare Telehealth Services List must include any supporting documentation the requester wishes CMS to consider. Because we use the annual PFS rulemaking process to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the Medicare Telehealth Services List, including where to send these requests, and to view the current Medicare Telehealth Service List, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

We did not receive any requests to add or remove services from the Medicare Telehealth Services List for CY 2027 by the February 10, 2026 deadline. However we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: We received comments requesting services to be added to the Medicare Telehealth Services List during the public comment period for the CY 2027 proposed rule.

Response: For consideration in the CY 2027 PFS rulemaking, requests to add services to the Medicare Telehealth Services List for CY 2027 must have been received by February 10, 2026. For CY 2028, requests to add services to the Medicare Telehealth Services List must be submitted to and received by CMS by February 10, 2027.

Comment: Commenters highlighted that we did not align certain services on the Medicare Telehealth List with services being deleted for CY 2027. As discussed in section II.D under Adaptive Behavior Services, at the September 2025 CPT Editorial Panel meeting, the CPT Editorial Panel deleted CPT codes 0362T and 0373T. These codes are being replaced with CPT codes 97148, 97149, 97159, 97160, and 97173. As discussed in section II.D. under Speech-Language Pathology Services, at the September 2025 CPT Editorial Panel meeting, CPT code 92507 was replaced with 10 new codes (92654, 92655, 92656, 92657, 92658, 92659, 92660, 92661, 92662, and 92663).

Response: We thank commenters for this information. We inadvertently maintained these codes on the Medicare Telehealth Services List. We believe that these codes represent replacements for the codes currently describing these services on the Medicare Telehealth Services List. As such, we are finalizing the deletion of CPT codes 92507, 0362T, and 0373T and the addition of CPT codes 97148, 97149, 97159, 97160, 97173, 92654, 92655, 92656, 92657, 92658, 92659, 92660, 92661, 92662, and 92663 to the Medicare Telehealth Services List.

In accordance with our longstanding policy, requests to add services to the Medicare Telehealth Services List must be submitted to and received by CMS by February 10, 2026. We will not consider requests to add services submitted during the public comment period for the CY 2027 proposed rule. That said, CPT codes 92507, 0362T, and 0373T will be removed from the Medicare Telehealth Service List as they were inadvertently maintained. We will be replacing deleted CPT code 92507 with CPT codes 92654, 92655, 92656, 92657, 92658, 92659, 92660, 92661, 92662, and 92663. We will be replacing deleted CPT codes 0362T and 0373T with 97148, 97149, 97159, 97160, and 97173.

b. CMS Requirement To Add New Codes to the List

In the CY 2027 PFS proposed rule, we proposed to add HCPCS G-codes G0572 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), first 20 minutes of clinical staff time with the patient, family member(s), directed by a treating physician or other treating qualified health care professional*), G0573 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), each additional 20 minutes with the patient, family member(s), directed by a treating physician or other treating qualified health care professional (List separately in addition to code for primary procedure*)), G0686 (*Voluntary, group-based medical session involving multiple patients with common medical condition(s), receiving medical care in a group setting; billed and led by a physician or qualified nonphysician practitioner and may include services provided by other qualified healthcare professionals, clinical staff, or auxiliary personnel under the direction of the supervising physician or other practitioner. Session integrates group education, counseling, and peer support with individualized patient clinical assessment and care, 2–10 patients, billed once per patient, per session.*), G0903 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual; for the pediatric population age 21 and under*), and G0576 (*Office or other outpatient evaluation and management service(s) for the diagnosis and treatment of vaccine adverse effects, new or established patient; each 15 minutes personally performed by the physician or qualified healthcare professional (list separately in addition to CPT codes 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350))* to the Medicare Telehealth Services List. In the CY 2027 PFS proposed rule, we stated that these services, if finalized, will be separately payable under the PFS and will subject to the provisions of section 1834(m) of the Act, as they are inherently face-to-face services and would serve as a substitute for an in-person encounter. We also stated that we believe that the elements of these services as described by the HCPCS codes are capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3). We refer readers to the relevant requirements in section II.D. of this final rule for further background on these codes.

We received public comments on our proposal to add G0572 and G0573 to the Medicare Telehealth Services List. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported our proposal to add these services to the Medicare Telehealth Services List. Many of these commenters supported our proposal to add the services to the Medicare Telehealth Services List if the codes are finalized.

Response: We appreciate the feedback from the commenters.

After consideration of public comments, we are finalizing as proposed to add GACP1 and G0573 2 to the Medicare Telehealth Services List, beginning in CY 2027.

We received public comments on our proposal to add G0686 to the Medicare Telehealth Services List. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported our proposal to add this service to the Medicare Telehealth Services List.

Response: We appreciate the feedback from the commenters. As discussed in section II.D of this rule, we are finalizing an add-on code for shared medical appointments, G0687.

After consideration of public comments, we are finalizing as proposed to add G0686 and G0687 to the Medicare Telehealth Services List, beginning in CY 2027.

We received public comments on our proposal to add G0903 to the Medicare Telehealth Services List. The following is a summary of the comments we received and our responses.

Comment: Commenters pointed out a discrepancy between the code descriptor for HCPCS code G0903 described in sections of the NPRM, which we described as ''pediatric population up to 18 or 21''. The finalized code descriptor, as described in II.D, is ''Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual; for the pediatric population age 21 and under''.

Response: We thank commenters for pointing out the discrepancy. The corrected code descriptor for HCPCS code G0903 is ''Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual; for the pediatric population up to age 21.''

Comment: Commenters generally supported our proposal to add these services to the Medicare Telehealth Services List.

Response: We appreciate the commenters for their feedback. After consideration of public comments, we are finalizing as proposed to add HCPCS code G0903 to the Medicare Telehealth Services List, beginning in CY 2027.

We received public comments on our proposal to add HCPCS code G0576 to the Medicare Telehealth Services List. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported our proposal to add these services to the Medicare Telehealth Services List.

Response: We appreciate the commenters for their feedback. After consideration of public comments, we are finalizing as proposed to add HCPCS code G0576 to the Medicare Telehealth Services List, beginning in CY 2027.

We are finalizing the addition of HCPCS codes G0576, G0572, G0573, G0686, G0687, and G0903 to the Medicare Telehealth Services List.

2. Telehealth Flexibilities and Modifiers

As discussed in the CY 2021 PFS final rule (85 FR 84506), legislation enacted to address the PHE for COVID–19 provided the Secretary with new authorities under section 1135(b)(8) of the Act, as added by section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020) and subsequently amended by section 6010 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020) and section 3703 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020), to waive or modify Medicare telehealth payment requirements during the PHE for COVID–19.

We used these authorities to establish several flexibilities to accommodate changes in the delivery of care during the PHE. Through waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for COVID–19. We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology. At the end of the PHE for COVID–19, these waivers and interim policies were set to expire, and payment for Medicare telehealth services would have once again been limited by the requirements of section 1834(m) of the Act. These flexibilities have been extended by Congress numerous times since, most recently in the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119—75, February 3, 2026).

Section 6209(a) and (b) of the CAA, 2026 extends the flexibilities for Medicare telehealth services to remove the geographic restrictions, extends the expanded list of acceptable originating sites, and extends the expanded array of practitioners eligible to furnish telehealth services from January 30, 2026 to the extended date of December 31, 2027. Section 6209(d) of the CAA, 2026 delays the in-person visit requirements for mental health services furnished through telehealth from January 30, 2026 to the extended date of January 1, 2028. Section 6209(e) of the CAA, 2026 extends the flexibilities to allow audio-only Medicare telehealth services from January 30, 2026 to the extended date of January 1, 2028. To align with these extensions, § 410.78 has been revised, detailed later in this final rule.

Additionally, section 6209(g) of the CAA, 2026, requires CMS to establish modifiers for telehealth services in certain instances, effective January 1, 2027. These modifiers do not affect payment and are required for claims for telehealth services that are furnished through a virtual telehealth platform by a physician or practitioner that contracts with an entity that owns such virtual platform; or for which a physician or practitioner has a payment arrangement with an entity for use of such virtual platform; and for claims for telehealth services that are furnished incident to a physician's or practitioner's professional service.

In accordance with section 6209(g) of CAA, 2026, we are creating modifiers BB and BC. Guidance on use of these modifiers will be available on the CMS website. Any updates to this policy will be issued via subregulatory guidance in accordance with section 6209(h) of the CAA, 2026, which authorizes the Secretary to implement section 6209 via program instruction or otherwise.

We did not solicit comments on creating modifiers BB and BC, however we received public comments on this topic from interested parties. The following is a summary of the comments we received and our responses.

Comment: Commenters requested additional information and clarifications on the use of these modifiers.

Response: Telehealth modifiers BB (*Claims for telehealth services that are furnished through a telehealth virtual platform by a physician or practitioner that contracts with an entity that owns such virtual platform, or for which a physician or practitioner has a payment arrangement with an entity for use of such virtual platform.*) and BC (*Telehealth services that are furnished incident to a physician's or practitioner's professional service.*) are required beginning January 1, 2027. These modifiers do not have payment implications. Information on these modifiers is available on the CMS website here: *https://www.cms.gov/medicare/coverage/telehealth*.

3. Telehealth Critical Care Consultations

In the CY 2017 PFS final rule (81 FR 80352 through 80353), we established HCPCS codes G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth*) and G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth*) to report telehealth consultations for a patient requiring critical care services. These services were modeled after CPT

codes 99291 (*Critical care, evaluation and management of the critically ill or critically injured patient; first 30 to 74 minutes*) and 99292 (*Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (list separately in addition to code for primary service*)).

When adding some services to the Medicare Telehealth Services List in the past, we have included certain frequency restrictions on how often physicians and other practitioners may furnish the service via telehealth. These include a limitation of one critical care consultation service furnished via telehealth per day, added in the CY 2017 final rule (81 FR 80198). In the CY 2026 PFS final rule, we finalized permanently removing frequency limitations on furnishing these services via telehealth (90 FR 49324 through 49325).

We continue to believe that physicians and other practitioners, who have the greatest familiarity and insight into the needs of individual beneficiaries, can use their complex professional judgment to determine whether they can safely furnish a service via telehealth, given the entirety of the circumstances, including the clinical profile and needs of the beneficiary, to determine the appropriate service modality. We strive to balance the goals of increasing physician or practitioner and patient choice of service modality with consideration of patient safety for all Medicare beneficiaries. As technology advances and more services may be safely furnished via telehealth and paid under the PFS, it is increasingly important for physicians and other practitioners to exercise their professional judgment in determining the generally appropriate service modality for their patients to receive a service.

Since the permanent removal of the frequency limitation of one critical care consultation service furnished via telehealth per day, we have received questions about language in the code descriptors for HCPCS codes G0508 *(Telehealth consultation, critical care, initial , physicians typically spend 60 minutes communicating with the patient and providers via telehealth*) and G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth*) describing ''initial'' and ''subsequent'' consultations, as well as questions regarding the language about the typical time spent on the service. To clarify the requirements for billing these services, we proposed the following revised code descriptors:

- G0508: *Telehealth consultation, critical care; first 30 to 74 minutes.*
- G0509: *Telehealth consultation, critical care; each additional 30 minutes (List separately in addition to code for primary service*).

The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported our proposal to revise the code descriptors for HCPCS codes G0508 and G0509, as these revisions would clarify and streamline billing requirements. Commenters who did not support our proposal believed that the proposed code descriptors too closely mirror the code descriptors for CPT codes 99291 and 99292 and may cause more confusion, and that in practice, these codes may be used interchangeably. A few commenters suggested that we delete HCPCS codes G0508 and G0509 and only use CPT codes 99291 and 99292. One commenter stated that they are submitting CPT proposals to revise many CPT codes 99291 and 99292, and requested that we do not adopt any time increment changes for critical care until that CPT code proposal has been reviewed.

Response: We thank commenters for their feedback. After further review of claims data, we disagree that HCPCS codes G0508 and G0509 and CPT codes 99291 and 99292 are used entirely interchangeably, and we see a programmatic need to maintain both sets of codes. After consideration of public comments, we are finalizing as proposed.

4. Changes to Teaching Physicians' Billing for Services Involving Residents or Teaching Physicians With Virtual Presence

In the CY 2021 PFS final rule (85 FR 84577 through 84585), we finalized a temporary policy that allowed the teaching physician to have a virtual presence in all teaching settings, but only in clinical instances when the service was furnished virtually (for example, a three-way telehealth visit, with all parties in separate locations). This permitted teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment was sought, through audio/video real-time communications technology, in all residency training locations through December 31, 2024.

As summarized in the CY 2025 PFS final rule (89 FR 97764 through 97765), commenters encouraged CMS to establish this policy permanently and include in-person services to promote access to care, and stated that teaching physicians should be allowed to determine when their virtual presence would be clinically appropriate based on their assessment of the patient's needs and the competency level of the resident. In the CY 2026 PFS final rule, we finalized a policy to permanently allow teaching physicians to have a virtual presence in all teaching settings, and in clinical instances only when the service is a three-way telehealth visit, with the teaching physician, resident, and patient in different locations.

We have received feedback from interested parties that indicates that our current policy for teaching physicians and residents can, in somewhat rare cases, cause logistical complexities in scenarios where either the teaching physician or resident is already in the same physical location as the beneficiary. For CY 2027, we proposed a modification to our previously finalized policy. Rather than requiring the teaching physician, resident, and patient to each be in a different location, we proposed to allow teaching physicians to bill for services involving residents when either the teaching physician or resident is in the same physical location as the beneficiary. We will generally interpret physical presence to be defined as either the teaching physician or resident in the same room as the beneficiary, but we sought comment on other scenarios in which this may be appropriate. We also proposed that this would only be applicable to services that are on the Medicare Telehealth Services List. As always, documentation in the medical record must continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the Medicare telehealth service, which includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology. In accordance with section 1842(b)(7)(A)(i)(I) of the Act, the teaching physician must have personal oversight and involvement over the management of the portion of the case for which the payment is sought. We sought comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal, stating that the requirements finalized in the CY 2026 PFS final rule create unnecessary barriers to care and do not reflect

modern clinical practice. Commenters believed our proposed policy would provide flexibility and eliminate unnecessary barriers to care.

Response: We thank commenters for their feedback.

Comment: Commenters requested clarification regarding this policy. Specifically, commenters asked if clinical instances when the service is a three-way telehealth visit, with the teaching physician, resident, and patient all in different locations, would still be permitted.

Response: Yes, this proposal was intended to be additive to the policy finalized in the CY 2026 Final Rule.

Comment: Commenters requested confirmation that teaching physicians may bill for services involving residents when either the teaching physician or resident is in the same physical location as the beneficiary.

Response: As stated in the CY 2027 proposed rule (91 FR 43864), either the teaching physician or resident may be in the same physical location as the beneficiary.

Comment: Commenters requested that we allow for the teaching physician and resident to be in the same location, with the beneficiary being present remotely. Another commenter requested that we define these services based on the location of the patient, not of the teaching physician and/or resident.

Response: We thank commenters for their feedback and may consider this for future rulemaking.

Comment: Commenters requested information about the use of telehealth restrictions/guidance for teaching physicians billing for services involving residents or teaching physicians with virtual presence.

Response: All requirements for telehealth services would apply to these services, such as place of service codes and modifiers.

After consideration of public comments, we are finalizing as proposed and amending § 415.172.

5. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00, and specifies that, for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The proposed MEI percentage increase for CY 2027 was 2.5 percent and was based on the expected historical percentage increase of the 2017-based MEI. We proposed incorporating historical data through the second quarter of 2026 to determine the final CY 2027 MEI percentage increase. The final MEI update for CY 2027 is 2.6 percent reflecting historical data through the second quarter of 2026.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the proposed update. A commenter requested that CMS assess whether the statutory update adequately accounts for the actual cost of supporting a telehealth encounter.

Response: We appreciate the feedback from commenters. As noted above, the payment amount and annal updates to the telehealth originating site facility fee are set in statute. Specifically, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. It is not subject to recalculation based on additional external cost information.

After consideration of public comments, we are finalizing the CY 2027 increase to the telehealth originating site facility fee based on the most recent percentage increase in the 2017-based MEI of 2.6 percent, reflecting historical data through the second quarter of 2026 and shown in Table A–C1.

TABLE A-C1: THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	n/a	$20.00
2003	3.0	$20.60
2004	2.9	$21.20
2005	3.1	$21.86
2006	2.8	$22.47
2007	2.1	$22.94
2008	1.8	$23.35
2009	1.6	$23.72
2010	1.2	$24.00
2011	0.4	$24.10
2012	0.6	$24.24
2013	0.8	$24.43
2014	0.8	$24.63
2015	0.8	$24.83
2016	1.1	$25.10
2017	1.2	$25.40
2018	1.4	$25.76
2019	1.5	$26.15
2020	1.9	$26.65
2021	1.4	$27.02
2022	2.1	$27.59
2023	3.8	$28.64
2024	4.6	$29.96
2025	3.5	$31.01
2026	2.7	$31.85
2027*	2.6	$32.68

*Reflects the most recent estimate of the CY 2027 MEI percentage increase, based on historical data through the second quarter of 2026.

D. Valuation of Specific Codes Including Potentially Misvalued Services Under the PFS

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the AMA's Relative Value Unit Update Committee (RUC) identified a number of potentially misvalued codes each year using various identification screens, as outlined in section II.C. of this final rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comments about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886),

and re-proposed values for those codes in the CY 2017 PFS proposed rule. We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with interested parties, including the RUC, regarding our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

a. Background

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the non-facility setting.

We have developed several standard building block methodologies to value services appropriately when they have common billing patterns. For example, in cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs discuss our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist, we also include a summary of interested party reactions to our approach. We noted that many commenters and interested parties have expressed concern over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been

particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we use to make the adjustments is derived from their survey process. We note that we are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we adjusted work RVUs to account for significant changes in time, we started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we employed different approaches (including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation) to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs, we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure (such as building blocks or crosswalks to key reference or similar codes).

Several interested parties, including the RUC, have expressed general objections to our use of these methodologies and suggested that our actions in adjusting the recommended work RVUs are inappropriate; other interested parties have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we employed to identify potential values that reconcile the RUC-recommended work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

We received several comments regarding our methodologies for work valuation in response to the CY 2027 PFS proposed rule (91 FR 43865 through 43929) and the following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with CMS' reference to older work time sources and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, were not surveyed, and therefore, were not resource based. Commenters also stated that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: We agree that it is important to use the recent data available regarding work times and note that when many years have passed since work time has been measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had been routinely overestimated, this would undermine the relativity of the work RVUs on the PFS in general, in light of the fact that codes are often valued based on comparisons to other codes with similar work times. Such an assumption would also undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times that have been used in PFS ratesetting are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer

readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the use of time ratio methodologies for work valuation. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system, which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters suggested that CMS determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time. Commenters recommended that CMS embrace the clinical input from practicing physicians when valid surveys were conducted and provide a clinical rationale when proposing crosswalks for valuation of services.

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for survey information that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. In accordance with the statute, we believe that changes in time and intensity must be accounted for when developing work RVUs. When our review of recommended values reveals that changes in time are not accounted for in a RUC-recommended work RVU, the obligation to account for that change when establishing proposed and final work RVUs remains.

We recognize that it would not be appropriate to develop work RVUs solely based on time, given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. We clarify that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and this would not be accurate, as indicated by the many services that share the same time values but have different work RVUs. For example, among the codes reviewed in this CY 2027 PFS final rule, the following all share the same total work time of 45 minutes: CPT codes 55705, 61783, 63048, and 92527. However, these codes had very different proposed work RVUs of 1.88, 3.66, 3.38, and 0.92, respectively. These examples demonstrate that we do not value services purely based on work time; instead, we incorporate time as one of multiple different factors in our review process. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key references or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion in the CY 2017 PFS final rule (81 FR 80272 through 80277).

We do not believe that our review process is arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). Regarding the commenter's concerns regarding clinically relevant relationships, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

We have historically relied on survey data provided by the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC) to estimate practitioner time, work intensity, and practice expense for the purpose of establishing RVUs for the codes used for payment under the PFS. As described in section II.D. of this final rule, CMS regularly revalues codes as part of its potentially misvalued codes initiative, as required by section 1848(c)(2)(K) of the Act, using RUC survey data that shows clinicians' estimates of how long a particular service takes to complete. In the CY 2025 PFS final rule, we summarized public comments that we had received expressing concerns with using RUC data as a source of valuation and identifying a need for empirical data in the context of valuing advanced primary care management services (89 FR 97898). In response to these comments, we indicated that we were open to alternative recommendations for how to price these and other services, and that we would consider all options presented to us with a preference for information with empirical evidence behind it. We also reminded commenters that we do not exclusively rely on RUC recommendations and can receive data and recommendations from other outside sources as well.

In the CY 2019 PFS final rule (83 FR 59515), in response to comments, we clarified that terms ''reference services,'' ''key reference services,'' and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purpose of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate feedback from interested parties, we stated that we would seek to limit the use of the term, ''crosswalk,'' to those cases where we made a comparison to a CPT code with the identical work RVU (83 FR 59515). We noted that we also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher

work RVU and one at a lower work RVU.

We look forward to continuing to engage with interested parties and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and we will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table A–DX contains a list of codes and descriptors for which we finalized work RVUs for CY 2027; this includes all codes for which we received RUC recommendations by February 10, 2026. The finalized work RVUs, work time and other payment information for all CY 2027 payable codes are available on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

b. Efficiency Adjustment

In the CY 2026 final rule, we finalized the establishment of an efficiency adjustment to the work RVUs, as well as corresponding updates to the intraservice portion of physician time inputs for non-time-based services, with refinements (90 FR 49334 through 49345). We finalized a policy to apply this efficiency adjustment to the intraservice portion of physician time and work RVUs every 3 years. To calculate the efficiency adjustment, we finalized the use of the MEI productivity adjustment over a 5-year look back period from CY 2022 to CY 2026. We noted that using more recent historical data from the BLS yielded an efficiency adjustment of 3.6 percent. As we discussed in the CY 2026 PFS proposed rule, our approach in applying an efficiency adjustment was to take into account changes in medical practice and to better reflect resources involved, and it was designed to be conservative in nature, as we were concerned about making too many changes at once to the current methodology. Therefore, we finalized the proposed efficiency adjustment of 2.5 percent. We also exempted additional codes, specifically time-based codes, services on the CMS telehealth list, and new codes for CY 2026, as reflected in the Codes Subject to Efficiency Adjustment file. We stated in the proposed rule that this file with efficiency adjustment exemptions would be issued annually and could be found in the public use files for CY 2027 but we note that this language was inadvertently included in the proposed rule. We plan to post the Codes Subject to Efficiency Adjustment file for each year that the efficiency adjustment is applied, therefore the file will be posted again for CY 2029 rulemaking. For a full discussion of the efficiency adjustment, we directed readers to the CY 2026 PFS final rule (90 FR 49334 through 49345).

For CY 2027 rulemaking, the RUC made a number of work RVU recommendations prior to the finalization of the efficiency adjustment in the CY 2026 PFS final rule. In these cases, where the RUC's work RVU recommendation was based on a pre-adjusted work RVU, we have treated the recommendation as though the RUC had recommended the efficiency adjusted valuation. For example, the RUC initially recommended a work RVU of 0.35 for CPT code 95944 based on a crosswalk to the pre-adjusted work RVU of CPT code 95885. The work RVU of this crosswalk code became 0.34 after applying the efficiency adjustment, which we have used as the recommended valuation for CPT code 95944. This policy affected a relatively small number of the codes reviewed for CY 2027, and we have noted in the preamble where the efficiency adjustment affected a work valuation.

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code-by-code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or non-facility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table A–D11 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain refinements that will be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. In this final rule, we also note that many of the refinements listed in Table A–D11 result in changes under the $0.35 threshold and would be unlikely to result in a change to the RVUs.

We note that the finalized direct PE inputs for CY 2027 are displayed in the CY 2027 direct PE input files, available on the CMS website under the downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*. The inputs displayed there have been used in developing the CY 2027 PE RVUs as displayed in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined

or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, in that rule we referred readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this final rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2027 we received invoices for several new supply and equipment items. Tables A–D11 and A–D12 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this final rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage interested parties to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables A–D11 and A–D12 also include the number of invoices received and the number of non-facility allowed services for procedures that use these equipment items. We provide the non-facility allowed services so that interested parties will note the impact the particular price may have on PE relativity, as well as to identify items that are used frequently, since we believe that interested parties are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs, and we encourage interested parties to provide additional invoices so that we may identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows

us to identify clinically appropriate proxy items, we may use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the proposed PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the Outpatient Prospective Payment System (OPPS) Cap

We noted in the proposed rule that the list of services for the upcoming calendar year that are subject to the MPPR for diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services are displayed in the public use files for the PFS proposed and final rules for each year. In addition, the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap, are also displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2027 are available on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*. For more information regarding the history of the MPPR policy, we referred readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted on February 8, 2006) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The technical component (TC) (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare outpatient department (OPD) fee schedule amount established under the prospective payment system (PPS) for hospital OPD services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under section 1833(t)(2)(D) of the Act, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor under the PFS, for the fee schedule amount for such TC for such year. As required by section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.'' For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we referred readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2027, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined at section 1848(b)(4)(B) of the Act for purposes of this cap. Beginning for CY 2027, we proposed to include the following services in Table A–D1 on the list of codes to which the OPPS cap applies:

TABLE A-D1: CY 2027 CODE ADDITIONS TO THE OPPS CAP LIST

CPT Code	CPT Long Descriptor
70560	*Magnetic resonance angiography, head and neck, including image postprocessing; without contrast material(s)*
70561	*Magnetic resonance angiography, head and neck, including image postprocessing; with contrast material(s)*
70562	*Magnetic resonance angiography, head and neck; without contrast material(s) in one or both body regions, followed by contrast material(s) and further sequences in one or both body regions, including image postprocessing*
97611	*Real-time fluorescence wound imaging with clinical darkness to identify presence, location, load of bacteria and measur wound size, per day*
92978	*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to code for primary procedure)*
92979	*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to code for primary procedure)*

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the addition of CPT codes 70560, 70561, and 70562 to the OPPS cap list.

Response: We thank the commenters for their support.

We are finalizing the addition of the services listed in Table A–D1 to the list of codes subject to the OPPS cap as proposed.

c. Valuation of Specific Codes for CY 2027

(1) Fine Needle Aspiration (CPT codes 10005 and 10006)

The RUC received notification of interest from a specialty society to re-

review CPT codes 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*) and 10006 (*Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion*) at the January 2026 meeting.

We proposed the RUC-recommended work RVUs of 1.35 for CPT code 10005 and 1.00 for 10006.

We proposed the RUC recommended direct PE inputs for CPT codes 10005 and 10006 with one modification. The RUC submitted an invoice associated with this code family for an update in the price of the portable ultrasound (EQ250) equipment from its current price of $41,612.53 to $83,750.00. However, based on our review of current market pricing for portable ultrasounds, it appears that this type of equipment is becoming less expensive, not doubling in price over current. We also have reason to believe that the type of portable ultrasound listed on the submitted invoice represented the upper end of the market as opposed to the typical case. This invoice stated that the product in question constitutes ''a high-performance diagnostic ultrasound system'' including a 23-inch flat panel monitor. It is also not clear from the submitted invoice that the product in question is even a portable version of an ultrasound system.

Given that the price on this invoice was significantly higher than other portable ultrasounds available for purchase, we did not propose to update the price of the EQ250 portable ultrasound which is used in many other HCPCS codes. Instead, we proposed to create a new equipment item that describes a ''Fine Needle Aspiration portable ultrasound'' (ER130) which we proposed to price at the submitted $83,750.00 price. The ER130 equipment is proposed to replace the previous EQ250 portable ultrasound at the same 37 minutes for CPT code 10005 and 17 minutes for CPT code 10006 as recommended by the RUC.

Comment: A few commenters expressed concern that the proposed work RVU for CPT code 10005 would result in nearly a 5 percent reduction in reimbursement, which would significantly affect interventional radiology and procedural services. These commenters reiterated that fine needle aspiration (FNA) is essential for prompt diagnosis of cancer and other serious illness and frequently helps patients avoid more invasive surgery, and cautioned that reduced reimbursement could jeopardize access to this high-value, cost-effective care. Commenters stated that FNA procedures were undervalued prior to the resurvey and stressed the importance of continued collaboration among specialty societies, the RUC, and CMS to preserve beneficiary access.

Response: We appreciate commenters' concerns regarding the magnitude of the change in reimbursement for CPT code 10005. However, absent additional data or an alternative survey-based valuation from commenters, we believe the survey 25th percentile work RVU of 1.35 (based on 268 responses) represents the best available information for valuing this service at this time. We did not receive an alternative survey-based valuation or additional data in the comments that would support a different work RVU for CPT code 10005. We will continue to work with the RUC and specialty societies, including interventional radiology, on the ongoing valuation of these services in future rulemaking cycles.

Comment: The majority of commenters supported the proposed work RVUs and modified direct PE inputs for CPT codes 10005 and 10006 and urged CMS to finalize them as proposed. Several commenters also supported creation of the new ER130 equipment item for portable ultrasound used in image-guided FNA, noting that equipment pricing has not kept pace with the cost of the technology needed to safely localize target lesions, and urged CMS to finalize the item as proposed.

Response: We appreciate commenters' support. We are finalizing the work RVUs of 1.35 for CPT code 10005 and 1.00 for CPT code 10006 as proposed. We also appreciate commenters' support for the new ER130 equipment item. We did not receive comments disputing this approach or the $83,750.00 price and therefore we are finalizing the ER130 equipment item, along with the other direct PE inputs, as proposed.

(2) Skin Cell Suspension Autograft (CPT codes 15006, 15007, 15008, and 15009)

In September 2025, the CPT Editorial Panel created four codes to report skin cell suspension autograft (SCSA): CPT code 15006 *(Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1% of body area of infants and children),* CPT code 15007 *(Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)),* CPT code 15008 *(Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children),* and CPT code 15009 *(Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)).* The existing eight skin cell suspension autograft CPT codes (CPT codes 15011–15018) were deleted, and the ''Skin Cell Suspension Autograft'' guidelines were revised. The four new codes were surveyed for the January 2026 RUC meeting.

For CY 2027, we proposed the RUC-recommended work RVUs of 10.97 for CPT code 15006, 0.59 for CPT code 15007, 11.28 for CPT code 15008, and 0.98 for CPT code 15009. We proposed the RUC-recommended direct PE inputs for CPT codes 15006, 15007, 15008, and 15009 without refinement.

Comment: Commenters supported CMS' proposal of the RUC-recommended work RVUs and direct PE inputs for CPT codes 15006, 15007, 15008, and 15009. A commenter stated that two surgeons may perform distinct portions of the procedure simultaneously, which can reduce overall operative and anesthesia time and benefit the patient. The commenter stated that co-surgeon payment should be limited to circumstances where the surgeons' involvement is medically necessary and the documentation supports the distinct work performed by each surgeon, consistent with Medicare's existing co-surgery requirements. The commenter encouraged CMS to allow co-surgeon payment for the new SCSA codes when these requirements are met rather than creating a payment limitation that could discourage the most efficient surgical approach.

Response: We appreciate the commenters' support and feedback about the co-surgeon payment. We agree that co-surgeon payment may be appropriate for this service and are finalizing a co-surgery indicator of ''1'' for CPT codes 15006, 15007, 15008, and 15009.

After reviewing the comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 15006, 15007, 15008, and 15009, as proposed, with the clarification that we are finalizing a co-surgery indicator of ''1'' for these services.

(3) Computer Assisted Surgical Navigation (CPT code 20985)

CPT code 20985 *(Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (List separately in addition to code for*

primary procedure)) was first identified via the high-volume growth screen in April 2024.[7] The RUC's Relativity Assessment Workgroup (RAW) reviewed the action plan for 20985 and recommended that the RUC refer CPT code 20985 to the CPT Editorial Panel for revision, to modify the descriptor and address overlap with codes 0054T and 0055T. At the February 2025 CPT Editorial Panel meeting, CPT code 20985 was revised to remove ''image-less'' for reporting computer-assisted surgical navigational procedures for musculoskeletal procedures.

We proposed the RUC-recommended work RVU of 2.44, which is the current work RVU of CPT code 20985 after the efficiency adjustment was applied at the start of CY 2026. The RUC did not recommend and we did not propose direct PE inputs for CPT code 20985.

We did not receive any public comments on this policy, and therefore, we are finalizing as proposed.

(4) Ablation Therapy—Bone Tumors (CPT code 20994)

In February 2025, the CPT Editorial Panel approved new Category I add-on code 20994 (*Ablation therapy for reduction or eradication of bone tumor, including adjacent soft tissue when involved by tumor extension, cryoablation, open*) to describe and report cryoablation during an open surgical procedure where the bone is frozen after a tumor resection. CPT code 20994 was surveyed for the April 2025 meeting where the specialty recommended an interim value; the code was resurveyed at the September 2025 RUC meeting and recommendations submitted to CMS.

We proposed the RUC-recommended work RVU of 2.70 for CPT code 20994. The RUC did not recommend and we did not propose any direct PE inputs for this code.

Comment: A commenter stated that they supported the CMS proposal of the RUC-recommended work RVU for CPT code 20994.

Response: We appreciate the support for our proposed valuation from the commenter.

After consideration of the comments, we are finalizing the proposed work RVU of 2.70 for CPT code 20994.

(5) Intraosseous Fiducial Marker Placement (CPT codes 20988 and 20989)

At the May 2025 CPT Editorial Panel Meeting, CPT approved the addition of two codes and guidelines to report percutaneous intraosseous fiducial marker placement for the first target site and each additional target site, respectively: CPT codes 20988 (*Placement of localization marker(s) (e.g., fiducial marker[s]), intraosseous, percutaneous, including imaging guidance, when performed; first target site)* and 20989 *(Placement of localization marker(s) (e.g., fiducial marker[s]), intraosseous, percutaneous, including imaging guidance, when performed; each additional target site).* The specialties clarified that these codes are not new technology but are new codes to more accurately describe existing technology. These codes were surveyed for the October 2025 RUC meeting.

We proposed the RUC-recommended work RVU of 3.00 for CPT code 20988 and the RUC-recommended work RVU of 1.76 for CPT code 20989. We proposed the RUC-recommended direct PE inputs for both codes in the family without refinement.

Comment: Commenters supported our proposed values for the Intraosseous Fiducial Marker Placement codes.

Response: We appreciate the comments and after consideration of public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Intraosseous Fiducial Marker Placement family as proposed.

(6) Osteotomy—Spine (CPT codes 22210, 22212, 22214, and 22216)

In CY 2025 rulemaking, CPT codes 22210 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical*), 22212 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic*), 22214 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar*), and 22216 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (List separately in addition to primary procedure)*) were nominated as potentially misvalued services.

At the September 2025 CPT Editorial Panel Meeting, CPT revised the existing codes and guidelines to clarify that the codes include complete resection of the interspinous ligament and the entirety of the ligamentum flavum (ie, laminar and subarticular) to allow deformity correction through spinal column realignment. The osteotomy includes resection of the inferior portion of the lamina, the inferior facet of the cranial vertebra, the superior portion of the lamina, and the superior facet of the caudal vertebra. Following the revisions to the CPT guidelines and parentheticals for the code family, CPT codes 22210, 22212, 22214, and 22216 were surveyed for the January 2026 RUC meeting.

We disagree with the RUC's recommended work RVU for CPT codes 22210, 22212, and 22214 and we proposed lower work RVUs in all three cases. We reviewed the RUC's recommended work valuations and found them to be high, relative to other codes with the same or similar times. We noted that although the surveyed intraservice work time decreased substantially for all three of these codes, the RUC recommended either maintaining the current work RVU (for CPT code 22210) or increasing the work RVU (for CPT codes 22212 and 22214), stating that there was compelling evidence for increased work valuation based on a change in the patient population and a change in technology. However, these services maintained the same code descriptors, with only minor changes to their billing guidelines, indicating that despite the changes in technology and patient population the underlying procedure remains significantly similar. Therefore, we do not agree with the RUC that there has been an increase in intensity which would account for these recommended work RVUs. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs, we do believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner.

In the case of CPT codes 22210, 22212, and 22214, we believe that the work RVUs should be reduced to account for the significant decreases in surveyed intraservice work time.

Additionally, the postoperative office visit levels in this code family are increasing from three level 2 evaluation and management visits to one level 4 and two level 3 office visits. The shifting of the post-operative visits in this code family to higher level office visit codes that require more time, maintains the total time and thus reflects a higher intensity and can contribute to a higher work RVU which highlights our overall concerns with visits during the global period and how we believe that all of these visits are not typically occurring. We refer readers to section II.B. of this final rule under ''b. Global Surgical Packages'' for that discussion.

We disagree with the RUC recommended value of 24.75 for CPT

[7] *https://www.ama-assn.org/system/files/raw-progress-report.pdf.*

code 22210 and we instead proposed a work RVU of 23.12 based on a crosswalk to CPT code 34701 (*Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)*). This code has a lower intraservice time and a similar total time. We noticed that the surveyed intraservice time for CPT code 22210 is decreasing by nearly an hour, from 170 minutes to 120 minutes, indicating that the procedure typically takes much less time to perform than it did at the time of last review. Although the RUC has recommended significantly more postoperative time in the inpatient and outpatient visits, which has caused the total time of the procedure to increase slightly, we noted that this postoperative care should take place at a significantly lower intensity than the 50 minutes of intraservice time being removed from the code. We are concerned that, while the intraservice time for CPT code 22210 is decreasing from 170 to 120 minutes, this intraservice work time is being replaced with higher levels of post operative care to result in the total time being maintained similar to the current time. We believe that with the intraservice time going down, this reflects that the procedure has a lesser intensity than before and therefore it does not makes sense that the intensity of the post operative visit levels would increase. Separately, we continue to have concern with the post-operative visits in general and we do not believe the post-operative visits are happening and therefore would not justify the higher value.

We believe that it better serves relativity to propose a work RVU of 23.12, which maintains the current intensity of CPT code 22210, as opposed to proposing the RUC's recommended work RVU of 24.75 which results in an intensity increase for this code. We are supporting this proposed work RVU of 23.12 with a pair of other 90-day global codes with similar work time values: CPT code 34718 *(Endovascular repair of iliac artery, not associated with placement of an aorto-iliac artery endograft at the same session, by deployment of an iliac branched endograft, including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer), unilateral),* valued at a work RVU of 23.40 with an intraservice time of 120 minutes, and CPT code 34707 *(Endovascular repair of iliac artery by deployment of an ilio-iliac tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally to the iliac bifurcation, and treatment zone angioplasty/stenting, when performed, unilateral; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation)),* valued at a work RVU of 21.72 with an intraservice time of 120 minutes.

We disagree with the RUC recommended value of 23.20 for CPT code 22212 and we instead proposed a work RVU of 21.72 based on a crosswalk to CPT code 34707. This code has a lower intraservice time and a slightly lower total time. We noticed that the surveyed intraservice time for CPT code 22212 is also decreasing significantly, from 147 minutes to 120 minutes, which is offset by the RUC's recommendation of significantly more time in the postoperative visits. We do not agree with the RUC that the work RVU should be increasing by nearly 3.00 RVUs for a procedure where the intraservice time, which is likely to be the most difficult and dangerous part of the procedure, is going down by approximately half an hour. We believe that the RUC's recommended work RVU of 23.20 results in an intensity increase for this code and therefore it better serves relativity to propose a work RVU of 21.72, which maintains the current intensity of CPT code 22212. This proposed work RVU of 21.72 accounts for the decrease in intraservice time and change in the level of the postoperative office visits and is well bracketed by CPT code 34701, valued at a work RVU of 23.12 work with an intraservice time of 120 minutes, and CPT code 38115 *(Repair of ruptured spleen (splenorrhaphy) with or without partial splenectomy),* valued at a work RVU of 21.33 with an intraservice time of 120 minutes.

We disagree with the RUC recommended value of 21.72 for CPT code 22214 and we instead proposed a work RVU of 19.53 based on a crosswalk to CPT code 44125 (*Enterectomy, resection of small intestine; with enterostomy*). This code has a lower intraservice time and a higher total time and its use as a crosswalk code maintains the current intensity of CPT code 22214. As was the case with the first two codes, we noticed that the surveyed intraservice time for CPT code 22214 is decreasing significantly, from 163 minutes to 120 minutes, which is offset by the RUC's recommendation of significantly more time in the postoperative visits. We do not agree with the RUC that the work RVU should be increasing for a procedure where the intraservice time, the most difficult and dangerous part of the procedure, is going down by more than half an hour. We believe that it better serves relativity to propose a work RVU of 19.53, which maintains the current intensity of CPT code 22214, as opposed to proposing the RUC's recommended work RVU of 21.72 which results in an intensity increase for this code. This proposed work RVU of 19.53 accounts for the decrease in intraservice time and change in the level of the postoperative office visits and is well bracketed by CPT code 38115, valued at a work RVU of 21.33 with an intraservice time of 120 minutes, and CPT code 42890 *(Limited pharyngectomy),* valued at a work RVU of 18.65 with an intraservice time of 120 minutes.

We proposed the RUC recommended work RVU of 3.00 for CPT code 22216, as this code maintains its current intensity at the RUC's recommended valuation and maintains relativity with other similar add-on codes.

We proposed the RUC recommended direct PE inputs for all the codes in this family without refinement.

Comment: For CPT code 22210 commenters disagreed with CMS's crosswalk proposal because it does not accurately account for the full amount of physician work or capture the overall intensity/complexity of the service. Commenters recommended more post-operative time in both the inpatient and outpatient visits.

Response: We continue to believe that the proposed work RVU of 23.12 for CPT code 22210 is the most accurate valuation for this service. In our review of this code, we compared CPT code 22210 to other similar 90-day global codes with 90 minutes of intraservice time and found that the RUC's

recommended work RVU of 24.75 was higher than other codes with similar time values.

The surveyed intraservice time for CPT code 22210 decreased by 50 minutes, from 170 to 120 minutes, indicating that the procedure typically takes less time to perform than it did when it was last reviewed by the RUC. The RUC recommended significantly more post-operative time in the inpatient and outpatient visits which caused the total time to increase for this service. The decrease in intraservice time directly relates to the intensity and we continue to believe that the decrease in intensity would lead to a decrease in work RVU. Looking at the time ratios based on the existing times for CPT code 22210 (170 minutes of total time) to the new proposed time values (120 minutes of total time), that further points to the RUC recommendation for this code as being too high. In addition, we do not believe that the post-operative visits contributing to the increase in total time are happening. We continue to believe that the two 90-day crosswalk codes selected fully capture the same time and intensity of the service.

Comment: For CPT code 22212 some commenters disagreed with the crosswalk codes selected by CMS. Some commenters believe that the physician work was underestimated. Commenters disagreed and stated that a significant decrease in intra-operative time does not necessarily reflect a decrease in intra-operative work but rather an increase in efficiency and intensity and that is captured by the RUC process. We note that the intraservice time ratio provided by the RUC does not support a higher work RVU for this code. Commenters stated that this procedure is often done with other procedures at the same time and would be subject to the MPPR policies and also note changes in the patient population who undergo these procedures and thus require higher level of postoperative care.

Response: We continue to believe that the proposed work RVU of 21.72 for CPT code 22212 is the most accurate valuation for this service. In our review of this code, we compared CPT code 22212 to other similar 90-day global codes with 90 minutes of intraservice time and found that the RUC's recommended work RVU of 23.20 was higher than other codes with similar time values based on our searches.

We continue to believe that the two determining factors of the work RVU are time and intensity and continue to believe that these elements were reflected in the 90-day codes selected as crosswalks. Looking at the time ratios based on the crosswalk code selected by the RUC, the time ratio suggests that the work RVU should be lower than the RUC recommendation. We believe that the work RVUs selected based on the crosswalks selected by CMS continue to maintain relativity within the family of codes. Given the roughly half hour decrease for this code in intraservice time based on the RUC survey, we believe that the crosswalk codes selected with similar time values accurately capture the time and intensity for the service.

Comment: For CPT code 22214 commenters disagreed with the crosswalk codes selected by CMS stating that they did not accurately account for the full breadth of work, intensity and complexity necessary to perform the services. Commenters noted that this procedure is often performed with other spine procedures and that there has been a change in the complexity of the patient population and it should be therefore cross walked to a code with higher post-operative care.

Response: We continue to believe that the proposed work RVU of 19.53 for CPT code 22214 is the most accurate valuation for this service. In our review of this code, we compared CPT code 22214 to other similar 90-day global codes with 90 minutes of intraservice time and found that the RUC's recommended work RVU of 21.72 was higher than other codes with similar time values.

We continue to believe that the time and intensity was accurately captured in the crosswalk codes selected by CMS. There was a decrease of 43 minutes of intraservice time for this code and that would directly correlate to a linear decrease in the work RVU. We believe the two other 90-day global codes selected accurately represent the same time and intensity and maintain relativity of the codes in this family.

We continue to believe that the determining factors of valuation are time and intensity and this is reflected in our proposed crosswalks. We understand that while the intra-time went down, the increase in total time resulted from a change in the level of post operative visits. Additionally, we want to note that the shifting of the post-operative visits in this code family to higher level office visit codes that require more time, maintains the total time and thus reflects a higher intensity and can contribute to a higher work RVU which highlights our overall concerns with visits during the global period and how we believe that all of these visits are not typically occurring.

After consideration of public comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 22210, 22212, 22214, and 22216 as proposed.

(7) Arthroplasty—Shoulder (CPT Codes 23470 and 23472)

In April 2025, the RAW identified CPT code 23472 as having a site of service anomaly where Medicare data from 2021–2023 indicated it was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital E/M services within the global period. The RAW concluded that CPT code 23472 represented a site of service anomaly and identified CPT code 23470 as part of this family of services. The RUC therefore surveyed CPT codes 23470 (*Arthroplasty, glenohumeral joint; hemiarthroplasty*) and 23742 (*Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (e.g., total shoulder))*) for the September 2025 meeting.

We disagreed with the RUC's recommended work RVU of 15.60 for CPT code 23470 and we instead proposed a work RVU of 13.81 based on a crosswalk to CPT code 27416 (*Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])*). The RUC recommended a work RVU of 15.60, which is the current work RVU of the RUC's crosswalk code 67107 (*Repair of retinal detachment; scleral buckling (such as lamellar scleral dissection, imbrication or encircling procedure), including, when performed, implant, cryotherapy, photocoagulation, and drainage of subretinal fluid*) after the efficiency adjustment was applied at the start of CY 2026. In reviewing CPT code 23470, we noted that the recommended intraservice time is decreasing from 113 minutes to 90 minutes (20 percent reduction), and the recommended total time is decreasing from 390 minutes to 330 minutes (22 percent reduction); however, the RUC-recommended work RVU is only decreasing from 17.44 to 15.60, which is a reduction of just over 10 percent. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner.

More specifically, CPT code 23470 was identified by the RAW as having a

site of service anomaly in which the service was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RUC has recommended the removal of five inpatient hospital visits along with recommending a decrease of 23 minutes to the intraservice work time based on the survey. We stated in the proposed rule, that we did not believe that the RUC's recommended work decrease of fewer than two RVUs appropriately captures this decrease in procedure time and physician work for CPT code 23470. We also noticed that the RUC's recommended work RVU of 15.60 results in an intensity increase for CPT code 23470. We stated in the proposed rule that we disagreed that an increase in intensity for this code is warranted, particularly given that the typical case for the procedure is moving from the inpatient to outpatient setting. The code descriptor for CPT code 23470 also remains unchanged which suggests that there has been no significant change in the procedure's performance or intensity. Furthermore, we also found that the recommended work RVU of 15.60 was higher than nearly all of the other 90-day global codes with similar time values, and we noted in the proposed rule that we did not believe that this type of shoulder arthroplasty procedure, which is typically done on a routine and elective basis, would warrant an intensity and work valuation at the very top of the scale relative to other 90-day globals with similar time values. Because the PFS uses a relative value system, we noted that we believed it is important to highlight that these codes fail to maintain relativity with related surgical services. We therefore proposed a work RVU of 13.81 based on a crosswalk to CPT code 27416 which we stated in the proposed rule preserves the current intensity of CPT code 23470 and better maintains relativity with the rest of the PFS.

We disagreed with the RUC's recommended work RVU of 19.35 for CPT code 23472 and we instead proposed a work RVU of 17.49 based on a crosswalk to CPT code 67414 (*Orbitotomy without bone flap (frontal or transconjunctival approach); with removal of bone for decompression*). The RUC recommended a work RVU of 19.35, which is the current work RVU of the RUC's crosswalk code 61798 (*Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion*) after the efficiency adjustment was applied at the start of CY 2026. In reviewing CPT code 23472, we note that the recommended intraservice time is decreasing from 140 minutes to 120 minutes (15 percent reduction), and the recommended total time is decreasing from 448 minutes to 348 minutes (24 percent reduction); however, the RUC-recommended work RVU is only decreasing from 21.58 to 19.35, which is a reduction of just over 10 percent. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner.

More specifically, CPT code 23472 was identified by the RAW as having a site of service anomaly in which the service was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RUC has recommended the removal of 3 inpatient hospital visits, one outpatient E/M visit, a decrease from a full to a half discharge visit, along with recommending a decrease of 20 minutes to the intraservice work time based on the survey. We stated in the proposed rule that we did not believe that the RUC's recommended work decrease of just over two RVUs appropriately captures this decrease in procedure time and practitioner work for CPT code 23472. We also noticed that the RUC's recommended work RVU of 19.35 results in an intensity increase for CPT code 23472. We stated in the proposed rule that we disagreed that an increase in intensity for this code is warranted, particularly given that the typical case for the procedure is moving from the inpatient to outpatient setting. We noted that the code descriptor for CPT code 23472 also remains unchanged which suggests that there has been no significant change in the procedure's performance or intensity. Furthermore, we also found that the recommended work RVU of 19.35 was higher than nearly all of the other 90-day global codes with similar time values, and we stated in the proposed rule that we did not believe that this type of total shoulder arthroplasty procedure, which is typically done on a routine and elective basis, would warrant an intensity and work valuation at the very top of the scale relative to other 90-day globals with similar time values. We therefore proposed a work RVU of 17.49 based on a crosswalk to CPT code 67414 which we stated in the proposed rule preserves the current intensity of CPT code 23472 and better maintains relativity with the rest of the PFS.

We proposed the RUC-recommended direct PE inputs for CPT codes 23470 and 23472 without refinement.

We received a large volume of comments disagreeing with the proposed valuations for CPT codes 23470 and 23472, as well as the related codes in the Arthroplasty—Hip (CPT code 27130) and Arthroplasty—Knee (CPT code 27447) code families. We will first address the general comments regarding this group of arthroplasty codes before addressing the comments specifically regarding valuation of each CPT code in their respective sections.

Comment: Many commenters detailed the clinical benefits of joint replacement procedures, stating that these were among the most successful procedures in modern medicine, restoring mobility, relieving pain, reducing disability, and allowing millions of Medicare beneficiaries to maintain their independence. Commenters stated that payment for the arthroplasty codes should accurately reflect the work, technical skill, clinical judgment, and risk required to perform these complex operations.

Response: We appreciate the additional detail provided by the commenters regarding the clinical benefits of these procedures. We agree with the commenters that these are important services that can restore mobility and improve quality of life for Medicare beneficiaries.

Comment: Many commenters stated that the proposed valuations for these arthroplasty procedures constituted unsustainable payment reductions and threatened the ability of independent orthopedic practices to continue caring for Medicare patients. Commenters stated that practices would have no choice but to limit Medicare volume, leaving local seniors to face significant delays in accessing surgical care, resulting in prolonged pain, loss of autonomy, and a higher demand for non-surgical interventions. Commenters stated that this would lead to delays in treatment and other barriers to accessing care as well as accelerating the acquisition of independent physician practices by hospitals and national health insurers.

Response: We share the concern of commenters regarding the importance of access to care for these services. We have factored these access concerns into the finalized work RVUs for these codes; see later in this section.

Comment: Many commenters disagreed that the shift in the typical site of service from inpatient to outpatient for the arthroplasty codes constituted less work. Commenters stated that what changed with the site of service was not whether postoperative work occurred, but how efficiently it could be delivered, stating that when a patient is discharged within hours of surgery, caregiver surveillance does not disappear but converts into a diffuse and less efficient set of activities. Commenters stated that the practitioner and the practitioner's staff absorb the care coordination that inpatient nursing and hospitalist services previously provided: same-day discharge planning, home health and durable medical equipment arrangement, anticoagulation management, wound and drainage monitoring by telephone and portal, early physical therapy coordination, and rapid triage of the complications that previously surfaced on an inpatient ward. Commenters stated that the practitioner's work does not decrease but actually increases when the patient leaves the hospital sooner.

Response: We clarify for commenters that we do not believe the movement of these procedures from typically inpatient to typically outpatient site of service has necessarily resulted in less work, or that the same postoperative care is no longer being provided by practitioners and clinical staff. Our proposed valuations recognize that longer and more complex outpatient E/M visits are now taking place for these procedures, such as CPT code 23470 changing from Level 2 outpatient E/M visits to Level 3 and Level 4 outpatient E/M visits in its global period. We believe that the removal of the inpatient hospital visits, combined with the increase in the visit level of the outpatient E/M visits, accurately reflects how the postoperative care has shifted along with the typical site of service. Our proposed valuations for the arthroplasty codes are largely based on the surveyed changes in work time, not the shift in site of service. We discussed the change in site of service since it reinforced our belief that there has been no significant change in the performance or intensity of these services. We agree with the commenters that merely changing the typical site of service has not necessarily reduced the work of these procedures; however, we disagree that changing the site of service has made the procedures *more* intense as the RUC recommended and some commenters suggested. We can also clarify for commenters that these services can still be provided in the inpatient setting, even if it is not the typical case, just as they previously could be provided in the outpatient setting when inpatient was typical.

Comment: Several commenters stated that some of the services for the arthroplasty codes continue to take place in the inpatient setting. Commenters stated that the arthroplasty codes were valued identically whether the patient was discharged within hours of surgery or remained hospitalized for several days, with the proposed valuations containing no stratification by site of service, no adjustment for length of stay, and no severity tier. Commenters stated that CMS should restore the inpatient hospital visits and full discharge visit to account for the resource cost of these services.

Response: We remind commenters that the PFS values services based on the typical case. Although some of these arthroplasty services will continue to be provided in the inpatient setting, it is clear that this is no longer the typical site of service. We therefore agree with the RUC's recommendation to remove the inpatient hospital visits and full discharge visit from the global period of these codes.

Comment: Several commenters stated that practitioners of these arthroplasty procedures have been at the forefront of the transition to value-based care as high-volume, high-value procedures present significant opportunities for improvements in quality and efficiency. Commenters stated that much of the effectiveness of these programs, however, has come from the shift from reactive, hospital-based postoperative work to proactive, office-based preoperative work which fall outside of the global surgical bundle because they are not included in the traditional RUC survey definition of ''pre-service activities,'' nor the time clinical staff spent providing certain pre-service activities for the patient and family. Commenters stated that penalizing surgeons for this successful collaboration, by eliminating valuation for postoperative visits while not reimbursing preservice optimization time, does not lead to more accurate payments.

Response: We appreciate these efforts by practitioners to deliver care for arthroplasty services which is both more proactive and more efficient, which we believe has been reflected in the decreased intraoperative survey times for these procedures. However, we believe that this additional work has been accurately captured in the updated survey times for the procedures, which include higher preservice and immediate postservice work times, as well as more complex postoperative E/M visits within the global period. For example, CPT code 23470 was recommended by the RUC and proposed by CMS in the proposed rule with 15 additional minutes of preservice work time (58 to 73 minutes) and 16 additional minutes of immediate postservice work time (19 to 35 minutes), along with the upcoding of the outpatient E/M visits described previously.

Comment: Several commenters stated that the proposed valuations for the arthroplasty codes were especially difficult to justify given their ongoing increase in utilization. Commenters stated that annual primary total knee arthroplasty volume among Medicare beneficiaries grew from roughly 604,000 in 2013 to over 1 million in 2022, and was projected to reach nearly 2.8 million by 2040, a further 176 percent increase from current levels. Primary total hip arthroplasty volume was projected to grow even faster, from roughly 595,000 in 2022 to over 2.1 million by 2040, an increase of roughly 265 percent. Commenters stated that reducing payment for hip, knee, and shoulder replacement at the same time demand for these procedures was rising sharply risked discouraging the workforce capacity needed to meet that demand.

Response: As stated previously, we share the concern of commenters regarding the clinical benefits and importance of access to care for these services. However, rapid utilization growth of these services only further emphasizes the need for accurate, resource-based valuation of the arthroplasty codes. We continue to believe that the updated work time data from the most recent surveys supports our proposed valuations for these codes.

Comment: Several commenters stated that the arthroplasty codes had been repeatedly reviewed over the past two decades. Commenters stated that CPT code 27130 has been reviewed five times, CPT code 27447 has been reviewed six times, and CPT code 23472 has been reviewed five times, with every review of all three codes since 2013 reducing their work RVUs. Commenters stated that a valuation process that produces a further reduction at every review for more than a decade is not converging on an accurate value.

Response: We disagree with the commenters that frequent review of the arthroplasty codes has produced inaccurate valuations. Since these are high volume services with rapidly increasing utilization, we believe that frequent reviews of these codes have

been warranted to ensure accurate valuations. These reviews have repeatedly produced surveys with reduced work times which have then been reflected in reduced work RVUs for the arthroplasty codes; this has been reflected in both the RUC's recommendations and CMS' finalized values. We believe that these updated valuations reflect the improved efficiencies in the arthroplasty codes, which no longer require the same time and effort that they did two decades earlier.

Comment: Several commenters cited a 2018 study published in the Journal of the American Medical Association which found that total hip arthroplasty took 5% longer than the PFS valued time, while total knee arthroplasty had an equal duration. Commenters stated that when the authors made these conclusions in 2018, the arthroplasty procedures had higher work RVUs than what CMS was proposing for CY 2027.

Response: While we appreciate this additional study provided by the commenters, it dates back to 2018 prior to the current review of these procedures. We believe that it is more accurate to base valuation on the most recent work and time surveys that took place in 2025.

The following comments were specifically directed at the proposed work RVUs for the shoulder arthroplasty (CPT codes 23470 and 23472).

Comment: Several commenters disagreed with the proposed work RVU of 13.81 for CPT code 23470. Commenters stated that the current valuation for CPT code 23470 was based on a review during the Harvard study that included responses from only 11 general orthopedic surgeons for intraservice time. Commenters stated that the existing Harvard times were not valid for relative comparison to the current survey or to other codes.

Response: We agree that it is important to use the recent data available regarding time, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The times currently associated with codes play a very important element in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times and it would undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 final rule (81 FR 80273 through 80274).

Comment: Several commenters stated that they disagreed with the proposed crosswalk to CPT code 27416 at a work RVU of 13.81 to value CPT code 23470, and suggested that CMS should instead use the RUC's recommended crosswalk to CPT code 67107 at a work RVU of 15.60. Commenters stated that CPT code 27416 was not a valid crosswalk code because it is less intense due to lower neurovascular risk and lower risk of positioning complications. Commenters stated that CPT code 67107 was a more appropriate crosswalk, as its most recent survey was in 2016, whereas CPT code 27416 was last surveyed in 2008. Commenters stated that the intensity and risk of impact on vision in CPT code 67107 hold a risk that more closely approximates the risk of functional loss with neurovascular or infection complications that can be associated with CPT code 23470.

Response: We continue to have concerns regarding the increased intensity of CPT code 23470 as valued at the RUC's recommended work RVU of 15.60. As we discussed in the proposed rule, we also have concerns that the RUC's valuation does not adequately capture the changes in surveyed work time. However, we were persuaded by commenters that finalizing the proposed work RVU of 13.81 for CPT code 23470 could significantly affect providers, create barriers to accessing care for Medicare patients, and does not fully capture the resource costs of these procedures. For these specific codes, we were persuaded that the RUC-recommended work RVU of 15.60 reflected the associated time and intensity described by the commenters. We continue to remain concerned regarding the overall accuracy of these values and welcome additional information that we could consider for future rulemaking. We are therefore finalizing the RUC's recommended work RVU of 15.60 for CPT code 23470.

Comment: Several commenters disagreed with the proposed work RVU of 17.49 for CPT code 23472. Commenters stated that the typical operative technique for a total shoulder arthroplasty has changed since the last review 10 years ago to a ''reverse total shoulder arthroplasty'' (RTSA), under which the normal ''ball-and-socket'' structure of the shoulder is reversed. Commenters stated that this is the opposite of standard (anatomic) shoulder arthroplasty (ATSA) and that over the past decade, both the technology and indications for reverse procedures have expanded, making the surgery significantly more complex due to broader application, more challenging patient anatomy, and the need for specialized surgical skill and implant design. Commenters stated that comparison of current survey data for CPT code 23472 with older 2012 data reveals less intraoperative time but at a higher complexity and intensity, along with fewer hospital visits but higher-level office work. Commenter stated that the RUC's recommended work RVU of 19.35 reflected the increased intensity of the more complex procedure while also recognizing a decrease in total time.

Response: We appreciate the additional clinical details regarding CPT code 23472 provided by the commenters. We concur with the commenters that the clinical description of work for CPT code 23472 has undergone modest changes since the time of last review, which may account for a modest increase in the intensity of the procedure.

Comment: Several commenters stated that they disagreed with the proposed crosswalk to CPT code 67414 at a work RVU of 17.49 to value CPT code 23472, and suggested that CMS should instead use the RUC's recommended crosswalk to CPT code 61798 at a work RVU of 19.35. Commenters stated that CPT code 67414 has consequential risk with injury to the muscles or nerves of the orbital region but involves debridement or removal of structures with no

reconstruction. Commenters stated that CPT code 23472 has greater intensity than the CMS crosswalk code based on the need for approach, preparation, and critically extensive reconstruction using metal implants and polyethylene, along with moderate neurovascular risk due to retraction or direct injury during approach and implantation, risk of fracture, risk of injection, and risk of dislocation. Commenters stated that CPT code 23472 was most appropriately valued based on a direct work RVU crosswalk to CPT code 61798.

Response: We continue to have some concerns regarding the increased intensity of CPT code 23472 as valued at the RUC's recommended work RVU of 19.35. As we discussed in the proposed rule, we also have concerns that the RUC's valuation does not adequately capture the changes in surveyed work time. However, we were persuaded by commenters that finalizing the proposed work RVU of 17.49 for CPT code 23472 could significantly affect providers and create barriers to accessing care for Medicare patients, and does not fully capture the resource cost of these procedures. For these specific codes, we were persuaded that the RUC-recommended work RVU of 19.35 reflected the associated time and intensity described by the commenters. We continue to remain concerned regarding the overall accuracy of these values and welcome additional information that we could consider for future rulemaking. We are therefore finalizing the RUC's recommended work RVU of 19.35 for CPT code 23472.

After consideration of the comments, we are not finalizing our proposed work RVUs and are instead finalizing the RUC's recommended work RVUs for CPT codes 23470 and 23472. We are finalizing the direct PE inputs for these CPT codes as proposed.

(8) Arthroplasty—Hip (CPT Code 27130)

In April 2025, the RAW identified CPT code 27130 as having a site of service anomaly where Medicare data from 2021 through 2023 indicated it was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RAW concluded that the code represented a site of service anomaly, and the RUC therefore surveyed CPT code 27130 (*Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft*) for the September 2025 meeting.

We stated in the proposed rule that we disagreed with the RUC's recommended work RVU of 16.70 for CPT code 27130 and we instead proposed a work RVU of 15.37 based on a crosswalk to CPT code 43774 (*Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components*). The RUC recommended a work RVU of 16.70, which is the current work RVU of the RUC's crosswalk code 67108 (*Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique*) after the efficiency adjustment was applied at the start of CY 2026. In reviewing CPT code 27130, we noted that the recommended total time is decreasing from 377 minutes to 305 minutes (19 percent reduction); however, the RUC-recommended work RVU is only decreasing from 19.11 to 16.70, which is a reduction of 13 percent. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner.

More specifically, CPT code 27130 was identified by the RAW as having a site of service anomaly in which the service was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RUC has recommended the removal of 2 inpatient hospital visits, a decrease from a full to a half discharge visit, along with recommending a decrease of 10 minutes to the intraservice work time based on the survey. We stated in the proposed rule that we do not believe that the RUC's recommended work decrease of just over two RVUs appropriately captures this decrease in procedure time and practitioner work for CPT code 27130. We also noticed that the RUC's recommended work RVU of 16.70 results in an intensity increase for CPT code 27130. We stated in the proposed rule that we disagreed that an increase in intensity for this code is warranted, particularly given that the typical case for the procedure is moving from the inpatient to outpatient setting. The code descriptor for CPT code 27130 also remains unchanged which suggests that there has been no significant change in the procedure's performance or intensity. Furthermore, we also found that the recommended work RVU of 16.70 was higher than nearly all of the other 90-day global codes with similar time values, and we stated in the proposed rule that we did not believe that this type of total hip arthroplasty procedure, which is typically done on a routine and elective basis, would warrant an intensity and work valuation at the very top of the scale relative to other 90-day globals with similar time values. We therefore proposed a work RVU of 15.37 based on a crosswalk to CPT code 43774 which we stated in the proposed rule preserves the current intensity of CPT code 27130 and better maintains relativity with the rest of the PFS.

We proposed the RUC-recommended direct PE inputs for CPT code 27130 without refinement.

Comment: A commenter stated that CMS cited a reduction in time for total hip arthroplasty from 377 minutes to 305 minutes, an approximately 19 percent decrease, as support for the proposed work value. The commenter requested that CMS clarify in the final rule precisely which time component this figure represents and how it was derived.

Response: We can clarify for the commenter that these updated work times for CPT code 27130 were recommended by the RUC based on new survey data. The work times for CPT code 27130, and all other CPT codes listed on the PFS, are included in the ''CY 2027 PFS Final Rule Physician Work Time'' public use file available on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

Comment: Several commenters disagreed with the proposed work RVU of 15.37 for CPT code 27130. Commenters stated that the work for CPT code 27130 has remained the same and is performed in less time, as captured by the RUC process, which accounts for an increase in intensity. Commenters stated that by definition the same work performed in less time is more intense; since CPT code 27130 still involves the same basic steps since its inception, an increase in efficiency should not be conflated with less work or less intensity.

Response: We remain unconvinced that there has been a significant increase in intensity for this code. Intensity of

work under the Physician Fee Schedule reflects skill, expertise, effort, stress, and other factors that influence the assessed relative value of time spent. We disagree with the commenters that performing the same work in less time inherently means that the intensity of a procedure has increased; changes in practice patterns, improvements in technology, or greater efficiencies in the delivery of care can all account for shorter procedure times without a corresponding increase in intensity. Commenters agreed with our statement in the proposed rule that CPT code 27130 had undergone no significant change in the procedure's performance as reflected by its unaltered code descriptor. Under our methodology for work valuation, if the surveyed work times are decreasing and there is general agreement that the procedure itself has remained unchanged, this supports a decrease in the work RVU, not a conclusion that the intensity of the procedure has increased to match the decrease in surveyed work time. However, we do note that the RUC's recommended work RVU of 16.70 for CPT code 27130 already constitutes a reduction from the current work RVU of 19.11 which we have concluded is more appropriate than the proposed work RVU of 15.37.

Comment: Several commenters stated that they disagreed with the proposed crosswalk to CPT code 43774 at a work RVU of 15.37 to value CPT code 27130, and suggested that CMS should instead use the RUC's recommended crosswalk to CPT code 67108 at a work RVU of 16.70. Commenters stated that CPT code 27130 has greater intensity/complexity than the CMS crosswalk code based on the need for approach, preparation, and critically extensive reconstruction using metal implants and polyethylene. Commenters stated that CPT code 27130 requires significantly more perioperative work, including management of pain/opioid medications, anticoagulation, dressing/closure, and perioperative services such as physical therapy and that total hip arthroplasty is performed standing, often with a lead apron, and involves significant soft tissue manipulation and limb support. Commenters stated that the proposed work RVU of 15.37 for CPT code 27130 creates a rank order anomaly when compared to CPT codes 27236 and 27125, which are less intense, of shorter duration, and typically performed for a fracture, implying less pre-operative work. Commenters stated that CPT code 27130 was most appropriately valued based on a direct work RVU crosswalk to CPT code 67108.

Response: We continue to have concerns regarding the increased intensity of CPT code 27130 as valued at the RUC's recommended work RVU of 16.70. As we discussed in the proposed rule, we also have concerns that the RUC's valuation does not adequately capture the changes in surveyed work time. However, we were persuaded by commenters that finalizing the proposed work RVU of 15.37 for CPT code 27130 could significantly affect providers and create barriers to accessing care for Medicare patients and does not fully capture the resource cost of these procedures. For these specific codes, we were persuaded that the RUC-recommended work RVU of 16.70 reflected the associated time and intensity described by the commenters. We continue to remain concerned regarding the overall accuracy of these values and welcome additional information that we could consider for future rulemaking. We are therefore finalizing the RUC's recommended work RVU of 16.70 for CPT code 27130.

After consideration of the commenters, we are finalizing the RUC's recommended work RVU of 16.70 for CPT code 27130. We are finalizing the direct PE inputs as proposed.

(9) Sacroiliac Joint Arthrodesis (CPT codes 27278 and 27279)

At the May 2025 CPT Editorial Panel meeting. CPT code 27278 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive, including imaging guidance, unilateral; placement of intra-articular structural bone graft, metal and/or synthetic device(s) without cortical piercing, including use of osteopromotive material and/or obtaining bone graft, when performed*) was revised to include imaging guidance, placement of intra-articular structural bone graft, metal, and/or synthetic device(s) without cortical piercing and CPT code 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive, including imaging guidance, unilateral; placement of transarticular and/or intra-articular device(s) that engage bone with intrinsic fixation (e.g., screw[s], flange[s], blade[s]) piercing the lateral cortex of the sacrum and the medial cortex of the ilium (with or without piercing the lateral cortex of the ilium), including use of osteopromotive material and/or obtaining bone graft, when performed*) was revised to include placement of transarticular and/or intra-articular device(s) that engage bone with intrinsic fixation (*e.g.,* screw(s), flange(s), blade(s)) piercing the lateral cortex of the sacrum and the medial cortex of the ilium. CPT codes 27278 and 27279 were surveyed for the September 2025 RUC meeting.

We proposed the RUC-recommended work RVUs of 7.66 for CPT code 27278 (which is the current work RVU of the code after the efficiency adjustment was applied at the start of CY 2026) and 11.00 for CPT code 27279. We also proposed the RUC-recommended direct PE inputs for CPT codes 27278 and 27279 without refinement.

Comment: Commenters supported CMS's proposal of the RUC-recommended work RVUs and direct PE inputs for CPT codes 27278 and 27279 without refinements

Response: We thank the commenters for their support. After consideration of the public comment, we are finalizing as proposed.

(10) Arthroplasty—Knee (CPT code 27447)

In April 2025, the RAW identified CPT code 27447 as having a site of service anomaly where Medicare data from 2021–2023 indicated it was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RAW concluded that the code represented a site of service anomaly, and the RUC therefore surveyed CPT code 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*) for the September 2025 meeting.

We stated in the proposed rule that we disagreed with the RUC's recommended work RVU of 16.70 for CPT code 27447 and we instead proposed a work RVU of 15.94 based on a crosswalk to CPT code 65730 (*Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)*). The RUC recommended a work RVU of 16.70, which is the current work RVU of the RUC's crosswalk code 67108 (R*epair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique*) after the efficiency adjustment was applied at the start of CY 2026. In reviewing CPT code 27447, we noted that the recommended total time is decreasing from 374 minutes to 305 minutes (19 percent reduction); however, the RUC-recommended work RVU is only decreasing from 19.11 to

16.70, which is a reduction of 13 percent. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner.

More specifically, CPT code 27447 was identified by the RAW as having a site of service anomaly in which the service was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RUC has recommended the removal of two inpatient hospital visits, a decrease from a full to a half discharge visit, along with recommending a decrease of 7 minutes to the intraservice work time based on the survey. We stated in the proposed rule that we did not believe that the RUC's recommended work decrease of just over two RVUs appropriately captures this decrease in procedure time and practitioner work for CPT code 27447. We also noticed that the RUC's recommended work RVU of 16.70 results in an intensity increase for CPT code 27447. We stated in the proposed rule that we disagreed that an increase in intensity for this code is warranted, particularly given that the typical case for the procedure is moving from the inpatient to outpatient setting. We further noted that the code descriptor for CPT code 27447 also remains unchanged which suggests that there has been no significant change in the procedure's performance or intensity. Furthermore, we also found that the recommended work RVU of 16.70 was higher than nearly all of the other 90 day global codes with similar time values, and we stated in the proposed rule that we did not believe that this type of total knee arthroplasty procedure, which is typically done on a routine and elective basis, would warrant an intensity and work valuation at the very top of the scale relative to other 90 day globals with similar time values. We therefore proposed a work RVU of 15.94 based on a crosswalk to CPT code 65730 which we noted preserves the current intensity of CPT code 27447 and better maintains relativity with the rest of the PFS.

We proposed the RUC-recommended direct PE inputs for CPT code 27447 without refinement.

Comment: Several commenters disagreed with the proposed work RVU of 15.94 for CPT code 27447. Commenters stated that the work for CPT code 27447 has remained the same and is performed in less time, as captured by the RUC process, which accounts for an increase in intensity. Commenters stated that by definition the same work performed in less time is more intense; since CPT code 27447 still involves the same basic steps since its inception, an increase in efficiency should not be conflated with less work or less intensity.

Response: As we stated for CPT code 27130, we remain unconvinced that there has been a significant increase in intensity for this code. Intensity of work under the Physician Fee Schedule reflects skill, expertise, effort, stress, and other factors that influence the assessed relative value of time spent. We disagree with the commenters that performing the same work in less time inherently means that the intensity of a procedure has increased; changes in practice patterns, improvements in technology, or greater efficiencies in the delivery of care can all account for shorter procedure times without a corresponding increase in intensity. Commenters agreed that with our statement in the proposed rule that CPT code 27447 had undergone no significant change in the procedure's performance as reflected by its unaltered code descriptor. Under our methodology for work valuation, if the surveyed work times are decreasing and there is general agreement that the procedure itself has remained unchanged, this supports a decrease in the work RVU, not a conclusion that the intensity of the procedure has increased to match the decrease in surveyed work time. However, we do note that the RUC's recommended work RVU of 16.70 for CPT code 27447 already constitutes a reduction from the current work RVU of 19.11 which we have concluded is more appropriate than the proposed work RVU of 15.94.

Comment: Several commenters stated that they disagreed with the proposed crosswalk to CPT code 65730 at a work RVU of 15.94 to value CPT code 27447, and suggested that CMS should instead use the RUC's recommended crosswalk to CPT code 67108 at a work RVU of 16.70. Commenters stated that CPT code 27447 has greater intensity/complexity than the CMS crosswalk code based on the need for approach, preparation, and critically extensive reconstruction using metal implants and polyethylene. Commenters stated that CPT code 27447 also has moderate neurovascular risk due to retraction or direct injury during approach and implantation, risk of fracture, risk of infection, and risk of dislocation, as well as total knee arthroplasty is performed standing, often with a lead apron, and involves significant soft tissue manipulation and limb support. Commenters stated that CPT code 27447 was most appropriately valued based on a direct work RVU crosswalk to CPT code 67108.

Several commenters stated that the RUC affirmed its April 2021 work RVU recommendation of 16.70 for CPT code 27446 (*Arthroplasty, knee, condyle and plateau; medial OR lateral compartment*). Commenters stated that CPT codes 27446 and 27447 should be valued similarly to preserve relativity with the other arthroplasty codes and requested that CPT code 27447 should be finalized at the RUC's recommended work RVU of 16.70 to match CPT code 27446.

Response: We continue to have concerns regarding the increased intensity of CPT code 27447 as valued at the RUC's recommended work RVU of 16.70. As we discussed in the proposed rule, we also have concerns that the RUC's valuation does not adequately capture the changes in surveyed work time. However, we were persuaded by commenters that finalizing the proposed work RVU of 15.94 for CPT code 27447 could significantly affect providers and create barriers to accessing care for Medicare patients and does not fully capture the resource cost of these procedures. For these specific codes, we were persuaded that the RUC-recommended work RVU of 16.70 reflected the associated time and intensity described by the commenters. We also concur that this code should be valued comparably to CPT code 27446 as identified by commenters. We are therefore finalizing the RUC's recommended work RVU of 16.70 for CPT code 27447. We continue to remain concerned regarding the overall accuracy of these values and welcome additional information that we could consider for future rulemaking.

After consideration of the comments, we are finalizing the RUC's recommended work RVU of 16.70 for CPT code 27447. We are finalizing the direct PE inputs as proposed.

(11) Implantation of Extra-Articular Shock Absorber—Medial Knee (CPT Code 27494)

At the September 2025 CPT Editorial Panel Meeting, CPT created a new Category I code to describe the implantation of a medial knee extra-articular shock absorber. CPT code 27494 (*Implantation of medial knee extra-articular shock absorber,*

including fluoroscopic guidance) was surveyed at the January 2026 RUC meeting.

We proposed the RUC-recommended work RVU of 13.16 for CPT code 27494. We proposed the RUC-recommended direct PE inputs for CPT code 27494 without refinement.

Comment: Commenters were generally not in support of our proposed values for Implantation of Extra-articular Shock Absorber—Medial Knee. Commenters disagreed with the proposed work RVU which was lower than the survey 25th percentile. Many commenters argued that the proposed work RVU did not account for the time and intensity needed to perform the service along with the cognitive load, demanding precision, and lack of margin for error with placement of the device under fluoroscopy. Several commenters noted that the RUC survey did not include other codes for joint replacements or neutral comparators such as knee arthroplasty or medial compartment orthopedic procedures. Several commenters noted that if the joint-sparing option is valued below the joint-replacing option, practitioners may not offer the procedure to beneficiaries which would decrease access to this less invasive option.

Response: We continue to believe that the proposed work RVU of 13.16 for CPT code 27494, based on the RUC recommendation, is the most accurate valuation for this service. In our review of this code, we compared CPT code 27494 to other similar 90-day global codes with 90 minutes of intraservice time and found that the RUC's recommended work RVU of 13.16 matched other codes with similar time values. The RUC looked at two key reference codes and compared the surveyed code to the top key reference code, CPT code 29916 (*Arthroscopy, hip, surgical; with labral repair)* which has a work RVU of 14.63 and intraservice time of 90 minutes, and CPT code 29888 (*Arthroscopically aided anterior cruciate ligament repair/ augmentation or reconstruction)* which has a work RVU of 13.94 and intraservice time of 98 minutes. The RUC noted that both services typically involve the same amount or slightly higher intraservice time as compared with CPT code 27494. Ninety percent of the survey respondents indicated the surveyed CPT code 27494 was more intense and complex to perform than these key references, making them relative to one another. We do not believe that other codes for joint replacements or neutral comparators such as knee arthroplasty procedures would necessarily be appropriate comparator codes solely based on clinical similarity, or that it would maintain relativity for CPT code 27494 to be valued significantly higher than every other 90-day global code in this range of time values. We continue to believe that the PFS is a relative value based system and we do not base valuation only on things that are clinically related but rather on time and intensity.

After consideration of the public comments, we are finalizing the work RVU and direct PE inputs for CPT code 27494 as proposed.

(12) Osteochondral Acellular Scaffold Implantation, Knee (CPT Code 27417)

At the September 2025 CPT Editorial Panel Meeting, CPT created a new Category I CPT code 27417 (*Acellular scaffold(s) (e.g., aragonite) implant(s), for osteochondral lesion(s), knee, open*), which describes open cartilage knee repair procedures with an acellular scaffold implant. Based on the inorganic nature of these implants, the CPT Editorial Panel included the term ''acellular scaffold'' in the code descriptor for 27417, as it is a more comprehensive term and further defines the types of regenerative implants being used that are neither autologous nor allogenic. The CPT Editorial Panel did not request deletion for existing Category III code 0737T, which is currently being reported for this procedure, since it may appropriately describe procedures with this type of implant joints other than the knee. CPT code 27417 was surveyed for the January 2026 RUC meeting.

We proposed the RUC-recommended work RVU of 9.53 for CPT code 27417. We proposed the RUC-recommended direct PE inputs for CPT code 27417 without refinement.

Comment: Commenters were not in support of our proposed values for CPT code 27417. Commenters recommended that CMS assign a work RVU of 12.00 which corresponds to the survey median result and would better reflect the procedure's complexity and required technical skill.

Response: We continue to believe that the proposed work RVU of 9.53 for CPT code 27417, based on the RUC recommendation, is the most accurate valuation for this service. The RUC based its recommendation on a crosswalk to CPT code 50590 *(Lithotripsy, extracorporeal shock wave*) which shares the same 60 minutes of intraservice time as CPT code 27417 and has a comparable total time. When we reviewed this code, we found that the RUC's recommended work RVU of 9.53 was already above the median valuation when compared to other 90-day global procedures with similar time values. Although we believed that this was appropriate given the open incision and implantation of an acellular scaffold implant device taking place in CPT code 27417, we disagree with the commenters that a work RVU of 12.00 based on the median survey result would appropriately preserve relativity. A work RVU of 12.00 would value CPT code 27417 higher than all other 90-day global codes with similar time values and create a rank order anomaly in terms of intensity. We continue to believe that the proposed work RVU of 9.53 is a more accurate valuation.

After consideration of public comments, we are finalizing the work RVU and direct PE inputs for CPT code 27417 as proposed.

(13) Cardiac Contractility Modulation (CPT Codes 33290, 33291, 33292, 33293, 33294, 33295, 33296, 33297, 33307, 33308, 33309, 93154, 93155, 93156, and 93157)

In May 2025, the CPT Editorial Panel approved a new family of 11 Category I CPT codes for insertion, removal, and replacement of cardiac contractility modulation (CCM) systems, generators, and leads in several combinations. A separate set of four codes was created to describe the corresponding CCM programming, interrogation, and remote interrogation services. All 11 of the insertion, removal, and replacement/ repositioning/revision CCM codes, as well as three programming, interrogation, and remote interrogation CCM services that involve physician work, were surveyed for the September 2025 RUC meeting.

The specialty societies detailed the four code subsets within the CCM code family. These include CCM insertion services: CPT codes 33290 (*Insertion of permanent cardiac contractility modulation system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; pulse generator and transvenous electrodes*), 33291 (*Insertion of permanent cardiac contractility modulation system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; pulse generator only*), 33292 (*Insertion of permanent cardiac contractility modulation system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; transvenous electrode, single*), and 33293 (*Insertion of permanent cardiac contractility*

modulation system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; transvenous electrode, dual); CCM removal services: CPT code 33294 (*Removal of a permanent cardiac contractility modulation system; pulse generator and transvenous electrodes*), 33295 (*Removal of a permanent cardiac contractility modulation system; pulse generator only*), 33296 (*Removal of a permanent cardiac contractility modulation system; transvenous electrode, single*), and 33297 (*Removal of a permanent cardiac contractility modulation system; transvenous electrode, dual*); CCM replacement, repositioning, and revision services: CPT code 33307 (*Removal and replacement of permanent cardiac contractility modulation system, pulse generator only*), 33308 (*Repositioning of previously implanted cardiac contractility modulation transvenous electrode(s), including fluoroscopic guidance and programming of sensing and therapeutic parameters*), and 33309 (*Relocation or revision of skin pocket for implanted cardiac contractility modulation pulse generator*); and CCM programming, interrogation, and remote interrogation services: CPT code 93154 (*Programming of the cardiac contractility modulation system (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report by a physician or other qualified health care professional*), 93155 (*Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified healthcare professional, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system*), 93156 (*Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation system with interim analysis, review and report(s) by a physician or other qualified health care professional*), and 93157 (*Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation system, remote data acquisition(s), receipt of transmissions, technician review, technical support, and distribution of results*).

We proposed the RUC-recommended work RVU for all of the codes in this family. We proposed a work RVU of 8.83 for CPT code 33290, work RVU of 5.66 for CPT 33291, work RVU of 6.00 for CPT 33292, work RVU of 6.23 for CPT 33293, work RVU of 9.90 for CPT 33294, work RVU of 4.79 for CPT 33295, work RVU of 7.30 for CPT 33296, work RVU of 8.39 for CPT 33297, work RVU of 6.00 for CPT 33307, work RVU of 5.00 for CPT 33308, work RVU of 5.12 for CPT 33309, work RVU of 0.90 for CPT 93154, work RVU of 0.80 for CPT 93155, and work RVU of 0.59 for CPT 93156. We note that several of these work RVUs were affected by the efficiency adjustment which was applied at the start of CY 2026, as the RUC recommendations were based on pre-adjustment work valuations. The RUC did not recommend, and we did not propose, a work RVU for CPT code 93157.

We proposed the RUC-recommended direct PE inputs for CPT codes 33290–33309 as well as for CPT codes 93154–93157 without refinement.

Comment: All commenters were in support of our proposal of the RUC-recommended work RVU and direct PE inputs for this code family.

After consideration of public comments, we are finalizing the RUC-recommended work RVU for CPT codes 33290–33297, 33307, 33308, 33309, 93154, 93155, 93156 as well as the RUC-recommended direct PE inputs for CPT codes 33290, 33309, 93154 and 93157 without refinement, as proposed.

(14) Insertion and Removal of Surgical Ventricular Assist Device (CPT Codes 33996, 33998, and 33994)

At the September 2025 CPT Editorial Panel meeting, the CPT Editorial Panel created three new category I CPT codes to describe the insertion and removal of a left heart ventricular assist device (VAD), specifically using an open arterial with conduit surgical approach. These new category I CPT codes include the insertion CPT codes 33994 *(Insertion of left heart ventricular assist device, including radiological supervision and interpretation, open; axillary, subclavian or innominate artery exposure with creation of conduit by infraclavicular or supraclavicular incision, unilateral)* and 33996 *(Insertion of left heart ventricular assist device, including radiological supervision and interpretation, open; aorta exposure with creation of conduit by transthoracic (e.g., median sternotomy, thoracotomy) incision)* as well as the removal CPT code 33998 *(Removal of left heart ventricular assist device with resection and stapling of graft conduit and skin closure (e.g., infraclavicular, supraclavicular).*

We proposed the RUC-recommended work RVU of 13.65 for CPT code 33994, work RVU of 17.52 for CPT 33996, and work RVU of 6.58 for CPT 33998.

We proposed the RUC-recommended direct PE inputs for CPT codes 33994, 33996, and 33998 without refinement.

Comment: All commenters were in support of our proposal of the RUC-recommended work RVU and direct PE inputs for this code family.

After consideration of public comments, we are finalizing the RUC-recommended work RVUs and direct PE inputs for CPT codes 33994, 33996, and 33998 without refinement, as proposed.

(15) Transcatheter Tricuspid Valve Implant, Edge-to-Edge Repair (CPT Codes 33469, 33466, and 33467)

In September 2025, the CPT Editorial Panel approved the addition of CPT codes 33469 *(Transcatheter tricuspid valve implantation (TTVI)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed),* CPT code 33466 *(Transcatheter tricuspid valve edge-to-edge repair (T–TEER), percutaneous approach; initial clip),* and CPT code 33467 *(Transcatheter tricuspid valve edge-to-edge repair (T–TEER), percutaneous approach; each additional clip during same session).* These codes were surveyed for the January 2026 RUC meeting.

The RUC recommended the inclusion of an inpatient hospital visit (CPT code 99233) within the global period of CPT codes 33469 and 33466, despite the fact that both codes were recommended with 0 day global periods. We disagree that this inpatient hospital visit should be included within the valuation of these services, as 0 day global periods are specifically defined to include only postoperative care that takes place on the day of the procedure itself without incorporating any postoperative days. We therefore proposed to remove the inpatient hospital visit (CPT code 99233) from both CPT codes 33469 and 33466, including the removal of 55 minutes of associated work time from each procedure.

We disagree with the RUC-recommended work RVU of 24.38 for CPT code 33469 and we instead proposed a work RVU of 17.52 based on a crosswalk to CPT code 95391 *(Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve).* Our review of CPT code 33469 found that the RUC's recommended work RVU of 24.38 placed it far higher than any other 0-day global code with similar time values on the PFS, especially after accounting for the removal of the work time associated with the inpatient hospital visit

described earlier in this section. Most codes with 120 minutes of intraservice time and approximately 220 minutes of total time were valued around a work RVU of 13.00–15.00 and there were zero codes valued higher than a work RVU of 17.52. While we concur that CPT code 33469 is a difficult and intensive procedure to perform, we do not believe it is accurately valued at 7 RVUs higher than any other code with comparable time values. We instead proposed a work RVU of 17.52 based on a crosswalk to CPT code 95391, the highest 0-day global valuation with comparable work times, as this will avoid distorting relativity with other services on the PFS. We also note that CPT code 33469 has comparable intensity at our proposed work RVU to the top reference code from the survey, CPT code 33477, which we believe better serves relativity than the RUC's recommended work RVU. The RUC's recommended work RVU of 24.38 would result in an intensity for CPT code 33469 nearly 50 percent higher than the already complex and difficult transcatheter pulmonary valve implantation procedure described in the reference code, which we do not believe would be typical.

For CPT code 33466, we disagree with the RUC's recommended work RVU of 23.92 and we instead proposed a work RVU of 17.06. Although we disagree with the RUC-recommended work RVU for CPT 33466, we concurred that the relative difference in work between CPT codes 33469 and 33466 is equivalent to the recommended interval of 0.46 RVUs. Therefore, we proposed a work RVU of 17.06 for CPT code 33466, based on the recommended interval of 0.46 below our proposed work RVU of 17.52 for CPT code 33469.

For CPT code 33467, we disagree with the RUC-recommended work RVU of 8.00 and we instead proposed a work RVU of 6.34 based on a crosswalk to CPT 22552 *(Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure).* Our review of CPT code 33467 found that the RUC's recommended work RVU of 8.00 placed it far higher than almost any other add-on code with similar time values on the PFS, with the sole exception of CPT code 61642 (Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in different vascular territory) which is an outlier valuation at a work RVU of 8.66. Most add-on codes with approximately 50 minutes of total time were valued around a work RVU of 3.00–5.00 and there was only a single code valued higher than a work RVU of 6.34. While we concur that CPT code 33467 is a difficult and intensive procedure to perform, we do not believe it is accurately valued at nearly two RVUs higher than other codes with comparable time values. We instead proposed a work RVU of 6.34 based on a crosswalk to CPT code 22522, the highest non-outlier add-on code valuation with comparable work times, as this will avoid distorting relativity with other services on the PFS. We note that this valuation will also maintain relative intensity between CPT code 33467 and the first two codes in the family at our proposed work RVUs.

The RUC did not recommend and we did not propose any direct PE inputs for the three codes in this family.

Comment: The majority of commenters disagreed with our proposal to exclude the inpatient hospital visit (CPT code 99233) from both CPT codes 33469 and 33466, including the removal of 55 minutes of associated work time from each procedure. These commenters believe the inpatient hospital visit should be included based on a survey for TTVR and T–TEER where the specialty societies requested, and the Research Subcommittee approved, use of the 000-day Global with visit survey template for the 000-day codes. Commenters also mentioned the TTVR codes are similar to the TAVR codes, which include a same-day post-operative visit. For CPT code 33469 many commenters disagreed with our crosswalk to CPT 95391 and recommended CMS to retain the RUC-recommended value. For CPT code 33466, many commenters disagreed with our proposal to adjust the relative difference through the usage of a recommended interval of 0.46 RVUs. These commenters stated that while they support a slightly higher value for this code, they do not believe any formulaic approach should be used as the primary methodology and rather CMS should rely on clinical inputs and specialty society committees to value services. Lastly, for CPT code 33467, many commenters disagree with our valuation based on the crosswalk to CPT code 22522 stating that it falls below the survey 25th percentile and is less intense than the surveyed code. A commenter also stated that CPT code 61642 is not an outlier, explaining that its high intensity as an add-on code reflects the significant inherent risk throughout the procedure.

Response: We thank the commenters for their feedback. We wish to clarify that our proposal to exclude an inpatient hospital visit (CPT code 99233) from both CPT codes 33469 and 33466 does not suggest that TTVR or T–TEER patients do not require inpatient postoperative care but rather, because 33469 and 33466 have 0-day global periods, we determined that a subsequent-day hospital visit (99233) and its associated 55 minutes should not be incorporated into the procedural work RVU. Accordingly, the exclusion of the inpatient visit is accounting for whether that subsequent-day visit represents physician work intrinsic to the typical tricuspid procedure, rather than considering whether TAVR codes historically included such a visit.

Additionally, for CPT code 33466, we stated in our proposal that we established the recommended interval of 0.46 based on the difference in work values between CPT codes 33469 and 33466. We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. For example, in the CY 2025 PFS Final Rule, CMS concurred that the relative difference in work between CPT codes 66682 and 66683 is equivalent to the recommended interval of 1.93 RVUs (89 FR 97710). We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. Lastly, regarding CPT code 33467, we recognized in our proposal that CPT code 33467 is a difficult and intensive procedure to perform. As a result, we finalized a crosswalk to the highest add-on codes with comparable work times, CPT code 22522, the highest non-outlier add-on code to have a similar level of valuation.

After consideration of public comments, CMS will finalize as proposed (1) removal of the inpatient hospital visit (CPT code 99233) from both CPT codes 33469 and 33466, including the removal of 55 minutes of associated work time from each procedure; (2) a work RVU of 17.52 for CPT code 33469; (3) a work RVU of 17.06 for CPT code 33466; and (4) a work RVU of 6.34 for CPT code 33467. We are also finalizing no direct PE inputs for the three codes in this family as proposed.

(16) Percutaneous Transcatheter Closure (CPT Code 33340)

In April 2025, the RAW identified CPT code 33340 (*Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation)* as a code that has Medicare utilization of 10,000 or more that has increased by at least 100 percent from 2018 through 2023. The specialty societies indicated and the RUC agreed that CPT code 33340 be surveyed for the January 2026 RUC meeting.

We disagree with the RUC's recommendation of the current work RVU of 9.99 for CPT code 33340 and we instead proposed a work RVU of 9.00 based on crosswalk to CPT code 37271 *(Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel).* The RUC survey indicated that the typical time needed to perform CPT code 33340 has decreased, with the intraservice time decreasing from 70 minutes to 62 minutes and the total time decreasing from 165 minutes to 154 minutes. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner. The RUC's recommendation to maintain the current work RVU of 9.99 for CPT code 33340 can only be justified if the intensity to perform the service has increased over time. However, there has been no change to the code descriptor for CPT code 33340 and no apparent change in clinical practice which would warrant the roughly 15 percent increase in intensity as recommended by the RUC. Since we do not believe that there is evidence indicating that CPT code 33340 has typically become more intense to perform, we therefore proposed a work RVU of 9.00 which maintains the current intensity of the service. This valuation is based on a crosswalk to CPT code 37271, a recently reviewed service from CY 2026 that has a higher intraservice time and nearly identical total time.

We proposed the direct PE inputs for CPT code 33340 as recommended by the RUC without refinement.

Comment: The majority of commenters disagreed with our proposal due to what they stated was an underestimation of intensity for CPT 33340, significant cuts in the overall payment for CPT code 33340 in preceding years, and the belief that the proposed crosswalk does not reflect the clinical procedure and complications that can arise with CPT 33340. These commenters requested CMS to maintain the current value of the work RVU of 9.99 for this code.

Response: We thank commenters for their feedback. We continue to believe our proposed work RVU of 9.00 for CPT code 33340 is the most accurate valuation for this service based on a crosswalk to CPT 37271, which maintains the current intensity. Differences in clinical procedures alone do not establish that the crosswalk is inappropriate or that a different valuation is warranted. Additionally, as mentioned in our proposal, the recommendation to maintain the current work RVU of 9.99 for CPT code 33340 can only be justified if the intensity to perform the service has increased over time. However, there was no evidence to suggest the intensity has increased. Furthermore, CPT code 33340 was surveyed and because physician work reflects both the time and intensity required to furnish a service, a decrease in intensity supports a corresponding decrease in the work RVU.

In consideration of public comments, we are finalizing the work RVU and direct PE inputs for CPT code 33340 as proposed.

(17) Treatment of Incompetent Veins (CPT Codes 36470, 36471, 36465, 36466, 36473, and 36474)

In April 2025, the RAW identified CPT code 36465 (*Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein*), as a code that has Medicare utilization of 10,000 or more that has increased by at least 100 percent from 2018 through 2023. The RAW reviewed the action plan and the RUC recommended CPT code 36465 along with the family of services be surveyed for the January 2026 RUC meeting.

The RUC reviewed this family of services at the January 2026 meeting including all sclerosant treatment of incompetent veins. These services are: CPT code 36465; CPT code 36466 (*Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (e.g., great saphenous vein, accessory saphenous vein), same leg*); CPT code 36470 (*Injection of sclerosant; single incompetent vein (other than telangiectasia)*); CPT code 36471 (*Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg*); CPT code 36473 (*Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated*); and CPT code 36474 (*Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)*).

For CY 2027, we proposed the RUC-recommended work RVUs for five of the six codes in this family. We proposed the RUC-recommended work RVU of 2.29 for CPT code 36465, 0.73 for CPT code 36470, 1.18 for CPT code 36471, 3.41 for CPT code 36473, and 1.71 for CPT code 36474.

We disagree with the RUC recommended work RVU of 2.93 for CPT code 36466. Instead, we proposed a work RVU of 2.62 based on a crosswalk to CPT code 57156 (*Insertion of a vaginal radiation afterloading apparatus for clinical brachytherapy*). In reviewing CPT code 36466, we noted that the recommended intraservice time is decreasing from 35 minutes to 30 minutes (14 percent reduction), and the recommended total time is decreasing from 76 minutes to 68 minutes (11 percent reduction); however, the RUC recommended maintaining the current work RVU of 2.93. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale

for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner. The RUC's recommendation to maintain the current work RVU of 2.93 for CPT code 36466 can only be justified if the intensity to perform the service has increased over time. However, there has been no change to the code descriptor for CPT code 36466 and no apparent change in clinical practice which would warrant the roughly 17 percent increase in intensity as recommended by the RUC. Since we do not believe that there is evidence indicating that CPT code 36466 has typically become more intense to perform, we therefore proposed a work RVU of 2.62 which maintains the current intensity of the service. This valuation is based on a crosswalk to CPT code 57156, which has the same intraservice work time of 30 minutes and higher total time.

Comment: We received a small number of comments. All commenters supported finalizing the proposed work RVU values that had been recommended by the RUC for CPT codes 36470, 36471, 36465, 36473, and 36474.

Response: We thank all the commenters for their feedback. After consideration of the comments received, we are finalizing as proposed the RUC-recommended work RVUs for five of the six codes in this family. We are finalizing the RUC-recommended work RVU of 2.29 for CPT code 36465, 0.73 for CPT code 36470, 1.18 for CPT code 36471, 3.41 for CPT code 36473, and 1.71 for CPT code 36474.

Comment: Most commenters disagreed with our proposed value for CPT code 36466. Commenters felt that CPT code 36466 was in fact more intense than had been represented in the prior RUC survey. They felt the RUC survey in 2016 was ambiguous about which veins were typically being treated. They asserted that CPT code 36466 typically involves more time treating the small saphenous and is more intense to perform.

Response: We do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs, but we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner. In the proposed rule we said that the RUC's recommendation to maintain the current work RVU of 2.93 for CPT code 36466 can only be justified if the intensity to perform the service has increased over time. In light of the RUC's own survey showing a reduction in time for CPT code 36466 with intraservice time decreasing from 35 minutes to 30 minutes (14 percent reduction), we are not persuaded by commenters' assertions that the service had previously been reported for procedures that were actually less intense. We recognize that the clinical vignette has been updated but note that the code descriptor has not changed.

Comment: A commenter questioned how many CPT 36465/36466 treatment sessions are actually obtained, on average, from the Varithena product represented by the SD324 direct practice expense input.

Response: We do not have a way of independently verifying the supply quantity associated with the use of SD324. However, we are open to revisiting this in the future if an interested party can supply alternate data indicating that the 0.33 supply quantity is not typical for the procedures.

After consideration of the comments, we are finalizing the work RVU for CPT code 36466 as proposed. This value, maintaining the current intensity of the service, is based on a crosswalk to CPT code 57156 (Insertion of a vaginal radiation after loading apparatus for clinical brachytherapy) which has the same intraservice work time of 30 minutes and higher total time.

We are finalizing the direct PE inputs for all CPT codes in this family as proposed.

(18) Microvascular Bypass, Lymphatic Vessels (CPT Codes 38800 and 38801)

In September 2025, the CPT Editorial Panel approved two new Category I codes to describe microvascular bypass of lymphatic vessels, a microsurgical procedure. This newly created Category I CPT code family describes two services: a base code for the initial anastomosis, CPT code 38800 (*Microvascular anastomosis between a single vein opening and any number of lymphatic vessels, per limb; initial anastomosis*), and the add-on code for each additional anastomosis, CPT code 38801 (*Microvascular anastomosis between a single vein opening and any number of lymphatic vessels, per limb; initial anastomosis; each additional anastomosis (List separately in addition to code for primary procedure)*). CPT codes 38800 and 38801 were surveyed for the January 2026 RUC meeting.

We reviewed the RUC's recommended work valuations and found the RUC's recommended work RVU of 16.00 for CPT code 38800 to be high, based on a search of similarly timed codes in the RUC database. For CY 2027 we proposed a work RVU of 14.00, based on the RUC survey 25th percentile, for CPT code 38800. We proposed the RUC recommended work RVU of 6.00 for CPT code 38801. We proposed the RUC-recommended direct PE inputs for both CPT codes without refinement.

Comment: We received a handful of comments. A commenter asked that CMS ensure that payment for this procedure be adequate but did not opine as to what amount of work RVUs that would be. The rest opposed the proposed work RVU of 14.00, based on the RUC survey 25th percentile, for CPT code 38800 stating that the proposed work RVU did not accurately account for the physician work's intensity and complexity. A commenter described the physician work as almost entirely under an operating microscope at 10–30x magnification, suturing lymphatic channels of 0.2 to 1 millimeter with 10–0 and 11–0 suture far finer than a human hair. Another commenter stated that while ophthalmologic procedures use similar magnification and 10–0 or 11–0 sutures, they do not entail the complexity of CPT code 38800 which creates a patent lymphatic-to-venous anastomosis, a connection between a blocked lymphatic vessel and a small vein to bypass the blockage and drain trapped fluid back into the bloodstream. Commenters stated that CMS should finalize the RUC-recommended work RVU of 16.00 based on the median value from the survey.

Response: We continue to disagree with the commenters and believe that the proposed work RVU of 14.00 is a more accurate valuation for CPT code 38800. While we appreciate the additional clinical details associated with CPT code 38800 provided by the commenters, we continue to disagree that the intensity of this procedure would warrant a work valuation higher than approximately 95 percent of 90-day global codes with comparable time values. We note that the RUC recommended removing 17 minutes of preoperative work time, one CPT code 99231 inpatient hospital visit, and half of the CPT code 99238 discharge visit from the surveyed work time of CPT code 38800, a total of 56 minutes, which suggests that the survey respondents overestimated the work time and the work RVU for this code at the median value of 16.00. It is for this very reason that the RUC recommends the survey 25th percentile work RVU for most newly created codes that have no direct predecessor code. Although we do not

believe that the survey 25th percentile is always the most accurate valuation in these cases, we do believe that it best describes the work RVU of CPT code 38800 at 14.00.

After consideration of the comments, we are finalizing the work and direct PE inputs as proposed for CPT code 38800 and CPT code 38801.

(19) Diaphragmatic Hernia Repair (CPT Codes 39540, 39541, 39542, 39543, 39544, 39571, 39572, 39573, 39581, 39582, and 39590)

At the September 2025 CPT Editorial Panel, the committee revised two existing CPT codes, CPT code 39540 *(Repair, diaphragmatic hernia (other than neonatal), via laparotomy; traumatic, acute)* and CPT code 39541 *(Repair, diaphragmatic hernia (other than neonatal), via laparotomy; traumatic, chronic),* describing diaphragmatic hernia repair. They also created nine new Category I codes, CPT codes 39542 *(Repair, diaphragmatic hernia (other than neonatal), via laparotomy; nontraumatic (i.e., Bochdalek, Morgagni*)), 39543 *(Repair, diaphragmatic hernia (other than neonatal), via thoracotomy; traumatic, chronic),* 39544 *(Repair, diaphragmatic hernia (other than neonatal), via thoracotomy; nontraumatic (i.e., Bochdalek, Morgagni)),* 39571 *(Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, acute),* 39572 *(Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, chronic),* 39573 *(Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); nontraumatic (i.e., Bochdalek, Morgagni)),* 39581 *(Thoracoscopy surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, chronic),* 39582 *(Thoracoscopy surgical, with repair of diaphragmatic hernia (other than neonatal); nontraumatic (i.e., Bochdalek, Morgagni)),* and 39590 *(Implantation of mesh or other prosthesis with open, laparoscopic, or thoracoscopic diaphragmatic hernia repair (List separately in addition to code for primary procedure))* that expanded the range of surgical interventions included in this code family. The RUC reviewed these services at the January 2026 meeting.

For CY 2027, we proposed the RUC recommended work RVUs of 24.00 for CPT code 39540, 26.00 for CPT code 39541, 25.75 for CPT code 39542, 26.41 for CPT code 39543, 25.94 for CPT code 39544, 22.04 for CPT code 39571, 26.60 for CPT code 39572, 27.00 for CPT code 39573, 25.44 for CPT code 39581, 25.94 for CPT code 39582, and 3.00 for CPT code 39590.

We proposed the RUC-recommended direct PE inputs for all CPT codes in this family without refinement.

Comment: Commenters were supportive of CMS' proposed work RVUs and direct PE inputs for this code family.

Response: We thank the commenters for their support. After consideration of the public comments, we are finalizing the work RVU and direct PE inputs as proposed.

(20) Diaphragm Repair (CPT Codes 39545 and 39580)

In May 2025, the CPT Editorial Panel revised CPT code 39545 (*Plication of diaphragm for eventration or paralysis, via thoracotomy*) to specify plication of the diaphragm for eventration or paralysis, via thoracotomy, and created CPT code 39580 (*Thoracoscopy, surgical, with plication of diaphragm for eventration or paralysis*) to report thoracoscopic plication of the diaphragm for eventration or paralysis.

For CY 2027, we proposed the RUC recommended work RVUs of 18.45 for CPT code 39545 and 20.00 for CPT code 39580. We proposed the RUC-recommended direct PE inputs for both CPT codes without refinement.

Comment: We received a couple of comments in support of CMS' proposed work RVUs and direct PE inputs for both CPT codes.

Response: We thank the commenters and appreciate their support for the proposal. After consideration of the comments received, we are finalizing the work and direct PE inputs as proposed for CPT code 39545 and CPT code 39580.

(21) Division of Median Arcuate Ligament (CPT codes 39562 and 39570)

In February 2025, the CPT Editorial Panel created two new codes to report open and laparoscopic median arcuate ligament syndrome (MALS) treatment: CPT code 39562 (*Division of median arcuate ligament and release of celiac trunk, with ganglionectomy, when performed*) and CPT code 39570 (*Laparoscopy, surgical, with division of median arcuate ligament and release of celiac trunk, with ganglionectomy, when performed*). The two new codes were surveyed for the April 2025 RUC meeting.

We proposed the RUC-recommended efficiency adjusted work RVUs of 26.41 for CPT code 39562 and 25.94 for CPT code 39570. We proposed the RUC-recommended direct PE inputs for CPT codes 39562 and 39570 without refinement.

Comment: A few commenters supported the proposed direct PE inputs for CPT codes 39562 and 39570. A commenter disagreed with the efficiency adjustment due to new services whose physician work was recently surveyed and evaluated through the valuation process. The commenter stated that CMS has not demonstrated that the physician time or intensity required for these specific procedures is reduced by the economy-wide productivity assumption underlying the efficiency adjustment.

Response: We appreciate the commenters' support of the proposed direct PE inputs for CPT codes 39562 and 39570. Regarding the comment on the efficiency adjustment, we clarify that we did not apply the efficiency adjustment directly to CPT codes 39562 or 39570. Rather, the RUC's recommended valuations for these new codes were based on crosswalks to existing codes, and the efficiency adjustment had previously been applied to those crosswalk codes as part of their own valuation. Because the crosswalk methodology relies on the current, adjusted work RVUs of the reference codes, it would not be appropriate to instead use the pre-adjustment values of those codes as the basis for crosswalking. We therefore believe it is appropriate that the valuations for CPT codes 39562 and 39570, derived from these crosswalks, reflect the adjustment as it applies to the source codes.

After consideration of the comments, we are finalizing as proposed the work RVUs of 26.41 for CPT code 39562 and 25.94 for CPT code 39570, and the direct PE inputs.

(22) Endoscopic Submucosal Dissection (CPT codes 4349843498 and 4599145991)

At the May 2025 CPT Editorial Panel Meeting, two new CPT codes were created for reporting endoscopic submucosal dissection (ESD) of both the upper and lower GI tract, including mucosal closure: CPT codes 4349843498 (*Endoscopic submucosal dissection (ESD) of upper gastrointestinal tract, including mucosal closure, when performed*) and 4599145991 (*Endoscopic submucosal dissection (ESD) of lower gastrointestinal tract, including mucosal closure, when performed*). These new CPT codes were surveyed at the September 2025 AMA RUC meeting.

For CY 2027, we proposed the RUC-recommended work RVUs of 15.00 for CPT code 4349843498 and 16.38 for CPT code 4599145991. We proposed the RUC-recommended direct PE inputs for

CPT codes 4349843498 and 4599145991 without refinement.

Comment: Several commenters stated that they supported the CMS proposal of the RUC-recommended work RVUs and work times for the new endoscopic submucosal dissection codes. Commenters stated that they appreciated CMS' recognition of the substantial practitioner time, skill, intensity, and clinical complexity involved in performing endoscopic submucosal dissection (ESD) of the upper and lower gastrointestinal tract.

Response: We appreciate the support from the commenters for our proposed valuations.

After consideration of the comments, we are finalizing the proposed work RVUs and direct PE inputs for the codes in the Endoscopic Submucosal Dissection family.

(23) Transoral Oropharyngeal Procedures (CPT codes 42808, 42985, and 42986)

In February 2025, the CPT Editorial Panel approved two new Category I codes that describe transoral endoscopic surgery under magnification for the removal of tumors in the oropharynx, including robotic assistance when performed: CPT code 42985 (*Transoral removal of oropharyngeal and/or pharyngeal neoplasm under magnification (e.g., microscope or telescope), includes robotic assistance, when performed, tongue base*) and CPT code 42986 (*Transoral removal of oropharyngeal and/or pharyngeal neoplasm under magnification (e.g., microscope or telescope), includes robotic assistance, when performed; tongue base; lateral pharyngeal wall, including tonsil*). CPT code 42808 (*Excision or destruction of lesion of pharynx, without magnification, any method*) was revised to clarify that it is done without magnification, and it was surveyed along with the two new codes at the April 2025 RUC meeting.

We proposed the RUC-recommended work RVU for all three codes in this family. We proposed a work RVU of 2.29 for CPT code 42808 (which is the current work RVU of the code after the efficiency adjustment was applied at the start of CY 2026), a work RVU of 20.00 for CPT code 42985, and a work RVU of 20.05 for CPT code 42986. We note that the RUC's recommended work RVU of 2.29 for CPT code 42808 assigns an intensity value of zero for this service; we sought comment from interested parties as to whether an alternate work valuation, such as the survey 25th percentile work RVU of 2.70, would be more appropriate.

We proposed the RUC-recommended direct PE inputs for all three codes without refinement.

Comment: Several commenters stated that they appreciated CMS proposing the RUC recommended work RVUs and direct PE inputs for CPT codes 42808, 42985 and 42986 without refinement.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters stated that maintaining the current work RVU of 2.29 as proposed was appropriate for CPT code 42808, which is lower than the survey 25th percentile work RVU of 2.70. Commenters stated that this recommendation maintained relativity with other similar otolaryngology codes in the 10-day global period in this work RVU range. Commenters stated that they did not believe there was compelling evidence to justify an increased work RVU for this service, even though the RUC recommended and CMS proposed work RVU of 2.29 for CPT code 42808 assigned an intensity value of zero for this service. The commenters urged CMS to finalize its proposal of the current work RVU of 2.29 for CPT code 42808.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs as proposed for the codes in the Transoral Oropharyngeal Procedures family.

(24) Congenital Duodenal Obstruction Repair (CPT codes 44011 and 44181)

At the May 2025 CPT Editorial Panel Meeting, two new CPT codes were created for reporting surgical treatment for congenital duodenal obstruction via an open or laparoscopic approach, that were previously reported using unlisted codes: CPT codes 44011 (*Duodenoduodenostomy or duodenojejunostomy for congenital duodenal obstruction*) and 44181 (*Laparoscopy, surgical; duodenoduodenostomy or duodenojejunostomy for congenital duodenal obstruction*). These new CPT codes were surveyed at the September 2025 AMA RUC meeting.

For CY 2027, we proposed the RUC-recommended work RVUs of 50.00 for CPT code 44011 and 52.60 for CPT code 44181. We proposed the RUC-recommended direct PE inputs for CPT codes 44011 and 44181 without refinement.

Comment: A commenter stated that they supported the CMS proposal of the RUC's recommended work RVUs and direct PE inputs.

Response: We appreciate the support for our proposals.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs as proposed for the codes in the Congenital Duodenal Obstruction Repair family.

(25) Irreversible Electroporation of Tumor, Pancreas (CPT code 48990)

In May 2025, the CPT Editorial Panel approved the addition of a new CPT code 48990 (*Ablation, irreversible electroporation of tumor(s) of the pancreas, open, including imaging guidance*) to report open irreversible electroporation (IRE) ablation of tumors of the pancreas.

We proposed the RUC-recommended work RVU of 25.19 for CPT code 48990, and the RUC-recommended direct PE inputs without refinement.

Comment: A commenter supported our proposal of the RUC recommendations.

Response: We thank the commenter for their support. After consideration of the public comments, we are finalizing as proposed.

(26) Prostate Biopsy Services (CPT codes 55705, 55707, 55708, 55709, 55710, 55711, 55714, 55715, and 55716)

This service was identified via the April 2022 RAW review of services performed by the same physician on the same date of service 75 percent of the time or more and was surveyed for the September 2024 RUC meeting. The data from the September 2024 survey indicated that the long descriptors did not adequately describe these services. While the codes were valued for the CPT 2026 cycle, the specialties and the RUC agreed that a new coding change application should be developed for the CPT Editorial Panel for restructuring in the CPT 2027 cycle. CPT revised the prostate biopsy code family in 2026 and it was surveyed for the January 2026 RUC meeting. The revisions to the family are as follows: CPT codes 55705 (*Biopsy, prostate, any approach, non-imaging guided*), 55707 (*Biopsy, prostate, transrectal, including imaging guidance, regional*), 55708 (*Biopsy, prostate, transrectal, including imaging guidance, regional and fusion-targeted lesion(s)*), 55709 (*Biopsy, prostate, transperineal, including imaging guidance, regional*), 55710 (*Biopsy, prostate, transperineal, including imaging guidance, regional and of fusion-targeted lesion(s)*), 76872 (*ultrasound, transrectal*), and 55714 (*Biopsy, prostate, including imaging guidance, in-bore-CT-or-MRI-guided; first targeted lesion*) have work RVUs that were reaffirmed from CY 2026 by the RUC. CPT codes 55711 (*Biopsy, prostate, transrectal or transperineal,*

including imaging guidance, fusion), 55716 (*Biopsy, prostate, transrectal or transperineal, including imaging guidance, fusion-targeted lesion(s) without regional; each additional targeted lesion (List separately in addition to code for primary procedure)*) and 55715 (*Biopsy, prostate, including imaging guidance, in-bore CT- or MRI-guided; each additional targeted lesion (List separately in addition to code for primary procedure)*) are new and/or revised codes for CY2027.

For CY 2027, we proposed the RUC-recommended work RVU for eight of the nine codes in the family. We proposed the RUC-recommended work RVUs of 1.88 for CPT code 55705, 2.63 for CPT code 55707, 3.39 for CPT code 55708, 3.23 for CPT code 55709, 3.81 for CPT code 55710, 2.37 for CPT code 55711, 3.62 for CPT code 55714, and 1.80 for CPT 55715.

For CPT code 55716, we disagree with the RUC-recommended work RVU of 0.80. In the interest of maintaining relativity with similarly timed codes, we instead proposed a work RVU of 0.68 based on a crosswalk to CPT code 93567 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography (List separately in addition to code for primary procedure)*). CPT code 55716 was surveyed with only 6 minutes of intraservice and total work time, yet the RUC recommended a work RVU of 0.80. We compared this recommended valuation against CPT code 55715, another add-on code within this same family, which was surveyed at 35 minutes of intraservice and total work time but with a recommended work RVU of 1.80. This results in CPT code 55716 having an intensity nearly triple that of CPT code 55715 which we do not believe would be typical. We also found that there were no other add-on codes in the RUC database with comparable time values to CPT code 55716 which had a work RVU approaching 0.80. The closest was CPT code 77063 (*Screening digital breast tomosynthesis, bilateral*) at a work RVU of 0.59, with that code having 8 minutes of work time instead of 6 minutes, and all other comparable add-on codes had a work RVU of 0.37 or lower. Although we agree that CPT code 55716 is a difficult and intensive procedure, we believe that the RUC's recommended work RVU of 0.80 assigns too much work valuation and intensity to the service, and does not maintain relativity with other related codes on the PFS.

We instead proposed a work RVU of 0.68 for CPT code 55716 based on a crosswalk to CPT code 93567. Our proposed work RVU of 0.68 is also supported with add-on CPT codes with similar work time values. CPT code 93566 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (List separately in addition to code for primary procedure)*) is valued at a work RVU of 0.49 with an intraservice time of 10 minutes and CPT code 64484 (*Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), lumbar or sacral, each additional level (List separately in addition to code for primary procedure)*) is valued at a work RVU of 0.98 with an intraservice time of 10 minutes.

We proposed the RUC-recommended direct PE inputs for all CPT codes in this family without refinement.

Comment: Several commenters supported the proposed work RVUs for CPT codes 55705, 55707, 55708, 55709, 55710, 55711, 55714, and 55715.

Response: We appreciate the support for our proposed valuations from the commenters.

Comment: Some commenters disagreed with the proposed work RVU of 0.68 for CPT code 55716. Commenters requested the RUC's recommended work RVU of 0.80 for the add-on CPT code 55716 rather than the proposed work RVU of 0.68. Commenters stated that the proposed valuation for CPT code 55716 understates the work involved and a work RVU of 0.68 would create a rank order anomaly with CPT code 76872. Commenters argued that the proposed crosswalk code for CPT code 55716 (CPT code 93567) does not accurately reflect the physician work or the intensity of this service being performed. Commenters stated that CPT code 55716 needs to be valued higher than CPT code 76872 because the former code has imaging and biopsy work while the later code is only an imaging code. Commenters felt the proposed work RVU of 0.80 would not maintain relativity within the family. Commenters felt the proposed work valuation of 0.68 would also be compounded by the effect of the conversion factor.

Response: We continue to believe CPT code 55716 is less intense compared to the predecessor CPT code 55715 which has a work RVU of 1.05 and included imaging in the code's valuation. Additionally, a work RVU of 0.80 would be vastly higher than any other comparable add on code in this range of time values. We also disagree with commenters that a work RVU of 0.68 would create a work order anomaly within the code family as compared with the imaging code CPT code 76872. However, CPT code 76872 is significantly longer than CPT code 55716, nearly quadruple the time with a total time of 23 minutes as compared to 6 minutes in duration for CPT code 55716. We agree with commenters that CPT code 55716 is significantly more intense but disagree that it is inappropriate for these codes to be valued similarly given the large discrepancy in their work times. We disagree with commenters that a work RVU of 0.68 would pose a rank order anomaly in this family as the greater intensity of CPT code 55716 is offset by the far greater time of CPT code 76872.

After consideration of the comments, we are finalizing a work RVU of 0.68 for CPT code 55716. We are also finalizing the work RVUs and direct PE inputs for the remaining codes in the Prostate Biopsy family as proposed.

(27) Maternity Care Services (CPT codes 59320, 59325, 59412, 59871, 59080, 59081, 59082, 59083, 59030, 59051, 59431, 59432, 59414, 59300, 59502, 59503, 59504, 59623, 59433, 59434, and 59160)

a. Background and Update

At the January 2026 AMA RUC meeting, the maternity global codes were revised to delete 17 legacy CPT codes, create 12 new CPT codes, and revise 9 CPT codes describing maternity care services. See Table A–D2 for a summary of the codes and their long descriptors. These codes were restructured from the maternity (MMM) global period to individual codes to reflect changes in practice. The previous MMM global period included 12 prenatal E/M visits bundled into CPT codes 59400, 59510, 59610, and 59618. In May 2025, the American College of Obstetricians and Gynecologists (ACOG) published new clinical guidelines, recommending that obstetrician-gynecologists and other maternity care professionals tailor the visit frequency and monitoring schedule to the needs of the pregnant woman. These new clinical guidelines provide a sample schedule for prenatal care services and visit frequency, which describes 8 visits for average-risk pregnant women without medical or pregnancy complications, and 13 visits for pregnant women with greater-than-average risk. This sample schedule specifies that additional services may be offered as needed throughout the pregnancy.

When the RUC reviewed these codes, they included 12 prenatal E/M visits (two level 2 established patient office

visits, eight level 3 established patient office visits, and two level 4 established patient office visits) in the calculations to make these changes budget-neutral despite the revisions to the clinical guidelines suggesting that 12 visits would no longer be typical. As the clinical guidelines have changed to reflect a revised assumption about the typical number of visits, estimating work neutrality based on the assumption that all 12 prenatal E/M visits in the base year would be reported in the predictive year overestimates the total utilization and as a result, undervalues the work RVUs as recommended by the RUC. To improve payment accuracy of the new codes, we proposed to refine the RUC's recommended utilization crosswalk to remove four E/M visits (two level 2 established patient office visits and two level 4 established patient office visits) from the utilization estimate calculation and reallocate those RVUs within the code family to the new labor and delivery codes. This would mean reallocating 11,810 additional work RVUs to the new labor and delivery codes (CPT codes 59080–594503). Since the RUC provided a utilization estimate of 12,791 for CPT codes 59080–594503, this would result in a 15 percent increase in work RVUs for each labor and delivery code. We would like to emphasize that we are not endorsing a reduced number of prenatal visits for pregnant women. Our recalculation of the utilization estimates in the valuation of these services should not be used to determine the appropriate number of visits to provide reasonable and necessary care to beneficiaries. As with all PFS services, maternity services should be furnished when medically reasonable and necessary.

There are no RUC-recommended direct PE inputs for these CPT codes. Table A–D2 also shows the RUC-recommended and CMS proposed work RVUs for the 21 CPT codes.

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TABLE A-D2: CPT LONG DESCRIPTORS AND WORK RVUS FOR MATERNITY SERVICES

CPT Code	Long Descriptors	RUC Recommended Work RVUs	CMS Work RVUs
Antepartum Care			
59320	*Cerclage of cervix, during pregnancy; vaginal*	3.02	3.02
59325	*Cerclage of cervix, during pregnancy; abdominal*	6.34	6.34
59412	*External cephalic version*	2.63	2.63
59871	*Removal of cerclage suture under anesthesia (other than local)*	2.15	2.15
Labor Management and Delivery			
59080	*Initial day labor management; straightforward, per day*	3.50	4.03
59081	*Initial day labor management; complex, per day*	4.50	5.18
59082	*Subsequent day labor management; straightforward, per day*	3.00	3.45
59083	*Subsequent day labor management; complex, per day*	4.20	4.83
59431	*Vaginal delivery, with or without episiotomy;*	8.00	9.20
59432	*Vaginal delivery, with or without episiotomy; after previous cesarean delivery*	9.00	10.35
59450 2	*Cesarean delivery; primary*	12.00	13.80
59450 3	*Cesarean delivery; repeat*	14.66	16.86
Labor Procedures, Other Procedures, and Postpartum			
59030	*Fetal scalp blood sampling*	0.90	0.90
59051	*Fetal monitoring during labor by consulting physician (ie, non-attending physician) or other qualified health care professional, with interpretation and report*	0.93	0.93
59414	*Delivery of placenta only (separate procedure)*	1.61	1.61
59300	*Repair of first or second-degree episiotomy or laceration, by other than attending physician or other qualified health care professional performing vaginal delivery care (separate procedure)*	1.76	1.76
59433	*Repair of episiotomy or laceration; third-degree laceration*	2.47	2.47
59434	*Repair of episiotomy or laceration; fourth-degree laceration*	4.14	4.14
59504	*Subtotal or total hysterectomy after cesarean delivery*	15.56	15.56
59623	*Uterine tamponade (eg, balloon, catheter, vacuum, packing material)*	2.15	2.15
59160	*Curettage, postpartum*	2.93	2.93

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We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposals to adopt CPT codes 59320, 59325, 59412, 59871,

59080, 59081, 59082, 59083, 59030, 59051, 59431, 59432, 59414, 59300, 594502, 594503, 59504, 59623, 59X1159433, 59434, and 59160. Commenters stated that these revised codes would create a uniform system between payors, as many other payors and payment systems such as the OPPS, have already adopted or proposed to adopt the revised coding structure. Additionally, commenters discussed that these codes would increase the transparency of antepartum and postpartum visits performed. Commenters also believed that the updated codes better reflect modern, personalized maternity care. Many commenters supported our proposed work RVU increases to the labor and delivery codes, as these services have become increasingly complex and require significant clinical decision-making, care coordination, and clinician work. A few commenters did not support our proposed increases to the labor and delivery codes, and requested us to finalize the RUC recommendations, because they believed that the RUC's recommendations account for the number of E/M visits increasing for some patients and decreasing for others. Some commenters believed that we should increase the work RVUs for all of the CPT codes, since in some clinical scenarios, the new codes could pay less than the current maternity codes. We also received several questions seeking coding guidance for the new maternity CPT codes.

Response: We appreciate the commenters for this information and will consider additional refinements in future rulemaking. Although we are not specifying a maximum number of antepartum or postpartum visits that can be billed, we expect that ACOG's guidelines will be followed, and that, as with all services paid under the PFS, all services furnished must be reasonable and necessary. We will also continue to consider methods of bundling under the PFS, including information on the range of antepartum or postpartum visits as stakeholders develop more familiarity with the new code set. We defer to CPT and/or the billing practitioner's MAC for clarification on coding guidance for the new maternity CPT codes.

After consideration of public comments, we are finalizing as proposed.

b. Comment Solicitation on Maintaining Current Coding Through Creation of HCPCS G-Codes

We were interested in thinking about different approaches to how maternity care codes are valued and paid under the PFS. Although the RUC asserts that these proposed coding changes discussed previously reflect clinical consensus, we had concerns that our adoption of the new codes would be disruptive based on how the longstanding existing code structure is currently accounted for in clinical practice patterns. We sought comment on whether CMS should create HCPCS G-codes that would maintain the current coding and payment for maternity services to ameliorate this concern, while we continue to consider the potential impact that changes in the maternity care code family have on clinical outcomes for maternal care. These codes would be used in lieu of adoption of the new CPT codes for purposes of Medicare payment. We were specifically interested in additional information to support or oppose this concern, as well as additional information to support or oppose the use of the creation of HCPCS G-codes in lieu of adoption of the new CPT codes.

Specifically, for payment for maternity care services under the PFS, we were considering, and sought comment on, the creation of 15 new HCPCS G-Codes for CY 2027 that reflect the previous MMM global code structure, with the code descriptors and work RVUs detailed in Table A–D3, as an alternative to the revaluation of the codes as discussed in section (a), of the proposed rule (91 FR 43842 through 44557). We sought public comment on these HCPCS G-codes and, after consideration of public comment, could finalize payment for these codes. We sought comment on these HCPCS G-codes and also sought comment on any other HCPCS G-codes that may be needed to reflect the necessary service elements for this code family. These HCPCS G-codes would adopt all current conditions of payment for the MMM global codes, as well as maintain the MMM global period, if finalized.

TABLE A-D3: POTENTIAL G CODES TO MAINTAIN PREVIOUS CODE SET

HCPCS G-Code	Long Descriptors	G-Code Work RVUs
GMAT1	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care	37.00
GMAT2	Vaginal delivery only (with or without episiotomy and/or forceps);	14.37
GMAT3	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	18.76
GMAT4	Antepartum care only; 4-6 visits	7.8
GMAT5	Antepartum care only; 7 or more visits	14.3
GMAT6	Postpartum care only (separate procedure)	3.22
GMAT7	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care	41.05
GMAT8	Cesarean delivery only;	16.13
GMAT9	Cesarean delivery only; including postpartum care	22.79
GMA10	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery	38.71
GMA11	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	16.09
GMA12	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care	20.48
GMA13	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery	41.57
GMA14	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery;	16.66
GMA15	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	23.32

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Almost all commenters were opposed to maintaining current coding through the creation of HCPCS G-codes. Commenters stated that the creation of these codes for Medicare would increase administrative burden and market confusion, as well as not representing some of the services described in the proposed CPT codes (including tamponade and 3rd and 4th degree laceration repair). Many commenters believed that the structure of these codes no longer reflect health care delivery, and the proposed CPT codes allow information gathering about the services performed and encourage patient-centered care that these HCPCS G-codes do not. Some commenters did not support finalizing these codes since we did not publish the Practice Expense (PE) and Malpractice RVUs associated with these HCPCS G-codes.

A few commenters supported the creation of these HCPCS G-codes. These commenters expressed concerns about potential cost-sharing, claims denials, more complex billing, and the additional resources needed to adopt the new CPT codes. Some commenters supported a set payment that the HCPCS G codes would provide, and not having payments that vary patient to patient when services are performed with the CPT codes. A few commenters stated that E/M coding does not specifically describe antepartum or postpartum care.

Response: We appreciate the commenters for this information. We disagree with commenters that any change in maternity coding discussed in this rule, whether the new CPT codes or the proposed HCPCS G-codes, would change any policies impacting cost-sharing or claims denials. While we understand that additional resources may be needed for the higher overall number of codes being billed, we believe that this provides valuable utilization information that cannot be obtained with the continued use of bundled codes. Although E/M coding does not specifically describe antepartum or postpartum care, these codes are used by many specialties to describe professional services that may not explicitly be stated in the E/M code descriptor.

Comment: Most commenters who requested the adoption of the HCPCS G-codes requested that we adopt both the CPT codes and the HCPCS G-codes for CY 2027. Some commenters requested adopting both codes, but having a defined sunset date and limiting the use of both code sets to Medicare. One of the primary reasons why commenters requested both code sets for CY 2027 was due to concerns about billing guidance for pregnancies that begin in CY 2026 and continue into CY 2027.

Response: We defer to AMA and ACOG guidance on the correct billing structure for pregnancies that begin in CY 2026 and continue into CY 2027.We also understand that there may be cases in which the prior CPT codes may be needed when billing and paying for episodes of care with service start dates in 2026. CMS published an enforcement discretion under 45 CFR 162.1101 allowing HIPAA covered entities to temporarily use CPT 2026 Maternity Care Services codes for billing and

payment purposes after January 1, 2027. Payers and health plans may issue business rules in advance of January 1, 2027 instructing providers, clearinghouses and other trading partners regarding CPT code use when billing for Maternal Care Service episodes of care in which services begin in 2026 and end in 2027. Questions can be sent to *AdministrativeSimplification@cms.hhs.gov* with the subject line: Enforcement Discretion.

After consideration of public comments, we are not finalizing the creation of these HCPCS G-codes, although we may consider the creation of bundled codes describing maternity care services in future rulemaking using the information on the billing patterns associated with the unbundled visit codes.

(28) Stereotactic Computer-Assisted Volumetric Navigation (CPT Codes 61781, 61782, and 61783)

In April 2024, CPT code 61783 (*Stereotactic computer-assisted (navigational) procedure; spinal (List separately in addition to code for primary procedure)*) was identified via the high-volume growth screen. In January 2025, the RAW reviewed the action plan for CPT code 61783 and determined that this service should be surveyed with the appropriate family of codes. The RUC recommended that CPT code 61781 be surveyed with CPT codes 61782 (*Stereotactic computer-assisted (navigational) procedure; cranial, extradural (List separately in addition to code for primary procedure)*) and 61783 (*Stereotactic computer-assisted (navigational) procedure; spinal (List separately in addition to code for primary procedure)*) for September 2025.

We proposed the RUC-recommended work RVU of 3.66 for CPT codes 61781 and 61783, and the RUC-recommended RVU of 2.06 for CPT code 61782. We note that all three of these RUC-recommended RVUs reflect the application of the CY 2026 efficiency adjustment described in the CY 2026 PFS final rule (90 FR 49334 through 49345).

We proposed the RUC's recommended direct PE inputs for CPT code 61782. Since CPT codes 61781 and 61783 are performed in the facility setting only, the RUC did not recommend, and we did not propose, any direct PE inputs for these two codes.

Comment: A commenter stated that this code describes an important service in rhinologic practice, including use in complex sinonasal and skull-base procedures, and expressed concern about the magnitude of the proposed reduction from the current value of 3.10 to the RUC-recommended RVU of 2.06 for CPT code 61782. They noted image-guided navigation requires significant physician time, technical skill, and mental effort, since surgeons must constantly integrate navigation data with live anatomy while working near critical structures.

Response: We thank the commenters for their feedback. After consideration of the public comments and re-review of this code family, we believe that the proposed work RVUs for these codes are appropriately valued; thus, we are finalizing the work RVUs for the codes as proposed.

(29) Percutaneous Lumbar Decompression (CPT Code 62287)

At the January 2025 RUC meeting, the surveying societies requested deletion of CPT code 62287 *(Decompression, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar)* due to declining Medicare utilization. At the May 2025 CPT Editorial Panel meeting, CPT reviewed additional utilization estimates, and requests from neurosurgery and radiology were received to resurvey and retain the code. CPT code 62287 was surveyed at the September 2025 AMA RUC meeting since it was not deleted in January 2025 with the other codes in the family.

We disagree with the RUC's recommended work RVU of 7.06 for CPT code 62287 and we instead proposed a work RVU of 6.23 based on a crosswalk to CPT code 46707 *(Repair of anorectal fistula with plug (e.g., porcine small intestine submucosa [SIS]))*. We believe that the RUC's recommended work RVU of 7.06 is an overestimation based on a comparison to other codes with similar time values, particularly the key reference code CPT code 22869 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level*). There was a decrease in the surveyed work times, such as the intraservice time decreasing from 60 minutes to 37 minutes, which was not fully accounted for in the RUC's recommended work RVU of 7.06. We also note that the procedure does not seem to have become more intense, as the code descriptor did not change.

In the interest of maintaining relativity with similarly timed codes, we instead proposed a work RVU of 6.23 based on a crosswalk to CPT code 46707. This code has an almost identical intraservice time and similar total time. The proposed work RVU accounts for the decrease in both intraservice time and total time and is well bracketed by CPT code 67912 *(Correction of lagophthalmos, with implantation of upper eyelid lid load (e.g., gold weight))*, valued at a work RVU of 6.20 with an intraservice time of 40 minutes, and CPT code 24358 *(Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); debridement, soft tissue and/or bone, open)*, valued at a work RVU of 6.49 with an intraservice time of 40 minutes.

We proposed the RUC-recommended direct PE inputs for all of the codes in this family.

Comment: Commenters disagreed with the proposed work RVU of 6.23 for CPT 62287 stating that the complexity of the surveyed code's physician work was not adequately represented and was below the surveyed 25th percentile. Commenters also stated that the crosswalk does not maintain relativity within the code family and is not clinically related to the proposed code. Commenters stated that the proposed valuation does not adequately account for the technical precision, imaging interpretation, anatomical localization, clinical judgment, mental effort, procedural intensity, and risks associated with percutaneous lumbar decompression. Commenters disagreed that a time reduction alone deserves a lower value when the work is unchanged and that the valuation methodology should account for this shift in complexity rather than treat the reduced time alone as justification for a proportionally reduced work RVU.

Commenters stated that the RUC-recommended work RVU of 7.06 would be more appropriate for CPT code 62287 and cited CPT codes 62330 (*Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (i.e., CT or fluoroscopy), bilateral; one interspace, lumbar*) and 62331 (*Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (i.e., CT or fluoroscopy), bilateral; additional interspace(s), lumbar (List separately in addition to code for primary procedure)*) as relevant comparators within the lumbar decompression family. A commenter

identified CPT code 22869 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level*), the RUC's key reference service, as an appropriate crosswalk because it similarly involves invasive lumbar spine intervention, image guidance, spatial judgment, and spinal procedural risk.

Response: We thank the commenters for their feedback. We are not compelled by the arguments that a work RVU of 6.23 would not maintain relativity in the family. CPT code 62330 has a higher intraservice time and total time which accounts for why it has a higher work RVU as compared with our proposed valuation of CPT code 62287. We also note that CPT code 62330 has historically had a higher intensity than CPT code 62287, which would be reversed by the RUC's recommended work RVU of 7.06; we do not believe that this reversal of their relative intensities would be the case given that there was agreement from the commenters that the clinical practice of CPT code 62287 had not changed. We also do not believe that the work RVUs of CPT codes 62287 and 62331 are directly comparable since the latter code is an add-on procedure with only 43 minutes of total time. We disagree with the comment that identified CPT code 22869 as an appropriate crosswalk because it similarly involves invasive lumbar spine intervention, image guidance, spatial judgment, and spinal procedural risk. We want to reiterate that the PFS is a relative value-based system and not all reference codes are necessarily clinically related.

We continue to believe that since there was a decrease in the surveyed work times which was not fully accounted for in the RUC's recommended work RVU of 7.06, the work RVU should decrease correspondingly since valuation is based on time and intensity. We also continue to disagree that there has been a significant increase in intensity for this code which would warrant the work RVU recommended by the RUC. Intensity of work under the Physician Fee Schedule reflects skill, expertise, effort, stress, and other factors that influence the assessed relative value of time spent. We disagree with the commenters that performing the same work in less time inherently means that the intensity of a procedure has increased; changes in practice patterns, improvements in technology, or greater efficiencies in the delivery of care can all account for shorter procedure times without a corresponding increase in intensity. Commenters agreed that CPT code 62287 had undergone no significant change in the procedure's performance as reflected by its unaltered code descriptor. Under our methodology for work valuation, if the surveyed work times are decreasing and there is general agreement that the procedure itself has remained unchanged, this supports a decrease in the work RVU, not a conclusion that the intensity of the procedure has increased to match the decrease in surveyed work time. We believe that the agreement from the commenters that there has been no significant change in the clinical performance of CPT code 62287 supports our proposed work RVU of 6.23, not undermines it.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs for CPT code 62287 as proposed.

(30) Laminectomy (CPT Codes 63045, 63046, 63047, and 63048)

In April 2025, the RAW identified CPT code 63047 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar*) as a site of service anomaly where Medicare data from 2021 to 2023 indicated it was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period with 2023 Medicare utilization over 10,000. The RAW also worked with the specialty societies and identified other codes 63045 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; cervical*), 63046 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; thoracic*) and 63048 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; each additional vertebral segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)*) as part of this family of services. These services were surveyed for September 2025.

We proposed the RUC-recommended work RVUs for all four CPT codes in this family. We proposed a work RVU of 17.25 for CPT code 63045, a work RVU of 16.71 for CPT code 63046, a work RVU of 14.99 for CPT code 63047, and a work RVU of 3.38 for CPT code 63048. We note that several of these work RVUs were affected by the efficiency adjustment which was applied at the start of CY 2026, as the RUC recommendations were based on pre-adjustment work valuations.

We proposed the RUC recommended direct PE inputs for CPT codes 63045, 63046, 63047, and 63048 without refinement.

Comment: A commenter asked that the efficiency adjustment not be applied to these codes. We received other comments on this code family that were overall not in scope for CMS's proposal.

Response: We can clarify for the commenters that the efficiency adjustment was not directly applied to the review of these codes since their work and time survey data was newly produced for CY 2027. However, CPT codes 63045 and 63046 had their work valuations recommended by the RUC using crosswalks to other CPT codes, 22554 and 46710 respectively, which were subject to the efficiency adjustment. The proposed valuation for CPT code 63045 was therefore based on the adjusted work RVU of 17.25, the current work RVU of code 22554, rather than the pre-adjusted work RVU of 17.69 for that code. We do not agree that it would be appropriate to use crosswalks to pre-adjusted work RVUs as it would fail to maintain relativity and create significant confusion.

We are clarifying that the other comments received on this code family were overall not in scope for CMS's proposal.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 63045, 63046, 63047, and 63048 as proposed.

(31) Injection Anesthetic Agent (CPT Codes 64400 and 64405)

The RUC identified CPT code 64400 *(Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (i.e., ophthalmic, maxillary, mandibular))* via their database flag, ''Do not use to validate physician work'', and recommended to survey this CPT code and the related CPT code 64405 *(Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve)* for the September 2025 meeting.

For CY 2027, we proposed the RUC-recommended work RVUs of 0.73 for CPT code 64400 (which is the current

work RVU of the code after the efficiency adjustment was applied at the start of CY 2026) and 0.84 for CPT code 64405.

We proposed the RUC-recommended direct PE inputs for both CPT codes without refinement.

Comment: Commenters were supportive of CMS' proposed work RVUs and direct PE inputs for this code family.

Response: We thank the commenters for their support. After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs as proposed.

(32) MRA—Head, Neck (CPT Codes 70544, 70545, 70546, 70547, 70548, 70549, 70560, 70561, and 70562)

In April 2024, the RAW noted that the rate at which CPT codes 70547 (currently described as *Magnetic resonance angiography, neck; without contrast material(s)*) and 70544 (currently described as *Magnetic resonance angiography, head; without contrast material(s)*) are reported together continued to increase after the initial identification of the trend in April 2022 and a 2-year delay in review to allow practice patterns in the inpatient and outpatient setting go back to how they were prior to the COVID–19 pandemic. At the September 2025 CPT Editorial Panel, six CPT codes were revised to include ''image postprocessing'': CPT codes 70544 (*Magnetic resonance angiography, head, including image postprocessing; without contrast material(s)*), 70545 (*Magnetic resonance angiography, head, including image postprocessing; with contrast material(s)*), 70546 (*Magnetic resonance angiography, head, including image postprocessing; without contrast material(s), followed by contrast material(s) and further sequences*), 70547 (*Magnetic resonance angiography, neck, including image postprocessing; without contrast material(s)*), 70548 (*Magnetic resonance angiography, neck, including image postprocessing; with contrast material(s)*), and 70549 (*Magnetic resonance angiography, neck, including image postprocessing; without contrast material(s), followed by contrast material(s) and further sequences*). Three additional codes were created to bundle magnetic resonance angiography (MRA) head and neck with/without contrast: CPT codes 70560 (*Magnetic resonance angiography, head and neck, including image postprocessing; without contrast material(s)*), 70561 (*Magnetic resonance angiography, head and neck, including image postprocessing; with contrast material(s)*), and 70562 (*Magnetic resonance angiography, head and neck; without contrast material(s) in one or both body regions, followed by contrast material(s) and further sequences in one or both body regions, including image postprocessing*). The code family was surveyed for the January 2026 RUC meeting.

We proposed the RUC-recommended work RVU for all nine codes in the family. We proposed the RUC-recommended work RVUs of 1.17, 1.17, 1.44, 1.17, 1.46, 1.76, 1.77, 2.10, and 2.23 for CPT codes 70544, 70545, 70546, 70547, 70548, 70549, 70560, 70561, and 70562, respectively. We proposed the RUC recommended direct PE inputs for CPT codes 70544, 70545, 70546, 70547, 70548, 70549, 70560, 70561, and 70562 without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters appreciated our proposal of the RUC-recommended work RVUs and direct PE inputs for the MRA Head and Neck code family (CPT codes 70544, 70545, 70546, 70547, 70548, 70549, 70560, 70561, and 70562) without refinement.

Response: We thank the commenters for their support.

Comment: A commenter disagreed with the proposed work RVUs for CPT codes 70560, 70561, and 70562, and requested that CMS value these codes at the sum of the components. The commenter noted, for example, the current work RVUs for CPT codes 70546 for the head (1.44) plus 70549 for the neck (1.76) equals 3.20. Therefore, they recommended the RVU for bundled CPT code 70562 for the head and neck combined should also equal 3.20 instead of the RUC-recommended RVU of 2.23 proposed by CMS. The commenter stated that this is the steepest cut (30.3 percent) of the three new bundled MRA codes, compared to billing separately, even though this is the most complex interpretation of the three new MRA codes performed without contrast materials, followed by the study with contrast materials. The commenter stated that the physician work, intensity, and complexity associated with interpreting these procedures did not decrease because the codes have been bundled.

Response: We continue to believe that the proposed RUC-recommended work RVUs for CPT codes 70560, 70561, and 70562 are appropriate. It is reasonable to expect that these three new bundled codes will achieve savings via elimination of duplicative assumptions of the resources involved in furnishing particular servicers. We believe the new bundled coding assigns more accurate work times, and thus, reflects efficiencies in resource costs that exist but are not reflected when these services are reported separately. The proposed RVUs for these codes maintain relativity within the MRA Head and Neck code family and appropriately account for the physician work required for these services.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the MRA Head and Neck code family (CPT codes 70544, 70545, 70546, 70547, 70548, 70549, 70560, 70561, and 70562) as proposed.

(33) Computed Tomography-Upper Extremity With Contrast (CPT Codes 73200, 73201, and 73202)

In April 2025, the RAW identified CPT code 73201 (*Computed tomography, upper extremity; with contrast material(s)*) via the CMS/Other source and 2023 Medicare utilization over 20,000 screen. The family of services was surveyed for the January 2026 RUC meeting, including CPT codes 73200 *(Computed tomography, upper extremity; without contrast material*) and 73202 *(Computed tomography, upper extremity; without contrast material, followed by contrast material(s) and further sections).*

We proposed the RUC-recommended work RVUs of 1.00, 1.16, and 1.24 for CPT codes 73200, 73201, and 73202, respectively. We proposed the RUC recommended direct PE inputs for CPT codes 73200, 73201, and 73202 without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal of the RUC-recommended work RVUs and direct PE inputs for the Computed Tomography-Upper Extremity with Contrast (CPT codes 73200, 73201, and 73202) code family.

Response: We appreciate the support for our proposed values from the commenters.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Computed Tomography-Upper Extremity with Contrast code family as proposed.

(34) Radiation Oncology Treatment Delivery (CPT Codes 77402, 77407, and 77412)

In the CY 2026 PFS final rule (90 FR 49379 through 49383), we finalized our proposal to utilize the relationship

between the Hospital Outpatient Prospective Payment System (OPPS) Ambulatory Payment Classifications (APC) relative weights for APCs 5621, 5622, and 5623 to inform the valuation of PE-only CPT codes 77402 (*Radiation treatment delivery; Level 1 (e.g., single-electron field, multiple-electron fields, or 2D photons), including imaging guidance, when performed*), 77407 (*Radiation treatment delivery; Level 2, single-isocenter (e.g., 3D or IMRT), photons, including imaging guidance, when performed*), and 77412 (*Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (e.g., 2D, 3D, or IMRT) or a single-isocenter photon therapy (e.g., 3D or IMRT) with active motion management, or total skin electrons, or mixed-electron/photon field(s), including imaging guidance, when performed*) when paid under the PFS. We also stated that we calculated the RVUs for these codes so that the overall PE and MP RVUs for these services represent the same share of total PE and MP RVUs in CY 2025 and CY 2026. To accomplish this, we developed PE and MP RVUs using the assumed distribution of services indicated in the utilization crosswalk.

We proposed to utilize the RUC-recommended crosswalk for these services, which assumed that 45 percent of the billed charges would be reported with CPT code 77412. Some commenters stated that CPT code 77412 would represent only 15 percent of the volume for these services. We stated in the CY 2026 PFS final rule that it is difficult to ascertain how services furnished in the past would be most accurately reported using a future code set (90 FR 49385). In response to comments and considering the disparate information we received, we finalized a modified crosswalk that adjusted downward the estimated portion that CPT code 77412 would be reported compared to CPT code 77407 based on commenters who represent those who provide care in the non-facility setting. Specifically, we modified the utilization crosswalk to crosswalk 35 percent of the utilization to CPT code 77412 and 55 percent of the utilization to CPT code 77407. Since the publication of the CY 2026 PFS final rule, interested parties have reported that the 35 percent utilization assumption for CPT code 77412 was still overstated despite our downward adjustment in the CY 2026 PFS final rule, and that the actual utilization for CPT code 77412 is approximately 18 percent. Given the importance of the assumed distribution of services in ensuring that we achieved our target of maintaining the same share of total PE and MP RVUs, we reviewed the claims data to evaluate the actual distribution of utilization among CPT codes 77402, 77407, and 77412. We noted that during the first 3 months of 2026, CPT code 77412 comprised approximately 18 of the total volume of these services.

Given that we valued these services by utilizing the relative relationship between the OPPS APC relative weights rather than our standard PE methodology, shifts in utilization over time are not automatically incorporated into the annual development of PE RVUs for these services over time. Consequently, we proposed to refine the relativity within this family of codes for CY 2027 based on available claim data that corroborates the information submitted to us by outside parties. We did not propose to change the assumptions about the total number of services, but rather, to revalue the PE RVUs using the observed distribution of services, such that the PE and MP RVUs for these services represent the same share of total PE and MP RVUs as they did in CY 2025.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported recalibrating this family of codes but urged CMS to use both Q1 and Q2 CY 2026 claims data, not Q1 alone, for a more reliable utilization basis before finalizing CY 2027 values. One specialty society called the correction necessary, noting that OPPS-derived APC weights import hospital rate-setting anomalies into the PFS and that the restructured code set selects codes by clinical complexity, treatment area, target number, and dose rather than technique. This commenter said correcting the utilization assumption frees existing radiation oncology PE-pool RVUs to recalibrate CPT code 77407 without affecting overall PFS budget neutrality.

Other commenters cautioned that fixing the internal distribution within a fixed payment pool does not confirm the pool itself is adequate. Commenters reported a 23–30 percent decline in average radiation oncology payment from 2025 to 2026 that the proposed correction would not offset, and asked CMS to use existing authority to provide retrospective CY 2026 relief. This commenter stated that these payment reductions occurred with no corresponding drop in staffing, equipment, safety, or facility costs, calling current operations financially unsustainable. A freestanding practice cited a third-party financial model projecting only a 0.61 percent net increase in freestanding global revenue from 2026 to 2027, versus an estimated 14.21 percent increase under the OPPS methodology, with hospital outpatient departments paid about 34 percent more for the same three delivery levels. A commenter said the CY 2027 recalculation, though reasonable, preserves the same aggregate PE/malpractice pool without testing whether payment for a full treatment course is adequate.

Response: We appreciate the commenter's support for updating the utilization assumptions and its impact on recalibrating the valuation for CPT code 77407. We agree that aligning the utilization assumption with the restructured code set's selection criteria improves accuracy. Regarding the commenters who described declines in revenue of 23–30 percent from 2025 to 2026, we note that these figures are inconsistent with our estimates for Medicare payments. Regarding the commenter who stated that the proposed CY 2027 rate only yields a 0.61 percent net increase, we note that the proposed RVUs for CPT codes 77402, 77407, and 77412 increased significantly more than that: for instance, the total RVU for 77407 is approximately 12% higher than the CY 2026 total RVU.

With respect to the request to incorporate Q2 claims data for a more reliable utilization basis, we note that including these claims did not significantly alter the PE RVUs for these services. With respect to comments about payment adequacy, as we stated in the CY 2026 final rule, we calculated the proposed RVUs so that the aggregate PE and MP RVUs for this family of codes—weighted by each code's utilization volume—would remain consistent with CY 2025 levels. In other words, our goal was to preserve the overall RVU share represented by this code family, not to hold each individual code's RVUs constant. For CY 2027, we proposed to improve the precision of our calculation using actual utilization data. If interested parties believe other codes as part of the course of treatment are inadequately valued or should be closer to the OPPS values, we refer them to the potentially misvalued code process for consideration in future rulemaking. Under the PFS we use the best information available to calculate RVUs for a given year. We do not have statutory authority to provide retrospective 2026 payment adjustments.

Comment: A commenter recommended that CMS reassign CPT code 77407 to APC 5623 (Level 3

Radiation Therapy), reiterating a recommendation made in its CY 2026 comment letter. The commenter stated that the legacy IMRT codes (CPT codes 77385 and 77386) consolidated into the revised code family were previously assigned to APC 5623, and that keeping CPT code 77407 in APC 5622 undervalues a service now accounting for a substantial share of external-beam delivery volume. The same commenter recommended that CMS refine the transitional crosswalk mapping legacy CPT codes 77385/77386 and 77412 claims to the revised codes, noting that some services historically billed under legacy 77386 may more appropriately correspond to revised CPT code 77407 rather than CPT code 77412.

Response: We consider comments regarding APC assignments to be outside the scope of this final rule.

Comment: A commenter expressed concern regarding proposed reductions to core physician-work-based services, including radiation treatment planning (CPT code 77263), IMRT planning (CPT code 77301), conventional treatment management (CPT code 77427), and stereotactic treatment management (CPT codes 77432 and 77435). Commenters also expressed concern about reductions to other related services resulting from the efficiency adjustment. Commenters also expressed concerns about reduction resulting from the conversion factor reduction.

Response: We refer commenters to sections X.X and X.X of this final rule where we respond to comments about the efficiency adjustment and the reduction to the conversion factor.

Comment: Several commenters stated that because the CY 2026 code descriptors represent materially different, bundled services (including image guidance) but reuse legacy CPT numbers, many commercial payers have carried forward prior rates, edits, and authorization rules associated with the deleted codes, producing underpayment, downcoding, denials, and costly renegotiations outside traditional Medicare. Commenters requested that CMS recognize the redesigned codes as new services for payment purposes and work with the AMA CPT Editorial Panel and specialty societies to establish new, distinct CPT identifiers; pending such action, commenters recommended that CMS implement temporary HCPCS codes or another mechanisms to distinguish the redesigned services from prior code definitions and values.

Response: We acknowledge commenters' concerns about coding issues related to commercial payers. However, we consider these comments to be outside the scope of this final rule. We refer commenters to the CPT Editorial Panel to address issues related to CPT identifiers.

Comment: A commenter urged CMS not to treat the observed 18 percent Level 3 utilization rate as a quota or audit benchmark, arguing that early 2026 claims data were generated during a documented period of coding uncertainty, and that a longer, more mature claims period together with clear national coding/documentation guidance are needed before such a rate is relied upon. Commenters recommended that CMS formally clarify that the ~18 percent CPT code 77412 utilization figure is not intended to function as a fixed quota or audit trigger.

Response: The adjustment that we proposed to recalibrate the PE RVUs based on early claims history was intended to improve the accuracy of the PE RVUs. We did not intend to establish a benchmark for the percentage of claims billed with Level 3.

Comment: Commenters recommended that CMS evaluate the PFS and OPPS payment changes together, including their combined effects on practice closures, consolidation, Medicare spending, and rural access, and provide immediate transition protection for freestanding and rural centers while a fuller episode-level revaluation is completed. A commenter recommended that CMS support development of a longer-term, non-annually-volatile payment reform for radiation oncology, including the Radiation Oncology Case Rate (ROCR) Act, as a structural remedy to the volatility in payment.

Response: We acknowledge the commenters' concerns and may consider these issues in future rulemaking.

After consideration of the public comments, we are finalizing our proposal to revalue the PE RVUs using the observed distribution of services, such that the PE and MP RVUs for these services represent the same share of total PE and MP RVUs as they did in CY 2025.

(35) Proton Beam Treatment Delivery (CPT Codes 77520, 77522, 77523, and 77525)

Payment amounts for proton beam treatment delivery services described by CPT codes 77520 (*Proton treatment delivery; simple, without compensation*), 77522 (*Proton treatment delivery; simple, with compensation*), 77523 (*Proton treatment delivery; intermediate*), and 77525 (*Proton treatment delivery; complex*) are currently determined by local Medicare Administrative Contractors (MACs). We have not previously established RVUs for these services due to the unique nature of the equipment costs associated with these services compared to other capital costs addressed by our usual PE methodology. In the CY 2026 PFS proposed rule, we sought comment on establishing national payment rates for proton beam treatment delivery services. In the CY 2026 final rule (90 FR 49390), we indicated our intent to establish national pricing for proton beam treatment delivery services in future rulemaking.

Interested parties have raised concerns about wide geographic payment disparities with the current contractor pricing that are unrelated to the cost of providing care and have requested that CMS nationally price proton beam treatment delivery services. For example, 2024 claims data for CPT code 77525, which has the second highest utilization of the code family, reflects allowed charges that ranged from $122.15 to $1,374.26. Interested parties recommended that CMS establish identical payment rates for PFS and OPPS, calculating a weighted average of the payment rates to maintain budget neutrality across the PFS and OPPS. Other interested parties expressed concern about reliance on OPPS cost data to value proton beam treatment delivery services, as the substantial capital outlays required by freestanding centers could be greater than those faced by hospital systems and the freestanding centers lack the purchasing power or amortization flexibility that hospitals may have.

After considering the comments we received in response to the CY 2026 PFS rule regarding establishing national payment rates for proton beam treatment, similar to the policy we finalized for CY 2026 for radiation treatment delivery services, we proposed to calculate the PE RVUs for these services as follows:

- Use the total allowed charges paid by the MACs for CPT codes 77520, 77522, 77523, and 77525 to establish the pool of PE RVUs to allocate to the services in this code family.
- Allocate PE RVUs to the individual services using the relationship between the APC relative weights for APCs 5625 (to which CPT codes 77522, 77523, and 77525 are assigned) and APC 5623 (to which CPT code 77520 is assigned) under the OPPS. We believe our proposal appropriately balances interested parties' requests to establish national payment rates with the difficulties we have faced when considering the capital-intensive and

specialized resources for services like proton beam therapy services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters broadly agreed that replacing inconsistent, non-transparent MAC-based pricing with a national methodology is a reasonable long-term goal. However, most commenters stated that the specific inputs, data sources, and allocation methodology proposed for CY 2027 are flawed, insufficiently disclosed, and would produce underpayment. Some commenters supported the general direction while requesting technical fixes. Another commenter supported proceeding with national pricing on the proposed CY 2027 timeline.

Response: We appreciate commenters' support for establishing a national payment rate for proton beam treatment delivery.

We did not use direct PE inputs to calculate the PE RVUs for these services, as we would under our standard PE methodology. Instead, we used the following two-step approach:

First, we calculated a pool of PE RVUs equal to the amount implied by the rates that MACs currently pay for these services. In other words, we started from current MAC payment levels, converted to RVU terms, rather than building the rate up from individual PE inputs (equipment, supplies, labor time, etc.).

Second, we allocated that pool of RVUs across the individual codes based on the relative relationship between the applicable Ambulatory Payment Classifications (APCs). For example, CPT 77520 is assigned to APC 5623, while CPT codes 77522, 77523, and 77525 are each assigned to APC 5625. At the time of the development of the proposed rule, the relative payment ratio of APC 5625 to APC 5623 was approximately 2.24. We therefore allocated the pool such that the PE RVU for each of CPT codes 77522, 77523, and 77525 was approximately 2.24 times the PE RVU for CPT 77520.

We note that the public use files accompanying the proposed rule inadvertently included a different set of inputs—specifically, inputs from previous RUC recommendations and an equipment utilization assumption. These had not previously appeared in the files because the files are only populated with direct PE inputs for services we price nationally. We confirm that we did not use these inputs—the previous RUC recommendations or the equipment utilization assumption—in calculating the PE RVUs. Our calculation relied solely on the MAC-rate-derived pool and the APC-relationship allocation described previously.

We disagree with commenters who stated that we insufficiently disclosed our methodology. We used this same two-step approach—(1) maintaining the pool of RVUs implied by current rates and (2) allocating that pool based on the relative relationship between applicable APCs—to establish payment rates for radiation oncology treatment delivery and surface radiation treatment codes in the CY 2026 final rule (90 FR 49379).

Comment: Some commenters criticized the proposed 90% equipment utilization assumption as inappropriate and understated for proton beam treatment delivery equipment. Commenters noted this rate is typically reserved for diagnostic imaging equipment, while other radiation oncology equipment generally assumes 60–70% utilization. Sensitivity analyses cited by commenters indicated that adopting a 70% utilization assumption would raise the proposed per-treatment payment from approximately $1,029 to over $1,300.

Response: As we stated earlier in this section, we did not use the direct PE inputs in the PUF to calculate the PE RVUs for these services. The equipment utilization assumption is therefore irrelevant to this calculation.

Comment: Some commenters stated that CMS published materially different, inconsistent proposed rate figures for the same codes within a single rulemaking cycle without explaining why the methodology changed. Commenters stated this rollout undermines confidence that the methodology is ready for finalization and makes it harder for stakeholders to evaluate or comment meaningfully on the proposal.

Response: We acknowledge that the PE RVUs we initially published did not match our proposed methodology, due to a separate technical error. After interested parties raised this issue, we posted corrected PE RVUs. There was no underlying change in methodology. We corrected this technical error 1 week after we published the proposed rule, and stakeholders confirmed they were aware of the correction. We therefore do not believe this limited stakeholders' ability to comment meaningfully.

Comment: Several commenters noted that the CY 2026 elimination of separately payable image guidance (CPT code 77014, replaced by the professional-only CPT code 77387) removed reimbursement for a technical resource that should now be reflected in the bundled proton beam treatment delivery rates, particularly given that over 92% of patients receive daily image-guided radiation therapy (IGRT). Commenters argued that the proposed methodology does not adequately account for this shift in cost.

Response: We reviewed claims data from CY 2025 and CY 2026 in response to this concern. We found that MAC payment rates increased significantly in 2026, reflecting the bundling of image guidance. We are therefore calculating the pool of current RVUs using the first two quarters of CY 2026 claims, which increases the PE RVUs for these services.

Comment: Several commenters stated that using OPPS relative weights—derived from hospital outpatient cost structures—to allocate payments among freestanding, MPFS-paid centers does not adequately capture these facilities' capital and operating costs. Commenters calculated that the proposed freestanding rate (approximately $1,029) sits approximately 28–30 percent below the comparable OPPS hospital rate (approximately $1,434), despite similar underlying equipment and staffing costs. One provider organization noted that only 14 of the 50 operating proton beam treatment delivery facilities nationally are freestanding, community-based centers paid under the MPFS. This organization stated that these centers lack other service lines to offset losses from underpayment. A commenter supported proceeding with national pricing but proposed a specific compromise: adopt a fixed 70 percent equipment utilization rate, discontinue CPT codes 77520 and 77522 as separately payable, and set a single rate of approximately $1,280 for CPT codes 77523 and 77525. The commenter positioned this proposal as a middle path between the proposed MPFS rate and the OPPS benchmark rate.

Response: We proposed to use the relationship between the APCs to which these CPT codes are assigned to allocate the pool of PE RVUs. We believe the relative relationship between the resources required to furnish each of these services under the PFS are likely to be similar to the relative relationship of the resources required under the OPPS. We acknowledge commenters' concerns about the considerable difference between the freestanding rate and the comparable OPPS rate. The current payment structure already reflects this difference, and we proposed to maintain the current pool of PE RVUs based on that structure. We may consider these comments in future rulemaking. We appreciate the commenter's alternative proposal: to establish a single payment rate of approximately $1,280 for CPT codes

77523 and 77525, to adopt a fixed 70 percent equipment utilization rate, and to discontinue separate payment for CPT codes 77520 and 77522. The CPT Editorial Panel, not CMS, is responsible for coding changes to CPT codes. As we explained earlier in this section, the equipment utilization assumption is irrelevant to calculating PE RVUs for these services. We are not adopting a rate of approximately $1,280. We believe our proposed approach—using the total pool of PE RVUs implied by the existing MAC-priced claims, updated with the first two quarters of CY 2026 claims data as described previously in response to comments on image guidance bundling—produces a more accurate rate. Consistent with the commenter's recommendation, our approach also results in a single payment rate for CPT codes 77523 and 77525.

Comment: Some commenters noted that MACs used materially different, non-transparent methodologies to generate the historical allowed charges being pooled. They noted that CPT 77525/77522 payment ratios ranged from 1.159x to 1.382x across MACs, even within the same locality. Commenters also noted that utilization-weighting the pooled data gives two to three MACs outsized combined influence—approximately 78%—over the resulting national rates. Other commenters recommended that CMS refine the methodology using validated practice-expense data specific to freestanding centers that furnish proton beam treatment delivery, rather than hospital-based cost data. Another commenter offered to supply facility-level data to assist.

Response: Commenters supported nationally pricing these services in part because of these non-transparent contractor payment methodologies, as we summarized earlier in this section. We believe that, generally speaking, national pricing for individual services is preferrable to contractor pricing since it better maintains relativity across the PFS and minimizes regional variations that can create barriers to care access. Although contractor pricing is appropriate for some services, most often used for new and emerging technologies, we believe that CPT codes 77520, 77522, 77523, and 77525 will be more accurately valued using our proposed national pricing.

We agree that weighting the data by utilization means, by definition, that rates where MACs more frequently furnish these services have greater influence on the average. We believe weighting by utilization is reasonable here. When practitioners continue to furnish a service at a given rate over time, that provides at least some evidence the rate has sufficiently sustained provider participation. We believe this approach achieves our goal of maintaining the pool of total PE RVUs implied by the rates that MACs currently pay for these services. We acknowledge commenters' recommendation to use a validated cost study specific to proton beam treatment delivery. However, our approach is intended to move away from direct PE inputs and instead use the relative relationship between the APCs to which these CPT codes are assigned.

Comment: A commenter stated that this approach may not satisfy the Social Security Act's resource-based valuation requirements. Commenters requested that we defer national pricing until at least January 1, 2028, and establish a defined period to validate the methodology.

Response: Section 1848(c)(2)(N) of the Act authorizes us to establish or adjust PE RVUs using cost, charge, or other data. Our approach—using the relative APC relationships to allocate the PE RVUs implied by the claims data—is resource-based because the APC relationships reflect differences in resource costs. We do not believe that deferring national pricing to CY 2028 and adding a period to validate the methodology would produce a more accurate payment rate than the methodology we are finalizing. We believe the total pool of PE RVUs implied by the current MAC-priced claims should serve as the source for calculating PE RVUs. Because we would use this same source regardless, changing the methodology further would not materially change the resulting PE RVUs.

Comment: Commenters raised a range of access-related concerns, including potential impacts on pediatric, rural, and other vulnerable patient populations; the risk of facility closures, particularly among freestanding centers with limited ability to offset losses; the effect of reimbursement policy on hospital-versus-freestanding market dynamics; and high rates of commercial prior-authorization denials for proton beam treatment delivery. Numerous individual patients and a joint patient advocacy letter also described proton beam treatment delivery as critical to their care and urged CMS not to finalize a methodology that could lead to treatment center closures.

Response: We appreciate the concerns commenters raised about patient access, including impacts on pediatric and rural populations, the risk of facility closures among freestanding centers, and the effect of payment policy on the hospital-versus-freestanding market. As we discussed previously in response to comments on the proposed methodology, our approach maintains the total pool of PE RVUs currently implied by MAC-priced claims. We updated this pool to reflect the first two quarters of CY 2026 claims data to account for the bundling of image guidance. This is not a reduction in overall payment for proton beam treatment delivery; rather, our approach redistributes the existing pool across codes using a transparent, national methodology instead of inconsistent contractor-specific rates.

We believe this approach mitigates the closure risk commenters raised, because it does not cut payment relative to current levels for the pool of services as a whole. We recognize that a national rate may still shift payment for some codes or facilities relative to what a single MAC previously paid. We will monitor claims and utilization data after implementation to assess whether this affects access, including for freestanding centers and vulnerable populations.

Commercial prior-authorization denials involve non-Medicare payer practices and fall outside the scope of Medicare's practice expense methodology. We encourage stakeholders to raise this issue through the appropriate commercial payer or regulatory channels. We thank the individual patients and advocacy organizations who shared their experiences, and we will continue to consider patient access as we monitor this policy's impact in future rulemaking.

Comment: Multiple commenters cited the same third-party Medicare claims analysis (2019–2022) to argue that proton beam treatment delivery produces downstream systemic savings that justify adequate reimbursement. Cited findings included the lowest 90-day mortality (approximately 2%), the lowest inpatient admission rate (10–11% versus 14% or more for other modalities), the longest time to emergency-room visit, and the lowest emergency-room visit costs among comparable modalities.

Response: We appreciate the data commenters provided on mortality, admission, and emergency-department outcomes for proton beam treatment delivery. These findings speak to its clinical value relative to other modalities, but they do not bear on how we set practice expense rates. The resource-based PE methodology sets RVUs according to the relative cost of furnishing a service—equipment, supplies, and staff time—not according

to a service's downstream clinical or cost outcomes. Section 1848(c)(2) directs us to value services based on the resources used to furnish them; it does not authorize us to adjust PE RVUs based on comparative efficacy or systemic savings.

After consideration of the comments received, we are finalizing our proposal, with the modification of using the claims data from the first two quarters of 2026 to establish the total pool of RVUs implied by the MAC-paid claims.

(36) Biofeedback Training (CPT Codes 90901, 90903, 90912, and 90913)

CPT codes 90901 (*Biofeedback training by any modality (e.g., EMG, EEG, ECG); initial 15 minutes of direct patient contact by physician or other qualified health care professional*), 90912 (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient*) and 90913 (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)*) were surveyed at the January 2026 RUC meeting after having gone through revision at the September 2025 CPT Editorial Panel. CPT revised code 90901 to describe the initial 15 minutes of biofeedback training by a physician or other qualified health care professional with direct patient contact and created one new code, CPT code 90903 (*Biofeedback training by any modality (e.g., EMG, EEG, ECG); each additional 15 minutes of direct patient contact by physician or other qualified health care professional (List separately in addition to code for primary procedure)),* to describe each additional 15 minutes. CPT codes 90912 and 90913 were surveyed for the January 2026 RUC meeting since they are part of the same code family. CPT codes 90901 and new code 90903 were surveyed for the January 2026 RUC HCPAC Review Board meeting.

We proposed the HCPAC-recommended work RVUs of 0.61 for CPT code 90901 and 0.48 for CPT code 90903. We proposed the RUC-recommended work RVUs of 0.90 for CPT code 90912 and 0.50 for CPT code 90913.

We proposed the direct PE inputs recommended by the HCPAC and the RUC for all four codes in the family without refinement.

CPT codes 90901, 90912, and 90913 are all designated as sometimes therapy services, as such we proposed to designate CPT code 90903 as a sometimes therapy service.

Comment: Commenters supported the proposed values for Biofeedback Training. Commenters agreed with converting CPT code 90901 to a timed code and creating CPT code 90903. Commenters were generally supportive of designating CPT code 90903 as a sometimes therapy service.

Response: We appreciate the support for our proposed policies from the commenters.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 90901, 90903, 90912, and 90913 as proposed. We are also finalizing CPT code 90903 as a sometimes therapy service.

(37) Intracoronary Drug Delivery Balloon Services (CPT Codes 92922 and 92976)

In May 2025, the CPT Editorial Panel created two new codes, CPT code 92922 (*Percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloon (e.g., drug-coated, drug-eluting), including mechanical dilation by nondrug-delivery balloon angioplasty, single major coronary artery and/or its branch(es)*) and CPT code 92976 (*Percutaneous transcatheter therapeutic drug-delivery by intracoronary drug-delivery balloon (e.g., drug-coated, drug-eluting), single major artery and/or its branches (List separately in addition to code for primary procedure)*) to describe percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloons. The RUC reviewed these two new CPT codes at the September 2025 RUC meeting.

We reviewed the RUC's recommended work valuations and found the RUC's recommended work RVU of 10.00 for CPT code 92922 to be high, based on a search of 000 global day codes with between 45 and 75 minutes of intraservice time and between 109 and 149 minutes of total time in the RUC database. For CY 2027 we proposed a work RVU of 8.05, based on the RUC survey 25th percentile, for CPT code 92922. We proposed the RUC-recommended work RVU of 4.38 for CPT code 92976. The RUC did not recommend, and we did not propose any direct PE inputs for these codes.

Comment: We received a small number of comments. Nearly all commenters argued that CPT 92922 *(Percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloon (e.g., drug-coated, drug-eluting))* contains all of the work of CPT code 92920 (*Percutaneous transluminal coronary angioplasty, single major coronary artery and/or its branch(es)*) plus some additional resource costs. Some commenters also described the additional physician work involving lesion assessment, vessel preparation, drug coated balloon (DCB) selection and sizing, evaluation of the angioplasty result, and determination of whether a stent-free result is safe and durable. As such, the CMS proposed work RVU results in a work RVU anomaly. A couple commenters asserted that this additional work makes the work of the entire procedure similar to the work of placing a stent and that a crosswalk to CPT code 92928 (*Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch).*

Response: After consideration of the comments, we have increased the work RVU because we were persuaded by commenters that we were creating a work RVU anomaly with our proposed valuation of 8.05. However, we find the RUC's recommended work RVU of 10.00 (60 minutes intraservice time and 129 minutes total time) for CPT code 92922 to be too high relative to other CPT codes with similar time values. We do not agree the additional work described by commenters raises the intensity of the procedure to warrant a crosswalk to CPT code 92928. Based on a search of 000 global day codes with between 45 and 75 minutes of intraservice time and between 109 and 149 minutes of total time in the RUC database we identified CPT code 43276 (*Endoscopic retrograde cholangiopancreatography (ERCP); with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged*) with an RVU of 8.62, with similar work time of 60 minutes and 123 minutes total time. The 8.62 work RVU value more accurately reflects the work RVU of CPT code 92922 with 60 minutes of intraservice work time and 129 minutes of total work time.

We are finalizing a work RVU of 8.62 based on a crosswalk to CPT code 43276. We are finalizing as proposed a work RVU of 4.38 for CPT code 92976. The RUC did not recommend, and we did not propose any direct PE inputs for these codes.

(38) Rotational Vestibular Assessment (CPT Codes 92527 and 92528)

At the September 2025 CPT Editorial Panel Meeting, CPT code 92546 was deleted, and replaced with two new codes to report rotational vestibular assessment. The two new codes, CPT code 92527 (*Rotational vestibular assessment by sinusoidal harmonic acceleration (SHA) testing with calibrated, computer-controlled chair, with interpretation and report (do not report 92527 in conjunction with 92270)*) and 92528 (*Rotational vestibular assessment by sinusoidal harmonic acceleration (SHA) testing with calibrated, computer-controlled chair, with interpretation and report; with velocity step testing (VST) (List separately in addition to code for primary procedure)*) were surveyed for the September 2025 RUC meeting.

We proposed the RUC-recommended work RVU of 0.92 for CPT code 92527.

We disagree with the RUC's recommended value of 0.48 for CPT code 92528 and we are instead proposing a work RVU of 0.35 which is the survey 25th percentile valuation. As valued by the RUC, the work RVU for add-on CPT code 92528 is half of the RUC's recommended work RVU of the base code (92527), despite the fact that CPT code 92528 has only 12 minutes of work time as compared with 45 minutes of work time for CPT code 92527. This leads to the intensity of CPT code 92528 being valued at double that of the base code, which we do not believe would be typical given that the same SHA testing is taking place in both services. We disagree with the RUC that valuing the work RVU of the add-on CPT code 92528 at half the work of the base CPT code 92527 would be appropriate, as this does not account for the substantial preservice and postservice work time contained in CPT code 92527, which together account for 20 of the 45 total minutes. We agree with the RUC that the intensity of this code is higher than the base code, and our proposed work RVU of 0.35 assigns a higher intensity to CPT code 92528 than CPT code 92527, but we disagree that the intensity of the add-on service would be double that of the base code.

We proposed the RUC recommended direct PE inputs for CPT codes 92527 and 92528 without refinement.

Additionally, in the CY 2023 PFS final rule (87 FR 69656 through 69663) we created an exception to the physician order requirement at 42 CFR 410.32(a)(4) to allow patients to directly access audiologists. We also delineated the vestibular function tests as those not applicable for use with the AB modifier (for direct access)—see Audiology Services on the PFS website at *https://www.cms.gov/medicare/payment/fee-schedules/physician/audiology-services*. Based on the foregoing, for the new Rotational Vestibular Assessment Codes, CPT codes 92527 and 92528 will be added to the audiology services code list but they will not be eligible to be billed with the AB modifier.

Comment: Commenters agreed with the proposal of the RUC-recommended work RVU for CPT code 92527 and the direct PE inputs for both codes, as well as their proposed addition to the audiology services list.

Response: We appreciate the support for our proposed policies from the commenters.

Comment: Commenters disagreed with CMS's proposed work RVU of 0.35 for add-on CPT code 92528. Commenters emphasized the relativity with the base code (CPT code 92527) and factors beyond intraservice and total time, including technical complexity, cognitive effort, clinical judgment, psychological stress, and patient monitoring. A commenter stated that CMS' proposed work RVU of 0.35, based on the survey's 25th percentile, could undervalue the service and impair access in smaller or underserved communities.

Response: We disagree with commenters regarding the technical complexity of performing the service as it is related to the add-on code. The two key reference services selected by the RUC, CPT code 92621 (*Evaluation of central auditory function, with report; each additional 15 minutes (List separately in addition to code for primary procedure)*) and CPT code 92627 (*Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); each additional 15 minutes (List separately in addition to code for primary procedure)*), each had a work RVU of 0.33 and 0.35 respectively and each had greater total time and intraservice time that was more similar to the proposed work RVU. As we stated in the proposed rule, the RUC's recommended work RVU of 0.48 for CPT code 92528 leads to its intensity becoming double that of the base code which we do not agree would be typical for this service given that the same SHA testing is taking place in both services. As we stated in the proposed rule, we disagree with the RUC that valuing the work RVU of the add-on CPT code 92528 at half the work of the base CPT code 92527 would be appropriate, as this does not account for the substantial preservice and postservice work time contained in CPT code 92527, which together account for 20 of the 45 total minutes. Commenters did not provide an explanation for why the intensity of the add-on code would be so much higher than the intensity of the base code. We agree with the RUC that the intensity of this code is higher than the base code, and our proposed work RVU of 0.35 assigns a higher intensity to CPT code 92528 than CPT code 92527, but we disagree that the intensity of the add-on service would be double that of the base code.

Comment: A commenter identified a projected 28% payment reduction from replacing CPT code 92546 with two new codes and requests broader reconsideration of Medicare financing and coverage constraints affecting audiologists.

Response: We believe that the valuation of CPT codes 92527 and 92528 more accurately represent how SHA testing currently takes place as compared with CPT code 92546 which was last reviewed in CY 2010. To the extent that payment reductions are taking place while shifting from the old coding to the new coding, this is due to the elimination of direct PE items which the RUC's PE Subcommittee recommended as no longer being typical for the procedures.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 92527 and 92528 as proposed.

(39) Video Head Impulse—Vestibular Function (CPT Codes 92513 and 92514)

At the September 2025 CPT Editorial Panel, the committee approved the addition of new CPT codes, 92513 *(Video head impulse testing (vhit) with recording, interpretation and report of lateral semicircular canal function*) and 92514 (*Video head impulse testing (vhit) with recording, interpretation and report of lateral and vertical semicircular canal function*) to report video head impulse testing (vHIT) and a corresponding parenthetical note. The RUC reviewed these services at the January 2026 meeting.

For CY 2027, we proposed the RUC-recommended work RVUs of 0.53 for CPT code 92513 and 0.84 for CPT code 92514. We proposed the RUC-recommended direct PE inputs for both CPT codes without refinement.

Comment: Commenters were supportive of CMS' proposed work RVU and direct PE inputs for this code family.

Response: We thank the commenters for their support.

After consideration of public comments, we are finalizing the work RVU and direct PE inputs as proposed.

As with CPT codes 92527 and 92528 in the previous section for Rotational Vestibular Assessment, CPT codes 92513 and 92514 for Video head impulse testing will be added to the list of Audiology Services; however, since they are vestibular function tests, they will not be eligible to be billed with the AB modifier in accordance with our policy established at 42 CFR 410.32(a)(4) and discussed in the CY 2023 PFS final rule (87 FR 69656 through 69663). (40) Speech-Language Pathology Services (CPT codes 92654, 92655, 92656, 92657, 92658, 92659, 92660, 92661, 92662, 92663, and 92508)

At the September 2025 CPT Editorial Panel meeting, CPT code 92507 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual*) was replaced with 10 new codes to report fluency disorder, speech sound production disorder, language comprehension and expression disorder, speech sound production disorder and language comprehension and expression disorder, and voice, upper airway dysfunction and/or resonance disorders. CPT codes 92654 (*Treatment of fluency disorder (e.g., stuttering and cluttering), direct (one-on-one) patient contact; initial 30 minutes*), 92655 (*Treatment of fluency disorder (e.g., stuttering and cluttering), direct (one-on-one) patient contact; each additional 15 minutes (list separately in addition to code for primary service)*), 92656 (*Treatment of speech sound production disorder (e.g., articulation, phonological process, apraxia, dysarthria), direct (one-on-one) patient contact; initial 30 minutes*), 92657 (*Treatment of speech sound production disorder (e.g., articulation, phonological process, apraxia, dysarthria), direct (one-on-one) patient contact; each additional 15 minutes (list separately in addition to code for primary service)*), 92658 (*Treatment of language comprehension and expression disorder (e.g., receptive and expressive language), direct (one-on-one) patient contact; initial 30 minutes*), 92659 (*Treatment of language comprehension and expression disorder (e.g., receptive and expressive language), direct (one-on-one) patient contact; each additional 15 minutes (list separately in addition to code for primary service)*), 92660 (*Treatment of speech sound production disorder (e.g., articulation, phonological process, apraxia, dysarthria) and language comprehension and expression disorder (e.g., receptive and expressive language), direct (one-on-one) patient contact; initial 30 minutes*), 92661 (*Treatment of speech sound production disorder (e.g., articulation, phonological process, apraxia, dysarthria) and language comprehension and expression disorder (e.g., receptive and expressive language), direct (one-on-one) patient contact; each additional 15 minutes (list separately in addition to code for primary service)*), 92662 (*Treatment of voice, upper airway dysfunction, and/or resonance disorders, direct (one-on-one) patient contact; initial 30 minutes*), 92663 (*Treatment of voice, upper airway dysfunction, and/or resonance disorders, direct (one-on-one) patient contact; each additional 15 minutes (list separately in addition to code for primary service)*), and 92508 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder, group, 2 or more individuals*) are new and/or revised codes for CY 2027. Additionally, the introductory guidelines were revised to clarify reporting of the services. The code family was surveyed for the January 2026 RUC Health Care Professionals Advisory Committee (HCPAC) Review Board meeting.

For CY 2027, we proposed the HCPAC-recommended work RVU for all 11 codes in the family. We proposed the HCPAC-recommended work RVUs of 0.92 for CPT code 92654, 0.44 for CPT code 92655, 0.90 for CPT code 92656, 0.44 for CPT code 92657, 1.00 for CPT code 92658, 0.48 for CPT code 92659, 1.00 for CPT code 92660, 0.50 for CPT code 92661, 0.98 for CPT code 92662, 0.48 for CPT code 92663, and 0.28 for CPT code 92508.

We proposed the HCPAC-recommended direct PE inputs for all the codes in the family without refinement.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported replacing CPT code 92507 with 10 time-based, intervention-specific speech-language pathology codes and were generally in support of the proposed HCPAC-recommended work RVUs and direct PE inputs. Commenters supported the new codes as they recognize both the type of treatment being provided, the amount of clinician time required, and allow better transparency. Some commenters suggested that there be a delay in implementation of the 10 new CPT codes, stating that systems need to be updated. They requested implementation guidance, clinician education, audit flexibility, payment monitoring, telehealth inclusion, and protections against payment reductions, denials, and access disruptions. Several commenters requested a separate speech-language pathology impact analysis and some commenters asked for clarification of same-day billing with CPT codes 97129 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes*) and 97130 (*Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)*). Several commenters requested individualized National Correct Coding Initiative (NCCI) coding edits, and appropriate treatment of add-on codes under the multiple procedure payment reduction (MPPR).

Other commenters did not support the 10 new CPT codes as they believed the new codes would add administrative burden to updating the electronic health record with only weeks to update, build and test claims processing. Other commenters suggested that the codes mirror the other therapies such as physical therapy and occupational therapy in terms of having a base code and an add-on code for the services provided. Many commenters were against having separate valuation for the 10 new CPT codes as certain services that pay more may have unintended influence on clinical decision making and unintentionally influence which code is selected by practitioners. Some commenters noted that the transition to a 30-minute base code plus 15-minute add-on structure introduces rigid time constraints that could severely disrupt care. Several commenters noted the effects the Medicare rates have on other insurers, specifically Medicaid.

Response: We thank the commenters for their support of the 10 new CPT codes. We understand the feedback from commenters related to a request for a delay in implementation of the new code set. CMS has a statutory deadline in which to publish the final rule and other changes to the PFS that take effect on January 1, 2027. We typically publish codes and have them set to become active on January 1st of each

year and would not make an exception in this case. Therefore, the new coding will be effective starting January 1st. We thank commenters for the billing and implementation questions asked and we will take them into consideration for sub-regulatory guidance, MLNs, and other resources as needed. It is not typical for CMS to publish a separate impact analysis for an individual code family. CMS published the proposed RVUs and the proposed utilization crosswalk for all of the codes in this family which we believe was sufficient for interested parties to submit informed comments. We are aware of the effect Medicare rates have on other payers and we defer to state Medicaid programs to determine payment for the new G-code.

With regard to the NCCI edits, we defer to NCCI and the edits they put in place. This is outside of the scope of this proposal.

Comment: Some commenters disagreed with the reference codes selected by the HCPAC and specifically identified CPT code 97550 (*Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [iADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face to face; initial 30 minutes*) as a reference code. Commenters noted that CPT code 97550 describes 30 minutes of face-to-face caregiver training without the patient present whereas the proposed speech-language pathology codes describe direct treatment of the patient, requiring the speech-language pathologist to provide intervention. Commenters also noted that CPT codes 92584 (*Electrocochleography*) and 92651(*Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report*) were used repeatedly as comparison services which both describe diagnostic testing rather than therapeutic treatment.

Response: We thank the commenters for their feedback. We believe there was a typo in the CPT code number as referenced by some commenters as the key reference service used by the HCPAC was CPT code 97530 (*Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes*). We agreed with the HCPAC recommendations in the valuation of the 10 new codes for speech-language pathology. We understand the commenters inquiring why the services selected as reference codes were not identical to the new codes being created. We note that we looked at these compared to other similar XXX global day codes with similar intraservice times and the HCPAC recommendations matched other codes with similar time values. We want to reiterate that the PFS is a relative value-based system and not all reference codes are necessarily clinically related.

Comment: A few commenters gave suggestions of other comparator codes that can be used for the 10 new CPT codes. Commenters suggested that a more accurate work RVU comparison for 92658 and 92660 would be CPT codes 96158 (*Health behavior intervention, individual, face-to-face; initial 30 minutes*) with a work RVU of 1.66 and 90832 (*Psychotherapy, 30 minutes with patient*) with a work RVU of 1.94.

Response: We disagree with commenters regarding the suggested crosswalks for this code family. We continue to believe that the key reference services noted by the HCPAC accurately capture the time and intensity for these services.

Comment: Some commenters noted that the proposed valuation of the 10 new CPT codes poses a rank order issue.

Response: We disagree with the commenters that there is a rank order anomaly in the work valuation for the base codes in this family. We agree with the work RVUs recommended by the HCPAC and note that these codes are all valued similarly in terms of work RVUs and intensity. The codes with shorter surveyed work times, such as CPT codes 92654 and 92656, were proposed with lower work RVUs than the codes with longer surveyed work times, such as CPT codes 92658 and 92660, in recognition of the modest increases in duration for these services. We also note for commenters that the coding structure for these services has changed, consisting of 30 minute base codes and 15 minute add-on codes, which makes a direct comparison to the work RVUs of the predecessor codes infeasible.

Comment: Several commenters asked about specific CPT codes and whether they could be billed on the same date as the new speech-language pathology services. Other commenters noted other instances preventing speech-language pathologists from billing certain therapeutic interventions on the same date of service as any of the 10 new CPT codes. Other commenters asked about other audiology rehabilitation services.

Response: The 10 new CPT codes we proposed were merely replacing CPT code 92507. We believe that this would maintain the code and all associated billing rules which would apply to the 10 new codes. With regard to codes related to other therapeutic and auditory services, we thank the commenters for bringing them to our attention and note these comments were out of scope of this proposal. CMS may consider these comments for potential future rulemaking.

Comment: A commenter noted that the new CPT codes do not include a code for cognitive-communication and urged CMS to create a HCPCS G-code describing these services.

Response: We thank the commenter for their suggestion and may consider this for potential future rulemaking.

After consideration of public comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 92654, 92655, 92656, 92657, 92658, 92659, 92660, 92661, 92662, 92663, and 92508 as proposed.

We proposed to designate these codes as always therapy services which means they must be furnished under a therapy plan of care regardless of who provides them and billed with a therapy modifier (this includes physicians and NPPs when they furnish the service or therapists furnish the services incident to the physician/NPP). We also proposed to designate the new CPT codes that each represent the initial 30 minutes—92654, 92656, 92658, 92660, and 92662—as subject to the MPPR for therapy services. The new CPT codes that represent each additional 15 minutes—92655, 92657, 92659, 92661 and 92663—are not subject to the MPPR as they are all add-on codes which we excluded from the MPPR in the CY 2011 PFS final rule along with contractor-priced and bundled codes (75 FR 73240) and noted in section 10.7 of chapter 5 of the Medicare Claims Processing Manual (MCPM).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally in support of CMS' proposal to continue designating these services as always therapy services. Commenters were appreciative of CMS' proposal that the additional 15-minute add-on codes would not be subject to the therapy MPPR, although a few commenters asked CMS to exempt all speech-language pathology treatment codes including HCPCS code G0903 the from the MPPR. Many commenters requested that CMS clarify how the MPPR will apply to the new speech-language pathology codes, including HCPCS code G0903, and whether the MPPR is applied across therapy disciplines.

Response: Subsequent to the MPPR policy we established in the CY 2011

PFS final rule (75 FR 73232 through 73242), the therapy MPPR is applied to the PE component of the second and each subsequent code or unit of a service furnished to the same beneficiary, on the same date of service, by the same provider. If that provider furnishes physical and/or occupational therapy services in addition to speech-language pathology services, the MPPR will be applied across the therapy disciplines. The service with the highest PE relative value unit (RVU) is paid at 100% and, since April 1, 2013, the PE components of the remaining services are paid at 50%.

We appreciate the comments and after consideration of public comments, we are finalizing all 11 speech-language pathology treatment codes as always therapy (including the 10 new CPT codes and the revised CPT code 92508 that was previously designated as always therapy) and adding CPT codes 92654, 92656, 92658, 92660, and 92662 for the initial 30 minutes of the primary service to the list of codes that are subject to the therapy MPPR.

(a) Pediatric G–Code for Speech-Language Pathology Services

We have heard from interested parties of the need to preserve CPT code 92507 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual*) specifically related to the pediatric population. Interested parties stated that the 10 new CPT codes do not accurately capture the time and intensity of work as it relates to pediatric patients. To be responsive to interested parties, we proposed to create and pay separately for a new HCPCS code, HCPCS code G0903, to accurately reflect the time and resources spent in providing these services to pediatric patients.

We proposed the following code descriptor: HCPCS code G0903 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual; for the pediatric population up to age 21*). We proposed that HCPCS code G0903 would be reported by a speech-language pathologist performing these services specific to the pediatric population.

We proposed that this code could be billed only once per patient per day. We proposed to assign a XXX global period payment indicator for HCPCS code G0903. The XXX global period payment indicator would indicate that the global period does not apply to this service.

As previously discussed in this section, we proposed to designate HCPCS code G0903 as an always therapy service and add it to the list of codes that are subject to the MPPR for therapy services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters were in support of the pediatric G-code, while many commenters were mixed. Many commenters were not in support of the G-code for multiple reasons, citing duplication, inadequate clinical specificity, unclear pediatric age parameters, uncertain treatment time requirements, outdated valuation assumptions for CPT code 92507, and departure from the CPT process. Some commenters noted that replacing untimed CPT code 92507 with ten disorder-specific timed codes does not fit how pediatric therapy is delivered. Commenters questioned the time requirements and requested clarification regarding the proposed ''60-minute work time'' requiring 60 minutes of time for the service. Commenters specifically asked if the proposed 60-minute work time represented the valuation methodology only (similar to CPT code 92507), or if CMS is intending to require a minimum 60-minute treatment session in order to report the new G-code. Commenters noted concerns that the time requirement of 60 minutes is not clinically appropriate and may reduce the effectiveness of therapy due to fatigue, decreased attention, and diminished participation. A time of 60 minutes would also reduce the number of patients they could see and would as a result decrease access to care. Commenters also noted that face-to-face time alone cannot solely measure time for services.

Many commenters noted that if the new G-code was finalized, the code should be untimed as pediatric patients often cannot tolerate longer sessions. Commenters asked about the midpoint of time or if there was or was not a minimum of time required in order to bill the code. Other commenters asked if time referred to face-to-face time or total time of the encounter. Others asked if pre and post time were included. A few commenters requested the G-code to be timed. Other commenters shared concerns that inconsistent adoption of the new G-code across payors could create coding confusion, claim denials, and additional administrative burden.

Response: We note that the proposed new pediatric G-code was meant to maintain the current billing mechanism and valuation for CPT code 92507, which had a work RVU of 1.30. We believe that this value accurately captures the time and intensity of the work for providing these services. We understand from commenters the pre and post service work involved in furnishing these services and how the work for pediatric patients differs from that of an adult since there are many other components of care, caregivers who need training, follow ups, and school involvement. We did not propose for the G-code to be a timed code and did not include or propose a time in the code descriptor or a minimum session length. The midpoint of time would only apply to a code that is timed and as such, since we did not propose and are not finalizing the G-code to be a timed code, there would not be a minimum time required, of face-to-face time or total time, in order to bill for the service nor would there be a time threshold required for billing.

Comment: Many commenters asked for clarification and were unsure who in the pediatric population was eligible to bill the new G-code as the code descriptor was noted to be different and had separate references of ''up to 21'' and references of ''up to age 18 to 21'' in the telehealth section of the proposed rule. Commenters also asked CMS to obtain pediatric-specific data on time, intensity and cost before finalizing the valuation.

Response: We understand the confusion with regard to age that stemmed from different code descriptors in the proposed rule. We wish to clarify that the G-code may be billed for patients age 21 and under to be inclusive of as many pediatric patients as possible. In other words, the G-code may be billed for patients through age 21 years and 364 days, and after the patient's 22nd birthday, the 10 new CPT codes would be used.

Comment: Commenters requested clarification as to whether pediatric providers could bill using the 10 CPT codes or have to use HCPCS code G0903. Commenters asked CMS to allow clinicians to select HCPCS code G0903 or the timed treatment codes based on the service furnished, with the two pathways mutually exclusive on the same date of service. Commenters agreed that a mutually exclusive coding structure would prevent duplicate reporting while allowing for clinical need. Many commenters recommend using the differentiated CPT family for pediatric services while others suggested that CMS create HCPCS G-codes that mirrored all 10 new CPT codes but specific to the pediatric population. Commenters stated that the new proposed G-code does not distinguish between disorders.

Response: We thank commenters for their suggestion of creating 10 additional G-codes that would parallel

the 10 new CPT codes for speech-language services in the pediatric population. We wish to clarify that we did not preclude practitioners from utilizing the 10 new CPT codes for the pediatric population. We were persuaded by stakeholders that the new CPT codes may not work for all pediatric patients and that some practice workflows would work best with a specific G-code for billing pediatric patients. To provide the most flexibility to practitioners, we are allowing practitioners to select the codes, either the G-code or the 10 new CPT codes, that most appropriately encompass the services being provided. However, practitioners cannot use both codes (that is, the G-code and one of the 10 new CPT codes) concurrently as this would be double billing for services. We wish to clarify that CMS is permitting clinicians to report the new timed treatment codes for beneficiaries age 21 and under when those codes more accurately describe the clinical encounter. The G-code and the 10 new CPT codes would be mutually exclusive.

Comment: Many commenters asked CMS questions regarding the 10 new CPT codes and whether they can bill two of the CPT codes concurrently if two therapies were provided, for example if language and swallowing services are both provided concurrently. Many commenters submitted detailed lists of billing questions asking CMS to address in the final rule and prior to implementation for January 1st. Commenters asked CMS to provide clear guidance before implementation including reimbursement rates, authorization requirements, documentation standards, and billing rules.

Response: We thank the commenters for their comments. As stated previously, we will not preclude practitioners from using the 10 new CPT code for the pediatric population and we understand that there are different modalities in terms of treatment of speech-language disorders. We are providing flexibility to practitioners regarding the choice of coding they wish to use in their practice. We want to reiterate that billing the 10 new CPT code or the new G-code shall be mutually exclusive and practitioners cannot bill both at the same time. We are allowing clinicians to report the new timed treatment codes for beneficiaries age 21 and under when those codes more accurately describe the clinical services provided and it is possible for multiple CPT codes to be billed during a single encounter. We thank commenters for the billing and implementation questions asked and we will take into consideration for subregulatory guidance, MLNs, and other resources as needed. We wish to reiterate that we created the pediatric G-code, HCPCS G0903, in order to maintain the flexibility of the predecessor code, CPT code 92507. Therefore, all associated billing rules would apply to the new G-code.

We are finalizing the code descriptor for HCPCS code G0903 to read as follows: *Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual; for the pediatric population age 21 and under.* We note that 'age 21 and under' would include patients up to 21 years and 364 days old.

Comment: Many commenters also requested that CMS specifically propose adding several new HCPCS G-codes to the telehealth list, including the new pediatric G-code HCPCS code G0903, to allow payment for the G-code when services are provided via telehealth and all necessary conditions are met. Commenters noted that the 10 new disorder-specific speech-language pathology treatment codes were not identified for addition to the telehealth list. Commenters noted that, given that CPT code 92507 has historically supported access to speech-language pathology services delivered through telehealth, CMS should ensure that replacing CPT code 92507 did not unintentionally disrupt beneficiary access to clinically appropriate telehealth services.

Response: We appreciate the comments related to telehealth and the Speech-Language Pathology Services and we refer to section II.D of this final rule for that discussion. The new G-code is being added to the telehealth list for CY 2027.

After a review of the comments, we are finalizing the designation of HCPCS code G0903 as an always therapy service and are adding it to the list of separately payable always therapy codes that are subject to the therapy MPPR.

(b) Valuation for HCPCS Code G0903

We note that the proposed valuation of HCPCS code G0903 is meant to reflect the time and resource costs, for speech-language pathology services inherent to the pediatric population. Therefore, we believe that CPT code 92507 serves as an appropriate reference for the purpose of valuing HCPCS code G0903. We believe there will be relatively the same work involved for HCPCS code G0903 when compared to the work of CPT code 92507 as it relates to pediatric patients, considering the amount of time needed to furnish the elements discussed earlier in this section. Therefore, we proposed a work RVU of 1.30, which represents the assigned work for 60 minutes of CPT code 92507. Additionally, we proposed a work time of 60 minutes established for CPT code 92507, personally performed by the billing practitioner.

We proposed the same direct PE inputs for HCPCS code G0903 as CPT code 92507, as we believe that the relative resource costs for this service will remain the same. To help inform whether our proposed valuation reflects the typical service for the pediatric population, we sought comment on the typical time and intensity practitioners spend furnishing these services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that the proposed work RVU of 1.30 did not adequately value the time and intensity of the services and would cause a disparity between pediatric and adult services. Many commenters noted that therapists typically spend a lot of pre and post time related to the visit as well as follow up and caregiver training that is time not accounted for in the proposed valuation. Many other commenters maintained that the current valuation of CPT code 92507 would be best for the flow of their practices which serve primarily pediatric patients. Commenters asked for clarification on what the G0903 valuation assumption represents, including direct, pre-service, and post-service work. Commenters argued that pediatric services involve greater amounts of pre and post-service time and the proposed work RVU underestimates the time spent. Commenters questioned whether the proposed valuations adequately account for the clinician work and practice expenses involved in providing speech-language pathology services. Commenters also asked what pediatric data informed the valuation assumptions and said the survey used to establish the 10 new CPT codes was flawed.

Response: We mirrored the valuation of the new proposed G-code after the predecessor code CPT code 92507. It was our intention to maintain the existing billing mechanism for the pediatric population. We continue to believe that the same work is involved for HCPCS code G0903 when compared to the work of CPT code 92507 as it relates to pediatric patients, considering the amount of time needed to furnish the elements discussed earlier in this section.

Comment: Commenters suggested that a more accurate code comparator to the new proposed G-code, HCPCS code G0903, would be CPT code 90834 (*Psychotherapy, 45 minutes with patient*) as this captures the underlying definition behind CPT code 92507 and considers a similar underlying time of 38 to 52 minutes.

Most commenters strongly disagreed with the PE RVU assigned to the G-code as it was valued lower than the current PE RVU for CPT code 92507 and asked CMS to restore the CPT code 92507 PE value. Overall, many commenters were very concerned that the low valuation and reductions in speech therapy would directly impact their practices forcing them to close as a result of a significantly decreased reimbursement which will ultimately impact access to care and services that are most needed in the pediatric population. Commenters noted that this would impede practices from recruiting and retaining speech-language pathologists in their practices. Other commenters expressed that having the 10 different CPT codes for billing creates financial incentives to limit treatment of lower-reimbursed disorders.

Response: We thank commenters for their suggestions. We continue to believe our valuation is correct when compared to codes with similar time values. We continue to believe that the proposed work RVU of 1.30 for HCPCS code G0903 is the most accurate valuation for the new G-code. In our review of this code, we mirrored HCPCS code G0903 to the predecessor code, CPT code 92507 which is also a XXX global code with 60 minutes of intraservice time based on feedback we heard from interested parties. Maintaining the work RVU at 1.30 helps to maintain relativity among the therapy types.

Comment: We heard from many commenters regarding the significant cuts to practice expense and the financial impact to many pediatric practices and their ability to remain financially viable.

Response: We proposed to maintain the current PE RVU for CPT code 92507 (0.97) and continue to believe that maintaining the current PE RVU of CPT code 92507 for new code G0903 will help address the valuation and access concerns raised by commenters. Given our stated intention of keeping payment for HCPCS code G0903 consistent with the payment rate for CPT code 92507, we are finalizing maintaining the current PE RVU.

After consideration of public comments, we are finalizing the work RVUs and direct PE inputs for the new pediatric G-code as proposed with clarifications. We wish to clarify that the physician time of 60 minutes for the G-code is for the purpose of valuation and not a requirement for billing.

(41) Endoluminal Coronary Intravascular Ultrasound (IVUS) (CPT Codes 92978 and 92979)

In April 2025, the RAW identified CPT code 92978 (*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to code for primary procedure)*) as a code that has Medicare utilization of 10,000 or more that has increased by at least 100 percent from 2018 through 2023. CPT codes 92978 and 92979 (*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to code for primary procedure)*) were surveyed for the January 2026 RUC meeting.

We disagree with the RUC-recommended work RVUs for these codes and instead we proposed work RVUs of 1.40 for CPT code 92978 and 1.04 for CPT code 92979 to account for the significant decreases in physician intraservice time for both codes. The RUC's recommendation to maintain current work RVUs for these codes does not appear to fully account for these intraservice time decreases. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner, and we do not believe it is appropriate to decrease physician time while maintaining the current work RVUs.

We reviewed the RUC recommendations and found them to be high, relative to other codes with the same or similar work times. Based on a search of similarly timed codes in the RUC database, the RUC-recommended work RVU of 1.76 for CPT code 92978 is higher than 44 of 47 add-on codes with 15 minutes of physician intraservice time. Similarly, the RUC-recommended work RVU of 1.40 for CPT code 92979 would be the second highest work RVU for add-on codes with 12 to 14 minutes of physician intraservice time. Therefore, we disagree with the RUC recommended work RVU of 1.76 for CPT code 92978 and we are instead proposing a work RVU of 1.40 based on a crosswalk to CPT code 93572 (*Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, when performed; each additional vessel (List separately in addition to code for primary procedure)*). This proposed work RVU is higher than the reverse building block work RVU of 1.06 and results in a higher intensity for the code than its current work RVU and physician time. The resulting increase in intensity more accurately accounts for the RUC's assertion that the intensity and complexity has increased with the evolution of these services because a higher proportion of the skin-to-skin time is now dedicated to more intense activities and interventions.

We also disagree with the RUC recommendation to maintain the current work RVU of 1.40 for CPT code 92979 and proposed a work RVU of 1.04 based on the RUC-recommended increment of 0.36 work RVUs between CPT codes 92978 and 92979. Similarly, this represents an increase in intensity compared to the code's current work RVU and work time to account for the increased intensity that has occurred with the evolution of these services. The RUC did not recommend and we did not propose any direct PE inputs for CPT codes 92978 and 92979.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters disagreed with the proposed work RVUs for CPT codes 92978 and 92979 and stated that CMS should finalize the RUC-recommended work RVUs instead. Commenters stated that CMS had not adequately accounted for the intensity of physician work for these services and that the RUC recommendations preserved relativity within the code family and recognized their greater intensity. Commenters stated that a service should not lose a fifth of its value based on a survey time decrease.

Response: We continue to believe that changes in work time should be reflected in changes to the work RVU. We note that using the intraservice time ratio, the total time ratio, and the

reverse building block method for CPT codes 92978 and 92979 all would have resulted in even lower work RVUs of 1.06 and 0.73 respectively. The RVUs that we proposed resulted in a higher intensity for these codes than the current work RVUs and physician time.

Comment: A couple of commenters disagree with CMS making any valuation for CPT code 92979 based on an incremental difference.

Response: We continue to believe the use of an incremental work RVU difference of 0.36 between CPT codes 92978 and 92979 is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service.

After consideration of the public comments, we are finalizing the work RVUs for CPT codes 92978 and 92979 for the Endoluminal Coronary Intravascular Ultrasound (IVUS) code family as proposed. We did not propose and we are not finalizing any direct PE inputs for CPT codes 92978 and 92979.

(42) Autonomic Function Testing (CPT codes 95921, 95944, 95922, 95923, 95945, 95946, 95924, 95947, 95948, and 95949)

In February 2025, the CPT Editorial Panel created six new codes to report autonomic function testing with the use of a tilt table, sudomotor tests, and combined procedures to address an earlier RUC referral: CPT code 95944 (T*esting of autonomic nervous system function, with interpretation and report; use of tilt table*), CPT code 95945 (*Testing of autonomic nervous system function, with interpretation and report; sudomotor, thermoregulatory sweat test*), CPT code 95946 (*Testing of autonomic nervous system function, with interpretation and report; sudomotor, assessing the sympathetic skin response (SSR) potential*), CPT code 95947 (*Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint*), CPT code 95948 (*Testing of autonomic nervous system function, with interpretation and report; combined sympathetic adrenergic with at least 5 minutes of passive tilt (ie, tilt table) and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint*), and CPT code 95949 (*Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic, sympathetic adrenergic function with at least 5 minutes of passive tilt (ie, tilt table), and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint*). The CPT Editorial Panel also revised four existing codes to include interpretation and report and clarification on tilt table use: CPT code 95921 (T*esting of autonomic nervous system function, with interpretation and report; cardiovagal innervation (parasympathetic function), including 2 or more of the following: heart rate response to deep breathing with recorded R–R interval, Valsalva ratio, and 30:15 ratio*), CPT code 95922 (*Testing of autonomic nervous system function, with interpretation and report; vasomotor adrenergic innervation (sympathetic adrenergic function), including beat-to-beat blood pressure and R–R interval changes during Valsalva maneuver and at least 5 minutes of passive tilt (i.e., tilt table)*), CPT code 95923 (*Testing of autonomic nervous system function, with interpretation and report; sudomotor, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint*), and CPT code 95924 (*Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt (i.e., tilt table)*). This code family was surveyed for the April 2025 RUC meeting. We proposed the RUC-recommended work RVU for seven of the ten codes in this family. We proposed a work RVU of 0.34 for CPT code 95944, a work RVU of 0.96 for CPT code 95922, a work RVU of 0.88 for CPT code 95923, a work RVU of 1.00 for CPT code 95945, a work RVU of 0.50 for CPT code 95946, a work RVU of 1.50 for CPT code 95924, and a work RVU of 1.17 for CPT code 95947. We note that several of these work RVUs were affected by the efficiency adjustment which was applied at the start of CY 2026, as the RUC recommendations were based on pre-adjustment work valuations.

We disagree with the RUC-recommended work RVU of 0.88 for CPT code 95921 and we are instead proposing a work RVU of 0.74 based on a crosswalk to CPT code 97813 (*Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*). When reviewing this code family, we noticed that CPT code 95921 had one of the highest intensities in the family at the RUC-recommended work RVU of 0.88 despite having some of the shortest surveyed work times and describing one of the seemingly least intensive procedures. The revised code descriptor for CPT code 95921 describes a single test for cardiovagal innervation, and we do not agree that this service should be valued with a higher intensity than some of the other codes in this family that contain multiple kinds of autonomic function testing. The RUC's recommended work RVU would also value CPT code 95921 at the same 0.88 as CPT code 95923 despite the latter code having significantly more total work time (32 minutes as compared to 25 minutes). We are aware that these codes share the same current work RVU, however the new surveyed work times indicate that CPT code 95921 typically takes less time to perform than CPT code 95923, and, since the two components of work are time and intensity, we believe that CPT code 95921 should be valued at a lower rate. Therefore we proposed a work RVU of 0.74 based on a crosswalk to CPT code 97813, an acupuncture procedure with the identical intraservice and total work time as CPT code 95921. We also note that this valuation of CPT code 95921 maintains the current intensity of the procedure, as well as better maintaining relativity with the other codes in the family.

We disagree with the RUC-recommended work RVU of 1.75 for CPT code 95948 and we are instead proposing a work RVU of 1.56 based on a crosswalk to CPT code 77047 (*Magnetic resonance imaging, breast, without contrast material; bilateral*). We disagree with the RUC's recommended work RVU of 1.75, based on the survey median result, as it represents a significant increase in work valuation and intensity over the other codes in this family. For example, the RUC recommended a work RVU of 1.50 for CPT code 95924 in comparison to 1.75 for this code, despite CPT code 95948 having only 5 minutes of additional intraservice time and 3 minutes of additional total time (50 minutes as compared with 47 minutes). CPT code 95948 would require an anomalously high intensity relative to the rest of the family to justify the recommended work valuation of 1.75, which we do not agree would be warranted here given that this code is performing the same autonomic function tests that take place in CPT code 95922 and 95923. Therefore we proposed a work RVU of 1.56 based on a crosswalk to CPT code 77047, a breast

MRI procedure with the identical intraservice time and similar total work time as CPT code 95948. We believe that this valuation of CPT code 95948 better maintains relativity with the other codes in the family instead of requiring an anomalously high intensity as was the case at the RUC's recommended work RVU.

We disagree with the RUC-recommended work RVU of 1.91 for CPT code 95949 and we are instead proposing a work RVU of 1.77 based on a crosswalk to CPT code 78831 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (eg, pelvis and knees, chest and abdomen) or separate acquisitions (eg, lung ventilation and perfusion), single day imaging, or single area or acquisition over 2 or more days*). As was the case with CPT code 95948, we believe that the RUC's recommended work RVU of 1.91 for CPT code 95949, based on the survey 25th percentile result, represents a significant increase in work valuation and intensity over the other codes in this family. While we do agree with the RUC that CPT code 95949 includes the most autonomic function tests and should have the highest intensity within the code family, we disagree that CPT code 95949 should be valued at a work RVU that results in an intensity approximately 50 percent higher than the rest of this family. To use the same example again, the RUC recommended a work RVU of 1.50 for CPT code 95924 in comparison to 1.91 for this code, despite CPT code 95949 having only 5 minutes of additional intraservice time and 7 minutes of additional total time (52 minutes as compared with 47 minutes). We believe that the work valuation and intensity are simply too high at the RUC's recommended work RVU of 1.91 as this does not maintain relativity with the other codes in this family, given that the same tests are being performed. Therefore, we proposed a work RVU of 1.77 based on a crosswalk to CPT code 78831, a radiopharmaceutical procedure with the identical intraservice time and similar total work time as CPT code 95949. We note that this work valuation still assigns the highest intensity in the family to CPT code 95949, while bringing it more in accordance with its peer codes. We believe that this valuation of CPT code 95949 better maintains relativity with the other codes in the family instead of requiring an anomalously high intensity as was the case at the RUC's recommended work RVU.

We proposed the RUC-recommended direct PE inputs for CPT codes 95921, 95944, 95922, 95923, 95945, 95946, 95924, 95947, 95948, and 95949 without refinement.

Comment: Several commenters stated that they supported CMS' proposal the RUC recommended work RVU for seven of the ten codes in this family.

Response: We appreciate the support for our proposed values from the commenters.

Comment: Several commenters disagreed with the proposed work RVU of 0.74 for CPT code 95921. Commenters stated that CPT code 95921 is ''slightly more intense'' than the rest of the codes in this family due to the short duration of the procedure and the number of tests performed, including heart rate response to deep breathing with recorded R–R interval, Valsalva ratio, and 30:15 ratio tests. Commenters stated that CPT code 95921 required the same practitioner work as CPT code 95923 and the same intraservice time of 15 minutes. Commenters stated that the only variation was the difference in preservice and postservice time of seven minutes; commenters stated that this difference in time was minimal and it was appropriate that these services be valued at the same work RVU of 0.88.

Response: We disagree with the commenters and continue to believe that CPT code 95921 is more accurately valued at the proposed work RVU of 0.74. The RUC's recommended work RVU of 0.88 would have assigned an intensity to CPT code 95921 roughly 50–70% higher than the other single test procedures in this family, such as CPT codes 95922, 95923, and 95945, as well as increasing its intensity by roughly 35 percent above the current intensity of the code. This valuation would not be ''slightly more intense'' in comparison to the rest of the family. Our proposed work RVU of 0.74 maintains the current intensity of CPT code 95921, which is modestly higher than the other single test procedures and matches the request of the commenters for a slight increase in intensity relative to the other single test procedures.

We also disagree with the commenters that CPT codes 95921 and 95923 should have the same work RVU. As we stated in the CY 2027 PFS proposed rule (91 FR 43887), we are aware that these codes share the same current work RVU, however the new surveyed work times indicate that CPT code 95921 typically takes less time to perform than CPT code 95923, and, since the two components of work are time and intensity, we believe that CPT code 95921 should be valued at a lower rate. While it is true that the difference in work time between these codes occurs in the preservice and postservice periods, we disagree with the commenters that this difference is minimal: CPT code 95921 has 25 minutes of total work time as compared against 32 minutes for CPT code 92923. This is a difference of roughly 25% in total procedure time which we continue to believe should be reflected in a lower work RVU for CPT code 95921.

Comment: Several commenters stated that the crosswalk code CMS used for valuation (CPT code 97813) was marked by the RUC with ''Do Not Use to Validate Physician Work.'' Commenters stated that CPT code 97813 met the RUC's survey response threshold, over 30, however, it will be reviewed in April 2029 since related CPT code 97814 did not meet the survey response threshold with 29 responses. Commenters stated that therefore CMS should not use CPT code 97813 as a crosswalk for valuing CPT code 95921. A separate commenter stated that the structure and valuation of CPT code 97813 did not adequately represent the full work, malpractice, and practice expense associated with the patient's entire treatment period, including time during which the patient remains under the practitioner's responsibility but is not receiving continuous one-on-one contact.

Response: We remind the commenters that the RUC's ''Do Not Use to Validate Physician Work'' indicator is an internal RUC identification that has not been proposed or finalized by CMS. We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. In the case of CPT code 97813, we believe that it is a strong crosswalk choice for valuation since it is a recently reviewed service with exactly the same surveyed work time values as CPT code 95921.

Comment: Several commenters disagreed with the proposed work RVU of 1.56 for CPT code 95948. Commenters stated that the intensity in the RUC recommended work RVU of 1.75 and work time of 30 minutes for CPT code 95948 falls in line with the other services in this family, and that the intraservice work per unit of time calculation was not useful when comparing XXX global period services

with relatively short intraservice times. Commenters stated that CPT code 95948 would not be anomalous with the other services in this family if valued at the RUC recommended work RVU 1.75; since CPT code 95948 is reported when both sympathetic and sudomotor function are tested (and requires the use of a tilt table), commenters stated that the combined tests are more complex due to the necessity of integrating more data points into a cohesive interpretation. Commenters stated that CPT code 95948 requires more total work time and should be valued higher than CMS crosswalk code 77047, and urged CMS to finalize the RUC's recommended work RVU of 1.75.

Response: We disagree with the commenters and continue to believe that CPT code 95948 is more accurately valued at the proposed work RVU of 1.56. We do not agree that the intensity for CPT code 95948 falls in line with other services in the family at the RUC's recommended work RVU; as we stated in the proposed rule, CPT code 95948 would require an anomalously high intensity relative to the rest of the family (roughly 20–50% higher depending on the code) to justify the recommended work valuation of 1.75. We do not agree that this valuation would be warranted given that this code is performing the same autonomic function tests that take place in CPT code 95922 and 95923. We do concur with the commenters that performing the two autonomic tests taking place in CPT code 95948 is more complex than performing them separately, which is why our proposed work RVU still assigns a higher intensity to this procedure than the intensities of CPT codes 95922 and 95923. We also note that our proposed work RVU of 1.56 assigns a higher intensity to CPT code 95948 than the historic codes that previously described autonomic function testing in recognition of this complexity. However, we continue to believe that the RUC's recommended work RVU of 1.75 is excessive since it accounts for almost no overlap at all in performing the two tests. CPT codes 95922 and 95923 would have a work RVU of 1.84 if simply added together and the RUC's recommended work RVU of 1.75 represents a decrease of only 5 percent. Since the sum of the work times of CPT codes 95922 and 95923 is 68 minutes while CPT code 95948 by itself was surveyed at 50 minutes, a decrease of more than 30 percent, there are clearly significant time savings taking place from combining the two tests which we believe supports the proposed work RVU of 1.56.

We also disagree with the commenters that intensity is not useful for comparing XXX global services given that the statute specifically tasks CMS with valuing services based on time and intensity. Although intensity is not a ''one size fits all'' tool and needs to be employed with care, the codes in this family cannot be valued properly without incorporating both time and intensity into the analysis.

Comment: Several commenters disagreed with the proposed work RVU of 1.77 for CPT code 95949. Commenters stated that because the survey 25th percentile is already a conservative measure of work, CMS' proposal to assign a work RVU below that level would result in an excessive and inappropriate reduction. Commenters stated that this approach failed to recognize that CPT code 95949 includes parasympathetic, sympathetic adrenergic, and sudomotor testing, making it the most comprehensive and complex service in the family. Commenters stated that valuing the service below the 25th percentile would not accurately reflect the intensity, clinical judgment, and total physician work involved and urged CMS to finalize the RUC's recommended work RVU of 1.91.

Response: We disagree with the commenters and continue to believe that CMS code 95949 is more accurately valued at the proposed work RVU of 1.77. As we stated in the proposed rule, we agreed that CPT code 95949 includes the most autonomic function tests and therefore our proposed work valuation still assigned it the highest work RVU and highest intensity in the family. However, we disagreed that CPT code 95949 should be valued at a work RVU that resulted in an intensity approximately 50 percent higher than the rest of this family; commenters did not provide an adequate rationale which would support a valuation that high. We continue to believe that this valuation of CPT code 95949 better maintains relativity with the other codes in the family instead of requiring an anomalously high intensity as was the case at the RUC's recommended work RVU. We also note that the RUC itself recommended the work RVU for multiple codes within this same code family below the survey 25th percentile, including CPT codes 95944 and 95923.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Autonomic Function Testing family as proposed.

(43) Unattended Sleep Testing (CPT codes 95843, 95844, 95846, 95847, 95848, and 95849)

At the February 2025 CPT Editorial Panel meeting, CPT codes 95800 (*Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time*), 95801 (*Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)*) and 95806 (*Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoab dominal movement)*) were deleted. They were replaced with six new CPT codes: 95843 (*Unattended sleep study, set-up, data acquisition and technical analysis; low complexity of 3–4 channels that generate at least 3–5 parameter categories*), 95844 (*Unattended sleep study, set-up, data acquisition and technical analysis; moderate complexity of 5–10 channels that generate at least 6–8 parameter categories*), 95846 (*Unattended sleep study, set-up, data acquisition and technical analysis; high complexity of 11 or more channels that generate at least 9 parameter categories*), 95847 (*Unattended sleep study, interpretation and report by a physician or other qualified health care professional; low complexity of 3–4 channels that generate at least 3–5 parameter categories*), 95848 (*Unattended sleep study, interpretation and report by a physician or other qualified health care professional; moderate complexity of 5–10 channels that generate at least 6–8 parameter categories*), and 95849 (*Unattended sleep study, interpretation and report by a physician or other qualified health care professional; high complexity of 11 or more channels that generate at least 9 parameter categories*).

This code family describes the reporting of unattended sleep studies with set-up, data acquisition, and technical analysis, and with interpretation and report by a physician or other qualified health care professional. These new codes were surveyed for the April 2025 RUC meeting.

For CY 2027, the RUC recommended a work RVU of 0.81 for CPT code 95847, a work RVU of 1.05 for CPT code 95848, and a work RVU of 1.60 for CPT code 95849. These codes are professional component only services and have no direct PE inputs; we also note that the RUC recommendations for CPT codes 95847 and 95848 were affected by the efficiency adjustment which was applied at the start of CY 2026, as the RUC recommendations were based on pre-adjustment work valuations. For CPT code 95847, we proposed the RUC's recommended work RVU of 0.81 and for CPT code 95848, we proposed the RUC's recommended work RVU of 1.05.

However, we disagree with the RUC's recommended work RVU of 1.60 for CPT code 95849 and we instead proposed a work RVU of 1.42 based on a crosswalk to CPT code 92014 (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits*), which has 24 minutes of intraservice time and 37 minutes of total time. CPT code 95849 is a similarly timed code with 20 minutes of intraservice time and 39 minutes of total time. We are aware that the RUC's recommended work RVU is lower than the survey 25th percentile work RVU and further understand that the increase in intensity from moderate complexity of 5 to 10 channels that generate at least 6 to 8 parameter categories to complexity of 11 or more channels that generate at least 9 parameter categories may not be linear. The additional parameters could be more complex, which could result in higher intensity and may not be fully captured in the previous two codes. We agree that the intensity for CPT code 95849 should be higher; however, we do not believe that the intensity associated with the RUC recommended RVU of 1.60 is typical for this service since it would be nearly double the intensity of CPT codes 95847 and 95848. Therefore, we believe that CPT code 92014 is an appropriate crosswalk compared to the RUC's recommended crosswalk to CPT code 99203 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*). We believe that our proposed valuation of 1.42, based on the crosswalk from 92014, more accurately values CPT code 95849 since it does not result in the sizable increase in intensity as recommended by the RUC. In addition, we have maintained relativity between the codes in this family with similarly timed codes.

For CPT codes 95843, 95844, and 95846, which are Practice Expense (PE) only codes, we proposed the RUC-recommended direct PE inputs. However, we noted concerns regarding two direct PE inputs: CA021 (Perform procedure/service—NOT directly related to physician work time) and CA042 (Perform procedure/service in post-service period—NOT directly related to physician work time). For CPT codes 95843 and 95844, the RUC recommended 15 minutes for the CA021 activity, and 25 minutes for CPT code 95846. The rationale for this increase from 15 minutes for CPT codes 95843 and 95844 to 25 minutes for CPT code 95846 was not clearly stated in the PE Summary of Recommendations although this is an increase of 66.7 percent. Similarly, for the CA042 activity, the RUC recommended 40 minutes for CPT code 95843, 50 minutes for CPT code 95844, and 70 minutes for CPT code 95846. We noted that there is a 10-minute increase from CPT code 95843 to CPT code 95844, and a 20-minute increase from CPT code 95844 to CPT code 95846. The rationale for these 10-minute and 20-minute increases was also not clearly stated. We appreciate that explanations for the direct PE inputs were provided in the PE Summary of Recommendations, given that this is a non-standard clinical labor activity. However, as CPT code 95843 describes a low-complexity study, CPT code 95844 describes a moderate-complexity study, and CPT code 95846 describes a high-complexity study, we welcomed public comments providing additional information, particularly regarding the increases in time for these direct PE inputs across these three CPT codes.

Also, for CPT codes 95843, 95844, and 95846, the RUC recommended use of the ''other'' formula for three new equipment items and based the time assumption of 960 minutes (that is, 16 hours). We are soliciting comments on whether it would be typical for the equipment in question to be worn for the full 16 hours. According to the PE Summary of Recommendations, patients typically arrive later in the day (for example, around 4 p.m.) for an appointment to perform a test run with the equipment, then take the equipment home and return it the following morning (typically around 9 a.m.). Therefore, the RUC recommended a 16-hour period, representing two nights, as this duration currently exists in the RUC database and is generally consistent with clinical practice. However, we sought public comments on whether two nights of use are required and typical for home sleep testing, as the reported equipment time may represent the total period the patient has the device outside the office rather than the time it is actually in use.

Lastly, we received invoices for a new supply item and three new equipment items for CPT codes 95843, 95844, and 95846. The new supply item is SA143 (Nox A1 Sensor Kit adult), and the new equipment items are EQ417 (Nox A1s System with SpO2, US), EQ418 (Apnea Link Air), and EQ419 (Apnea Trak Legacy). However, a single invoice for each supply or piece of equipment may not be reflective of typical costs, we encouraged interested parties to submit invoices to improve the accuracy of pricing for these items in the direct PE database.

We proposed the RUC-recommended direct PE inputs for CPT codes 95843, 95844, and 95846 without refinement.

Comment: Commenters overwhelmingly opposed our proposed work RVU of 1.42 for CPT code 95849, which we crosswalked to CPT code 92014 (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits*).

The RUC disagreed with CMS's proposed work RVU of 1.42 for CPT code 95849 and urged CMS to finalize its original recommendation of 1.60 instead. The RUC stated that CPT code 95849 involves interpreting at least 11 channels and 9 or more parameter categories, representing roughly twice the complexity of the lowest-tier code in this family. The RUC identified the following reference comparator codes, which it noted have similar time values but higher work RVUs than CMS's proposed value: CPT code 74176 (*Computed tomography, abdomen and pelvis; without contrast material*); CPT code 78452 (*Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution*

and/or rest reinjection); and CPT code 93351 (*Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with supervision by a physician or other qualified health care professional*). Based on this comparison, the RUC urged CMS to finalize a work RVU of 1.60 for CPT code 95849.

Many commenters urged CMS to finalize the RUC-recommended work RVU of 1.60 for CPT code 95849, noting that the RUC's recommended value of 1.60 falls below the survey's 25th percentile value of 1.75. According to the commenters, CPT code 95849 requires interpreting 11+ channels and 9+ parameter categories (roughly double the complexity of CPT codes 95847/95848), and the proposed crosswalk to CPT code 92014 did not reflect that intensity. Commenters stated that the RUC's recommended work RVU of 1.60 was already a conservative valuation relative to survey data. A commenter suggested a work RVU of 2.44, the value assigned to CPT code 95810 (*Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist*), arguing that interpretation of unattended studies can require greater physician effort. Another commenter proposed a compromise work RVU of 1.52.

Response: We appreciate the commenters for their feedback. We disagree that CPT code 99203 is an appropriate crosswalk, as its intraservice time exceeds that of CPT code 95849 by approximately 20 percent. We also do not find sufficient support for the claim that CPT code 95849 is twice as complex as CPT code 95848, given that unattended sleep studies of the highest complexity typically record no more than 10 to 12 parameters.

However, we were persuaded by the commenters that the proposed work RVU of 1.42 did not fully capture the clinical work and intensity described by CPT code 95849. We believe that CPT code 64567 (*Percutaneous electrical nerve field stimulation, cranial nerves, without implantation*) serves as a better crosswalk in light of the additional information provided by commenters, sharing identical intraservice and total time with CPT code 95849 at a work RVU of 1.50. We further find that a work RVU of 1.50 preserves more consistent intervals across the CPT code 95847, 95848, and 95849 family than the RUC-recommended 1.60, which would create a disproportionately large gap relative to CPT code 95848. Thus, we are finalizing a work RVU of 1.50 for CPT code 95849, based on a crosswalk to CPT code 64567. We believe this valuation reflects the identical time components shared between CPT codes 95849 and 64567, addresses commenters' concerns regarding the proposed rule's valuation, and results in a more appropriate distribution of relative values across the CPT code 95847, 95848, and 95849 family than either the proposed work RVU of 1.42 or the RUC-recommended work RVU of 1.60.

Comments: A commenter submitted results from an independent survey of sleep testing providers who subscribe to Sleep Review Magazine; this study shows that WatchPAT devices, not ApneaTrak Legacy, are the typical device for moderate-complexity sleep testing. Based on this data, the commenter asked CMS to replace equipment code EQ419 with supply code SD362 for CPT code 95844.

Response: We thank the commenter for the survey results. We note that the survey population consists of 60 subscribers to Sleep Review Magazine—a convenience sample of magazine subscribers, not a random or claims-based sample of Medicare-billing providers. Thus, these study results may not be representative of sleep medicine practitioners, patients, or providers broadly, and we believe that the study findings cannot be generalized beyond that limited group. We seek more generalizable study results.

Comments: Commenters raised concerns about the practice expense supply and equipment inputs for the new technical-component codes, with the greatest volume of comments addressing CPT code 95844. Commenters raised significant concerns about the direct practice expense inputs that CMS proposed for CPT code 95844 and suggested to weigh all supplemental invoices submitted.

Commenters stated that our proposed equipment input, based on equipment code EQ419 (ApneaTrak Legacy), does not reflect current clinical practice. Some commenters recommended to delete equipment code EQ419 from the direct PE inputs for 95844, and add supply code SD362 (WatchPAT ONE) as the replacement direct PE input by stating that one invoice for the new supply/equipment items may not reflect typical costs. Commenters further stated that EQ419 reflects approximately $20 in direct costs, compared with approximately $100 for SD362. Commenters recommended that CMS substitute SD362 for EQ419 in the direct PE inputs for this code.

Commenters submitted approximately 800 invoices to support an update in the pricing of the SD362 supply. Another commenter recommended adding a supply item for code CPT code 95844 priced between $73.32 and $105.97 per test and submitted 49 invoices for their own SANSA sensor kit.

Response: We thank the commenters for submitting invoices. We will update the price of supply code SD362 accordingly; based on the very large quantity of submitted invoices associated with this item and the wide range of prices varying from $45 to $243, we are finalizing the median price of $100.35 rather than attempting to calculate an average to avoid the effects of outliers. However, we were not persuaded by the commenters that the use of a disposable device would be more typical than the reusable equipment recommended by the RUC for CPT code 95844. Commenters described a wide variety of different devices that used different pricing structures, making it difficult to determine if any one of these would represent the typical case. Given this conflicting information, we are finalizing the direct PE inputs as proposed and not adding this new supply item to CPT code 95844, as it may not reflect typical cost.

Comments: Commenters were divided on the proposed equipment time of 960 minutes (16 hours) for the unattended sleep testing device used across this code family. Some commenters supported the proposed 960-minute input. These commenters, including the RUC, supported the proposed value, stating that it appropriately reflects the period the device is dedicated to one patient and unavailable for reuse, consistent with our existing PE methodology. Other commenters stated that 960 minutes understates real-world equipment time, particularly for mail-based distribution and repeat-night testing, both of which extend the period a unit is unavailable for reuse well beyond a single overnight cycle. These commenters recommended higher equipment time values, with several converging on approximately 64 hours as a conservative minimum.

Response: After consideration of the public comments, we believe that the time assumption of 960 minutes accurately reflects the typical equipment time. Although commenters provided examples of cases where patients could require more than two nights of use for the equipment, we remind interested parties that direct PE

inputs for the PFS are valued based on typical usage, not unusual or outlier cases.

Comments: Commenters including the RUC supported the RUC-recommended clinical labor time inputs CA021 and CA042 for CPT codes 95843 through 95846, stating that the incremental increases in staff setup, demonstration, and post-service data processing time appropriately reflect the added complexity of each code in the family. A commenter stated that if CMS revised the equipment input for these codes to reflect disposable rather than reusable devices, the post-service time in CA042 should be reduced accordingly, since disposable devices would eliminate the retrieval, cleaning, and refurbishment work currently reflected in that time.

Response: We thank the RUC and commenters for providing additional explanation regarding practice expense inputs for 95843–95846. We are finalizing the RUC recommended CA021 and CA042 clinical labor time inputs for CPT codes 95843 through 95846 as proposed.

Comments: Commenters also suggested that CMS define these terms clearly, tie them to FDA clearance, and align CPT coding with coverage policy. They stated that without clear and shared definitions, providers, manufacturers, and Medicare Administrative Contractors (MACs) could classify functionally similar devices into different complexity tiers, or count channels differently (for example, counting derived measurements or multiple EEG derivations as separate channels).

Response: We thank the commenters for their feedback and for the additional information provided.

Comment: Several commenters, including the RUC, stated that they would like to offer a technical correction to the utilization crosswalk from several 2026 deleted codes to new 2027 codes. The commenters stated that CPT codes 95843 and 95847 should crosswalk from CPT code 95800, while CPT codes 95844 and 95848 should crosswalk from CPT code 95806; the prior crosswalk used in the proposed rule was an unintended technical error submitted to CMS.

Response: After reviewing the information provided by the commenters, we agree with this technical correction. We are finalizing an update to the utilization crosswalk as described previously for CY 2027; the full utilization crosswalk table is available in the file titled ''CY 2027 PFS Final Rule 2025 Utilization Data Crosswalked to 2027'' on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.*

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Unattended Sleep Testing family as proposed, with the exception of finalizing a work RVU of 1.50 for CPT code 95849 as detailed previously.

(44) Laser Treatment for Inflammatory Skin Diseases (CPT Codes 96920, 96921, and 96922)

In May 2025, the CPT Editorial Panel revised three codes to reflect the intended use for inflammatory or auto-immune skin diseases (*e.g.,* psoriasis): CPT codes 96920 *(Laser treatment, 308–312 nanometer wavelengths, for inflammatory or auto-immune skin diseases (e.g., psoriasis); total area less than 250 sq cm),* 96921 *(Laser treatment, 308–312 nanometer wavelengths, for inflammatory or auto-immune skin diseases (e.g., psoriasis); 250 sq cm to 500 sq cm),* and 96922 *(Laser treatment, 308–312 nanometer wavelengths, for inflammatory or auto-immune skin diseases (e.g., psoriasis); over 500 sq cm).* These codes were last discussed in the CY 2025 PFS final rule (89 FR 97797 through 97801) and CY 2026 PFS final rule (90 FR 49303 through 49306). These revisions were based on flaws in the prior valuation process and a change in the patient population. The specialty society surveyed the code family for the September 2025 RUC meeting.

For CY 2027, we proposed the RUC-recommended work RVUs of 1.00 for CPT code 96920, 1.24 for CPT code 96921, and 1.50 for CPT code 96922. We proposed the RUC-recommended direct PE inputs for CPT codes 96920, 96921, and 96922 without refinement.

Comment: Commenters generally supported our proposal of the RUC recommended work RVUs and direct PE inputs for CPT code 96920, 96921, and 96922. A commenter requested refinements to various practice expense inputs, including the equipment utilization rate, maintenance costs, and recurring consumables that the commenter stated are required to operate the device for CPT codes 96920–96922. The commenter also requested that CMS treat excimer laser systems as a supply-based item.

Response: We thank commenters for their support of our proposals. For the practice expense refinements, we would like to acknowledge that the RUC's PE Subcommittee reconsidered direct PE inputs, which were developed based on typical clinical practice and current AMA RUC/PE guidelines, at the September 2025 RUC meeting, where no modifications were made. As stated in section II.B. of this final rule, we currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act. We do not agree with the commenter that it would be appropriate to drastically reduce the utilization rate based on the limited data provided, as the utilization rate assumption of 50 percent is used for most equipment.

Additionally, as discussed in section II.B. of this final rule, we finalized a 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we stated that this estimate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding data sources containing equipment maintenance rates, commenters could not identify an auditable, robust data source that CMS could use on a wide scale. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, a variable maintenance factor for equipment cost per minute pricing was not proposed as we did not believe that we had sufficient information at that present time. Therefore, we reminded readers that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs.

As previously discussed in the CY 2025 PFS Final Rule (89 FR 97798), CMS currently does not include the costs of consumable gas (code EQ154) and the optical delivery system (code EQ155) in the direct practice expense cost for these services. The commenter requested the inclusion of EQ154 and EQ155 in our PE calculations for these services; however, the commenter's letter characterizes EQ154 and EQ155 as replacement/maintenance items, not equipment items that are used for each service. In response to the commenter's request that CMS treat excimer laser systems as a supply-based item, we

continue to believe, as was previously discussed in the CY 2025 PFS Final Rule (89 FR 97798), that the equipment item EQ161 (excimer laser), which the specialty society confirmed remains the typical equipment used for this code set, is available for purchase and is already accounted for under our equipment methodology. We previously did not propose the May 2023 RUC recommendation to change the business model for excimer lasers to a pay-per-use subscription-based model, as rental and licensing fees are typically considered forms of indirect PE under our methodology. We continue to believe that CPT codes 96920 through 96922 should not be valued based on a significantly more expensive pay-per-use rental version of the excimer laser when the same treatment is cheaper and available as a purchasable form of equipment.

After consideration of public comments, we are finalizing CPT codes 96920, 96921, and 96922 as proposed.

(45) Real-Time Fluorescence Wound Imaging (CPT Code 97611)

In September 2025, the CPT Editorial Panel created a new code to report real-time florescence wound imaging, CPT code 97611 (*Real-time fluorescence wound imaging with clinical darkness to identify presence, location, load of bacteria and measure wound size, per day*). The specialty society did not conduct a survey for CPT code 97611 because they determined it would be unable to conduct a successful survey that met the RUC's minimum survey threshold, and therefore, the RUC recommended contractor pricing for CY 2027.

Due to persistent payment variability for the predecessor CPT codes 0598T and 0599T, and limited geographical uptake of the technology, the device manufacturer requested that CMS actively price CPT code 97611 and provided work RVU and direct PE input recommendations. After consideration of the manufacturer's recommendations, we proposed a work RVU of 0.80 and physician pre-evaluation time of 6 minutes, intraservice time of 15 minutes, and immediate post service time of 5 minutes, totaling 26 minutes of physician time. For direct PE in the non-facility, we proposed a direct crosswalk of clinical labor activities and time from CPT code 97610 (*Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day*), with the addition of 10 minutes for CA026 Clean surgical instrument package for CPT code 97611, for a total of 42 minutes of clinical labor time. Additionally, we proposed the following supply items and quantities in the non-facility for CPT code 97611.

TABLE A-D4: SUPPLY ITEMS FOR CPT CODE 97611

Supply Code	Supply Description	Supply Quantity in the Nonfacility
SA043	pack, cleaning, surgical instruments	1
SB007	drape, sterile barrier 16in x 29in	1
SB019	drape-towel, sterile 18in x 26in	1
SB022	gloves, non-sterile	2
SB028	gown, surgical, sterile	1
SB044	underpad 2ft x 3ft (Chux)	1
SC056	syringe 50-60ml	1
SG018	bandage, Kling, non-sterile 3in	1
SG035	dressing, 3in x 4in (Telfa, Release)	2
SG051	gauze, non-sterile 4in x 4in	8
SG052	gauze, self-adherent roll 0.5in to 2in (Fabco, Gauztex)	72
SG079	tape, surgical paper 1in (Micropore)	12
SH069	sodium chloride 0.9% irrigation (500-1000ml uou)	1
SB061	MolecuLight DX Eco Dark Drapes	1

Additionally, we proposed the following equipment items and equipment minutes in the non-facility to correspond with the 30 and 36 minutes of clinical labor time included in the default and instrument pack equipment formulas, respectively, for CPT code 97611. The real-time fluorescence wound imaging system (ER131) was added to the direct PE database for inclusion in CPT code 97611 assuming a 5-year useful life and purchase price of $21,500 based on the provided invoices. We did not propose to include the carrying case for the real-time fluorescence wound imaging system in the equipment costs for CPT code 97611 as recommended by the device manufacturer. We have a longstanding policy that medical equipment must be at least $500 and all equipment inputs under $500 are considered indirect expense. We welcomed public comment on the appropriateness of our proposed work RVU and the typicality of our proposed physician work times and direct PE inputs.

TABLE A-D5: EQUIPMENT ITEMS FOR CPT CODE 97611

Equipment Code	Equipment Description	Equipment Minutes in the Nonfacility
EF015	mayo stand	30
EF031	table, power	30
EQ137	instrument pack, basic ($500-$1499)	36
EQ168	light, exam	30
ER131	real-time fluorescence wound imaging system	30

We sought comments on whether this service will typically be billed alongside wound debridement codes (that is, greater than 50 percent of the time), and if so, which of the proposed direct PE inputs may be duplicative of those already included in the wound debridement codes, such as CPT codes 11042 (*Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less)* and 97597 (*Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less)*). We noted in the proposed rule that CPT code 97611's predecessor codes, CPT codes 0598T and 0599T, were billed with wound debridement codes 35.1 percent and 46.6 percent of the time, respectively. However, we understand that such concurrent billing with wound debridement may become more common as adoption of this technology increases. For example, we sought comments on whether the following proposed supply items are duplicative of debridement codes if it is anticipated that these codes will be typically billed together: SB007, SB019, SB044, SC056, SF007, SG018, SG035, SG051, SG052, SG079, SH069 and SJ046. We also sought comments on whether these wound care supply items are typical for CPT code 97611, given that the code descriptor specifies wound imaging but does not include any wound care elements. Finally, we noted in the proposed rule that the direct PE crosswalk code, CPT code 97610, is billed alone 64.4 percent of the time and with debridement CPT code 11042 only 4.3 percent of the time. Therefore, we sought comments on the appropriateness of this code as a direct PE crosswalk considering the different billing patterns of CPT code 97610 and 97611 based on its predecessor codes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported the proposed valuation for CPT code 97611 and stated that it accurately represented the work and practice expense involved in providing a typical real-time wound imaging procedure.

Response: We thank the commenters for their support.

Comment: A couple of commenters did not support the proposed RVU of 0.80 and recommended contractor pricing for CPT code 97611 instead.

Response: We continue to believe that the proposed valuation for CPT code 97611 is appropriate and accurately represents the work and practice expense involved in performing this procedure. We believe that, generally speaking, national pricing for individual services is preferrable to contractor pricing since it better maintains relativity across the PFS and minimizes regional variations that can creates barriers to care access. Although contractor pricing is appropriate for some services, it is most often used for new and emerging technologies, and we believe that CPT code 97611 will be more accurately valued using our proposed national pricing.

Comment: A couple of commenters requested that the name of the new ER131 equipment item should be changed from the proposed ''MolecuLight DX System'' to ''real-time fluorescence wound imaging system.'' The commenters stated that direct PE item descriptions should accommodate qualifying technologies from multiple manufacturers and requested that CMS clarify that a product name in the PE database does not restrict payment to that manufacturer.

Response: We agree with the commenters that direct PE item descriptions should typically use generic descriptions rather than product names from specific manufacturers. We are therefore finalizing this change in the name of the ER131 equipment to the requested ''real-time fluorescence wound imaging system'' and clarifying that the equipment is not restricted to a single manufacturer. Also, all references to ER131 have been updated with the generic description.

Comment: A few commenters recommended removing supply items SF007 (blade, surgical (Bard-Parker)) and SJ046 (silver nitrate applicator) from the direct PE inputs for CPT code 97611 because neither of these items are used in performing fluorescence wound imaging. Commenters stated that a surgical blade is a debridement instrument and silver nitrate a hemostatic agent.

Response: We agree with the commenters and we are finalizing the removal of supply items SF007 and SJ046 from the direct PE inputs for CPT code 97611.

Comment: For new supply item SB061 (MolecuLight DX Eco Dark Drapes), a commenter wanted CMS to clarify that clinical darkness is an imaging condition achieved consistent with the real-time fluorescence wound imaging device's labeling, and that supply item SB061 may not always be required each time this service is performed, depending on the lighting conditions.

Response: We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. A supply item that is used more than 50 percent of the time when performing a service would be considered typical for that service. We were not persuaded by the commenter that the SB061 drape would be used less than 50 percent of the time given the need for clinical darkness in this procedure. We also note that we received several comments in support of the direct PE inputs proposed for CPT code 97611, including the SB061 drape.

Comment: Many commenters requested that CPT code 97611 not be considered a therapy service and remain on the Skilled Nursing Facility

Consolidated (SNF) Billing Exclusion list.

Response: We agree with the commenters and will not designate CPT code 97611 as a sometimes therapy service, which will allow it to remain on the list of services excluded from SNF consolidated billing.

Comment: A commenter stated that in hospital outpatient department (HOPD) wound care settings, the proposed facility PE RVU of 1.05 for 97611 should be evaluated against actual equipment, clinical labor, and supply costs. The commenter requested that CMS engage with HOPD wound care programs with real-time fluorescence imaging experience to validate whether the proposed PE inputs adequately reflect HOPD-specific cost structures.

Response: We did not propose any direct PE inputs in the Facility setting for CPT code 97611, following our standard PE methodology, as these costs would be borne by the institution under non-PFS payment systems. The PFS payment for this service in the facility setting only covers practitioner work, malpractice, and indirect PE costs; for hospital outpatient expenses, these would be accounted for under the OPPS.

Comment: A commenter noticed a typo for supply item SG018 (bandage, Kling, non-sterile 3in) as it was inadvertently listed as SF018 when we sought comments on whether the proposed supply items for 97611 are duplicative of those used for debridement codes. The description for SF018 is: cautery, monopolar, electrode, needle.

Response: We thank the commenter for pointing this out and agree that SF018 as it appeared in the text was a typo. We also note that SG018 was correctly listed in Table A–D4 for the supply items for CPT code 97611 and elsewhere.

Comment: We sought comments on whether CPT code 97611 would typically be billed with wound debridement codes (that is, greater than 50 percent of the time), and asked which of the proposed direct PE inputs may be duplicative of those already included in the wound debridement codes. Many commenters stated that CPT code 97611 would not typically be billed with debridement codes and that CMS should maintain separate, unbundled reimbursement for these PE inputs when imaging is furnished during the same encounter as wound debridement. Commenters stated that real-time fluorescence wound imaging informs clinical decision-making rather than performing tissue removal and that the imaging and the debridement are not interchangeable steps. Therefore, commenters stated that the direct PE inputs for 97611, including specialized imaging equipment and supplies, were separate and non-duplicative of those used in debridement procedures. A commenter's personal experience was that a debridement procedure was performed with real-time fluorescence wound imaging 42 percent of the time. Several other commenters said that it was reasonable to expect CPT code 97611 to be billed in a similar pattern as predecessor CPT codes 0598T and 0599T, which were only billed with wound debridement codes 35.1 percent and 46.6 percent of the time, respectively. Another commenter stated that CPT code 97611 would be separate from cellular, acellular, and matrix-like products (CAMP) application and debridement procedures (not a component of the procedural encounter).

Response: We thank the commenters for their feedback.

After consideration of public comments, we are finalizing the work RVU and direct PE inputs for CPT code 97611 as proposed, with the exception of the removal of supply items SF007 and SJ046 as detailed previously.

(46) Lactation Care Services (CPT Codes 98963 and 98964)

At the May 2025 CPT Editorial Panel meeting, two new CPT codes were created for reporting lactation care directed by a physician or qualified health care professional (QHP): CPT codes 98963 (*Lactation care directed by a physician or other qualified health care professional, including history, assessment, training, and report; first 30 minutes*) and 98964 (*Lactation care directed by a physician or other qualified health care professional, including history, assessment, training, and report; each additional 15 minutes*). These new CPT codes were surveyed at the September 2025 AMA RUC Meeting.

For CY 2027, we proposed the RUC-recommended work RVU of 0.18 for CPT code 98963. The RUC did not recommend, and we did not propose a work RVU for CPT code 98964, which has been designed as a PE only service.

We proposed the RUC-recommended direct PE inputs for CPT codes 98963 and 98964, including the creation of a new clinical staff type for Lactation Consultant (L076A) and a new EF052 equipment item (scale, infant, digital, fine gradation). We adopted CPT language and requirements for the Lactation Consultant: ''The qualifications of the lactation consultant/counselor must be recognized by a physician society, nonphysician health care professional society/association, or other appropriate source.'' We proposed to value this new clinical staff type at the same 0.76 rate per minute currently used by the RN (L051A) clinical staff type as recommended by the RUC; we sought comment regarding this new clinical staff type and whether there may be a more appropriate crosswalk than the RN clinical staff type. We proposed the RUC-recommendation of the RN clinical staff type as a proxy for pricing purposes, but sought comment on whether Lactation Consultants are typically RNs with additional credentialing/certification to be qualified to serve as a lactation consultant.

Comment: We received a large volume of public comments regarding the Lactation Care Services codes. Many commenters provided additional information concerning the clinical benefits of the care provided by lactation consultants. Commenters stated that lactation consultants obtain and evaluate maternal and infant histories, assess milk production and feeding effectiveness, observe feeds, evaluate milk transfer, identify maternal and infant risk factors, develop individualized care plans, provide counseling and education, document clinical findings, reassess response to interventions, and determine when referral or coordination with another healthcare professional is necessary. Commenters stated that families frequently present with multiple, overlapping concerns including pain while feeding, low milk production, pumping challenges, supplementation, bottle refusal, or concerns about the infant's ability to feed effectively which cannot always be addressed through a standardized approach. Many commenters provided personal accounts detailing the importance of the care that they received from lactation care services.

Response: We appreciate the additional details provided by the commenters regarding the clinical benefits of these services. We agree with the commenters regarding the importance of these lactation care services which have now been recognized with formal CPT coding.

Comment: Many commenters responded to the comment solicitation in the proposed rule regarding whether lactation consultants are typically RNs with additional credentialing/certification. Many commenters stated that lactation consultants are not necessarily RNs with additional credentialing; this included personal accounts from many lactation

consultants who clarified that they had significant training but were not certified as RNs. Commenters stated that holding both credentials reflects meeting two separate sets of requirements, rather than one credential containing the other, and cited other groups (such as registered dietitians, occupational therapists, and speech-language pathologists) who all practice in hospital settings without being expected to hold RN licensure. Commenters stated that an RN prerequisite for lactation consultants would add years of unrelated education and cost, restrict access to skilled lactation care, and could shrink a workforce that's already stretched thin. Many commenters cited International Board Certified Lactation Consultants (IBCLCs), an independent, lactation-specific credential with established education, clinical training, and certification requirements separate from RNs. Commenters requested CMS clarify that lactation consultants, including IBCLCs, are not required to be registered nurses.

Response: We appreciate the detailed feedback from the commenters regarding our lactation consultant comment solicitation. We can clarify for the commenters that our solicitation was intended for informational purposes and that we are not finalizing a requirement that lactation consultants must also be certified as RNs. Our proposed use of the RN was a proxy for the pricing of the lactation consultant clinical labor type, not intended as a new certification requirement.

Comment: Commenters stated that the code descriptors for CPT codes 98963 and 98964 were unclear whether these codes are intended to recognize the IBCLC as the professional furnishing and reporting the service, or whether they assume a model in which the IBCLC functions as clinical staff beneath another independently billing practitioner. Many commenters requested that CMS expressly recognize IBCLCs as qualified practitioners who may directly bill for the lactation services they provide. Commenters stated that lactation challenges most often emerge in the days and weeks after hospital discharge so a direct-supervision standard requiring the billing practitioner to be immediately available on-site would make these codes unusable in the postpartum setting where they are needed most.

Response: As we stated in the proposed rule, we adopted CPT language and requirements for the Lactation Consultant: ''The qualifications of the lactation consultant/counselor must be recognized by a physician society, nonphysician health care professional society/association, or other appropriate source.'' These licensing requirements are outside the scope of the code valuation for CPT codes 98963 and 98964 discussed in this portion of the rule; we did not propose and we are not finalizing IBCLCs or other lactation consultants as qualified practitioners who may directly bill for the lactation services they provide.

Comment: Several commenters requested that CMS add CPT codes 98963 and 98964 to the Medicare Telehealth Services List so that lactation support could reach patients in the home.

Response: We did not propose and we are not finalizing the addition of these codes to the Medicare Telehealth Services List. Although we understand that these lactation care services are sometimes provided in a home setting, the CPT codes as designed by the CPT Editorial Panel were not intended to be provided via telehealth.

Comment: Several commenters stated that comprehensive lactation care frequently involves two patients: the lactating parent and infant. Commenters stated that separate billing for the mother and infant when both receive distinct, medically necessary services is imperative to accurately value lactation healthcare. Commenters stated that separate billing should not be considered duplicate billing when the mother and infant are separate patients and each receives separately identifiable, medically necessary services supported by documentation.

Response: The coding instructions for CPT code 98963 specifically state that it is used to report lactation care services ordered by a physician or other QHP and provided by a lactation consultant/counselor in the office or other outpatient setting for a mother/baby dyad. Separate billing that requires additional medically necessary services would therefore not be typical for these codes.

Comment: Many commenters stated that lactation care services lasted significantly longer than the 30 minute duration described by CPT code 98963. Commenters stated that lactation care does not stop requiring professional judgment after the first 30 minutes and stated that the clinician continues to assess the parent-baby dyad, interpret findings, modify the care plan, evaluate response to interventions, and provide counseling for a much longer span of time. Different commenters stated that 60 minutes, 90 minutes, or 120 minutes constituted a typical amount of time for lactation care services and disagreed with the 30 minutes of time associated with CPT code 98963 as both insufficient to provide care and not typical of their patient encounters.

Response: We appreciate the feedback from the commenters regarding the typical duration of patient encounters for lactation care services. We note that the new CPT codes do not mandate 30 minute patient encounters, as CPT code 98963 can be billed for the first 30 minutes followed by CPT code 98964 for each additional 15 minutes. We believe that this remains the most appropriate time structure for the coding based on the current data available to CMS. However, given the volume of comments regarding how the proposed times for these codes did not match the experience of lactation care services providers, this is a subject that may warrant revisiting by CMS, the RUC, or the CPT Editorial Panel at a later date.

Comment: Many commenters disagreed with the proposed work RVU of 0.18 for CPT code 98963 and the lack of a proposed work RVU of CPT code 98964. Commenters stated that lactation care does not stop requiring professional judgment after the first 30 minutes. Commenters stated that the proposed work valuations undervalue the complex work involved in providing comprehensive lactation care, as lactation consultations are a clinical assessment that considers the needs of both the parent and the infant. Several commenters stated that CPT code 98963 should be valued comparably to CPT code 99213 at a work RVU of 1.30. Commenters requested that CMS assign an appropriate work RVU to add-on CPT code 98964 to compensate clinicians for direct, prolonged face-to-face care.

Response: We continue to believe that the proposed work RVU of 0.18 for CPT code 98963 as recommended by the RUC is the most accurate current valuation for this service. We agree with the RUC that CPT code 99211 is the most direct analog for CPT code 98963, as it describes an office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional. Similarly, we continue to believe that CPT code 98964 was accurately valued as a PE-only code with no work RVU since it only contains clinical staff time for the lactation consultant. Based on the information that we have at present, we believe that these are the appropriate work valuations for CPT code 98963 and 98964. However, we do note that there was a flawed survey used by the RUC for these codes, due to a potential

misunderstanding by survey respondents regarding who was performing the service. As we stated previously in regard to the work times of these codes, given the volume of comments regarding how the proposed work RVUs for these codes did not match the experience of lactation care services providers, this is a subject that may warrant revisiting by CMS, the RUC, or the CPT Editorial Panel at a later date.

Comment: Several commenters stated that they supported the proposed direct PE inputs for CPT codes 98963 and 98964, including the proposed RN crosswalk as a reasonable minimum proxy for the time, skill, and clinical intensity of the lactation consultant. Other commenters disagreed and stated that the proposed 0.76 rate for the L076A clinical labor type did not represent the amount paid to an IBCLC, nor did it capture the complete cost of operating an accessible, compliant lactation care service. A commenter requested valuing the L076A clinical labor type at 0.90 per minute based on a study published in the Journal of Human Lactation in 2013 [8] along with current benchmarked salary data for the lactation consultant profession.

Response: We appreciate the additional data provided by the commenters regarding the typical salary of a lactation consultant. Based on this additional data, we are finalizing an increase in the pricing of the L076A lactation consultant clinical labor type, from the proposed 0.76 to 0.90 as provided by the commenters.

Comment: A commenter stated that the direct practice expense file also appeared to use the L076A clinical labor type for CPT code 98963 but the RN (L051A) clinical labor type for the add-on CPT code 98964. The commenter stated that CMS should correct or explain this inconsistency and use the lactation consultant staff type consistently when lactation care is performed by an appropriately qualified lactation consultant.

Response: We appreciate the assistance from the commenter in identifying this unintended technical error. We are correcting this error for the final rule; both CPT code 98963 and 98964 were intended to use the L076A lactation consultant for their clinical labor.

[8] Chetwynd E, Meyer A–M, Stuebe A, Costello R, Labbok M. Recognition of International Board Certified Lactation Consultants by Health Insurance Providers in the United States: Results of a National Survey of Lactation Consultants. Journal of Human Lactation. 2013;29(4):517–526. doi:10.1177/0890334413499974.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for CPT code 98963 and 98964 as proposed, with the update to the pricing of the L076A clinical labor type and technical correction to the clinical labor used in CPT code 98964 detailed previously.

(47) Adaptive Behavior Services (CPT Codes 97151, 97152, 97148, 97149, 97180, 97153, 97154, 97159, 97160, 97155, 97173, 97156, 97157, 97158)

At the September 2025 CPT Editorial Panel meeting, the CPT Editorial Panel deleted CPT codes 0362T (*Behavior identification supporting assessment, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.*) and 0373T (*Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.*), revised eight existing CPT codes: 97151 (*Behavior identification assessment, administered by a physician or other QHP, each 15 minutes of the physician's or other QHP's time face-to-face with patient and/or caregiver(s) administering assessments and discussing findings and recommendations, and non- face-to-face analyzing past data, scoring and/or interpreting the assessment, and preparing the report and/or treatment plan*), 97152 (*Behavior identification-supporting assessment, administered by technician, face-to-face with the patient, each 15 minutes*), 97153 (*Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient, each 15 minutes*), 97154 (*Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients, each 15 minutes*), 97155 (*Adaptive behavior direction of technician and analysis by physician or other QHP, face-to-face with a patient, each 15 minutes*), 97156 (*Family adaptive behavior treatment guidance with analysis, administered by physician or other QHP (with or without the patient present), including discussing protocols and treatment targets and/or training the caregiver(s) to implement assessment or treatment protocols with the patient, face-to-face with caregiver(s) for 1 patient, each 15 minutes*), 97157 (*Multiple-family group adaptive behavior treatment guidance with analysis, administered by physician or other QHP (without the patient present), face-to-face with multiple sets of caregivers for multiple patients, each 15 minutes*) and 97158 (*Group adaptive behavior treatment with analysis, administered by physician or other QHP, face-to-face with multiple patients, each 15 minutes*), and created six new CPT codes: 97148 (*Behavior identification supporting assessment of harmful behavior, each 15 minutes of technician time face-to-face with a patient, requiring the following components: delivered by two technicians, for a patient who exhibits harmful behavior, conducted in an environment that is customized to the patient's behavior,*), 97149 (*Behavior identification supporting assessment of harmful behavior, each 15 minutes of technician time face-to-face with a patient, requiring the following components: delivered by two technicians, for a patient who exhibits harmful behavior, conducted in an environment that is customized to the patient's behavior, additional technicians present, each 15 minutes (list separately in addition to code for primary procedure)*), 97180 (*Adaptive behavior non-face-to-face services, personally performed by a physician or other QHP, each 15 minutes, with any of the following elements, when performed: review and analysis of data and session notes on patient treatment targets, clinical decision making regarding the need to modify treatment targets, goals, or protocols and/or making those modifications, clinical decision making regarding the need for additional assessment and developing or modifying assessment protocols, developing discharge or transition plan, reviewing treatment targets and/or revised assessment or treatment protocols with technician(s).*), 97159 (*Adaptive behavior treatment of harmful behavior, each 15 minutes of technician time with a patient, requiring the following components: delivered by two technicians, for a patient who exhibits harmful behavior, conducted in an environment that is customized to the patient's behavior.*), 97160 (*Adaptive behavior treatment of harmful behavior, each 15 minutes of technician time with a patient, requiring the following components: delivered by two*

technicians, for a patient who exhibits harmful behavior, conducted in an environment that is customized to the patient's behavior, each additional technician present, each 15 minutes (List separately in addition to code for primary procedure)), and 97173 (*Adaptive behavior treatment with analysis, administered by physician or other qualified health care professional, face-to-face with 1 patient, each 15 minutes*), to better specify appropriate time, define terms, address reporting gaps, and clarify reporting for technician and physician/QHP face-to-face and non-face-to-face adaptive behavior services. The RUC HCPAC Review Board reviewed the 14 codes in the revised code family at the January 2026 RUC HCPAC.

The RUC is recommending contractor pricing for all fourteen codes in the family. The existing CPT codes 97151 through 97158 are currently contractor priced. We proposed to contractor price the six new codes and make no change to the status indicator for the eight revised existing codes that are already contractor priced.

Comments: We received many comments on our proposal to adopt and contractor price the six new adaptive behavior services, CPT codes 97148, 97149, 97159, 97160, 97173 and 97180, and make no change to the status indicator for the eight revised CPT codes 97151, 97152, 97153, 97154, 97155, 97156, 97157, and 97158 that are already contractor priced. Nearly all commenters expressed support for the proposals. Many commenters asked CMS to add the new CPT codes to the telehealth list. Many commenters focused on the benefit of two new codes, CPT code 97159 and CPT code 97160, billing two technicians simultaneously.

A few commenters did not support CMS adoption of the new CPT codes. A commenter recommended the adoption of a bundled Adaptive Behavior Services coding framework of 3 comprehensive service categories: Assessment, Treatment, and Caregiver Training instead of adopting the six new codes into the existing code family. Another expressed concern that the adoption of CPT codes 97148, 97149, 97159, 97160, 97173 and 97180, particularly CPT code 97180 for non–face-to-face services, created heightened risks of insufficient documentation, upcoding, and duplicative or concurrent billing, potentially increasing spending without clear evidence of additional clinical value. Another commenter similarly recommended monitoring of utilization patterns to better understand how services are being furnished across settings and provider types and to assess whether beneficiaries are receiving evidence-based and clinically appropriate care. Another commenter advocated national pricing for CPT codes 97173 and 97180 but did not offer an opinion on what that pricing should be.

Response: We thank all the commenters and appreciate the support for our proposals. We believe that the coding framework developed by the CPT Editorial Panel will help specify appropriate times, define terms, address reporting gaps, and clarify reporting for face-to-face and non-face-to-face adaptive behavior services. We believe that the new coding better defines these services and provides a more comprehensive framework than the prior, more patchwork methods of reporting. With regards to national pricing, we agree with the HCPAC that since these services are currently contractor priced and the existing payment models and practice patterns are varied, the newly revised codes should also remain contractor priced at this time.

After consideration of the comments, we are finalizing contractor pricing for all fourteen codes in the family as proposed. Finally, we are adding CPT codes 97148, 97149, 97159, 97160, and 97173 to the Medicare Telehealth Services list. We are not adding CPT code 97180 as the service is a non-face-to-face service.

(48) Remote Monitoring (CPT Codes 98975, 98976, 98977, 98978, 98980, 98981, 98984, 98985, 98986, 98979, 99091, 99453, 99454, 99457, 99458, 99473, 99474, 99445, and 99470)

(a) Background and Overview

In recent years, we have established payment for two code families that describe certain remote monitoring services: remote physiologic monitoring (RPM) and remote therapy monitoring (RTM). In the CY 2018 PFS final rule, we summarized feedback from a comment solicitation aimed at informing new payment policies that would allow for separate payment for remote monitoring services (82 FR 53014). In the CY 2019 PFS final rule (83 FR 59574 through 59576), we established valuations and payment policy for the RPM code family. In the CY 2020 PFS final rule (84 FR 62697 through 62698), we explained that the RPM code family describes chronic care RPM services that involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan and the managing of a patient under the treatment plan (84 FR 62697). In the CY 2020 PFS final rule, we finalized that CPT codes 99457 and 99458 would be included as designated care management services, allowing RPM services to be furnished under the general supervision of the physician or other qualified health care professional (who is qualified by education, training, licensure/regulation and facility privileging) (84 FR 62698). In the CY 2023 PFS final rule, in response to comments, we clarified that RTM or RPM services could be billed concurrently with Chronic Care Management (CCM), Transitional Care Management (TCM), Principal Care Management (PCM), Chronic Pain Management (CPM), or Behavioral Health Integration (BHI) (86 FR 69528 through 69539).

In September 2024, the Current Procedural Terminology (CPT) Editorial Panel added one code and made code revisions to report RPM device supply for 2 to 15 days and 16 to 30 days within a 30-day period; created one new code and code revisions to report RPM treatment management services for the first 10 minutes, first 20 minutes, and each additional 20 minutes thereafter; added three RTM device supply codes to report respiratory, musculoskeletal and cognitive behavioral therapy for 2 to 15 days and 16 to 30 days within a 30-day period; created one new code and made code revisions to report RTM treatment management services for the first 10 minutes, first 20 minutes, and each additional 20 minutes thereafter; and revised remote monitoring guidelines. We reviewed the RUC recommendations for these services in the CY 2026 PFS final rule (90 FR 49394 through 49404). In response to recent reports and recommendations from the Office of the Inspector General (Additional Oversight of Remote Patient Monitoring in Medicare Is Needed [9] and Billing for Remote Patient Monitoring in Medicare [10]), for CY 2027, we proposed refinements to the policies surrounding remote physiologic and remote therapeutic monitoring, as detailed later in this section.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters agreed with CMS' concern for protecting against fraud, waste, abuse, and fragmented care, such as programs that

[9] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/.*

[10] *https://oig.hhs.gov/reports/all/2025/billing-for-remote-patient-monitoring/.*

solicit beneficiaries for services they do not need and care models in which the billing practitioner lacks meaningful oversight. However, many commenters provided information about remote monitoring programs that deliver quality care and improve outcomes in a deflationary manner. Some commenters felt that requirements that could limit the adoption of RPM and RTM services were not in alignment with other stated CMS goals on advancing rural health and the adoption of innovative health technology, or with specific programs, including the Rural Health Transformation Program (RHTP) and the CMS Innovation Center's Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model.

Response: We thank commenters for their support. We agree that there are many remote monitoring programs that provide reasonable and necessary care, and we agree with commenters that identified potential fraud, waste, and abuse as concerns. We do not believe that these requirements would limit CMS goals on advancing rural health, or the adoption of innovative health technology, and CMS remains committed to expanding beneficiary and clinician access to high-value, technology-supported care, as evidenced by the Rural Health Transformation Program (RHTP) and the CMS Innovation Center's ACCESS model. Rather, the requirements would minimize factors that may contribute to potential fraud, waste, abuse, and fragmented care in remote monitoring services paid under the PFS.

Comment: Some commenters raised questions about the relationship between the ACCESS model and the proposed RPM and RTM policies, noting differences in their scope and payment approaches.

Response: We thank commenters for these comments. The ACCESS model is a separate CMS Innovation Center model testing outcome-aligned payments for technology-supported chronic care in Original Medicare, with payment primarily tied to beneficiary outcomes rather than specific activities. RPM and RTM services are PFS services that pay for the furnishing of specified remote monitoring services and related activities. The policies finalized in this final rule are intended to preserve access to appropriate RPM and RTM services while strengthening safeguards to maintain beneficiary and clinician access to technology-supported care and minimizing factors that may contribute to potential fraud, waste, abuse, and fragmented care for remote monitoring services paid under the PFS.

Comment: The AMA informed CMS that in response to our concerns over a lack of data to inform accurate valuation of these services, all 19 RPM and RTM codes will have their practice expense reviewed at the January 2027 RUC meeting.

Response: We thank the AMA for this information and look forward to reviewing any forthcoming recommendations from the RUC regarding the practice expense for these services.

Comment: Some commenters did not support the use of OIG reports to refine the policies surrounding RPM and RTM, including expressing concern that CMS was proposing to implement requirements not explicitly called for in the relevant OIG reports on RPM and RTM services. Some commenters stated that OIG's findings identified only a small number of practices as being of particular concern.

Response: We would like to clarify that the recommendations specified in the OIG reports are not the only measures that CMS is limited to in order to ensure that remote monitoring services paid under the PFS are not subject to potential fraud, waste, and abuse. Although we cited OIG's concerns around RPM in the proposed rule, CMS has also observed troubling trends that may indicate potential fraud, waste, abuse, and fragmented care. These trends align with, but also sometimes go beyond, what OIG has cited.

Comment: A few commenters stated that the OIG reports used data collected during the public health emergency (PHE), when observed growth in remote monitoring was part of a larger digital health transformation.

Response: The OIG report, Additional Oversight of Remote Patient Monitoring in Medicare Is Needed [11], used claims and encounter records with dates of service from January 1, 2019, through December 31, 2022. The OIG report, Billing for Remote Patient Monitoring in Medicare,[12] used claims and encounter records with dates of service from January 1, 2024, through December 31, 2024. Both OIG reports analyze claims and encounter data from before and after the COVID–19 PHE, which began on January 31, 2020 (retroactive to January 27, 2020) and ended on May 11, 2023. We agree with commenters that some of the growth in remote monitoring services during this time may have been in response to the PHE, but we have continued to see high growth of these services in the years since the end of the PHE that may indicate potential fraud, waste, abuse, and fragmented care.

Comment: Several commenters wrote that findings in published OIG reports were only applicable to RPM and not to RTM. Commenters stated that RPM and RTM are unique services, and that there is not sufficient published evidence to support applying uniform policies to both. These commenters believe that RTM should not raise the same program integrity concerns that may exist for RPM since RTM furnished by therapists has existing incident to, plan of care, and recertification requirements. Commenters also cited that RTM has not experienced recent high growth like RPM. Commenters also believed that RTM valuation was accurate and did not need to be refined, as RTM has gone through the RUC process twice in the past four years.

Response: We thank commenters for this information. While we agree with commenters that the OIG report was focused on RPM, we continue to believe that the concerns specified in the OIG reports and in this rule also apply to RTM. The RTM codes are newer and have not been subject to audits, as RPM has. We note that RTM services were not payable under the PFS until January 1, 2022. The OIG report, Additional Oversight of Remote Patient Monitoring in Medicare Is Needed,[13] used claims and encounter records with dates of service from January 1, 2019, through December 31, 2022. The OIG report, Billing for Remote Patient Monitoring in Medicare,[14] used claims and encounter records with dates of service from January 1, 2024, through December 31, 2024. At the time of these analyses, RTM was not payable for the entirety of the claims and encounter data review or was a new service with limited claims and encounter data. Although we agree with commenters that RTM has not experienced as large an increase in utilization as compared to RPM, we have observed an increase in utilization since these services have become payable under the PFS and since the OIG reports reviewed claims and encounter records. The program integrity concerns expressed in the proposed rule apply to both RPM and RTM services. We reiterate our concerns that RTM, like RPM, services may be

[11] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/.*

[12] *https://oig.hhs.gov/reports/all/2025/billing-for-remote-patient-monitoring/.*

[13] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/.*

[14] *https://oig.hhs.gov/reports/all/2025/billing-for-remote-patient-monitoring/.*

susceptible to fraud, waste, abuse, and fragmented care.

(b) Established Patient Requirements

In the CY 2021 PFS final rule (85 FR 84542 through 84546), we established that, when the PHE for COVID–19 ended, we again required that RPM services be furnished only to an established patient. Patients who received initial remote monitoring services during PHE were considered established patients for purposes of the new patient requirements that were effective after the last day of the PHE for COVID–19.

For CY 2027, we proposed to require that RTM services also be furnished only to established patients. We proposed this condition of payment because we believe that a practitioner with an established relationship with a patient would likely have had the opportunity to collect relevant patient history and conduct a physical exam, as appropriate. As a result, the practitioner would possess information needed to understand the current medical status and needs of the patient prior to ordering RTM services to collect and analyze the patient's data and would be able to use the results of remote therapeutic monitoring to manage the patient under a specific treatment plan or therapy plan of care.

This proposal would also assist in resolving OIG's findings that some practices did not have a prior relationship with patients for whom they billed remote monitoring services for (Billing for Remote Patient Monitoring in Medicare [15]).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for the requirement that RTM services be furnished only to established patients, as these changes would create symmetry between requirements for RTM and RPM services. We also received comments supporting both the established patient requirement and the initiating visit requirement as reasonable program integrity measures. Some commenters did not support our proposed requirement for RTM, and a few commenters requested that we no longer require that RPM have an established patient requirement. Some commenters expressed concern that requiring that patients be established before RTM services can be furnished adds unnecessary cost and administrative burden to practices and could delay the onset of monitoring for some patients.

Response: We thank commenters for their comments on our proposal. At this time, we continue to believe that an established patient requirement ensures that the practitioner would possess information needed to understand the current medical status and needs of the patient prior to ordering RTM services. This requirement also ensures that the practitioner collects and analyzes the patient's data and uses the results of remote therapeutic monitoring to manage the patient under a specific treatment plan or therapy plan of care.

Comment: Commenters requested CMS publish a precise definition of ''established patient'' for purposes of remote monitoring services.

Response: We are adopting the definition of ''established patient'' used elsewhere in the PFS. An established patient is one who has received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the same specialty who belongs to the same group practice within the past three years (see Medicare Claims Processing Manual, Chapter 12, section 30.6.7). Although, we note that for certain healthcare professionals, such as physical therapists, occupational therapists, and speech-language pathologists, an established patient is one who is receiving services furnished under a therapy plan of care that may extend throughout the length of that episode of care (see (86 FR 65116) and (87 FR 69643 and 69647)).

Comment: Many commenters requested that a beneficiary be considered an established patient after they have received an initiating visit. Commenters expressed that this would be important in scenarios where early intervention is important (post-discharge, post-injury, etc.).

Response: For the purposes of this policy, we would like to clarify that a beneficiary may be considered an established patient after they have met the initiating visit requirements for remote monitoring services detailed later in this section.

After consideration of public comments, we are finalizing the requirement that RTM services be furnished only to established patients.

(c) Initiating Visit Requirements

For CY 2027, we proposed that practitioners reporting RPM or RTM services must furnish a separately reportable initiating visit in association with the onset of RPM or RTM services, since these services require a level of care coordination that cannot be effective without appropriate evaluation of the patient's needs. The initiating visit would also ensure the billing practitioner assesses the beneficiary to determine clinical appropriateness of RPM or RTM and provide an opportunity to obtain the required beneficiary consent to receive RPM or RTM services. We proposed that RPM or RTM services must be initiated by the billing practitioner during a face-to-face (in-person or telehealth) visit. CPT codes that do not involve a face-to-face visit by the billing practitioner or are not separately payable under Medicare cannot be used as the visit for RPM or RTM initiation. If RPM or RTM is not discussed with the patient at that visit, that visit cannot count as the initiating visit for RPM or RTM. The RPM or RTM initiating visit can be separately billed.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the overall objective of ensuring that patient monitoring begin from a clinical decision by a practitioner who has evaluated the patient.

Response: We thank commenters for their support of this proposal.

Comment: We received many comments suggesting additional clarification and requirements for our initiating visit proposal. Some commenters recommended CMS create a standard for documentation on how RTM/RPM data will be incorporated into the patient's treatment plans, as a condition of payment. A few commenters commented that such requirements could include information about the ordering provider, the type of health information being monitored, and the suspected/target health condition being monitored.

Response: We thank commenters for their suggestions and may consider this for future rulemaking. We are not finalizing any additional documentation requirements at this time, as we believe additional documentation requirements may create unnecessary administrative burden.

Comment: We received several comments seeking clarification and offering suggestions on which specific visit types and which specific practitioners would satisfy the requirements for an initiating visit. Many commenters recommended that a separate initiating visit only be required for certain beneficiaries or clinical scenarios, including exempting beneficiaries aligned to an Accountable Care Organization (ACO). Commenters suggested CMS adopt the same initiating visit requirements for RPM and RTM as are required for Chronic Care

Management (CCM) and Advanced Primary Care Management (APCM) services.

Response: We would like to clarify that while RPM or RTM services must be initiated by the billing practitioner during a face-to-face (in-person or telehealth) visit, the initiating visit does not have to be for the sole purpose of discussing remote monitoring services. CPT codes that do not involve a face-to-face visit by the billing practitioner or are not separately payable under Medicare cannot be used as the visit for RPM or RTM initiation. If RPM or RTM is not discussed with the patient at that visit, that visit cannot count as the initiating visit for RPM or RTM. At this time, we are not finalizing any exemptions to initiating visit requirements, including for patients aligned to ACOs, as these services require a level of care coordination that cannot be effective without appropriate evaluation of the patient's needs. We continue to believe that an initiating visit is the best way to ensure this evaluation is occurring.

Comment: Commenters additionally sought clarification on the definition of ''onset'' of RPM or RTM services. Commenters asked CMS to define the permissible amount of time between the initiating visit and the activation of monitoring. A number of commenters expressed concern that requiring a separate face-to-face initiating visit with the billing practitioner for patients already established with RTM services via discharge from a hospital or other facility would be duplicative and may lack a meaningful clinical benefit. Some commenters expressed concern that requiring practitioners reporting RPM or RTM services to furnish a separately reportable initiating visit in association with the onset of RPM or RTM services adds unnecessary cost and administrative burden to practices, could disadvantage some patients, and could delay the onset of monitoring for others. Some also expressed concern that some patients may be unduly burdened if required to travel solely for purposes of attending an initiating visit.

Response: We thank commenters for this information. At this time, we continue to believe that these services require a level of care coordination that cannot be effective without appropriate evaluation of the patient's needs and that an initiating visit before RPM or RTM services can begin is the best way to ensure this evaluation is occurring. For the purposes of this policy, the onset of RPM or RTM services refers to the onset of these services at the billing provider level. Billing for RPM or RTM services may not begin until the initiating visit has been furnished. We are not finalizing a restriction on the amount of time between the initiating visit and the activation of monitoring, as long as RPM or RTM is discussed with the patient at that visit. To minimize beneficiary burden associated with this initiating visit requirement, we are allowing initiating visits to be furnished via telehealth when furnished in accordance with the requirements in section 1834(m) of the Act. In addition, for the purposes of this policy, a beneficiary may be considered an established patient after they have met the initiating visit requirements. We are not establishing a definition of ''onset'' for RPM and RTM in this rule, however, we welcome ongoing feedback on this policy and may consider this additional information for future rulemaking.

Comment: Several commenters requested clarification on whether the initiating visit must be performed by the billing practitioner, or if it can be furnished by practitioners within the same practice.

Response: Like other services paid under the PFS, physicians in the same group practice who are in the same specialty must bill and be paid as though they were a single physician. We note that this is consistent with the Medicare Claims Processing Manual, Chapter 12, § 30.6.5—Physicians in Group Practice (Rev. 1, 10–01–03), where, ''Physicians in the same group practice who are in the same specialty must bill and be paid as though they were a single physician; physicians in the same group practice but in different specialties may bill and be paid without regard to common group membership.''

Comment: Commenters sought confirmation as to whether an initiating visit can be held over telehealth. We received several comments seeking clarification on how the telehealth pathway for the initiating visit will operate if the statutory telehealth flexibilities lapse.

Response: As discussed in the proposed rule, the initiating visit must be face-to-face, which may be an in-person or telehealth visit. CMS does not have statutory authority to further extend telehealth flexibilities. After December 31, 2027, absent further legislation, the use of telehealth services for purposes of the initiating visit for remote monitoring services will be limited by the requirements of section 1834(m) of the Act that remain in effect.

Comment: Some comments requested clarification on the documentation requirements needed to substantiate the initiating visit.

Response: We are not finalizing the requirement of any additional documentation requirements at this time outside of the documentation requirements for all services paid under the Physician Fee Schedule.

Comment: Several commenters sought clarification on whether the discussion of RPM and RTM needed to be the sole purpose of the visit, for it to qualify as an initiating visit.

Response: We would like to clarify that the initiating visit does not have to be for the sole purpose of discussing remote monitoring services. RPM or RTM must be discussed with the patient at that visit, but does not have to be the sole purpose of the visit or sole topic discussed.

Comment: We received multiple comments seeking clarification on what is meant by ''separately billable'' for purposes of an initiating visit. Commenters asked whether service could be initiated as part of a discharge service or global surgical service.

Response: We would like to clarify that the initiating visit can be separately billable, but does not have to be in all scenarios. We refer readers to the CY 2024 PFS Final Rule (88 FR 78883 through 78884) for additional discussion of RPM or RTM services during a global period.

Comment: Some commenters asked for clarification on how the new initiating visit requirement applies under the Community Health Center (CHC) or Federally Qualified Health Center (FQHC) Prospective Payment System (PPS), specifically whether a same-day qualifying visit requirement applies, and how the ''separately billable'' standards operate under encounter-based CHC billing versus the Physician Fee Schedule fee-for-service billing.

Response: Effective January 1, 2025, Rural Health Clinics (RHCs) and FQHCs are required to bill the individual CPT/HCPCS base codes and add-on codes for each of the care coordination services to receive payment separate from the Rural Health Clinic All-Inclusive Rate (RHC AIR) or FQHC PPS. RHCs and FQHCs may bill care coordination services either alone or with other payable services. If the care coordination service is furnished on the same day as a qualifying visit, the RHC or FQHC will receive two separate payments. Care coordination services are paid at the national non-facility PFS payment rates. Since RHCs and FQHCs report the individual care coordination codes, they must follow the requirements established under the PFS for each code.

Comment: Commenters asked whether each new episode of monitoring requires its own initiating visit. Commenters requested

clarification on whether a new initiating visit would be required when oversight of a patient is passed from an established billing practitioner to a new billing practitioner located within the same practice. Some commenters requested clarification on whether a new initiating visit would be required when a new or upgraded monitoring device is acquired by or for the patient. Commenters requested clarification on whether a new initiating visit would be required for patients after a clinical change, a temporary hold status has ended, or after a re-enrollment into an active monitoring program.

Response: We would like to clarify that an initiating visit would only be required before the onset of remote monitoring services for that beneficiary. A separate visit is not required for routine clinical changes, which could include, but are not limited to a change of device, clinical change, or change of billing practitioner within the same practice.

Comment: In situations where monitoring is initiated during a visit that also includes a higher-valued global-period procedure, a commenter recommended CMS not reduce the separately reportable E/M visit per the modifier 25 proposal.

Response: We refer readers to section XX of this final rule for additional details discussing modifier 25. As discussed in that section, we are not finalizing service level exceptions at this time. We believe that there are overlapping resource costs for procedures, including an initiating visit for remote monitoring.

Comment: We received several comments requesting that beneficiaries already established in a remote monitoring program be considered ''grandfathered'' for purposes of the initiating visit requirement.

Response: We agree with commenters that requiring beneficiaries who are already receiving remote monitoring services to have an initiating visit would be particularly burdensome. We would like to clarify that beneficiaries who are already receiving remote monitoring services before this policy becomes effective on January 1, 2027, would not need to have an initiating visit to continue remote monitoring services, so long as all other requirements for these services are met. CMS discourages any misuse of enrolling beneficiaries in remote monitoring services between the publication of this rule and January 1, 2027. As with all services paid under the PFS, all remote monitoring services furnished must be reasonable and necessary.

After consideration of public comments, we are finalizing as proposed.

(d) Supervision Requirements

Currently, RPM or RTM services may be outsourced to third-party companies that provide services via telephone and online contact only, using staff who have little to no established relationship with the beneficiary or other members of the care team and have little to no interaction with the office staff and billing practitioner. After reviewing the findings discussed in recent OIG reports, such as companies ''cold calling'' beneficiaries to solicit them for remote monitoring services they may not need (Additional Oversight of Remote Patient Monitoring in Medicare Is Needed [16]) and working to improve the transparency of ''incident to'' services, we believe outsourcing RPM/RTM services to a third party can fragment care, lead to insufficient involvement and oversight of the billing practitioner, or result in services that do not actually represent or facilitate all required aspects of RPM or RTM services. Provision of these services by entities having only a loose association with the treating practitioner can detract from longitudinal, patient-centered care. We do not believe that RPM or RTM services provided by clinical staff contracted by a third party can ensure the billing practitioner has adequate oversight, management, or collaboration to bill RPM or RTM services. If there is little oversight by the billing practitioner or a lack of clinical integration between a third-party providing RPM/RTM and the billing practitioner, we do not believe that the full scope of service elements required to bill these codes are being met.

We proposed to only allow payment for RPM or RTM services when furnished by clinical staff employed by the practice. To count the time spent by clinical staff providing aspects of RPM or RTM services, the clinical staff must be a direct employee of the practitioner or the practitioner's practice. This would have meant that for the purposes of billing Medicare, beginning January 1, 2027, the RPM and RTM codes could not be billed in cases where the service is not performed by clinical staff of the billing practitioner and will not allow contracting out to third-party companies. This does not mean the clinical staff must necessarily always be physically located within the practice, nor does it require that the beneficiary be on-site for the provision of remote monitoring services. Under our proposed revised policy, the time spent by clinical staff providing RPM or RTM services can be counted, provided that the clinical staff are under the general supervision of the billing practitioner, all other requirements of the ''incident to'' regulations at § 410.26 are met, and the clinical staff is a direct employee of the practitioner or the practitioner's practice. We sought comment on this proposal, specifically on how often third-party billing currently occurs and how this policy, if finalized, could impact access to remote monitoring services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed support for CMS' proposal to only allow payment for RPM or RTM services when furnished by clinical staff employed by the practice. Some commented that it would better ensure that clinicians are made aware of relevant data collected, would support fraud prevention, and support quality outcomes.

Response: We thank commenters for supporting our proposal.

Comment: Several commenters suggested other program integrity-related requirements CMS could pursue in the future instead of this policy. Several commenters suggested CMS consider establishing stricter credentialing requirements for clinicians and vendors delivering RPM and RTM services. A few commenters suggested CMS consider limiting payment to conditions or disease states that have robust data demonstrating the value of remote monitoring services.

Response: We thank commenters for the additional information and may consider this for future rulemaking.

Comment: Many commenters requested that CMS clarify how this proposal relates to the technology used for remote monitoring services. For example, commenters requested that working with outside companies to license software platforms, purchase devices, and resolve technical issues not be prohibited.

Response: We would like to clarify that a practitioner or practice's use of a third-party technology platform does not affect the requirement that clinical staff must be a direct employee of the practitioner or the practitioner's practice. This policy would not prohibit working with vendors who do not supply third-party staff time, but supply software, devices, technical support, etc. The intent of this policy was not to

[16] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/.*

require billing practitioners to develop proprietary monitoring platforms or devices. Practices may obtain devices, software, connectivity, data hosting, cybersecurity, implementation support, technical assistance, and interoperability services from outside companies.

Comment: Commenters requested clarification regarding CMS' reasoning that remote monitoring services should be held to a higher standard than other services paid under the PFS that are assigned general supervision, as detailed in ''incident to'' regulations at 42 CFR 410.26. Commenters specified that the regulation text under § 410.26 defines employee, leased employee, and independent contractors, and permits these clinical staff types.

Response: We note that these services are assigned general supervision and we are not finalizing any changes to supervision requirements or to the regulation text under § 410.26, as it pertains to remote monitoring services.

Comment: Many commenters stated that allowing payment for RPM or RTM services only when they are furnished by clinical staff employed by the practice would unintentionally limit the types of practices that can offer these services and limit access to care for patients. Several commenters cited the example of academic health systems that employ clinical staff and faculty staff under different entities. Several commenters also cited hospitals utilizing clinical staff who are not direct employees as an example of an entity that would no longer be able to provide RPM or RTM services. A number of commenters expressed concerns that patients receiving RPM or RTM services would experience limited access to clinical staff and cited specific examples such as access becoming limited to only regular business hours instead of the 24/7/365 service that may be available via third parties. Some commenters stated that a reduction in the number of practices offering RPM or RTM services could increase overall costs to the healthcare system by driving patients towards in-person care and utilization of urgent care and emergency services.

Response: We thank commenters for their comments on our proposal. At this time, we continue to believe that allowing payment only when RPM or RTM services are furnished by clinical staff employed by the practice is the best way to ensure care is integrated, there is sufficient oversight and involvement of the billing practitioner and that services provided represent all required aspects of RPM or RTM services.

Comment: Commenters, whether they did or did not support our proposal, cited the increased cost of employing clinical staff in-house as opposed to using a third-party contractor. Many commenters expressed concern that small and independent practices lack the financial resources to fully manage remote monitoring programs with only staff under their direct employment. Some expressed concern this would disproportionally impact patients living in rural and underserved communities, those with multiple chronic conditions, and those with specialized needs. Many commenters expressed concerns that limiting payments to only RPM or RTM services furnished by clinical staff employed by the practice will exacerbate workforce shortages. Some stated that practices would be unable to hire adequate staff due to geographic limitations and other concerns. Some commenters noted that contracting with third parties afforded practices flexibility during periods in which they may be short-staffed or need access to clinical expertise not otherwise available in their own practice. Commenters also expressed concern that not allowing practices to contract out to third-party companies would limit their ability to develop partnerships with community providers not directly employed by the practitioner or the practitioner's practice, such as EMS agencies, paramedicine providers, and pharmacists.

Response: We thank commenters for this information. At this time, we continue to believe that allowing payment only when RPM or RTM services are furnished by clinical staff employed by the practice is the best way to ensure care is integrated, there is sufficient oversight and involvement of the billing practitioner and that services provided represent all required aspects of RPM or RTM services.

Comment: A few commenters noted that findings published by the OIG regarding the cold-calling and solicitation of beneficiaries could be properly addressed by requirements related to an initiating visit. Some suggested CMS pursue oversight and credentialing of third parties before implementing supervision requirements. Many commenters stated that requiring direct employment is not a reliable indication that staff are integrated into workflows and contributing to quality outcomes. Some suggested CMS should implement guidelines more closely connected to quality outcomes and audit to ensure compliance.

Response: We thank commenters for their comments on our proposal. At this time, we continue to believe that allowing payment only when RPM or RTM services are furnished by clinical staff employed by the practice is the best way to ensure care is integrated, there is sufficient oversight and involvement of the billing practitioner and that services provided represent all required aspects of RPM or RTM services.

Comment: Many commenters requested clarity on what ''employed by the practice'' means for purposes of payment for RPM or RTM services. Many cited examples of specific employment and contracting arrangements and asked for clarification on whether they would be acceptable under the proposed policy. Many also requested CMS consider exemptions for specific arrangements. Some commenters requested CMS define ''direct employee of the practitioner or the practitioner's practice'' for purposes of providing RPM or RTM services. Many commenters requested CMS delay any new requirements related to supervision requirements until at least January 1, 2028. Several provided specific examples of challenges that would be encountered if the proposed policy were to take effect on January 1, 2027. Some commenters expressed concerns that health systems relying on contracted staff for some portion of their RPM or RTM services would be unable to alter or discontinue their existing contracts prior to a January 1, 2027 effective date. Commenters stated that practices would need beyond January 1, 2027 to hire and train sufficient staff and establish appropriate workflows and processes. Many commenters requested CMS delay any new requirements related to supervision of staff until at least January 1, 2028. A few commenters expressed concern that not allowing adequate time for implementation could cause providers to be less willing to make substantial, multi-year investments in technology and infrastructure in the future.

Response: We thank commenters for this information. We disagree that the proposed policy would discourage future investment by practices in technology and infrastructure. However, we agree that it is appropriate to delay implementation of the proposed policy to allow sufficient time for implementation. We also agree with commenters that there may be a need for additional time for CMS to specify additional clinical staff arrangements that may be appropriate for remote monitoring services. Due to the additional information provided by

commenters, we are finalizing this proposal with modifications. Specifically, we are providing a 2-year delay in implementation to allow for practices to hire and train staff for ''in-house'' workflows for remote monitoring services. We would like to emphasize that, although we will continue to allow contracting out to third-party companies until December 31, 2028, all of the existing ''incident to'' and other rules for billing remote monitoring services under the PFS must be met. If there is little oversight by the billing practitioner or a lack of clinical integration between a third party and the billing practitioner, we do not believe the criteria for billing remote monitoring services are actually being met and therefore, the practitioner should not bill for remote monitoring services in those instances. As such, the billing practitioner must retain a certain level of involvement in remote monitoring services. The codes for reporting clinical staff time are valued to include a certain amount of ongoing work and supervision by the billing practitioner consistent with the included service elements that may not be delegated to any other parties. After consideration of public comments, we are finalizing that for the purposes of billing Medicare, beginning January 1, 2029, the RPM and RTM codes cannot be billed in cases where the service is not performed by clinical staff that is a direct employee of the practitioner or the practitioner's practice and contracting out to third-party companies will not be allowed after that time. Prior to this date, CMS will be publishing sub-regulatory guidance further clarifying clinical staff arrangements that may be appropriate for remote monitoring services.

(e) Valuation

Remote physiologic monitoring (RPM) represents the remote monitoring of parameters such as weight, blood pressure, and pulse oximetry to monitor a patient's condition and inform their management. The remote physiologic monitoring code set currently includes CPT codes 99091, 99445, 99453, 99454, 99457, 99458, 99470, 99473, and 99474 (code descriptors in Table A–D6). Remote therapeutic monitoring (RTM) represents the monitoring of adherence to at-home therapeutic interventions. For RTM, there are distinct device supply codes for three types of therapeutic monitoring: respiratory system, cognitive behavioral therapy, and musculoskeletal system monitoring. The remote therapeutic monitoring code set currently includes CPT codes 98975, 98976, 98977, 98978, 98979, 98980, 98981, 98984, and 98985 (code descriptors in Table A–D6). There are three components of RPM and RTM services: education and setup, device supply, and treatment management.

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TABLE A-D6: CY 2027 REMOTE MONITORING CODES

CPT Code	Long Descriptor
98975	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); initial set-up and patient education on use of equipment
98976	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 16-30 days in a 30-day period
98977	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 16-30 days in a 30-day period
98979	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 10 minutes
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)
98984	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period
98985	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 2-15 days in a 30-day period
98986	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 2-15 days in a 30-day period
99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
99445	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial: device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)
99470	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 10 minutes
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient

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For CPT codes 99453 and 98975, which are PE-only codes describing RPM and RTM initial set-up and patient education on use of equipment, respectively, we proposed to crosswalk the direct PE inputs from CPT code 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*), as we believe the existing valuation of CPT codes 99453 and 98975 may not accurately reflect the resource costs involved in those services. Specifically, we are concerned that, due to lack of information regarding the typical device used to perform these procedures, these services are overvalued. We believe that the typical device used for these procedures in the physician office setting may not be accurately captured in the data previously used for valuation, as we have received very little invoice or pricing information from interested parties for the specific devices used in RTM and RPM services. We believe that a crosswalk to the direct PE inputs associated with CPT code 99473 may more accurately capture the resource costs associated with a typical device set-up and patient education on use of equipment. We sought comment on this proposal, specifically information regarding the typical clinical workflow for the initial set-up and patient education on use of equipment services used in furnishing RPM or RTM and their associated costs.

For CPT codes 99445 and 99454, which are PE-only codes describing RPM device(s) supply with daily recording(s) or programmed alert(s) transmission, we proposed to crosswalk the direct PE inputs from CPT code 99474 (*Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient*). For CPT codes 98976, 98977, 98978, 98984, 98985, and 98986, which are PE-only

codes describing RTM device(s) supply for data access or data transmissions, we proposed to crosswalk the direct PE inputs from CPT code 93270 (*External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)).* We believe the existing valuation of CPT codes 99445, 99454, 98976, 98977, 98978, 98984, 98985, and 98986 may not accurately reflect the resource costs involved in these services, especially since we continue to lack data surrounding the typical RPM and RTM devices and the costs associated with them. Specifically, we are concerned that, due to lack of information regarding the typical device used to perform these procedures, these services are overvalued. We believe that the typical device used for these procedures in the physician office setting may not be accurately captured in the data previously used for valuation, as we have received very little invoice or pricing information from interested parties for the specific devices used in RTM and RPM services. We believe that the crosswalk to the direct PE inputs associated with the proposed codes discussed earlier may more accurately capture the resource costs associated with a typical device. We solicited comments on this proposal, specifically information regarding the typical devices used in furnishing RPM or RTM, not just their associated costs and invoices, but robust evidence detailing what providers are actually paying for these devices, including discounts or other typical pricing details. We sought other types of pricing data and information for RPM or RTM devices, including if the costs include software, hardware, or both, as well as more information about the typical devices. For CPT codes 99470, 99457, 99458, 98979, 98980, and 98981, which describe the physician/QHP work associated with treatment management, we proposed to eliminate PE inputs for these codes, as we believe resource costs for these services are accurately captured in the work RVUs, and we do not believe the typical clinical workflow for these services would involve clinical staff time. We proposed that the current work RVUs and current work times for these codes be maintained. We welcomed information regarding the typical clinical workflow for these services.

We solicited comments on these proposals, as well as requested general feedback from the public that may be useful in further development of our payment policies for remote monitoring services that are currently separately payable under the PFS.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for the revaluation of RPM and RTM codes as RPM payment in its current form incentivizes a focus on generating billable encounters, regardless of whether those interactions provide meaningful clinical value. We also received a comment expressing concern regarding incentive systems that rewarded intervention rather than clinical restraint. A few other commenters agreed with CMS that remote monitoring device costs have declined since the codes were first valued and requested CMS pair the revaluation with a published methodology and a transparent, periodically updated device cost benchmark.

Response: We thank commenters for their support of our proposals.

Comment: Many commenters expressed concern that CMS lacked adequate information on costs to properly revalue codes and requested CMS gather more information related to true costs of RPM and RTM services from stakeholders, including the RUC, before finalizing any revaluation of codes. Some recommended confidential submissions on cost data be accepted. Many commenters did not believe the services used in the crosswalks were analogous to the services described in the remote monitoring code set, including that the remote monitoring services are more comprehensive in the crosswalk codes. Commenters were concerned that the lower valuations may reduce incentives for thorough set up, education, and treatment management services. Some commenters stated that devices represented in the crosswalk were not analogous to the universe of devices used in RPM and RTM services. Commenters stated that some devices include enhanced features such as built-in internet connectivity, automatic data transmission capabilities, the generation of clinically actionable alerts, and connectivity capabilities in otherwise connectivity-limited areas. Commenters believed such devices were undervalued in the proposed crosswalk. A few commenters commented that RPM programs would be incentivized to adopt hardware based solely on price rather than devices selected for clinical benefit and recommended CMS base reimbursement on the capability of the device. Some commenters requested CMS disclose the data used to inform the final valuation of codes. Many commenters expressed concern that the proposed crosswalk of codes did not take into account fixed costs practices incur to support RPM and RTM programs, including infrastructure upkeep and connectivity costs, and costs related to accessing device-specific platforms and data generated from devices. Some commenters recommended CMS carry the current values forward while the revaluation is completed or phase-in any revaluation codes over a period of multiple years.

Response: We thank commenters for this additional information. The AMA informed CMS that in response to our concerns over a lack of data to inform accurate valuation of these services, all 19 RPM and RTM codes will have their practice expense reviewed at the January 2027 RUC meeting. We look forward to reviewing the information from the RUC, as well as any additional information that interested parties provide regarding the costs of these services for future rulemaking. We would also like to clarify that, for many of these remote monitoring CPT codes, the phase-in of significant RVU reductions and its associated adjustment will be applied (cite PE step 19). Section 1848(c)(8) of the Act requires CMS to phase-in decreases in total RVUs for a service that is not a new or revised code over two years if the RVUs would otherwise be decreased by an estimated amount equal to or greater than 20 percent. Since a 19 percent reduction is the maximum 1-year reduction for any service not described by a new or revised code, many of these changes will be phased in over multiple calendar years.

After consideration of public comments, we are finalizing the work and direct PE inputs as proposed for CPT codes 99445, 99453, 99454, 98975, 98976, 98977, 98984, and 98985.

Comment: A few commenters requested that CMS clarify the status and valuation of CPT codes 98978 and 98986.

Response: As discussed in the proposed rule, CPT codes 98978 and 98986 will be actively priced beginning in CY 2027. Since these codes were formerly contractor priced, they are considered to be ''new or revised'' codes and therefore the phase-in transition does not apply like it does to the other remote monitoring codes (for additional information regarding the phase-in of significant RVU reductions, we direct readers to the CY 2016 PFS final rule (80 FR 70927 through 70929)). In the

proposed rule, the valuation of CPT codes 98978 and 98986 was lower than the RTM device supply codes for other conditions. Due to being assigned different indirect PE allocations in the NPRM, CPT codes 98978 and 98986 had different valuations. We agree with commenters data that these codes do not have drastically different resource costs than RTM device supply codes for other conditions and that CPT codes 98978 and 98986 should be treated like other device supply codes. As discussed in the CY 2026 PFS final rule, we continue to believe that since the device is supplied to the beneficiary for the full 30-day period, regardless of the number of days that data is transmitted, these codes should be assigned the same valuation.

After consideration of public comments, for CY 2027, we are finalizing that CPT codes 98978 and 98986 be crosswalked to CPT code 98977 to ensure that all three codes share the same PE RVU.

Comment: Some commenters expressed concern that the proposed reimbursement valuation changes do not adequately recognize the clinical resources required to furnish clinically meaningful RPM and RTM services. Several commenters suggested that the proposals to eliminate expenses associated with clinical labor based on an assumption that a typical clinical workflow for some services would not involve clinical staff time, were inherently in tension with other proposals to only allow payment for RPM or RTM services when furnished by clinical staff employed by the practice. Many commenters also identified that clinical staff time is specified in the code descriptors for these services.

Response: We thank commenters for the additional information regarding the typical clinical workflow for these services. After reviewing this information, we agree with commenters that clinical staff are often used when furnishing treatment management services for remote physiologic and remote therapeutic monitoring.

After consideration of public comments, we are not finalizing as proposed to eliminate direct PE inputs for CPT codes 99470, 99457, 99458, 98979, 98980, and 98981.

(f) Comment Solicitation in the Proposed Rule

We have concerns about the administrative burden of the numerous remote monitoring codes and proliferation of this code family. We also continue to work to implement recommendations from the recent OIG reports that we are concerned cannot be fully resolved with the current coding structure of the remote monitoring code family, such as ensuring that beneficiaries receive all components of the remote monitoring service. For example, the OIG report found that, ''About 43 percent of enrollees who received remote patient monitoring did not receive all 3 components of it, raising questions about whether the monitoring is being used as intended.'' (Additional Oversight of Remote Patient Monitoring in Medicare Is Needed [17]).

We also considered, and sought comment on, bundling CPT codes 99453, 99445, 99454, 99091, 99470, 99457, 99458, 98975, 98984, 98976, 98985, 98977, 98986, 98978, 98979, 98980, and 98981 through the creation of new codes that describe initial set up and monthly monitoring/management for RPM and RTM, respectively. For payment for remote monitoring services under the PFS, we also considered, and sought comment on, the creation of four new HCPCS G-Codes:

- GRPM1: RPM initial set-up and patient education.
- GRPM2: Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), per calendar month, including:

++ Device(s) supply with daily recording(s) or programmed alert(s) transmission.

++ 2 or more days of data transmission.

++ Treatment management services, requiring at least one real-time interactive communication with the patient/caregiver; time totaling at least 20 minutes.

- GRTM1: RTM initial set-up and patient education.
- GRTM2: Remote monitoring of therapeutic parameter(s) (e.g., therapy adherence, therapy response, digital therapeutic intervention), per calendar month, including:

++ Device(s) supply for data access or data transmissions.

++ 2 or more days of data transmission.

++ Treatment management services, requiring at least one real-time interactive communication with the patient or caregiver; time totaling at least 20 minutes.

We sought comment on these HCPCS G-codes and also sought comment on any other revisions needed to the code descriptors to reflect the necessary service elements for this code family. These HCPCS G-codes would adopt all current conditions of payment for the remote therapeutic and remote physiologic codes finalized in prior rulemaking, as well as the proposed established patient, initiating visit, or supervision or both requirements outlined earlier in this section, if finalized. As drafted, all service elements outlined in the G-code descriptors would be required each calendar month. We sought public comment on these HCPCS G-codes.

The creation of these G-codes could alleviate administrative burden, as this would reduce the number of remote monitoring codes from 17 to four. These HCPCS G-codes would also ensure that beneficiaries receive treatment management services when receiving remote monitoring services. According to the OIG Reports, billing for Remote Patient Monitoring in Medicare [18] and Additional Oversight of Remote Patient Monitoring in Medicare Is Needed,[19] some beneficiaries do not regularly receive treatment management services. The OIG Report, Additional Oversight of Remote Patient Monitoring in Medicare Is Needed,[20] also stated that 43 percent of enrollees who received remote patient monitoring did not receive at least one of the three components (patient education and set-up, device supply, and treatment management). Although we have not required that providers bill for all three components, this data from the OIG Report raises questions about how these services are being used. By incorporating device supply, data transmission, and treatment management into one code, we could ensure that those service elements are always provided.

In the CY 2024 PFS final rule (88 FR 79071 through 79073), we finalized the policy to add the suite of services that comprise RPM and RTM services to the general care management code, G0511 beginning January 1, 2024 as the requirements for RPM and RTM services are similar to the non-face-to-face requirements for the general care management services furnished in RHCs and FQHCs. Beginning January 1, 2025, RHCs and FQHCs are required to bill the individual codes that make up the general care management HCPCS code, G0511 (89 FR 97998 through 98010). Accordingly, we sought comment on

[17] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/.*

[18] *https://oig.hhs.gov/reports/all/2025/billing-for-remote-patient-monitoring/.*

[19] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/.*

[20] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/.*

implementing these HCPCS G-codes in RHCs and FQHCs.

We sought comment on valuation for these HCPCS G-codes. For GRPM1 and GRTM1, which could be PE-only codes describing RPM and RTM initial set-up and patient education on use of equipment, respectively, we could crosswalk the direct PE inputs from CPT code 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*). We sought comment on this valuation, specifically information regarding the typical clinical workflow for the initial set-up and patient education on the use of equipment services used in furnishing RPM or RTM and their associated costs.

For GRPM2, we could crosswalk the work RVU input of 0.61 RVUs from CPT code 99457 and the direct PE inputs from CPT code 99474 (*Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient*).

For GRTM2, we could crosswalk the work RVU input of 0.62 RVUs from CPT code 98980 and the direct PE inputs from CPT code 93270 (*External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)).*

We received public comments on this comment solicitation. We appreciate the commenters for their comments. After consideration of public comments, we will take the comments into consideration for possible future rulemaking.

(49) National Payment for Non-Sheet Form Skin Substitutes

In the CY 2026 PFS final rule (90 FR 49500), we finalized contractor pricing for non-sheet form skin substitutes. We stated that these products have the potential to be payable as skin substitutes; but that the units, as expressed in a product's coding, are difficult to standardize for payment purposes. Therefore, we finalized that we would maintain the current coding mechanism for these products and would direct the Medicare Administrative Contractors (MACs) to determine appropriate payment, which is generally consistent with how these products are currently paid. We stated that we would continue to evaluate payments for these products to determine if an alternative payment methodology may be better suited to non-sheet products.

Based on ongoing analysis and feedback from internal and external interested parties, we have come to believe that, on the balance, the resource costs per cm^2 for non-sheet form skin substitutes is consistent with the resource costs associated with sheet form skin substitutes. For non-sheet skin substitute products, cm^2 reflects the wound surface area treated rather than the physical dimensions of the product. Therefore, for CY 2027, we proposed to nationally price the non-sheet form skin substitutes consistent with the payment rates associated with the sheet form skin substitutes. For a list of the non-sheet form skin substitutes, please refer to the skin substitutes section located on the CMS website (*https://www.cms.gov/medicare/payment/fee-schedules/physician-fee-schedule/skin-substitutes*).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters raised concerns with our previously finalized skin substitute policy in the CY 2026 PFS Final Rule. These commenters stated specific concerns with the decision to weigh the national payment rate for sheet form skin substitutes of $127.14 per cm^2 for CY 2026 using product-specific hospital outpatient data as they believe it is not indicative of true costs across both settings of care. Commenters also mentioned they believe the $127.14 per cm^2 payment rate is too low. Additionally, commenters noted that CMS should not update the skin substitute payment rate using ASP data and instead use an inflationary update to ensure increases in manufacturer costs are appropriately captured in the payment rate. Lastly, some commenters also suggested CMS should remove the geographic adjustments to skin substitute products serviced in office settings due to patient access issues.

Response: We appreciate the feedback expressed by commenters regarding their concerns about our overall approach to payment for skin substitute products. However, we note that we did not propose any changes to the payment rate itself nor any changes to how the payment rate is calculated or updated. Instead, we proposed in the CY 2027 PFS Proposed Rule to establish the same national payment rate for non-sheet skin substitutes that is consistent with the payment rate established for the sheet form skin substitutes.

Comment: A few commenters requested CMS to clarify what payment amount will be used for the non-sheet form skin substitute products.

Response: The same rate established for the sheet-form skin substitutes of $127.14 per cm^2 will apply for the non-sheet form skin substitute products.

Comment: Many commenters raised concerns that measuring non-sheet form skin substitute products per cm^2 does not fully account for three-dimensional wound characteristics, including depth and volume. Additionally, a few commenters suggested that CMS recognize the concepts of Internal Surface Area (ISA) and Therapeutic Treatment Area (TTA) as described in the recently published wound-care consensus recommendations as an alternative unit of measure.

Response: We acknowledge commenters' concerns that non-sheet skin substitute products may be used to treat wounds of varying depth and volume. However, we do not believe that these factors prevent the use of a per cm^2 payment methodology as a per cm^2 payment rate accounts for differences in wound surface area that can be used to estimate volume. We therefore do not believe that differences in product form, or variations in wound depth and volume alone, necessarily warrant a separate payment methodology for non-sheet products.

Comment: A few commenters questioned that the per cm^2 approach for non-sheet form skin substitute does not align with the products' code descriptors because they contain various forms of measurement such as, ''per mL,'' ''per cc,'' or ''per mg.'' These commenters requested CMS to clarify how the proposed nationally priced payment approach of per cm^2 for non-sheet skin substitute products would correspond with the variety of measurements displayed in the current code descriptors.

Response: We acknowledged in the CY 2026 PFS final rule that non-sheet skin substitute products may be described and supplied using units other than square centimeters, including milliliters, cubic centimeters, milligrams, or other units (90 FR 49500). Similar to how non-sheet form skin substitute products are currently being paid under MAC pricing with no modifications to the code descriptors, we believe it is appropriate to maintain existing HCPCS descriptors that

accurately reflect the form and quantity of the product. Our proposal to establish a per cm^2 payment for non-sheet form skin substitute products based on wound surface area does not require that the product itself be packaged or marketed in a per cm^2 unit.

Comment: Many commenters brought to our attention the proposed rule provides limited instruction regarding the interaction between the new HCPCS application codes (G0681–G0684) and the corresponding non-sheet form skin substitute product HCPCS codes. Some of these commenters urged CMS to create national payment rates for G0681–G0684, with the same RVUs as the current administration codes for sheet form skin substitutes described under CPT codes 15271–15278.

Response: We thank commenters for their feedback and clarify that HCPCS application codes G0681–G0684 are only to be used for non-sheet form skin substitute products. CMS stated in the CY 2027 PFS Proposed Rule that we would align the same payment rate for sheet form skin substitute products as we would for the non-sheet form skin substitute products. We maintain this consistency is relevant for the application codes for non-sheet form skin substitutes described under HCPCS G0681–G0684. Therefore, CMS will establish a national payment rate for the non-sheet form skin substitute application codes G0681–G0684 similar to how CPT codes 15271–15278 are currently paid.

Comment: Some commenters requested CMS provide additional analysis, including HCPCS-defined billing units, price basis, cost data, conversion assumptions, and sensitivity analyses used to reach its resource-equivalence conclusion. These commenters stated our proposal is unsupported and additional information on analyses is required to understand how CMS came to the approach that non-sheet form skin substitutes can be treated on a per cm^2 basis.

Response: We thank commenters for their feedback. However, we disagree that our proposal to standardize payment for non-sheet form skin substitute products reflects an unsupported assumption of resource equivalence. In the CY 2026 rulemaking, we specifically sought comment on how non-sheet form skin substitute products furnished in units such as milliliters, cubic centimeters, and milligrams could be incorporated into a standardized payment methodology. After taking into consideration the comments received from the CY 2026 PFS Proposed Rule, we determined that additional evaluation was warranted and finalized contractor pricing for CY 2026 while we continued to assess an appropriate methodology. Our CY 2027 proposal reflects that continued evaluation and feedback from interested parties. We therefore believe our proposal effectively demonstrates the progression of our consideration of non-sheet form skin substitute products.

Comment: Many commenters were in support of our proposal to nationally price non-sheet form skin substitutes consistent with the payment rate associated with sheet form skin substitutes. These commenters agreed with CMS's assessment that the resource costs per cm^2 for non-sheet form skin substitutes is consistent with the resource costs associated with sheet form skin substitutes. Additionally, commenters noted our proposal would protect beneficiaries and ensure good value for the Medicare program and thus taxpayers. Lastly, commenters also stated they believe our proposal will continue to address unsustainable spending growth and clinical inconsistency in the skin substitute product space.

Response: We thank commenters for their support and reiterate our commitment to protecting beneficiaries, promoting appropriate use of Medicare resources, and safeguarding taxpayer dollars while further preventing fraud, waste, and abuse.

After consideration of the public comments, we are finalizing our proposal to nationally price the non-sheet form skin substitutes on a per cm^2 basis, consistent with the payment rates associated with the sheet form skin substitutes.

(50) Smoking and Tobacco Use Cessation (CPT Codes 99406, 99407) and Structured Assessment, Brief Intervention, and Referral to Treatment (SBIRT) (HCPCS Codes G2011, G0396, G0397)

The Trump Administration Executive Order, ''Establishing the President's Make America Health Again Commission''[21] is a top priority for CMS, as such we continue to focus on the prevention and management of chronic disease. Chronic disease remains a significant public health concern, with three in four American adults having at least one chronic condition, and more than half having two or more chronic conditions. Many preventable chronic diseases are caused by a short list of risk behaviors, including smoking, poor nutrition, physical inactivity, and excessive alcohol use.[22] These patterns reinforce the need for accessible behavioral health services that can help individuals reduce these risk behaviors.

In the CY 2024 PFS final rule (88 FR 79006 through 79010), we finalized an increase in the valuation for timed behavioral health services under the PFS by applying an upward adjustment of 19.1 percent to the work RVUs for time-based psychotherapy codes payable under the PFS. This increase is being implemented over a 4-year transition period.

We believe similar adjustments are warranted for smoking and tobacco use cessation, CPT codes 99406 (*Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes*) and 99407 (*Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes*) and screening, brief intervention, and referral to treatment (SBIRT) services, HCPCS codes G2011 (*Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention, 5–14 minutes*), G0396 (*Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes*), and G0397(*Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and intervention, greater than 30 minutes*).

Smoking and tobacco cessation and SBIRT services are evidence supported behavioral health interventions. Quitting smoking provides immediate health improvements including lowering the likelihood of developing lung cancer and other smoking-related cancers, and reduces the risks of coronary heart disease, stroke, and chronic obstructive pulmonary disease. Evidence based smoking and tobacco cessation treatments are effective, including the combination of behavioral counseling and medication therapy.[23] SBIRT effectively addresses substance use. In primary care and other clinical settings, SBIRT has been shown to help decrease unhealthy substance use and misuse.[24]

The smoking and tobacco cessation services (CPT codes 99406 and 99407) and SBIRT services HCPCS codes G0396 and G0397 were last valued in 2008, and the SBIRT service HCPCS code G2011 was created and last valued in

[21] *https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/.*

[22] *https://www.cdc.gov/chronic-disease/about/index.html.*

[23] *https://progressreport.cancer.gov/prevention/tobacco/cessation-aids#jump-links-field-background.*

[24] *https://pmc.ncbi.nlm.nih.gov/articles/PMC5551279/.*

2019. Given the evidence supported role these services play in preventing and managing chronic disease and behavioral health conditions including alcohol and/or substance misuse, we believe that valuation should more accurately reflect the clinical intensity and work associated with these time-based services.

Therefore, we proposed applying the same upward adjustment of 19.1 percent to the work RVUs for these time-based services aligning with the adjustments made to the time-based psychotherapy codes, in conjunction with the fourth and final year of the phase-in for time-based psychotherapy codes that we finalized in the CY 2024 PFS final rule (88 FR 79006 through 79010). Although the upward adjustment of 19.1 percent for the time-based psychotherapy codes has been implemented over a 4-year period, with CY 2027 being the fourth year, we proposed to apply the full 19.1 percent to smoking and tobacco use cessation services and SBIRT services in this final year of the transition. This approach ensures that these services are brought into alignment with the psychotherapy codes at the completion of the 4-year phase-in timeline, rather than initiating a new multiyear phase-in period. We proposed to refine the work RVU of smoking and tobacco use cessation services codes as follows: for CPT code 99406 by increasing the work RVU to 0.29 from the current 0.24, and CPT code 99407 by increasing the work RVU to 0.60 from the current 0.50; and for the SBIRT services codes, we proposed to refine the work RVU as follows, for HCPCS code G2011 by increasing the work RVU to 0.39 from the current 0.33, for HCPCS code G0396 by increasing the work RVU to 0.77 from the current 0.65, and for HCPCS code G0397 by increasing the work RVU to 1.55 from the current 1.30.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly in support of the proposed upward adjustment of 19.1 percent to the work RVUs for Smoking and Tobacco Use Cessation (CPT codes 99406, 99407) and SBIRT (HCPCS codes G2011, G0396, G0397) services. Commenters indicated that these services are important for prevention, chronic disease management, behavioral health integration, and improved patient outcomes.

Response: We thank the commenters for their support. Additionally, we are clarifying that although the proposed rule described SBIRT as *screening, brief intervention, and referral to treatment,* for purposes of PFS payment, SBIRT, specifically HCPCS codes G2011, G0396, and G0397, are defined as *structured assessment, brief intervention, and referral to treatment for substance use disorders.*

Comment: Many commenters recommended that similar upward valuation adjustments should also be applied to other time-based behavioral health codes, including neurobehavioral status exam, developmental test administration, psychological testing evaluation, neuropsychological testing evaluation, and test administration and scoring services. Some of the commenters indicated that these codes describe time-based behavioral health services and are intended to inform diagnosis and care recommendations for a wide range of medical and psychological issues. The commenters continued to state that lagging values for these services impacts patient access and discourages workforce development in these areas.

Response: We thank commenters for this feedback. After consideration of the comments, we continue to believe, as stated in the CY 2024 PFS final rule (88 FR 79009), that the codes referenced by the commenters are describing psychological and neuropsychological testing services, which are distinct from the psychotherapy services with regard to the nature of the work, such that, these codes describing psychological and neuropsychological testing services are not necessarily timed services that are provided without assistance from clinical staff. Therefore, these services do not fit the same criteria as the services addressed in the CY 2024 PFS final rule, which formed the basis for increasing the valuation of smoking and tobacco cessation and SBIRT services. However, we may consider updates to the valuation of these services for future rulemaking.

Comment: Several commenters supported applying the full upward adjustment of 19.1 percent to the work RVUs without an additional phase-in period. However, a couple of commenters recommended a phase-in approach in the work RVU increase, similar to how the psychotherapy codes were phased in over a four-year transition period.

Response: We thank commenters for this feedback. After consideration of the comments, we will apply the full 19.1 percent to the work RVUs to smoking and tobacco use cessation services and SBIRT services in this final year of the of the phase of these updates.

Comment: A few commenters requested that CMS re-evaluate and apply comparable adjustments to HCPCS code G2213 (*Initiation of medication for the treatment of opioid use disorder in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive services (list separately in addition to code for primary procedure)*) for consistency with SBIRT codes since CMS originally established the valuation of G2213 using a direct crosswalk to HCPCS code G10397, one of the SBIRT codes. A commenter recommended for CMS to apply the same work RVU adjustment to HCPCS codes G0442 (*Annual alcohol misuse screening, 5 to 15 minutes*) and G0443 (*Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes*), in future rulemaking.

Response: We thank commenters for this feedback; we may consider updates to the valuation of these services in future rulemaking.

Comment: A commenter recommended replacing HCPCS G0396 and G0397 with CPT codes 99408 and 99409, to assist with reducing administrative burden due to recognition of different codes by different payers.

Response: We thank the commenter for this feedback. As explained in the CY 2008 PFS final rule (72 FR 66371) and CY 2013 PFS final rule (77 FR 68955), the code descriptions for CPT codes 99408 (*Alcohol and/or substance (other than tobacco) abuse structured screening (e.g., AUDIT, DAST), and brief intervention (SBI) services; 15 to 30 minutes*) and 99409 (*Alcohol and/or substance (other than tobacco) abuse structured screening (e.g., AUDIT, DAST), and brief intervention (SBI) services; greater than 30 minutes*), suggest that these CPT codes may describe services that include screening services, and the screening component would not meet the statutory requirements for coverage under section 1861(a)(1)(A) of the Act. Screening services are not covered by Medicare without specific statutory authority, therefore, we will continue to use HCPCS codes G0396 and G0397.

Comment: A commenter recommended that CMS review and revalue HCPCS codes G3002 and G3003 as a potentially misvalued services.

Response: Commenters are welcome to submit codes by February 10th of the coming year for consideration as potentially misvalued services in the CY 2028 PFS proposed rule. See the discussion regarding Potentially Misvalued Services Under the PFS in this final rule for more information on how to submit a nomination for a potentially misvalued code.

Comment: A few commenters supported the proposal to increase the work RVUs for Smoking and Tobacco Use Cessation and SBIRT and requested CMS ensure that the change does not disrupt existing community health center (CHC) prospective payment system (PPS) reimbursement. The commenters also indicated that CHCs do not currently have a reimbursement pathway for SBIRT and recommend establishing a pathway for CHCs to receive payment for SBIRT.

Response: We thank commenters for the support. We do not intend for the changes in PFS valuation of Smoking and Tobacco Use Cessation and SBIRT to affect the CHC PPS payment for these services. The CHC reimbursement pathway for SBIRT is outside the scope of this proposal.

After consideration of public comments, we are finalizing our proposal to apply the same upward adjustment of 19.1 percent to the work RVUs for these time-based services, Smoking and Tobacco Use Cessation (CPT codes 99406, 99407) and SBIRT (HCPCS codes G2011, G0396, G0397), aligning with the adjustments made to the time-based psychotherapy codes, in conjunction with the fourth and final year of the phase-in for time-based psychotherapy codes that we finalized in the CY 2024 PFS final rule (88 FR 79006 through 79010).

(51) Psychiatric Collaborative Care Model (CoCM) (CPT Codes 99492, 99493, 99494, G2214) and APCM BHI add-on Codes (HCPCS Codes G0568, G0569)

Patients with chronic health conditions are ''more likely to have related behavioral health concerns and find it easier to improve chronic conditions when these concerns are also addressed.''[25] Integrating behavioral health with primary care has been shown to improve outcomes like reductions in depression severity and enhancing patient's experience of care.[26]

In the CY 2017 PFS final rule (81 FR 80230), we established separate payment for three services, HCPCS codes G0502 (*Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan if recommended; entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies*), G0503 (*Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies; monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment*), and G0504 (*Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (list separately in addition to code for primary procedure); (use G0504 in conjunction with G0502, G0503*), used to bill for monthly services furnished using the psychiatric collaborative care model (CoCM), an evidence-based approach to behavioral health integration that enhances ''usual'' primary care by adding care management support and regular psychiatric inter-specialty consultation. The G-codes were valued to account for the work of the treating physician or other qualified health care professionals, based on a direct crosswalk to the work values for the complex Chronic Care Management (CCM) services, CPT codes 99487 (*Complex chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.*) and 99489 (*Complex chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*). The valuation also accounted for the work of the psychiatric consultant, based on an estimated 10 minutes of psychiatric consultant time per patient per month, such that the work RVU was based on a crosswalk to the work per minute of a level 3 established patient office visit. These G-codes were replaced by CPT codes 99492, 99493, and 99494, which we established for payment under the PFS in the CY 2018 PFS final rule (82 FR 53077 and 53078). In the CY 2021 PFS final rule (85 FR 84548 through

[25] *https://integrationacademy.ahrq.gov/about/integrated-behavioral-health#:~:text=Integrated%20behavioral%20health%20offers%20many,these%20concerns%20are%20also%20addressed.*

[26] Balasubramanian, Bijal, Deborah Cohen, Katelyn Jetelina, Miriam Dickinson, Melinda Davis, Rose Gunn, Kris Gowen, Frank DeGruy 3rd, Benjamin Miller, Larry Green. ''Outcomes of Integrated Behavioral Health with Primary Care.'' J Am Board Fam Med. 2017 Mar-Apr;30(2):130–139.doi: 10.3122/jabfm.2017.02.160234.

84574), we increased the work RVUs for certain CPT codes that rely upon or are analogous to office/outpatient evaluation and management (O/O) (E/M) visits, consistent with the increases in values finalized for O/O E/M visits for CY 2021, such that the CoCM services valuation were updated as follows: 99492 (work RVU increased from 1.70 to 1.88), 99493 (work RVU increased from 1.53 to 2.05) and 99494 (work RVU remained 0.82).

Interested parties have expressed concerns regarding the current valuation of CoCM and requested revaluation for these services. They stated that the current valuation undervalues the medical decision-making performed by the billing practitioner and psychiatric consultant and undervalues the labor rates assigned to the CoCM service. The interested parties recommend valuing the work RVUs for the two physicians or other qualified health care professional based on a blended rate based on level 4 and 5 O/O E/M visits based on medical decision-making, CPT codes 99204 and 99205 (for new patients), and 99214 and 99215 (for established patients), to account for the medical decision-making required for the CoCM service. CPT code 99492 would be adjusted from a work RVU of 1.88 to 3.67, 99493 from a work RVU of 2.05 to 2.99, and 99494 from a work RVU of 0.82 to 1.50. The interested parties noted that their recommendation would result in a higher work RVU for the initial psychiatric collaborative care management service, CPT code 99492, compared to the subsequent psychiatric collaborative care management service, CPT code 99493, since the initial month generally involves a new patient requiring more medical decision making. The interested parties recommend valuing CPT code 99494 at 50 percent of CPT code 99493. In addition, the interested parties requested refinements to the direct PE inputs, specifically for the Behavioral Health Care Manager clinical labor type (L057B). They recommend increasing the clinical labor value for Behavioral Health Care Manager (L057B) from a per minute rate of $0.57 to $0.70 per minute by crosswalking the valuation to CORF social worker/psychologist (L045C), rather than to the genetic counselors (L057A) which was used when the original CoCM G-codes were established.

After reviewing the feedback from the interested parties, we reviewed the valuation of the CoCM codes and considered Medicare claims data for levels 3 through 5 O/O E/M services. The Medicare claims data shows that level 5 E/M visits (CPT codes 99205 and 99215), which represent the highest complexity of evaluation and management services, are billed substantially less frequently than level 3 E/M services (CPT codes 99203 and 99213) and level 4 E/M services (CPT codes 99204 and 99214). Based upon this billing pattern, we believe that a blended level 3 and 4 E/M rate would be more appropriate to value CoCM. Therefore, we proposed to refine the work RVUs of CoCM as follows: CPT codes 99492 would be adjusted from a work RVU of 1.88 to 2.75, 99493 from a work RVU of 2.05 to 2.26, and 99494 from a work RVU of 0.82 to 1.13, which is 50 percent of 99493.

We also proposed conforming changes to the valuation of HCPCS codes G2214, G0568, and G0569, which also describe psychiatric collaborative care services. For HCPCS code G2214 (*Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional),* we proposed to refine the work RVU from 0.77 to 1.13, representing one half of the time described by the existing code that describes subsequent months of CoCM services (CPT code 99493), consistent with how the code was valued in the CY 2021 PFS final rule (85 FR 84547 through 84548). For HCPCS code G0568 (*Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies (list separately in addition to the advanced primary care management code*)), we proposed to refine the work RVU from 1.88 to 2.75, aligning with the direct crosswalk to the work RVU of CPT code 99492. For HCPCS code G0569 (*Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment (list separately in addition to advanced primary care management code)),* we proposed to refine the work RVU from 2.05 to 2.26, as this code was valued based on a direct crosswalk to the work RVU of CPT code 99493.

Additionally, consistent with the changes proposed for CPT codes 99492–99494, we proposed refinements to the direct PE inputs for HCPCS codes G2214, G0568, and G0569 by revaluing the rate of Behavioral Health Care Manager (L057B) with a per minute rate of $0.57 to $0.70. This proposed change is based on a crosswalk of valuing Behavioral Health Care Manager (L057B) to the clinical labor CORF social worker/psychologist (L045C), as opposed to basing the rates to genetic counselors as discussed in the CY 2017 final rule (81 FR 80350). We also note that HCPCS codes G2086 (*Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month*), G2087 (*Office-based treatment for opioid use disorder, including care coordination, individual*

therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month), and G2088 (*Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (list separately in addition to code for primary procedure))* include clinical labor minutes for a Behavioral Health Care Manager (L057B), and therefore as part of this proposal, we also proposed that that same increase in valuation for L057B from $0.57 to $0.70 would also apply to HCPCS codes G2086–G2088.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly in support of the proposal to increase payment for CoCM (CPT codes 99492, 99493, 99494, G2214) and conforming changes to the APCM add-on codes (HCPCS codes G2214, G0568, and G0569). The commenters indicated that the current payment rates are undervalued. A commenter indicated the current CoCM rates are insufficient to sustain school-based pediatric implementation in underserved communities. A commenter indicated that the proposed increase would bring payment closer in line with the real resources required and would meaningfully strengthen the incentive for practices to adopt and sustain this model.

Response: We appreciate the support for our proposal.

Comment: Several commenters indicated that CMS' proposed blended level 3 and 4 E/M valuation remains inadequate. Some of the commenters recommend a blend of level 4 and 5 E/M rate to better reflect the clinical complexity and intensity of CoCM which would result in a work RVU of 3.67 for CPT code 99492, a work RVU of 2.99 for CPT code 99493, and a work RVU of 1.50 for CPT code 99494 and HCPCS code G2214. The commenters state that if CMS could not adopt the full work RVU recommendation, they urged a valuation floor at no less than a level 4 E/M valuation: a work RVU of 3.25 for CPT code 99492, a work RVU of 2.56 for CPT code 99493, and a work RVU of 1.28 for CPT code 99494 and HCPCS code G2214. The commenters recommended related increases for HCPCS codes G0568 and G0569. The commenters stated that the level 4 E/M benchmark more appropriately captures the clinical complexity, intensity and care coordination inherent in CoCM services than the current proposal.

Response: We appreciate the feedback regarding the valuation of CoCM services. We were persuaded by their comments and will finalize the CoCM codes (CPT codes 99492, 99493, 99494, and HCPCs code G2214) and APCM add-on codes (HCPCS codes G0568, G0569) based on the level 4 E/M valuation. Specifically we are finalizing a work RVU of 3.25 for CPT code 99492, a work RVU of 2.56 for CPT code 99493, work RVU of 1.28 for CPT code 99494 and HCPCS code G2214, a work RVU of 3.25 for HCPCS code G0568, and a work RVU of 2.56 for HCPCS code G0569.

Comment: Several commenters recommended increasing the valuation of the general behavioral health integration (BHI) codes (CPT code 99484 and HCPCS code G0323), alongside the CoCM codes. Some of the commenters stated that the general BHI codes should remain model-agnostic to support diverse evidence-based care models and support diverse workforce participation. Some commenters also recommended related increases in the valuation of HCPCS G0570, and office-based treatment for opioid use disorder service HCPCS code G2086, G20876 and G2088.

Response: We thank commenters for their input and welcome additional feedback on the valuation of general BHI services and office-based treatment for opioid use disorder services. We may consider valuation updates for these services in future rulemaking.

Comment: Commenters were overwhelmingly in support of increasing the Behavioral Health Care Manager (L057B) clinical labor rate from $0.57 to $0.70 per minute using the CORF social worker/psychologist crosswalk. Commenters indicated that this adjustment more accurately reflects the qualifications, training, and responsibilities of behavioral health care managers.

Response: We appreciate the support for this proposal.

Comment: A few commenters recommended removing unnecessary requirements that limit who can provide and/or bill for integrated care, such that psychologists, social workers, nurses, and other behavioral health professionals would be able to bill and get reimbursed directly for the integrated care services they provided. A commenter requested clarification that the management of alcohol use disorder (AUD) constitutes a qualifying behavioral health integration (BHI) activity under the Advanced Primary Care Management (APCM) behavioral add-on codes (G0568, G0569, and G0570).

Response: As discussed in CY 2017 Final Rule (81 FR 80231), we believe that the CoCM services would be reported by the treating physician or other qualified health care professional and include the services of the treating physician or other qualified health professional, the behavioral health care manager who would furnish the services incident to services of the treating physician or other qualified health care professional, and the psychiatric consultant whose consultative service would be furnished incident to services of the treating physician or other qualified health care professional. The management of alcohol use disorder (AUD) may qualify as behavioral health integration (BHI) under the APCM behavioral health add-on code. Beneficiaries can receive BHI services if they have an eligible condition, such as SUD, including AUD. Therefore, when all applicable billing and service requirements are met, management of AUD may be furnished as part of BHI services under the APCM behavioral health add-on code.

Comment: A commenter recommended that CMS should ensure that remote therapeutic monitoring (RTM) for cognitive behavioral therapy and the collaborative care model are treated as complementary rather than competing pathways, because a beneficiary receiving collaborative care may also benefit from an FDA-authorized digital therapeutic, and Medicare policy should not force a choice between them

Response: CoCM and RTM may be billed concurrently when reasonable and necessary. The minutes counted for the CoCM services cannot also be counted towards other services.

Comment: A commenter encouraged CMS to explicitly recognize appropriately structured, evidence-based group intervention as permissible behavioral health care manager activities within CoCM.

Response: Please refer to the Shared Medical Appointments (SMA) section for a more detailed discussion. If the billing practitioner determines a shared medical appointment is the appropriate route for providing CoCM services for a patient, and the patient consents to the SMA, assuming all SMA criteria are met, the billing practitioner may bill the service using the SMA procedure code. We would also note that services provided under an SMA cannot be billed separately because the minutes of the service counted toward the SMA service code cannot also be counted for any other billed service.

After consideration of the public comments, we find many of the commenters' suggestions persuasive and are finalizing as proposed with a

modification to base the valuation for the CoCM codes and APCM add-on codes on a level 4 E/M visit. We are also finalizing revaluing the rate of the Behavioral Health Care Manager (L057B) clinical labor type with a per minute rate of $0.70.

(52) Tympanostomy (HCPCS Code G0561)

In January 2026, the Practice Expense (PE) Subcommittee reviewed the following practice expense only add-on HCPCS code G0561 (*Tympanostomy with local or topical anesthesia and insertion of a ventilating tube when performed with tympanostomy tube delivery device, unilateral)* on the Medicare Physician Fee Schedule which is currently contractor priced.

The RUC recommended one direct PE input for a new supply item, an Automated PE tube delivery device (SD395), and submitted invoices to price the supply at $497.50. We proposed the RUC-recommended direct PE input for HCPCS code G0561 without refinement.

The RUC did not recommend, and we did not propose a work RVU for HCPCS code G0561, which has been designed as a PE only service.

We received public comments on our proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter explained that because a bilateral procedure requires two separate, single-use tympanostomy tube delivery devices—one for each ear—application of the standard 150-percent bilateral adjustment would recognize only half the cost of the second device. The commenter noted that if the 150-percent bilateral payment methodology were applied to HCPCS code G0561, it would recognize only 50 percent of the practice expense (PE) value of the second device, despite the fact that the second device is purchased and consumed at 100 percent of its cost. The commenter requested that CMS establish a payment and claims-processing methodology for HCPCS code G0561 that recognizes 100 percent of the PE value associated with each separately utilized single-use device in a bilateral procedure, along with clear guidance on billing units and modifiers.

An additional commenter recommended addressing this issue through unit-based reporting rather than a modifier, explaining that the automated tube delivery device described by HCPCS add-on code G0561 is supplied, purchased, and billed as a discrete unit, meaning that modifier 50 would not be appropriate to use when reporting a bilateral case. This commenter stated that when the primary tympanostomy procedure (CPT code 69433) is performed bilaterally, HCPCS code G0561 should be reported with two units to reflect the utilization of two automated tube deployment devices, rather than by appending modifier 50.

Another commenter, while supporting the proposed valuation, requested that CMS ensure that the G code is paid in full for both ears so that the provider is not unintentionally disadvantaged by application of a multiple procedure payment reduction policy, reasoning that in cases where the G code is reported twice for bilateral procedures, two devices are used, so the G code should be reimbursed in full, once for each ear, when performed bilaterally.

Response: We appreciate commenters bringing this issue to our attention and agree that the standard bilateral payment adjustment methodology does not appropriately reflect the resource costs associated with HCPCS code G0561 when the underlying tympanostomy procedure is performed bilaterally. As commenters explained, HCPCS code G0561 describes the use of a discrete, single-use automated tympanostomy tube delivery device. When the primary procedure (CPT code 69433) is performed on both ears, two separate devices are purchased and consumed in their entirety—one for each ear. The standard bilateral adjustment under indicator ''1,'' which pays 100 percent for the first side and 50 percent for the second, is designed for procedures in which the bilateral performance generates efficiencies relative to a single-sided procedure (for example, shared setup, positioning, or overhead). That rationale does not apply to HCPCS code G0561, because the device used for the second ear represents a full, independent, non-reusable cost rather than an incremental or duplicative one.

We agree with commenters that reporting via modifier 50 is not well suited to this code. Because G0561 is defined and billed as a discrete per-device unit rather than as a procedure capable of being performed on paired anatomic structures in the same operative pass, we are finalizing an approach under which HCPCS code G0561 is reported with two units—rather than modifier 50 or modifiers RT/LT—when the primary procedure is performed bilaterally, consistent with the recommendation of the commenter who addressed this issue. This unit-based approach more accurately reflects that two distinct devices were supplied and used.

Consistent with this unit-based reporting methodology, we are also revising the bilateral surgery indicator assigned to HCPCS code G0561 from ''1'' to ''3.'' A bilateral indicator of ''3'' signifies that the standard bilateral payment adjustment does not apply to the code; rather, each reported unit is paid at 100 percent of the fee schedule amount, subject to any other generally applicable payment adjustments. This change ensures that both devices used in a bilateral procedure are reimbursed at their full PE value, addressing the concern raised by the first commenter that a 150-percent bilateral adjustment would otherwise recognize only 50 percent of the value of the second device.

We also agree with the commenter who requested that HCPCS code G0561 be paid in full for both ears without reduction under multiple procedure payment policies. Because each unit of HCPCS code G0561 reflects the full, independent cost of a separately purchased and consumed device rather than a duplicate or overlapping service, we do not believe it is appropriate to apply a multiple procedure payment reduction across the two reported units of this add-on code.

Comment: A commenter appreciated CMS's proposal to add supply code SD395 to the direct PE inputs for HCPCS code G0561 but stated that there are additional direct PE inputs for equipment, supplies, and labor that must be included for HCPCS code G0561. The commenter noted that when CMS originally adopted HCPCS code G0561, CMS explicitly acknowledged that the purpose of the code was to describe the additional resource costs related to higher expected intraservice work, plus the cost of the tympanostomy tube delivery device used during the tympanostomy procedure. The commenter therefore argued that it is not sufficient to adopt national pricing reflecting only the device supply cost. The commenter further stated that while it does not disagree with the establishment of supply code SD395 with an associated cost of $497.50, it strongly disagrees that the national average Medicare payment amount for HCPCS code G0561 should be less than $497.50. The commenter recommended that, if CMS requires additional time to determine appropriate additional inputs, CMS maintain contractor pricing for CY 2027 rather than finalize SD395 as the sole input.

Response: We appreciate the commenter's support for the addition of supply code SD395 to the direct PE inputs for HCPCS code G0561, and we

have considered the commenter's concerns regarding the sufficiency of this input and the recommendation to continue contractor pricing.

We disagree that contractor pricing should be maintained for HCPCS code G0561 for CY 2027. Having obtained the additional information we previously indicated was necessary (90 FR 49348), we no longer believe it is appropriate to delay the assignment of national pricing for this code. Contractor pricing is intended to serve as an interim payment mechanism while adequate information is developed to support accurate, nationally applicable direct PE inputs; it is not intended to persist indefinitely once that information becomes available.

With respect to the commenter's assertion that additional direct PE inputs for equipment, supplies, and labor beyond SD395 are necessary to fully capture the resource costs associated with HCPCS code G0561, we note that the same specialty society's RUC Advisors, who are positioned to evaluate the full scope of resources involved in furnishing this service, concluded that HCPCS code G0561 reflects additional practice expense only and specifically identified no additional physician work associated with the code. We are not aware of additional evidence in the record identifying specific equipment, supply, or labor inputs beyond those reflected in SD395 that the commenter believes should be included. To the extent the commenter possesses specific information regarding additional direct PE inputs it believes are necessary to accurately value HCPCS code G0561 or CPT code 69433, we direct the commenter to the established process for nominating a code as potentially misvalued. Under our regulations at § 414.22(b)(3), interested parties may submit a request, together with supporting evidence, that we examine a code believed to be potentially misvalued through the annual potentially misvalued code nomination process. We believe this process is the appropriate vehicle through which the commenter may submit the specific additional input information it believes supports a higher valuation, rather than through continued contractor pricing of HCPCS code G0561.

Comment: A commenter stated that they supported the RUC's recommendation to establish national pricing for HCPCS code G0561 based on direct invoice costs. The commenter submitted an invoice for $525.00 reflecting the acquisition cost of the Automated PE tube delivery device (SD395) supply and requested that CMS use this invoice to support HCPCS code G0561's pricing, rather than the proposed $497.50 supply cost.

Response: We appreciate the submission of this additional invoice associated with the SD395 supply. Rather than disregarding the earlier invoices used to establish the proposed $497.50 supply cost, however, we are instead averaging the two invoice prices together and finalizing a price of $511.25 for the SD395 supply.

After consideration of public comments, we are finalizing our proposal to adopt a new direct PE input under supply code SD395 and modify our proposed supply cost of $497.50 to $511.25. We are also finalizing our proposals to apply national pricing to HCPCS code G0561, retain it as a PE-only service, and provide payment at 100 percent of the applicable fee schedule amount for each unit when HCPCS code G0561 is reported with two units in connection with a bilateral tympanostomy procedure described by CPT code 69433.

(53) Evaluation and Management (E/M) Visit Complexity Add-On (HCPCS Code G2211)

(a) Background

In the CY 2024 PFS final rule (88 FR 78970 through 78982), we finalized separate payment for the O/O E/M visit complexity add-on code, HCPCS code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*). This policy was originally proposed in CY 2019, as part of a proposed overhaul to the E/M code set (83 FR 59628) where we proposed two codes, one for primary care and one for non-procedure specialty care. We learned that the CPT Editorial Panel and AMA RUC were planning to review and refine the O/O E/M code set, so we did not finalize this proposal or the other proposed changes to the E/M code set. The CPT Editorial Panel and AMA RUC reviewed and refined the O/O E/M code set, which were finalized by CMS in the CY 2021 PFS final rule (84 FR 62844 through 62856). We combined the two proposed complexity add-on codes into one, and we finalized separate coding and payment for HCPCS code add-on code GPC1X in the CY 2020 PFS final rule (84 FR 62854 through 62856). This became HCPCS code G2211 in the CY 2021 final rule (85 FR 84569). However, implementation of G2211 was delayed by Congress (section 113 of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, December 27, 2020) (CAA, 2021)), and we began actively paying for HCPCS code G2211 in CY 2024.

In the CY 2026 PFS final rule (90 FR 49462 through 49464), we finalized our proposal to allow HCPCS code G2211 to be billed as an add-on code with the home or residence E/M visits code family (CPT codes 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350). We finalized refinements to the code descriptor of HCPCS code G2211 *(Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to home or residence or office/outpatient evaluation and management service, new or established)* to reflect this change.

This service is intended to recognize the longitudinal relationship between the patient and the practitioner, which differentiates the E/M visit from visits that are not longitudinal in nature. As discussed in section II.E. of the proposed rule (91 FR 43842 through 44557), we are continuing to examine primary care in the PFS, and how we can appropriately recognize the resource costs of longitudinal and especially primary care, given the generality of E/M coding.

(b) Changes to the Billing Mechanism for Inherent Complexity

(i) Modifier MOD1

Since we began actively paying for HCPCS code G2211 in CY 2024, we have come to believe that the resource costs of furnishing longitudinal care for beneficiaries is not best characterized as a separate service requiring a separate code. Rather, we believe that since this work is an inherent part of the visit, it would be more accurately valued as a modifier to the base E/M code. We also believe that transitioning HCPCS code G2211 from an add-on code to a modifier will be more streamlined from an operational perspective. This should also reduce operational burden, as it will not require the submission of a separate claim line, because the modifier will be placed on the claim line for the associated E/M code. We therefore proposed to replace HCPCS

code G2211 with a modifier, which we referred to in the proposed rule as MOD1, which was a placeholder to be replaced with a two-digit HCPCS modifier. We are finalizing modifier B1 as the modifier to replace placeholder MOD1. Later in this section, we will discuss placeholder MOD2, which we are finalizing as modifier B2.

We proposed that modifier MOD1 will be billed under the same circumstances that HCPCS code G2211 is billed now. We discussed in the CY 2024 final rule (88 FR 78973) that HCPCS code G2211 was intended to characterize the associated E/M code as a service with a practitioner who serves as the continuing focal point for all needed health care services, or with medical care that is part of ongoing care related to a patient's single, serious, or complex condition. HCPCS code G2211 was meant to describe the inherent complexity of these visits that would otherwise be unaccounted for. The application of the add-on code is not based on the characteristics of particular patients (even though the rationale for valuing the code is based on recognizing the typical complexity of patient needs), but rather the relationship between the patient and the practitioner.

We proposed to match the code descriptor for HCPCS code G2211 to MOD1, with some technical changes. The new proposed modifier descriptor is: *Visit complexity inherent to new or established office/outpatient or home or residence evaluation and management service, associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.*

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed change, stating that the transition to a modifier eliminates duplicative documentation while preserving recognition of longitudinal, post-acute, and transitional care. Other commenters who supported the shift to a modifier stated that the modifiers will increase payer standardization and reduce confusion, denials, and EHR errors. Some commenters expressed concerns with the introduction of a new modifier, citing tracking and payer-adherence difficulties. Additionally, we received comments that noted that most EHR systems limit claims to four billing modifiers per code, and providers may already use all four slots in certain situations, leaving no room to add a fifth modifier.

Response: We appreciate commenters' support for the proposal and agree with commenters that the introduction of a modifier will simplify billing by reducing duplicative documentation and promoting consistency across payers. We also acknowledge the concerns regarding the administrative burden of transitioning from a standalone HCPCS code to a modifier.

Regarding the four-modifier limit some EHR systems impose, we note that the claim form itself is not limited to four modifiers. The Medicare Claims Processing Manual (CMS Internet-Only Manual, Pub. 100–04, Ch. 26) explains that the claim form has the ability to capture up to four modifiers, and if more than four modifiers are needed, providers should use modifier -99 (overflow) as the fourth modifier and enter the additional modifiers in the narrative field of the claim. We believe this overflow mechanism addresses the EHR slot limitation described by commenters, and we encourage providers and EHR vendors to configure billing systems to support modifier -99 and the narrative field where necessary to accommodate modifiers B1 and B2 alongside other required modifiers.

Comment: Commenters requested that we confirm whether the modifiers can be associated with virtual or telehealth visits.

Response: We thank commenters for requesting clarification regarding the applicability of the modifier when the service is furnished via telehealth. Since both HCPCS code G2211 and the O/O and home or residence E/M visits are currently on the Medicare telehealth services list, we are clarifying that Modifiers B1 and B2 can be used when an O/O or home/residence E/M visit is furnished via telehealth, provided all other requirements are met.

Comment: Commenters raised concerns that eliminating HCPCS code G2211 as a standalone code and replacing it with a modifier that carries no independent work RVU value would impact productivity-based compensation for physicians. Commenters asked that we publish a crosswalk file to map modifier values to comparable RVUs at each E/M level so practices and health systems can accurately account for physician compensation. Others requested that CMS publish its resource-based rationale, utilization assumptions, and specialty-level budget-neutrality effects before finalizing the differential, and asked CMS to revise its utilization estimates with additional evidence that the modifier payment scales proportionally with the E/M service.

Response: We acknowledge that this represents a shift in direct-RVU calculated income for this service. Although productivity-based models are a common compensation structure, there are other compensation strategies that could account for this modifier. Furthermore, modifiers B1 and B2 are only two of many modifiers that affect a HCPCS or CPT code's reimbursement amount, and for this reason we believe this change is consistent with other instances in which the PFS has adjusted payment mechanisms. We are sympathetic to the operational concerns that may arise from the switch from HCPCS code G2211 to modifiers B1 and B2. In response, we are publishing a public use file (PUF) with this final rule that maps modifier B1 and modifier B2 values to comparable RVUs at each E/M level. This file will be available on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*. Regarding specific data surrounding this policy such as utilization assumptions and specialty-level budget neutrality calculations, we are often asked for specific information regarding the impacts of a policy, however, we have historically only published the cumulative specialty-level impacts of all policies.

After consideration of public comments, we are finalizing the creation of modifier B1 as proposed. We note that modifier MOD1 was a placeholder code in the proposed rule. The finalized modifier descriptor for modifier B1 is: (*Visit complexity inherent to new or established office/outpatient or home or residence evaluation and management service, associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition).*

(ii) Modifier MOD1 Valuation

When HCPCS code G2211 was finalized in the CY 2020 PFS final rule (84 FR 82854 through 82855), we crosswalked it to 100 percent of the valuation of CPT code 90785 *(Interactive complexity (List separately in addition to the code for primary procedure)),* which was created to capture additional work that occurs with certain psychiatric and psychotherapy codes. We believed that this service was analogous to the additional work involved in maintaining a longitudinal relationship

with patients as described by CPT code 90785. CPT code 90785 has a work RVU of 0.33 and a physician time of 11 minutes. In reexamining this policy after a few years of utilization, we have come to believe that a flat rate as described by HCPCS code G2211 does not reflect the variation in work of the various E/M visit levels.

TABLE A-D7: COMPARISON OF HCPCS CODE G2211 WITH BASE CODES

Base CPT code	Total NF RVU of HCPCS code G2211	Total NF RVU of Base CPT code	HCPCS code G2211 as percentage of base-code
99212	0.52	1.78	0.52/1.78: **29%**
99215	0.52	5.76	0.52/5.76: **9%**

Table A–D7 illustrates that the addition of HCPCS code G2211 as an add-on to the associated E/M visit represents a higher increase in total value for base codes with lower total non-facility RVUs than it does for more intense services. For example, HCPCS code G2211 has a total RVU of 0.52 in the non-facility (NF) setting. CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*) has a total NF RVU of 1.78. So, when HCPCS code G2211 is appended to CPT code 99212, the overall value of the service is increased by 29 percent. However, when HCPCS code G2211 is appended to CPT code 99215 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.*) with a NF total RVU of 5.76, it only represents a 9 percent increase in the total value of the service. We believe that HCPCS code G2211 should reflect an increase to the base code that is proportional across all types of E/M visits. Therefore, we proposed a modifier to replace HCPCS code G2211 with the valuation of 16 percent of the base E/M code. We established this percentage using a weighted average of the percentage increase that G2211 comprised relative to the O/O E/M code, weighted by HCPCS code G2211 utilization and adjusted to achieve budget neutrality.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the underlying concept of scaling the complexity payment to the level of the base E/M service, specifically endorsing the 16 percent valuation rather than applying a flat amount. Several commenters noted that replacing HCPCS code G2211 with MOD1 more appropriately pays for complexity reflected in medical decision-making and physician work across E/M levels. Some commenters requested that CMS retain a flat rate valuation for the modifier rather than scaling it to the E/M level. A commenter supported this with a quantitative analysis showing that a percentage-based modifier would shift value away from the HCPCS codes 99213/99214 visits that make up most primary care. This commenter recommended retaining HCPCS code G2211's flat rate value and setting a floor so no E/M level receives less than 0.33 work RVUs.

Response: We appreciate commenters' support for the proposed valuation of modifier B1 and scaling the complexity payment to the level of the base E/M service and agree that this approach more accurately accounts for the complexity reflected in medical decision-making and physician work across E/M levels. We appreciate the concern that this valuation structure may shift value away from primary care; our intention is to more accurately pay for the intensity of longitudinal care by aligning it to a percentage of the base code. As illustrated in Table A–D7, a flat rate add-on produces a disproportionate benefit for lower-intensity visits and a comparatively smaller benefit for higher-intensity visits, and we understand that there are trade-offs in any system. We believe this approach is the correct one, but we appreciate commenters bringing this to our attention, and we may re-examine this in future rulemaking.

(c) G2211 in Medicare Accountable Care Organizations (ACOs)

(i) Background

The Medicare Shared Savings Program (Shared Savings Program) established under section 1899 of the Act, offers doctors, hospitals, and other health care providers an opportunity to create an Accountable Care Organization (ACO). Shared Savings Program ACOs are groups of doctors, hospitals, and other health care professionals that work together to give patients high—quality, coordinated service and health care, improve health outcomes, and manage costs.[27] In Original Medicare, physicians are reimbursed for reasonable and necessary services necessary for diagnosis or treatment of illness or injury. In an ACO, the doctor-patient relationship in Original Medicare is expanded such that the doctors, hospitals and other health care professionals are not just providing services under the reasonable and necessary standard, but there is additional work conducted to manage the beneficiaries' overall health, considering their personal health goals and values. This is how CMS defines an ''accountable care relationship,'' and this relationship may lead patients to be less likely to get repeated medical tests or unnecessary services, since clinicians consider a patient's entire health history when developing a treatment plan, and the doctors and other health professionals communicate and collaborate to improve the patient's long-term health.[28] CMS believes accountable care supports the professional ethos of health professionals to take responsibility for their patients in a way that beneficiaries expect. When these accountable care relationships succeed and the ACO succeeds in delivering high-quality care and reducing expenditures, the ACO may be eligible to share in the savings. For more information on the Shared

[27] ''Accountable Care and Accountable Care Organizations.'' *Centers for Medicare & Medicaid Services,* CMS Innovation Center, *https://www.cms.gov/priorities/innovation/key-concepts/accountable-care-accountable-care-organizations.* Accessed 16 June 2026.

[28] ''Accountable Care and Accountable Care Organizations.'' *Centers for Medicare & Medicaid Services, https://www.cms.gov/priorities/innovation/innovation-models/aco.* Accessed 16 June 2026.

Savings Program and policies directly relating to Shared Savings Program, see section III.G. of the proposed rule (91 FR 43842 through 44557).

The CMS Innovation Center recently announced the Long-term Enhanced ACO Design (LEAD) Model which will launch on January 1, 2027. LEAD builds upon previous accountable care work and was designed to attract health care providers that have previously had limited participation in ACOs. It also aims to encourage health care providers to deliver preventive care, empower beneficiaries to be more actively involved in their care, and support health care providers who serve high needs and dually eligible beneficiaries to improve care and reduce costs.

(ii) Modifier MOD2

In the PFS, we have established a complexity add-code (HCPCS code G2211) that we proposed to change to a modifier (MOD1) that supports care relationships which may approximate but are not accountable care. This modifier is meant to recognize the additional complexity of services associated with providing ongoing, longitudinal care to a beneficiary. We proposed that the complexity of care established in that longitudinal relationship fundamentally differs in Original Medicare where physicians are providing all reasonable and necessary care for diagnosis and treatment of a clinical condition versus when they are in an accountable care relationship. As previously discussed, we proposed applying the complexity add-on (we proposed to change this to a modifier) to reflect the ongoing resource costs associated with being the focal point for all needed health care services performed under this reasonable and necessary standard.

We believe this standard is distinct from care provided in an ACO, where in addition to being responsible for all needed health care services that are part of ongoing care, clinicians are also responsible for managing the accountable care relationship, which involves managing a beneficiary's overall health, personal goals, values, and coordinating care with responsibility for both quality and cost. We consider the complexity associated with serving as the focal point of care for all necessary services within an accountable care relationship, responsibility for the entire patient, and responsibility for quality and cost of care, to be inherently more complex than serving in this role outside of an accountable care relationship. We are therefore proposing two levels for this modifier to reflect the additional resource costs associated with accountable care.

For example, the most common condition for which HCPCS code G2211 was billed in 2024 in Original Medicare was hypertension.[29] Outside of an accountable care relationship, the complexity add-on (proposing in this rule to change to a modifier) would be billed by clinicians for E/M visits managing a beneficiary's hypertension over time. The additional time and resource costs for serving as this focal point in care may address a patient's reservations about initiating pharmacologic treatment for hypertension (for example, perhaps the beneficiary wishes to trial complementary or alternative medicine approaches, so the clinician and patient engage in shared decision-making to understand the risks and benefits of this approach preceding pharmacologic intervention).[30] They may also discuss risk factor reduction (for example, smoking cessation) and lifestyle changes (for example, following the dietary approaches to stop hypertension or 'DASH' diet and meeting physical activity recommendations), or perhaps engage in motivational interviewing to facilitate behavior change. While the current HCPCS code G2211 is meant to take into account the additional time and resource intensity for these services, we expect even more from clinicians participating in an ACO.

For example, a beneficiary has general anxiety disorder and hypertension and monitors their blood pressure at home. They have an instance in which their blood pressure exceeds 140/90mmHg, and they also feel panic or a sense of impending doom or chest pain. They decide to go to the emergency room, but the slightly elevated blood pressure may or may not be the physiologic trigger of their symptoms. This patient may continue to seek care at the emergency room for similar episodes indefinitely unless their practitioner identifies this trend on their own and provides education to the patient on distinguishing the symptoms of anxiety from hypertension, and when it may be appropriate to go to the emergency room. If this same patient was in an ACO, that ACO might have already established admission discharge transfer (ADT) notifications which would alert the team (near-real time) for the admission. This would allow for earlier intervention to ensure that both the patient's anxiety and blood pressure were being managed in the correct setting, and that the patient had the best information to understand their intersecting conditions.

The additional time and resources associated with coordinating care for this complex patient considering both quality and cost are distinct. We proposed differentiating the resource costs associated with HCPCS code G2211 outside of and within an accountable care environment to account for the additional resource costs associated with serving as the focal point of care for the entire beneficiary within an accountable care relationship. We are clarifying that we do not believe every encounter a patient has within an ACO qualifies as longitudinal. For example, if instead of presenting to the ED, the patient calls the clinic and is able to see another ACO participant, ACO professional, ACO provider/supplier (as each is defined at § 425.20, for the Shared Savings Program), or LEAD Participant Provider who is available the same day, this encounter would not necessarily meet the criteria of inherent complexity, if that practitioner is not supporting the beneficiary's longitudinal care, and if this visit is not more inherently complex. Simply providing an E/M visit while being part of an ACO does not necessarily meet the threshold of inherent complexity.

We believe that MOD2 aligns with the goals of the Shared Savings Program and LEAD, which involve groups of health care providers working together to enhance beneficiary health through high quality, longitudinal primary and preventative care. One of the features of Shared Savings Program and LEAD ACOs is that beneficiaries benefit from ACO participants balancing goals of having total cost of care accountability and improving quality of care, while avoiding unnecessary services and medical errors. While the specifics vary between the Shared Savings Program and the LEAD model, in general, participating ACOs are required to report quality measures that align with these objectives, and they are measured against their past performance, and the performance of similar ACOs.[31]

While these measures span a broad area of topics, many measures are focused on longitudinal care and care

[29] Ganguli I, Daley NE, Hicks AL, McWilliams JM, Rosenthal MB. Billing of Medicare's G2211 Longitudinal Care Code Among Traditional Medicare Beneficiaries. *JAMA*. 2026;335(11):1003–1006. doi:10.1001/jama.2026.0424.

[30] ''Hypertension (High Blood Pressure).'' *National Center for Complementary and Integrative Health,* U.S. Department of Health and Human Services, July 2018, *https://www.nccih.nih.gov/health/hypertension-high-blood-pressure.* Accessed 16 June 2026.

[31] *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations#quality.*

coordination, such as chronic disease management, preventive care and screenings and reducing avoidable hospitalizations.[32] Current participation in the Shared Savings Program helps provide and future participation in LEAD will help provide a framework to allow health care providers to collaborate to give coordinated high-quality care, while also enabling investment to achieve those goals. For example, health care providers may join ACOs to help defray the costs of large capital investments such as electronic medical records.[33] Health care providers also cite help with care coordination and quality reporting as a reason to join, increasing their access to resources and expertise to help with these areas in their practice.[34] We also want to encourage health care providers to form and join ACOs to coordinate care for their beneficiaries. Similarly, ACO participants, ACO professionals, ACO providers/suppliers (as each is defined at § 425.20, for the Shared Savings Program), and LEAD Participant Providers often provide advanced primary care to beneficiaries regardless of whether a particular beneficiary is assigned, aligned, or attributed to their ACO. Advanced primary care is a patient-focused approach to care wherein health care providers take extra steps to actively manage a beneficiary's health care needs.[35] Further, additional beneficiaries to whom a health care provider provides care might be assigned to that ACO in the future, so encouraging similar care to be provided to all beneficiaries served by health care providers in ACOs would be in the interest of the ACO. This level of care coordination, which includes advanced primary care, is often inherent by virtue of participation in an ACO.[36]

We proposed to match the descriptor of MOD2 to MOD1 and HCPCS G2211, with some small differences. The new proposed modifier descriptor is: *Visit complexity inherent to new or established office/outpatient or home or residence evaluation and management service, associated with medical care services furnished by a participant or practitioner participating in a Medicare accountable care organization. Services must serve as the continuing focal point for all needed health care services and/or be part of ongoing care related to a patient's single, serious condition or complex condition.*

(ii) Modifier Valuation for Medicare ACO Participants

With these goals in mind, we proposed that, in place of reporting G2211, ACOs would have the option to report a modifier on a claim (referred to in this proposed rule as placeholder MOD2, which if finalized would be replaced with a two-digit HCPCS modifier), which will be valued at 32 percent of the associated E/M visit when performed by Shared Savings Program ACO participants, ACO professionals, and ACO providers/suppliers (as each is defined at § 425.20), as well as Participant Providers in the LEAD Model. We proposed that MOD2 would pay twice the rate of MOD1 to better account for the inherent complexity of some visits in the ACO context, specifically applying to Shared Savings Program and LEAD ACOs in situations that require increased time and intensity. This increased valuation is meant to reflect the cognitive work of providing longitudinal care, follow-up discussions through an assigned care coordinator with the beneficiary or other providers, and expanded access to educational resources, care options, and provider communication methods. The value-based care provided through a Shared Savings Program or LEAD ACO puts greater emphasis on integrated care, meaning health care providers work together to address a person's physical, mental, behavioral and social needs. In this way, providers treat an individual as a whole person, rather than focusing on a specific health issue or disease.[37] [38]

The differential payment we proposed to provide to Shared Savings Program ACO participants, ACO professionals, and ACO providers/suppliers (as each is defined at § 425.20) and to LEAD Participant Providers would further support the CMS Innovation Center 2025 Strategy to Make America Healthy Again which focuses on empowering Americans to achieve their health goals and live healthier lives.[39] We recognize that not all E/M visits represent longitudinal care and so we would not expect MOD2 to be included on all claims for E/M visits, only visits that have an increased visit complexity that requires an increased valuation, as described in the examples provided earlier in this section.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received comments in support of the higher rate for modifier B2 noting that it would serve as an appropriate incentive for accountable care participation. Many commenters supported the differential as recognition of accountable care investments that are inherent to ACO participants. According to commenters, these investments include care coordination, data analytics, and population health management, none of which are reflected in standard fee-for-service payment. Commenters also noted that the differential accounts for the work of addressing social and behavioral factors that influence health outcomes. Additionally, they explained that improving quality while responsibly managing total cost of care requires infrastructure and interdisciplinary care teams and that the higher rate recognizes this investment. Commenters also stated that the higher payment rate creates a meaningful financial incentive for clinicians to participate in an accountable care relationship. A commenter suggested that CMS provide specific guidance to providers that beneficiaries assigned to an ACO are automatically eligible for the utilization of modifier B2 by ACO participants or automatically apply the modifier, when applicable. In addition to support modifier B2, we received comments opposed to paying the higher rate (32 percent) only to ACO-participating clinicians while limiting other clinicians to billing modifier B1 (16 percent) for what they characterized as identical clinical work. Some commenters supported the general shift from HCPCS code G2211 to a modifier but explicitly opposed the 32 percent ACO-specific tier. Commenters expressed concern that we have not provided empirical evidence for the differential, that MOD2 could be billed for beneficiaries not attributed to the ACO, that it would increase aggregate beneficiary cost-sharing, and that it could reduce net Medicare savings under ACO models by rewarding billing volume over shared-savings performance. Other commenters, including MedPAC, raised concerns that because the modifier increases payment as a percentage of the underlying E/M

[32] *https://www.cms.gov/priorities-innovation-key-concepts-accountable-care-accountable-care-organizations.*

[33] *https://www.cbo.gov/publication/60213.*

[34] Berenson, R. A., Burton, R. A., & McGrath, M. (2016). Do accountable care organizations (ACOs) help or hinder primary care physicians' ability to deliver high-quality care? *Healthcare, 4*(3), 155–159. *https://doi.org/10.1016/j.hjdsi.2016.02.011.*

[35] *https://www.cms.gov/medicare/payment/fee-schedules/physician-fee-schedule/advanced-primary-care-management-services* and *https://www.medicare.gov/coverage/advanced-primary-care-management-services.*

[36] Centers for Medicare & Medicaid Services. Care Transformation Toolkit. CMS Innovation Center; 2021. Available at *https://www.mathematica.org/publications/care-transformation-toolkit.*

[37] *https://www.cms.gov/priorities/innovation/key-concepts/value-based-care.*

[38] *https://www.cms.gov/priorities/innovation/key-concepts/person-centered-care.*

[39] *https://www.cms.gov/priorities/innovation/about/strategic-direction.*

service, beneficiaries receiving higher-level E/M visits would face correspondingly higher cost-sharing obligations, regardless of whether that beneficiary is assigned to an ACO. MedPAC additionally noted that this proposal could impact a Medicare ACO's ability to generate net savings for Medicare by maximizing payments through the delivery of services eligible for the MOD2 modifier.

Several commenters argued that the clinical resources of longitudinal care do not depend on ACO participation and that reserving the higher payment for ACO participants risks separating payment from the resources required to furnish care, explaining that independent practices also coordinate complex care and maintain ongoing relationships with patients.

Response: We acknowledge the concerns raised by many commenters who opposed paying modifier B2 at 32 percent only to ACO-participating clinicians while limiting other clinicians to the 16 percent modifier B1 rate for what they viewed as identical clinical work. We acknowledge the comments that increasing the value of the modifier when billed by ACO participants increases the cost sharing for beneficiaries and that it could impact an ACO's expenditures and shared savings. The use of the higher rate modifier is optional for ACO participants and ACOs can take the factors raised by commenters into consideration when choosing whether to bill the higher rate modifier. We also note that in Section III.G.6.2 of this final rule, we are finalizing a Part B cost sharing support policy under which eligible ACOs could offer cost sharing support for all Part B items and services except durable medical equipment, prosthetics, orthotics, supplies and prescription drugs for eligible beneficiaries under the Shared Savings Program. Under the Part B cost sharing support, an approved ACO could choose to offer cost sharing reductions for these services for their assigned beneficiaries which could, in some cases, mitigate for the higher cost sharing associated with the modifier.

We agree with commenters that clinicians in ACOs make investments in care coordination, data infrastructure, population health management, quality improvement, and patient engagement that extend beyond an individual billable encounter and that the PFS can better align fee-for-service payment with the infrastructure and support required to deliver accountable care. We agree with commenters that the proposal creates a direct financial incentive for clinicians to join and remain in ACOs and note that the higher modifier B2 rate serves as an appropriate recognition of the relative resource costs in this setting, including additional investments ACOs make, and that it continues CMS's recognition of the value of longitudinal care for beneficiaries with complex needs.

We acknowledge the comment suggesting that CMS consider providing guidance to practitioners that could increase the utilization of modifier B2 by ACO participants and will consider this for the future. We reiterate that we expect that not all E/M services provided by ACO participants would meet the definition of longitudinal care, and we remind practitioners that each code or modifier that is billed must be medically reasonable and necessary, which we feel would be a difficult standard to maintain in any automatic processes. We additionally explained in the proposed rule's Regulatory Impact Analysis (91 FR 44248) that the proposal to pay for services furnished in an ACO using a modifier (B2) that pays 32 percent of the total RVUs for the E/M service on the claim is expected to increase payment for practitioners that furnish a higher percentage of their services in ACOs.

After consideration of public comments, we are finalizing modifier B2 as proposed. We note that modifier MOD2 was a placeholder code in the proposed rule. The finalized modifier descriptor is B2 (*Visit complexity inherent to new or established office/outpatient or home or residence evaluation and management service, associated with medical care services furnished by a participant or practitioner participating in a Medicare accountable care organization. Services must serve as the continuing focal point for all needed health care services and/or be part of ongoing care related to a patient's single, serious condition or complex condition.).*

(iii) Use of MOD2 Modifier by ACOs

Modifier MOD2 would be exclusively available for ACO participants, ACO professionals, and ACO providers/suppliers (as each is defined at § 425.20, for the Shared Savings Program), as well as LEAD Participant Providers, when the visit complexity is met, provided the individual is a medical professional who can bill office and outpatient E/M visits or home visit services, regardless of specialty. Utilization and claims of either modifier will be included in ACOs' expenditure calculations for benchmarking and performance year expenditures and used in the determination of total cost of care.

As described earlier in this section, we proposed a differential payment for MOD2 that is meant to provide a meaningful increase in the way we pay for primary care provided by ACO participants, ACO professionals, and ACO providers/suppliers (as each is defined at § 425.20, for the Shared Savings Program), as well as LEAD Participant Providers who often provide additional care coordination to beneficiaries in their care as demonstrated by their participation in an ACO, as described in the examples provided earlier in this section. We are further proposing that the use of this modifier be voluntary; and ACO participants, ACO professionals, ACO providers/suppliers (as each is defined at § 425.20, for the Shared Savings Program), and LEAD Participant Providers would determine if this modifier is necessary based on visit complexity and would append MOD1, MOD2, or no modifier, as appropriate. Additionally, we proposed that ACO participants, ACO professionals, and ACO provider/suppliers (as each is defined at § 425.20, for the Shared Savings Program), as well as LEAD Participant Providers may bill this modifier for all beneficiaries to whom they provide care, regardless of whether that beneficiary is assigned, aligned, or attributed to an ACO, to encourage similar care to be provided to all beneficiaries served by health care providers who participate in ACOs. Given that ACO Primary Care Flex (ACO PC Flex) Model participation is predicated on participation in the Shared Savings Program, we proposed that ACO PC Flex Model ACOs may also utilize the MOD2 modifier. Finally, we proposed that LEAD Participant Providers billing under a Participant TIN that is in a LEAD ACO may bill modifier MOD2. Refer to the discussion later in this section for additional information on the use of modifier MOD2 on alignment in the LEAD model.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for the enhanced ACO payment as a lever to grow accountable care participation and improve care coordination, requesting that it apply to Advanced APMs as well as Shared Savings Program ACOs. Commenters supported allowing ACO participants to bill MOD2 for all beneficiaries they treat, not only those assigned to the ACO, viewing this as recognition of the broader care-management infrastructure ACOs maintain and use for all

beneficiaries. Commenters also asked CMS to extend MOD2 eligibility to CMS Innovation Center models Kidney Care Choices and Enhancing Oncology. Additionally, we received comments asking how the higher MOD2 payment interacts with ACO expenditure benchmarking, so the incentive does not partially cancel itself.

Response: We thank commenters for their support and agree with commenters that the enhanced ACO payment is a mechanism to grow accountable care participation and strengthen care coordination.

Regarding the comments mentioning that this incentive extends to Advanced APMs as well as Shared Savings Program ACOs, we clarify that the utilization of modifier B2 is specific to ACO participants in the Shared Savings Program ACOs, the LEAD model, and ACO PC Flex. While certain tracks within these or other CMS Innovation Center models may represent Advanced APMs, this policy does not extend to all Advanced APMs or to other CMS Innovation Center models. We may consider such an expansion for future rulemaking. In response to inquiries concerning ACO expenditure benchmarking, we clarify that claims including modifier B1 or B2 will not be carved out of Shared Savings Program, LEAD, or ACO PC Flex financial calculations, including benchmark determination, financial reconciliation, or assignment plurality determinations. Modifier B2 is meant to reflect the additional resources associated with longitudinal care provided by ACO participants; however, ACOs remain accountable for the total cost of care for their beneficiaries and carving out these expenditures would be counter to that goal.

Comment: Several commenters urged CMS to finalize the changes as proposed and, notably, to require Medicare Advantage plans to adopt the 32 percent modifier on the same timeline as traditional Medicare without added MA-specific documentation or prior authorization requirements.

Response: We appreciate commenters' interest in payment parity and in limiting administrative burden for practitioners who participate in both traditional Medicare and MA, however, we note that this rule is issued under our authority to establish payment policy for services furnished to beneficiaries under the traditional Medicare fee-for-service program under Part B. It does not directly govern the methodologies MA organizations use to pay contracted providers under Part C.

Comment: Some commenters requested that CMS broaden MOD1 and MOD2 eligibility across several settings and code sets. Commenters stated that the beneficiaries most in need of longitudinal care are also in settings such as nursing facilities, Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs), and Critical Access Hospitals (CAHs). Others asked for the use of MOD1 and MOD2 in conjunction with codes beyond E/M codes, such as collaborative care management services, the shared medical appointment codes proposed earlier in this section, and medical nutrition therapy.

Response: We thank commenters for their thoughtful feedback and interest in ensuring that beneficiaries get the longitudinal care they need. We note that many of the settings commenters recommended are paid under different payment structures or systems, and so extending this policy to those structures would need to be examined in separate rulemaking. We have received similar comments regarding the extension of HCPCS code G2211 (now modifiers B1 and B2) to other settings in several rulemaking cycles, and we addressed these concerns most recently in the CY 2026 PFS final rule (90 FR 49462 through 49464). We are clarifying that modifiers B1 and B2 may only be used in conjunction with E/M visits performed in the O/O or home or residence setting and may not be performed in conjunction with E/M visits in other settings, such as SNF, RHC, FQHC, CAH, or other places of service. The limit on place of service for use of these modifiers is tied to the location and type of the E/M visit, rather than the modifier. We may consider changes to this policy in future rulemaking, and we welcome continued engagement with practitioners in these settings.

We also thank the commenters for their ideas on other types of services that may be more inherently complex when the practitioner has a longitudinal relationship with the patient, such as collaborative care management services. However, we disagree that E/M services provided in other settings do not adequately recognize the increased complexity of this relationship in the valuation of those services. HCPCS code G2211 (now modifiers B1 and B2) was originally designed to capture the differences in complexity between different types of E/M visits provided in an office/outpatient or home/residence settings, which is not the case for E/M visits provided in other settings or services captured within a prospective payment system.

(A) Impacts on Assignment of Beneficiaries to Shared Savings Program ACOs

HCPCS code G2211 is included in the definition of primary care services used for purposes of assignment under § 425.400(c). Although we proposed that HCPCS code G2211 be deleted, under this proposal, it would remain in the regulations at § 425.400(c) to be included for purposes of determining the population of OM beneficiaries for whose care the ACO is accountable under 42 CFR subpart F, and for determining whether an ACO has achieved savings under 42 CFR subpart G, and will continue to be used for assigning beneficiaries to an ACO in benchmark years during which HCPCS code G2211 was still an allowable service. If the proposal is finalized, the code will no longer be payable, and there will be no impact on future calculations of allowed charges used for purposes of assignment.

We proposed that Modifier MOD2 can be appended to O/O or home or residence E/M services exclusively by ACO participants, ACO professionals, ACO providers/suppliers (as each is defined at § 425.20, for the Shared Savings Program), and LEAD Participant Providers who can bill O/O or home or residence E/M service, regardless of specialty. In performing claims-based assignment under the Shared Savings Program, CMS determines whether allowed charges for a beneficiary's primary care services (as identified for ACO professionals, including at Electing Teaching Amendment hospitals and Method II Critical Access Hospitals, and services furnished at an FQHC or RHC) in an ACO are greater than allowed charges for the beneficiary's primary care services in any other ACO, or other individual health care providers, or groups of health care providers identified by Medicare-enrolled billing TINs or CMS Certification Numbers that are not participating in the Shared Savings Program. In making this determination, we determine where the beneficiary received the plurality of his or her primary care services.

The allowed charges associated with O/O or home or residence E/M services billed with or without modifiers MOD1 or MOD2 will be used in determining beneficiary assignment. Since the CPT codes identified as O/O or home or residence E/M services are included in the definition of primary care services used for purposes of assignment as defined in 42 CFR 425.400(c), we do not believe that changes to the regulatory text are required. Certain operational changes will need to be implemented

which will be communicated via Change Request,[40] Medicare Learning Network (MLN) Matters® article,[41] or other sub-regulatory guidance.

We received no comments on this section of the proposal.

(B) Impacts on Assignment of Beneficiaries to LEAD ACOs

In LEAD, if this proposal is finalized, we will handle the deletion of HCPCS code G2211 and the transition to the modifiers similarly to the Shared Savings Program. As indicated in Appendix C of the LEAD Request for Applications, the HCPCS code G2211 code is one of the Primary Care Qualified Evaluation and Management (PQEM) services that CMS uses to align beneficiaries to LEAD ACOs via claims-based alignment. We will continue to use HCPCS code G2211 allowable charges to conduct claims-based alignment in LEAD when HCPCS code G2211 was an allowable service in the requisite claims look back period. For example, when conducting initial claims-based alignment in Performance Year (PY) 2027, we will reference claims from October 1, 2025 to September 30, 2026. HCPCS code G2211 allowable charges will be included in the claims-based alignment run since it is an allowable service during this period.

When aligning beneficiaries to LEAD ACOs, CMS looks first for an existing primary care relationship within the claims lookback period. If 10 percent or more of a beneficiary's PQEM allowable charges (measured by dollar amount) were billed by physicians or non-physician health care providers with a primary-care specialty (family medicine, internal medicine, geriatrics, general practice, nurse practitioner, physician assistant, and clinical nurse specialist), alignment is based solely on these primary care providers. If less than 10 percent of a beneficiary's PQEM allowable charges were billed by primary-care specialties, alignment considers certain non-primary care providers that manage chronic or complex conditions (for example, cardiology, nephrology, endocrinology, psychiatry, etc.). The beneficiary is aligned to a LEAD ACO if the Participant TIN that furnished the largest share of allowable charges incurred for PQEM services during the lookback period is participating in a LEAD ACO.

Once the claims-based alignment look back period rolls forward to include 2027 (and future years) the LEAD alignment methodology will include the allowed charges associated with modifier MOD1 and MOD2 when conducting claims-based alignment (the underlying O/O or home or residence E/M service that will be modified by MOD1 and MOD2 are already LEAD PQEM services). LEAD ACOs will be accountable for expenditures incurred by using either modifier MOD1 or MOD2. Expenditures associated with modifier MOD1 and MOD2 will be included in total Medicare Parts A and B expenditures when CMS conducts financial settlement for LEAD ACOs. More information on the impact to claims processing, capitated payments, and LEAD benchmarks will be shared with ACOs that were selected for participation in LEAD in PY 2027.

We received no comments specific to this section of the proposal.

(iv) MOD1 and MOD2 Billed With Modifier -25

When we finalized the HCPCS code G2211 policy in the CY 2021 PFS final rule (85 FR 84572), we did not limit the use of HCPCS code G2211 with O/O E/M visits in which CPT Modifier -25 was appended. CPT Modifier -25 denotes a significant, separately identifiable O/O E/M visit by the same physician or other qualified health care professional on the same day as a procedure or other service. We finalized HCPCS code G2211 as payable in the CY 2024 PFS final rule (88 FR 78974), and in the CY 2025 PFS final rule (89 FR 97856 through 97858), we finalized that we would allow payment of HCPCS code G2211 with Modifier -25 when the O/O E/M base code is reported by the same practitioner on the same day as an annual wellness visit (AWV), vaccine administration, or any Medicare Part B preventative service when furnished in the office or outpatient setting. For CY 2027, we proposed to maintain the same limitations we established for HCPCS code G2211 in the CY 2025 PFS final rule (89 FR 97856 through 97858) for MOD1 and MOD2 when billed with Modifier -25.

Later in this section, we are making additional proposals related to changes for payment when modifier -25 is appended. Given these changes, we sought comment on whether we should consider changes to this policy, such as allowing MOD1 or MOD2 to be billed with modifier -25 when an O/O E/M is performed on the same day as a 0-, 10-, or 90-day global procedure?

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters requested that CMS clarify how the proposed changes to payment for modifier -25 interact with the new HCPCS code G2211-replacement modifiers, given that both provisions affect the same E/M claim line. Commenters supported allowing the B1 and B2 modifiers with modifier -25 whenever both sets of requirements are independently met, and another asked CMS to confirm the modifiers would apply to 0-, 10-, and 90-day global procedures regardless of -modifier 25 status.

Response: We appreciate commenters' feedback on the interaction between modifiers B1 and B2 and modifier -25. Currently, as finalized in the CY 2025 PFS final rule (89 FR 97856 through 97858) and the CY 2026 PFS final rule (90 FR 49462 through 49464), HCPCS code G2211 is not payable when the O/O E/M visit or home or residence E/M is reported with modifier -25, except when the same-day service is an annual wellness visit, vaccine administration, or another Medicare Part B preventive service, including the Initial Preventive Physical Examination, furnished in the office or outpatient or home or residence setting. We are not revising this policy in this final rule.

(54) Shared Medical Appointment (HCPCS Codes G0686 and G0687)

In accordance with President Trump's Executive Order, ''Establishing the President's Make America Healthy Again Commission,'' [42] the Administration is directing agency focus towards understanding and drastically lowering chronic disease rates. As part of this commitment, we remain focused on the prevention and management of chronic disease, including through approaches that address underlying behavioral and lifestyle drivers of health.

In CY 2026, we solicited feedback on how CMS could further support the prevention and management of chronic diseases. In response to our request for information on chronic disease prevention and management, commenters indicated that many services that help prevent and manage chronic disease, such as lifestyle modification support, health education, and peer support, require time, coordination and multidisciplinary engagement that is not adequately supported under the current PFS. Additionally, many commenters indicated that social isolation and loneliness is a persistent barrier to

[40] Available at *https://www.cms.gov/medicare/regulations-guidance/transmittals.*

[41] Available at *https://www.cms.gov/training-education/medicare-learning-networkr-mln/resources-training/mln-matters-articles.*

[42] *https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/.*

effective care for Medicare beneficiaries. The commenters indicated that although health care providers are already implementing interventions to identify and address social isolation, these efforts are resource intensive and not adequately supported under the current PFS.

Based on this feedback, we recognize the importance of health care delivery approaches that enable multidisciplinary support, foster beneficiary engagement, and encourage sustainable lifestyle and behavioral changes. Shared medical appointments (SMAs) are one such approach to offer a group-based environment in which beneficiaries can receive clinical guidance while also engaging with peers facing similar health challenges. SMAs may also help address social isolation and loneliness for some beneficiaries.

SMAs, also known as shared medical visits or group visits, are voluntary group-based sessions where multiple patients with a common chronic condition, such as type 2 diabetes mellitus, receive medical care together. In general, SMAs involve more than one healthcare provider, such as a person trained or skilled in delivering patient education or facilitating patient interaction and a prescribing practitioner to make and initiate a comprehensive care plan. SMAs generally last from 60 to 120 minutes and incorporate time for social integration, interactive education, and adjustments to the patient's care plan.[43] Compared with group education alone, SMAs allow patients to participate in clinical care activities that are tailored to the needs of both the group and the individual participants.[44] During the SMA session, a practitioner may meet with a patient individually in a private or semi—private manner or conduct the visit in a group setting where other patients are able to listen and, in some cases, contribute to the discussion.[45]

Reported advantages of shared medical appointments include providing patients more time with their health care provider, creating opportunities for patients to learn from and share self-management strategies with one another, improving access to care, incorporating nonpharmacologic treatment approaches, enhancing the overall quality of care, and helping reduce emergency department visits.[46]

Currently there is no CPT or HCPCS code specifically designated for SMAs. However, practitioners typically bill SMAs using existing Evaluation and Management (E/M) codes, CPT codes 99212–99215, based on medical decision-making criteria; and if another billable clinician such as a registered dietician assists with the SMA, the registered dietician may also bill for their portion of the SMA separately (for example, CPT code 97804 (*Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes)*). Therefore, we proposed to create coding and valuation specifically for SMAs.

We proposed that SMAs be limited to beneficiaries who have received a professional service from the billing physician or other qualified health professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice within the previous 12 months. We believe this requirement is necessary to ensure beneficiaries have an existing clinical relationship with the practitioner before the beneficiary is integrated into a group-based medical care setting.

We proposed requiring beneficiaries to consent to SMA participation, since they may elect to receive individual medical appointments instead. Additionally, we proposed that beneficiaries must consent to confidentiality terms because personal health information would be discussed in the group setting.

SMA sessions generally last 60 to 120 minutes and may include up to 25 patients, however SMAs most commonly consist of 6 to 10 patients.[47] We proposed establishing SMAs as 60-minute sessions with a maximum of 10 beneficiaries per session.

The expansion of telehealth services has increased opportunities for SMAs to improve access for individuals in geographically remote areas, and those with transportation challenges. We proposed that SMA sessions can be held either in-person or via telehealth, and we proposed to add the SMA service to the Medicare Telehealth list accordingly.

We proposed that each shared SMA session be documented in each participating beneficiary's medical record. Each beneficiary receives individualized clinical care, and the medical record must reflect the specific services that the individual beneficiary received during the SMA session. The need for individualized care may depend on the intervention and surrounding evidence. Therefore, if a beneficiary requires a level of individualized care that extends beyond what can appropriately be provided within the group-based session of a SMA, that individualized care should be provided in a separate individual medical appointment. The services provided to the group as a whole at each session would also need to be captured in the medical record. We seek comments on additional guardrails to consider in preventing fraud, waste and abuse when billing SMAs, such as following an evidence-based protocol for delivery of the intervention, conducting fidelity checks to ensure it is being delivered as intended, identifying key outcomes and goals that are established in shared decision making, and ensuring that the interventionist is trained in the intervention as appropriate.

SMAs are an approach in managing chronic conditions, especially among motivated patients.[48] SMAs are an appropriate healthcare delivery approach for conditions that are modifiable with lifestyle change, including diabetes mellitus, obesity, hypertension, and hyperlipidemia, such that behavioral changes including diet, physical activity, and self-management can influence health outcomes. Therefore, we proposed to establish coding and payment for SMAs provided for medical conditions that are modifiable with lifestyle change. We seek comment on how to determine when SMAs would be appropriate, including identifying which medical conditions would be considered modifiable with lifestyle change, and suggest we would typically consider those conditions with medical guidelines that include lifestyle change as part of prevention and treatment of the condition in this category, such as evidence-based interventions that support lifestyle change.[49] For example,

[43] *https://www.ncbi.nlm.nih.gov/books/NBK99776/#.*

[44] Kirsh, Susan R., Aron, David C., Johnson, Kimberly D., Santurri, Laura E., Stevenson, Lauren D., Jones, Katherine R., and Jagosh, Justin. ''A realist review of shared medical appointments: How, for whom, and under what circumstances do they work?'' Available from *https://pmc.ncbi.nlm.nih.gov/articles/PMC5291948/pdf/12913_2017_Article_2064.pdf.*

[45] Thompson-Lastad, Ariana. ''Group Medical Visits as Participatory Care in Community Health Centers.'' Available from *https://pmc.ncbi.nlm.nih.gov/articles/PMC6500445/pdf/nihms-1015904.pdf.*

[46] Lacagnina, Salvatore, Tips, Jean, Pauly, Kaitlyn, Cara, Kelly, and Karlsen, Micaela. ''Lifestyle Medicine Shared Medical Appointments.'' Available from *https://pmc.ncbi.nlm.nih.gov/articles/PMC7781059/.*

[47] *https://www.hsrd.research.va.gov/publications/esp/shared-med-appt.pdf.*

[48] *https://pmc.ncbi.nlm.nih.gov/articles/PMC2464960/pdf/349.pdf.*

[49] Centers for Disease Control and Prevention. ''Evidence-Based Intervention Planning Guides.'' *CDC: Cancer,* National Center for Chronic Disease Prevention and Health Promotion, 21 May 2024,

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the 2026 Standards of Care in Diabetes published by the American Diabetic Association (ADA) include lifestyle changes including improving nutrient composition and reducing caloric intake, establishing physical activity regimens to support weight loss, and highlighting the role of Medical Nutrition Therapy (MNT) as part of nutrition education.[50] While the exact content the SMA and desired behavioral change would vary (for example, improving diet and exercise as part of both prevention and management of Type 2 Diabetes) we would not consider medication adherence or titrating medications for Type 2 Diabetes to be appropriate for an SMA, but we would consider SMAs focused on improving nutrient composition to be an appropriate SMA activity, for example. CMS acknowledges the substantial changes in patients' lives associated with coping with chronic illness, the behavioral modifications inherent in managing serious and unexpected illnesses, however we would reserve SMA provision for just those conditions which may be treated or prevented with lifestyle changes.

SMAs typically involve multiple healthcare providers, usually two to four. The sessions are generally led by a physician, physician assistant (PA), or an advanced practice registered nurse (APRN), and may have ancillary staff help when the provider is meeting with patients individually.[51] We proposed that a SMA session is billed and led by a physician or qualified nonphysician practitioner and may include other qualified healthcare professionals, clinical staff, or auxiliary personnel. We proposed that HCPCS code G0686 would be billed once per patient, per session and would accept any documentation to demonstrate the care was rendered so long as the physician or qualified nonphysician practitioner co-signature is included. In instances where another qualified healthcare professional, such as a registered dietitian, provides a service during the SMA session, such as CPT code 97804 (*Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes),* that service is considered part of the SMA and should not be billed separately, in addition to the physician or qualified nonphysician practitioner billing for the SMA.

We proposed requiring each SMA session to include the following components:

- Evaluation and Management (E/M) elements, consistent with the complexity of the beneficiary's condition. Individualized clinical care with medical documentation in the medical record that reflects the specific services that the individual beneficiary received during the SMA session.
- Education, based upon evidence-based content, and discussions related to self—care, wellness, and disease management.
- Discussion of positive lifestyle changes, focusing on behavior modification. Medication management, as clinically appropriate and applicable.

In the event it is medically necessary for a beneficiary to receive an E/M visit on the same day as a SMA by the same physician or other qualified health professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, we proposed that any time and effort cannot be counted more than once. We proposed not to consider and treat this as two E/M same-day visits and seek public comment on this proposal. Additionally, we seek comments on what components must be required for each SMA session.

We proposed the following descriptor for SMAs:

HCPCS code G0686: *Voluntary, group-based medical session involving multiple patients with common medical condition(s), receiving medical care in a group setting; billed and led by a physician or qualified nonphysician practitioner and may include services provided by other qualified healthcare professionals, clinical staff, or auxiliary personnel under the direction of the supervising physician or other practitioner. Session integrates group education, counseling, and peer support with individualized patient clinical assessment and care, 2–10 patients, billed once per patient, per session.*

Because SMA sessions would integrate group education, counseling, and peer support with individualized patient clinical assessment and care, in developing the valuation for the SMA HCPCS code, we proposed to use a building block methodology that sums up the values associated with two reference codes. For the overall E/M elements of the SMA service, we are incorporating the work RVUs, work time and direct PE inputs associated with a level 3 O/O visit for an established patient, CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.),* which has a work RVU of 1.30, and a total work time of 30 minutes, which is based on a pre-service evaluation time of 5 minutes, an intraservice time of 20 minutes, and a post service time of 5 minutes. E/M visit level selection does not need to be based on time; practitioners may select the visit level based on the level of medical decision making (MDM). Additionally, as we discussed earlier in this section, we proposed that SMAs be limited to beneficiaries who have received a professional service from the billing physician or other qualified health professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice within the previous 12 months. Given this pre-existing clinical relationship and the anticipated clinical profile of beneficiaries that would participate in an SMA, we believe that the level 3 O/O visit for an established patient represents the most typical level of service for the individualized patient clinical assessment component of the SMA.

For the group education, counseling, and peer support elements of the SMA service, we are incorporating CPT code 96202 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes*), which has a work RVU of 0.43 and a total work time of 15 minutes, which is based on a pre-service evaluation time of 2 minutes, an intraservice time of 10 minutes, and a post service time of 3 minutes.

While a SMA may include up to 10 beneficiaries in a 60—minute session, the individualized care for a participating beneficiary may vary, such that some beneficiaries may receive more or less individualized care than others; nonetheless, documentation in the medical record must reflect the specific services that the individual beneficiary received during the SMA session. As we price services under the PFS based on a typical case, the proposed valuation for HCPCS code G0686 reflects a typical SMA session and is not intended to represent the

https://www.cdc.gov/cancer/php/ebi-planning-guides/index.html. Accessed 7 July 2026.

[50] American Diabetes Association Professional Practice Committee for Diabetes. ''5. Facilitating Positive Health Behaviors and Well-Being to Improve Health Outcomes: Standards of Care in Diabetes—2026.'' *Diabetes Care,* vol. 49, suppl. 1, 2026, pp. S89–S131, *https://doi.org/10.2337/dc26-S005.*

[51] *https://pmc.ncbi.nlm.nih.gov/articles/PMC7781059/pdf/10.1177_1559827620943819.pdf.*

exact time distribution for every beneficiary in every SMA. We note that the total work time proposed is for the purposes of valuation and not meant as a requirement for billing. We believe this reflects a typical amount of time for both the individualized patient clinical assessment and the beneficiary's proportionate share of group education, counseling, and peer support that occurs concurrently across all participating beneficiaries during a SMA session.

Considering the aforementioned building block methodology for SMA valuation, we proposed a work RVU of 1.73 and a total work time of 45 minutes, which is based on a pre-service evaluation time of 7 minutes, an intraservice time of 30 minutes, and a post service time of 8 minutes.

In addition to seeking comments on establishing the proposed HCPCS code G0686, we also seek comment on the proposed work RVUs, work times, and direct PE inputs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed strong support for CMS's proposal to establish a dedicated code and payment pathway for SMAs and stated that SMAs are an effective approach for managing chronic conditions. Many stakeholders highlighted evidence for SMAs, noting improved patient outcomes, reduced emergency and inpatient utilization, enhanced engagement, and greater efficiency in chronic disease management. Several commenters emphasized that SMAs are particularly valuable for populations with multiple chronic conditions, behavioral health needs, and those facing social isolation or barriers to care. A few commenters recommended that CMS treat the creation of the SMA code as an iterative first step, with ongoing refinement based on utilization and outcomes data. A few commenters opposed the establishment of a dedicated code and payment for SMAs under the Medicare PFS, suggesting instead that CMS test these concepts through limited demonstration or alternative payment models (APM) first.

Response: We appreciate the feedback received from commenters regarding creating coding and payment for SMAs. As we recognize the value that SMAs may bring to managing chronic disease, we are finalizing coding and payment for SMAs.

Comment: Several commenters supported SMAs as an appropriate approach for conditions modifiable with lifestyle change. Commenters supported the creation of coding for SMAs and some recommended eligibility of specific conditions including but not limited to tobacco use disorder, alcohol use disorder, other substance use disorders, obesity, behavioral health conditions, fibromyalgia and central sensitization syndromes, polycystic ovary syndrome, and infertility-associated metabolic and hormonal conditions. Another commenter stated CMS should avoid establishing an exhaustive list of eligible diagnoses and instead recommended that eligibility be available when authoritative clinical guidelines or sufficient evidence base recognize lifestyle modification.

Many commenters supported broadening the eligible conditions for SMAs beyond the proposed ''lifestyle-modifiable'' criteria. Several commenters recommended not restricting SMAs to conditions deemed ''lifestyle-modifiable,'' citing reviews and/or experience demonstrating benefits across hypertension, diabetes, heart failure, obesity, COPD, osteoporosis, migraine, chronic pain, depression, cancer survivorship, Parkinson's disease, rheumatoid arthritis, neuromuscular disease, and prenatal care. Several commenters noted that most Medicare beneficiaries participating in SMAs have multiple chronic conditions, making diagnosis-specific or lifestyle-only restrictions impractical and inconsistent with real-world clinical care.

Response: We thank commenters for their feedback, including the commenters supporting SMAs as an appropriate approach for conditions modifiable with lifestyle change, and commenters that recommended specific conditions for SMA services. After consideration of the comments, we are not creating an exhaustive list of eligible diagnoses and conditions, and we continue to believe that SMAs are an appropriate approach for conditions that are modifiable with lifestyle change. To the extent that conditions, including those that commenters recommended for inclusion, are modifiable with lifestyle change, they would not be precluded from the SMA service.

Comment: Several commenters raised the importance of patient choice, privacy, and voluntary participation as considerations for SMA designs. A commenter stated that participation in SMAs should remain voluntary since HIPAA protects patient health information and many commenters may feel uncomfortable discussing sensitive medical concerns in front of others. The commenter cautioned that paying for SMAs could unintentionally encourage practices to rely more heavily on group visits for efficiency rather than patient preference, and SMAs should not replace the option of one-on-one appointments for patients who prefer them. A commenter recommended clarification on confidentiality terms including prohibition on beneficiaries posting information about other participants on social media. Commenters recommended that CMS require clear documentation of consent and confidentiality terms, with a couple comments specifically suggesting that consent be documented in the medical record.

Response: We thank the commenters for feedback regarding voluntary participation in SMAs and continue to believe that SMAs must be voluntary. We have updated the code descriptor to emphasize this point. We also continue to believe that beneficiaries need to consent to SMA participation and must consent to confidentiality terms. These requirements are intended to ensure that participation in SMAs is based on informed patient choice, and that privacy is protected. We agree that SMAs should not replace the option of one-on-one appointments for patients who prefer them and that clear documentation of consent and confidentiality, including prohibitions on sharing information about other participants are needed safeguards.

Comment: Many commenters recommended greater flexibility in the session duration for SMAs, rather than the proposed 60-minute limit. Many commenters recommended that CMS allow sessions to extend to 90 or 120 minutes, citing evidence and operational experience that longer sessions are often necessary to accommodate comprehensive education, peer discussion, individualized clinical care, and skills-based learning. Several commenters suggested either establishing add-on codes for longer sessions or permitting sessions to exceed 60 minutes, stating this would better reflect real-world practice and improve the effectiveness of SMAs. A few commenters noted that patient surveys and operational realities identify group discussion and shared learning as beneficial components of participation, and that additional time is needed to support these elements. Some commenters noted that rigid time limits could reduce access and limit the value of SMAs for patients with complex needs.

However, a few commenters supported the proposed 60-minute duration as a reasonable safeguard. A commenter expressed support for the 60-minute session requirement, noting it

provides a safeguard for quality and clinical appropriateness, but also encouraged CMS to evaluate future increases in session duration based on outcomes data and operational experience.

Response: We thank commenters for their input regarding SMA session duration. After consideration of comments received, we were persuaded by commenters that the SMA service code should allow for a longer session duration than the originally proposed 60-minutes. We are finalizing an add-on code (HCPCS code G0687) that will permit up to two units in 30-minute increments, providing greater flexibility for practitioners to accommodate group education, counseling, peer support, individualized clinical assessment and care. Practitioners may bill up to two additional 30-minute units when medically necessary, allowing an SMA to last up to 120 minutes in total. A 120-minute SMA session would have a combined work RVU of 3.47.

Comment: Many commenters recommended increasing the proposed group size limit of 10 beneficiaries per session, with many suggesting allowing up to 15 beneficiaries per session, and a few advocating for larger groups, such as up to 20 participants. Several commenters recommended increasing the group size to better reflect operational realities, peer-reviewed evidence, and the need to accommodate attrition and no-shows. Several commenters stated that group sizes of 12–15 are common in SMA models, and that a cap of 10 beneficiaries would result in smaller groups due to cancellations, thereby undermining peer dynamics. A few commenters recommended setting a minimum group size (such as five patients) to ensure operational flexibility for smaller or rural practices that may struggle to reach higher numbers. Some commenters suggested that CMS allow practitioners to use their judgment in determining the appropriate group size based on patient needs, session duration, and care team composition. One comment referenced peer reviewed literature supporting effective SMAs with groups of 8–20 patients and recommend allowing SMA billing for groups of up to 20 patients. A few commenters supported the proposed cap of 10 beneficiaries per session. One of the commenters stated that the cap sessions at 10 participants provide reasonable safeguards for quality and clinical appropriateness. Another commenter support that no more than 10 beneficiaries may participate in a SMA per session, as this is the maximum number of participants who can benefit from a session and whom practitioners can serve at a time. A couple of commenters support a limit of 2 to 10 patients per session as the requirement would provide reasonable safeguards while preserving flexibility for them to design group visits to meet their patients' needs.

Response: We thank commenters for their feedback regarding the proposed group size for SMAs. After consideration of comments, we continue to believe that we should limit SMAs to a maximum of 10 beneficiaries per session. This approach is intended to provide patients with more individualized time with the practitioner when needed, ensuring that each beneficiary participating in the SMA receives adequate attention and support. We understand that a larger SMA group size may boost operational efficiency and help accommodate attrition or no-shows, however we have concerns that increasing the group size further could dilute the quality of clinician-patient interaction and potentially undermine the peer dynamics that are central to successful SMA models.

Comment: A majority of commenters strongly supported the inclusion of multidisciplinary teams in SMAs, emphasizing that effective group visits depend on the participation of multiple clinicians, including physicians, nurse practitioners, physician assistants, dietitians, behavioral health specialists, pharmacists, physical therapists, health coaches, acupuncturists, and other allied health professionals. Several commenters highlighted the importance of team-based care for addressing the complex medical, behavioral, and lifestyle needs of Medicare beneficiaries. Many commenters urged CMS to ensure that the SMA payment structure adequately supports the work of the full interdisciplinary team, warning that insufficient valuation could push practices toward a bare-minimum version of the benefit rather than the comprehensive model intended.

Several commenters requested preserving separate billing for distinct, nonduplicative services furnished by qualified professionals during SMAs, such as group medical nutrition therapy (MNT), diabetes self-management training (DSMT), physical activity interventions, and behavioral health services. A few commenters recommended allowing registered dietitians and other specialists to bill for their services separately when appropriate, rather than bundling all work into a single SMA payment. A few commenters supported the proposed requirements for physician or qualified nonphysician practitioner leadership, describing them as reasonable safeguards for quality and clinical appropriateness. However, most commenters requested greater flexibility, including allowing auxiliary personnel and allied health professionals to furnish components of SMAs under appropriate supervision.

Response: We thank commenters for supporting and providing feedback regarding the inclusion of multidisciplinary teams in SMAs. We agree that team-based care is important for addressing the complex medical, behavioral, and lifestyle needs of Medicare beneficiaries. Services provided under an SMA cannot be billed separately because the minutes of the service counted toward the SMA service code cannot also be counted for any other billed service. This ensures that the SMA payment structure remains consistent and avoids duplication of billing for overlapping services.

Comment: A few commenters supported the proposed valuation for SMA as a reasonable starting point. A commenter expressed general support for the building block methodology and encouraged CMS to monitor outcomes and revisit the valuation as needed. Several commenters addressed the proposed valuation for SMAs, and several commenters expressed concerns that the building block methodology may undervalue the complexity and resources required for effective group visits. Many commenters stated the combination of CPT 99213 and 96202 (resulting in 1.73 work RVUs) may not adequately reflect the work involved in moderate or high-complexity SMAs, especially those serving patients with multiple chronic conditions and requiring multidisciplinary team input. A few commenters suggested a crosswalk to group health behavior intervention codes (CPT codes 96164 and 96165) instead of CPT code 96202 for the group education, counseling, and peer support elements, arguing that these codes better capture the service delivery and intensity of SMAs. Several commenters recommended tiered complexity codes (analogous to CPT codes 99213 and 99214), the addition of the complexity add-on code (HCPCS code G2211), or time-based payment options to ensure that the valuation matches the clinical work and team-based care required. A couple of commenters stated that the proposed valuation underestimates clinician time and administrative complexity, and recommended increases to the work RVU to incentivize the use of SMAs and

support sustainable delivery. A commenter raised concerns about the utilization estimate for SMAs. The commenter noted that CMS's addenda tables project 410,100 unadjusted allowed services for 2027 and stated the assumptions underlying this estimate were not clearly explained. The commenter cautioned that the projected number may be too high and could result in resources being removed from the fee schedule. The commenter requested CMS to clarify its methodology for estimating utilization to ensure that resource allocation is appropriate and sustainable.

Response: We thank commenters for their feedback regarding the valuation of SMAs. We appreciate the support for the proposed methodology and the encouragement to monitor outcomes and revisit the valuation as needed. As previously discussed, after consideration of comments, we are finalizing the addition of a new add-on code for SMAs (HCPCS code G0687) to account for additional time spent during the session, in 30-minute increments up to two units. The new add-on code will be valued at half the work RVU of the base code, resulting in a finalized work RVU of 0.87. With this additional coding and the option to add time as needed for the duration of the SMA, we believe that the valuation of the add on code and valuation of the base SMA code with a work RVU of 1.73 work is appropriate for SMAs.

Additionally, in response to the commenter who provided input on the SMA utilization estimate for 2027, we note that the estimate was based on approximately 3 percent of the utilization of CPT code 99213 specifically billed by primary care specialties, including family practice, general practice, and internal medicine; this translated into approximately 0.6 percent of all billings of CPT code 99213. Our understanding is that practitioners are currently billing for shared medical appointments using CPT code 99213, and the projected utilization for HCPCS code G0686 would replace some of this utilization. We derived the 3 percent estimate from a published survey,[52] in which 3 out of the 107 survey respondents were actively involved in group visits at the time of survey, which indicated that less than 3 percent of primary care clinicians were actively involved in furnishing group visits. We will continue to monitor utilization and outcomes, and welcome ongoing feedback as we may refine the valuation in future rulemaking.

Comment: Several commenters provided feedback regarding same-day billing for E/M visits and SMAs, with a majority expressing support for allowing separate billing when both services are medically necessary and distinctly documented. Many commenters recommended clarification to permit same-day billing for E/M visits and SMAs, provided that the time and work for each service are not double-counted and that documentation clearly supports the distinct nature of each encounter. Several commenters emphasized that prohibiting same-day billing could create barriers to comprehensive patient care, delay necessary evaluation and treatment, and increase administrative burden for both patients and providers. A couple of commenters requested clarification that the limitation on counting same-day SMA and E/M services separately would not preclude separate payment for distinct, medically necessary services that require privacy and cannot appropriately be furnished in a group setting. Other commenters recommended explicit billing guidance to ensure that practitioners can address acute issues that arise during SMA sessions without being penalized.

Response: We thank commenters for their feedback regarding same-day billing for E/M visits and SMAs. We agree with the majority of commenters and will finalize our proposal such that in the event it is medically necessary for a beneficiary to receive an E/M visit on the same day as an SMA by the same physician or more than one physician in the same specialty in the same group, we are finalizing that any time and effort cannot be counted more than once. Accordingly, we will not consider or treat this as two separate E/M same-day visits. This approach is intended to ensure that time and work are not double counted, maintaining the integrity of documentation and billing while supporting comprehensive patient care.

Comment: Many commenters expressed strong support for permitting SMAs to be delivered via telehealth, emphasizing that this flexibility would expand access for rural, mobility-limited, and underserved populations. Several commenters recommended finalizing the proposal to add SMAs to the Medicare Telehealth Services List. Many commenters highlighted that telehealth delivery is essential for overcoming transportation barriers, supporting continuity of care, and enabling participation for beneficiaries with functional limitations. A few commenters requested clarification in the final rule that SMAs may be furnished in hybrid formats, with some participants attending in person and others joining via telehealth, and that the SMA service should be billable for each beneficiary present regardless of modality.

Response: We appreciate the support from commenters and are finalizing that SMA sessions can be held either in-person or via telehealth and clarifying that SMAs may be furnished in hybrid formats, with some participants attending in person and others joining via telehealth.

Comment: Many commenters opposed the proposed 12-month existing clinical relationship with the practitioner requirement, arguing that it would unnecessarily restrict access to SMAs and delay care for patients who could benefit from group visits. Several commenters recommended removing or relaxing the 12-month existing clinical relationship with the practitioner requirement. Many commenters suggested that eligibility should be determined by medical necessity and practitioner judgment, rather than the timing of a prior visit. Several commenters requested to allow referrals from any treating clinician within a health system, not just the same specialty or group practice, to preserve continuity of care and expand timely access. A couple of commenters stated that conditioning SMA access on a documented prior encounter introduces avoidable delays, especially for patients newly diagnosed or identified as needing intervention. Some commenters stated that the 12-month existing clinical relationship with the practitioner requirement could exclude complex beneficiaries and create administrative burdens for small or rural practices.

A few commenters supported the proposed 12-month existing clinical relationship with the practitioner requirement and expressed support for the 12-month prior-visit requirement, describing it as a reasonable safeguard for quality and clinical appropriateness.

Response: We thank commenters for their feedback regarding the proposed 12-month existing clinical relationship with the practitioner requirement for SMAs. After consideration of comments, we continue to believe that a 12-month existing clinical relationship between the practitioner and patient is appropriate. This relationship is important for determining whether SMAs would be suitable and beneficial for the patient. By maintaining this requirement, we aim to safeguard clinical appropriateness and quality of

[52] *https://pmc.ncbi.nlm.nih.gov/articles/PMC5932677/.*

care, while supporting continuity between the practitioner and patient.

Comment: Several commenters described the operational frequency and cadence of SMAs based on their experience and other evidence. A commenter referenced evidence-based cadences from literature, referencing intensive weekly series of 6 to 16 weeks followed by monthly or quarterly maintenance. A couple of commenters reported that their programs commonly operate SMAs once weekly for several weeks or once monthly for ongoing support, reflecting the need for flexibility to accommodate patient needs and program goals. Many commenters recommended allowing operational flexibility and avoid imposing rigid frequency limits, noting that the optimal cadence may vary depending on the condition, patient population, and care model. A few commenters suggested that if CMS establishes a per-beneficiary limit, it should be set at not fewer than 36 sessions per calendar year to accommodate intensive and maintenance schedules documented in the literature.

Response: We thank commenters for providing valuable information regarding the operational frequency and cadence of SMAs. After consideration of the comments, we are finalizing a frequency limit of not more than one SMA session per week per beneficiary.

Comment: Many commenters provided detailed recommendations for program integrity and safeguards, reflecting broad consensus that robust protection is essential for SMAs. Several commenters emphasized the importance of individualized documentation for each participant, attendance verification (such as sign-in sheets or platform logs), documented consent and confidentiality terms, and staff training in group facilitation and SMA protocols. A couple of commenters recommended routine claims audits and periodic outcomes review as part of the integrity framework. Several commenters suggested establishing a reasonable annual encounter limit (for example, at least 36 sessions per beneficiary per year) to prevent runaway volume while supporting intensive and maintenance schedules.

A few commenters cautioned against rigid structural limits (such as diagnosis, duration, or group size) as primary safeguards, arguing that individualized documentation and compliance audits are more effective and less burdensome. Some commenters requested balanced safeguards against administrative burden, ensuring that legitimate SMAs remain practical for small, rural, and community practices.

Response: We thank the commenters for providing detailed recommendations regarding program integrity and safeguards for SMAs. After consideration of commenter's input, we are finalizing the requirement that each SMA session be documented in each participating beneficiary's medical record. This documentation ensures individualized care and accountability, and we will continue to monitor this process and welcome ongoing feedback. We note that it may be beneficial for practitioners to retain attendance verification for the SMAs (such as sign-in sheets or platform logs) as this may be helpful in the event of a routine claims audit. We would appreciate additional information on recommended staff training requirements for SMAs and may address this along with additional safeguards in future rulemaking.

Comment: Commenters stated that the proposed rule did not clearly address whether RHCs and FQHCs may furnish and bill for SMAs and requested that CMS explicitly extend G0686 eligibility to these settings. Commenters cited the high chronic disease burden and access barriers (rural geography, transportation, limited specialty care) faced by beneficiaries served by RHCs and FQHCs. Another commenter also requested that, if RHCs and FQHCs are permitted to furnish SMAs, CMS allow separate payment for a same-day individual E/M visit when a beneficiary requires individualized attention for an acute issue arising during a group session.

Response: We thank the commenters for their comments. A billable RHC or FQHC visit requires a medically necessary, face-to-face, one-on-one encounter between a beneficiary and an RHC or FQHC practitioner (§ 405.2463). SMAs, by design, involve concurrent group participation and do not meet this definitional requirement.

Comment: Several commenters raised concerns about cost sharing and out-of-pocket costs for beneficiaries participating in SMAs. A commenter recommended that CMS address beneficiary cost sharing in the final rule, urging that copayments for SMAs should not exceed those charged for individual appointments. A couple of commenters emphasized the importance of reducing cost-sharing barriers to ensure equitable participation, especially for underserved and vulnerable populations. Many commenters highlighted that minimizing out-of-pocket costs would help maximize access to SMAs and support health equity.

Response: We thank the commenters for their feedback. In response to the comments regarding elimination of beneficiary cost sharing for SMA services, most services covered under Medicare Part B carry cost sharing obligations (deductible and co-payment) unless the statute specifies that they do not apply. SMA services would be subject to applicable deductible and co-payment requirements as we do not have statutory authority that would allow us to remove or waive applicable cost sharing for SMA services.

Comment: Several commenters provided feedback on how HCPCS code G0686 should be described and coded. Many commenters recommended that the descriptor should clearly identify SMAs as voluntary, group-based medical sessions that integrate individualized clinical assessment and care with group education, counseling, and peer support. Several commenters requested that the code language explicitly require individualized documentation for each participant, consent and confidentiality terms, and allow for multidisciplinary team participation under appropriate supervision. Many commenters urged preserving flexibility in the descriptor language, allowing practitioners to determine session length, group size, and team composition based on clinical need and operational realities. Several commenters emphasized that SMAs should not be characterized as group visit, as this understates the SMA service, and they recommend adopting terminology that includes the term ''medical.''

A few commenters raised concerns about the use of the term ''peer support'' in the SMA descriptor as this may be confused with peer support services provided by peer support specialists. They recommended removing or avoiding the term in the SMA code description. Conversely, a few commenters appreciate explicitly identifying education and peer support in the code description.

Response: We thank commenters for providing feedback regarding the SMA descriptors. After considering comments, we are modifying the code descriptor with technical refinements and changes. Although the code descriptor already included the term ''voluntary'', we modified the code descriptor to emphasize the voluntary nature of SMAs. We also acknowledge commenters' emphasis that SMAs should be described by including the term ''medical'' and are finalizing the descriptor to begin with the terms

''Group-based medical session.'' The inclusion of the term ''peer support'' in the descriptor is intended to reflect the supportive interaction among patients within SMAs. The long descriptors for SMAs will be finalized as follows:

HCPCS code G0686: *Group-based medical session involving multiple patients with common medical condition(s) and receiving medical care in a group setting. The voluntary session is billed and led by a physician or other qualified healthcare professional (QHP) and may include services provided by other QHPs, clinical staff, or auxiliary personnel under the direction of the supervising physician or QHP. The voluntary session integrates group education, counseling, and peer support with individualized patient clinical assessment and care, includes 2–10 patients, billed once per patient, first 60 minutes.*

HCPCS code G0687: *Group-based medical session involving multiple patients with common medical condition(s) and receiving medical care in a group setting. The voluntary session is billed and led by a physician or other qualified healthcare professional (QHP) and may include services provided by other QHPs, clinical staff, or auxiliary personnel under the direction of the supervising physician or QHP. The voluntary session integrates group education, counseling, and peer support with individualized patient clinical assessment and care, includes 2–10 patients, billed per patient, each additional 30 minutes (list separately in addition to code for primary service).*

After consideration of the public comments, we are finalizing our proposal to create coding and separate payment for shared medical appointments with modifications. We are finalizing an add on code (HCPCS code G0687) with a work RVU of 0.87. Practitioners may bill up to two additional 30-minute units when medically necessary, allowing an SMA to last up to 120-minutes, and resulting in a combined work RVU of 3.47 for the SMA session. We are finalizing the HCPCS G0686 valuation as proposed. We are finalizing a frequency limit of not more than one SMA session per week per beneficiary. Additionally, we are finalizing a modified long descriptor for HCPCS G0686. However, we continue to welcome additional information and continued engagement on SMAs and may consider refinements through future rulemaking.

(55) Vaccine Adverse Effects Management (HCPCS Code G0576)

Vaccines prevent serious illnesses and even death in persons who receive them and serve a public health benefit. Vaccines are intended to produce active immunity to specific antigens. An adverse reaction is an undesirable side effect that occurs after a vaccination. Vaccine adverse reactions are classified as (1) local; (2) systemic; or (3) allergic. Local reactions (for example, redness) are usually the least severe and most frequent. Systemic reactions (for example, fever) occur less frequently than local reactions, and severe allergic reactions (for example, anaphylaxis) are the least frequent reactions.[53] Licensed vaccines are safe and effective; however, adverse events have been reported after administration of each type of available vaccine.[54] Vaccine providers should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Providers, including practitioners, should also have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction.[55]

Before a vaccine is licensed, the Food and Drug Administration (FDA) takes steps to make sure the vaccine is safe. FDA requires that a vaccine goes through extensive safety testing. Even though careful studies are done before a vaccine is licensed, rare adverse effects may not be found until a vaccine is given to millions of people with different backgrounds and medical histories.[56] According to clinical trial data, most vaccine-associated adverse events are mild; however, severe adverse reactions such as anaphylaxis, myocarditis, thrombotic events, and pneumonitis have been reported.[57] After a vaccine is licensed, the Vaccine Adverse Event Reporting System (VAERS) is one of the mechanisms used to monitor for any problems, or ''adverse events,'' that happen after vaccination.[58]

We believe that the CPT evaluation and management code set may capture the work and clinical decision making involved in the evaluation and management of most vaccine adverse reactions. However, we believe that physician and nonphysician practitioners' work may not be accurately reflected under the CPT medical decision-making framework relating to the evaluation and management of rare and severe vaccine adverse reactions. E/M visits, like other services under the PFS, are valued based on an assumption of a typical case. We believe that these are additional resource costs that don't fit under a typical E/M. Therefore, we proposed an add-on code and payment for diagnosis and management of a suspected vaccine adverse reaction for services going above and beyond those captured in an evaluation and management (E/M) visit. These services entail listening to patient concerns, answering questions, and building trust; selecting diagnosis strategies and conveying information in a manner specific to each patient's concerns, cultural and religious beliefs, and literacy level; providing patients with appropriate resources; and planning with patients the treatment of symptoms of vaccine adverse effects. We proposed that this add-on code, HCPCS code G0576 (*Office or other outpatient evaluation and management service(s) for the diagnosis and treatment of vaccine adverse effects, new or established patient; each 15 minutes personally performed by the physician or qualified healthcare professional (list separately in addition to CPT codes 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350)*), would be payable when a physician or nonphysician practitioner (NPP): (1) establishes and documents a temporal relationship to vaccination, and (2) performs a medically appropriate assessment to rule out alternative causes.

For the purposes of valuation, we proposed a direct crosswalk for HCPCS code G0576 to HCPCS code G2212 (*Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215, 99483 for office or other outpatient evaluation and management services) (do not report G2212 on the same date of service as 99358, 99359, 99415, 99416) (do not report G2212 for any time unit less than 15 minutes)*) for 0.61 work RVUs and for direct PE inputs.

[53] *https://www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html#cdc_report_pub_study_section_3-preventing-adverse-reactions*, accessed 5/1/2026.

[54] Ibid.

[55] Ibid.

[56] *https://vaers.hhs.gov/docs/VAERS_Brochure_for_Parents_and_Caregivers_EN_508_2026.pdf.*

[57] Suzuki T, Furuta H, Naganawa M, Hayashi K, Kiyotoshi H, Ohta C, Ninomiya S. COVID–19 Vaccine-Induced Severe Pneumonitis. Respirol Case Rep. 2025 Aug 21;13(8):e70274. doi: 10.1002/rcr2.70274. PMID: 40860748; PMCID: PMC12371123.

[58] Ibid.

We welcomed comments on whether a second HCPCS code for 15 minutes of physician or NPP work time should be finalized and structured as a stand-alone code to more accurately capture the work entailed in cases where a patient is being evaluated for only a vaccine related complaint, outside the context of an E/M visit being furnished for a separate complaint. We also welcomed comments on whether in finalizing such a stand-alone HCPCS code we should crosswalk its work RVU and PE inputs to HCPCS code G2212.

We received many public comments on these proposals. The following is a summary of the comments we received and our responses.

Comments: The majority of comments expressed were identical, anonymous comments expressing support for the new vaccine adverse effects HCPCS add-on code G0576. These commenters requested that this and other immunization administration codes be removed from National Correct Coding (NCC) bundling when billed with E/M codes on the same date of service, as bundling defeats the purpose of encouraging screening/preventive services. A few other commenters expressed unqualified support and a few others expressed support but asked CMS to monitor utilization for potential misuse of the code that would result in duplicative billing or unnecessary testing or services that are not supported by the patient's presentation. A couple of commenters requested consideration of policies beyond the scope of this rulemaking.

Finally, many commenters opposed the creation of the HCPCS code G0576 because they felt that the new coding is clinically unnecessary given existing coding mechanisms and furthermore the new coding risks generating misleading data that could be used to overstate vaccine-related harm and undermine public confidence in immunization. Some felt that the separate payment could create incentives to misattribute nonspecific symptoms to vaccination without clear clinical evidence. Nearly all of those that were opposed asked that CMS articulate a clearer distinction between the proposed HCPCS code G0576 service and work that is already reportable through established E/M coding and diagnosis reporting mechanisms. A commenter suggested that G0576 is fundamentally counseling services and should be explicitly described as such in the code descriptor and accompanying guidance. Another commenter asked that CMS issue clear guidance so that practitioners and billing staff can reliably determine when HCPCS code G0576 applies instead of a base code E/M or prolonged E/M service. Commenters generally requested clear guidance regarding the documentation necessary to establish the required temporal relationship and medically appropriate assessment of alternative causes stating that requirements should reflect reasonable clinical documentation and should not become rigid technical conditions that generate denials despite the furnishing of medically necessary care. Another commenter also felt that HCPCS code G0576 was more of a counseling service that should be taking place before a vaccination is given rather than after the vaccination has already taken place and bemoaned that CMS coding does not allow clinicians to report vaccine counseling time when a vaccine is not administered. Finally, a commenter stated that the apparent frequency of suspected vaccine adverse reactions could reflect differences in provider coding behavior, reimbursement incentives, documentation practices, and patient attribution—not differences in the underlying incidence or severity of adverse events.

Response: We thank commenters for their comments. We believe that physician and nonphysician practitioners' work may not be accurately reflected under the CPT medical decision-making framework relating to the evaluation and management of rare and severe vaccine adverse reactions. E/M visits, like other services under the PFS, are valued based on an assumption of a typical case. We believe that these services involve additional resource costs that do not fit under a typical E/M service code. These services entail listening to patient concerns, answering questions, and building trust; selecting diagnosis strategies and conveying information in a manner specific to each patient's concerns, cultural and religious beliefs, and literacy level; providing patients with appropriate resources; and planning with patients the treatment of symptoms of suspected vaccine adverse effects.

After consideration of public comments, we are finalizing coding and payment for HCPCS add-on code G0576 (*Office or other outpatient evaluation and management service(s) for the diagnosis and treatment of vaccine adverse effects, new or established patient; each 15 minutes personally performed by the physician or qualified healthcare professional (list separately in addition to CPT codes 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350)*) as proposed for the diagnosis and management of a suspected vaccine adverse reaction. We expect practitioners to support reporting of HCPCS code G0576 with sufficient evidence in the medical record for services going above and beyond those captured in an E/M visit. We are finalizing adding HCPCS code G0576 to the Medicare Telehealth List.

(56) Health Coaching (CPT Codes 0591T, 0592T, and 0593T)

Per the Trump Administration's Executive Order, ''Establishing the President's Make America Healthy Again Commission,'' [59] the Administration is directing agency focus towards understanding and drastically lowering chronic disease rates, through thinking on nutrition, physical activity, healthy lifestyles, over-reliance on medication and treatments, the effects of new technological habits, environmental impacts, and food and drug quality and safety. Furthermore, the Executive Order directs that agencies shall ensure the availability of expanded treatment options and the flexibility for health insurance coverage to provide benefits to support beneficial lifestyle changes and disease prevention.

As such, in the CY 2026 PFS proposed rule, we sought comment on a wide range of possible rulemaking topics to promote prevention and management of chronic disease, and in particular, asked more detailed questions surrounding health coaching and motivational interviewing. More specifically, we asked whether we should consider coding and payment for health coaching and motivational interviewing beyond the current contractor-priced CPT codes describing health coaching, as an incident-to service performed under general supervision of a billing practitioner, what an appropriate description would be, what types of clinical staff perform motivational interviewing, how long a session lasts, the overlap between motivational interviewing and health coaching, training requirements for motivational interviewing and health coaches, the types of clinical circumstances where motivational interviewing and health coaching are performed, relevance for audiovisual or audio-only telecommunication, the experience of payers and providers using the CPT Category III CPT codes, and relevance for Evidence-Based Programs that effectively manage or prevent chronic disease. Commenters

[59] *https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/.*

responded, stating that health coaching could support CMS' goal of preventing or managing chronic disease. Many health coaches wrote about their personal experience working with patients with chronic diseases, assisting them in making behavioral and lifestyle changes to self-manage their conditions, and noted that health coaching is a low-cost and highly effective strategy that empowers patients to manage their health. Many commenters requested paying separately for health coaching via the creation of HCPCS G-codes or another payment mechanism that would allow providers to reliably schedule and bill for health coaching services. Commenters also emphasized the importance of requiring that these services be provided by health coaches with appropriate training and certification.

To ensure we adequately capture the time and resources for health coaching, we proposed conditions of payment and valuation for 0591T (*Health and well-being coaching face-to-face; individual, initial assessment, 60–90 minutes*), 0592T (*Individual, follow-up session, at least 30 minutes),* and 0593T (*Health and well-being coaching, group [2 or more individuals], at least 30 minutes*). CPT code 0593T would be billed once per beneficiary in the group.

We also proposed to adopt the CPT prefatory language for 0591T, 0592T, and 0593T: ''Health and well-being coaching is a patient-centered approach wherein patients determine their goals, use self-discovery or active learning processes together with content education to work toward their goals, and self-monitor behaviors to increase accountability, all within the context of an interpersonal relationship with a coach. The health and well-being coach is qualified to perform health and well-being coaching by education, training, national examination and, when applicable, licensure/regulation, and has completed a training program in health and well-being coaching whose content meets standards established by an applicable national credentialing organization. The training includes behavioral change theory, motivational strategies, communication techniques, health education and promotion theories, which are used to assist patients to develop intrinsic motivation and obtain skills to create sustainable change for improved health and well-being.''

We proposed that CPT codes 0591T, 0592T, and 0593T may be performed under direct supervision of the billing practitioner, as defined by § 410.26(a)(3). We also proposed that when the service is performed under direct supervision by auxiliary personnel, the auxiliary personnel must have received appropriate certification to perform the services, which includes, but is not limited to, fulfilling the National Board for Health and Wellness Coaching National Standards, the National Commission for Health Education Credentialing eligibility for Certified Health Education Specialists, or the American Holistic Nurses Credentialing national standards for Certified Nurse Coaches. In response to the Request for Information (RFI) in the CY 2026 PFS proposed rule (90 FR 49479 through 49480), we received comments from interested parties pointing us towards these standards. We also proposed that appropriate certification for auxiliary personnel to perform the services can also be fulfilled by receiving training from the evidence-based health promotion and disease prevention programs funded under the Older Americans Act and overseen by the Administration for Community Living (ACL). These programs undergo review, meet significant evidence thresholds, and have training requirements built into the program requirements. We solicited comments on these certification standards for auxiliary personnel performing these services.

Furthermore, we understand that occasionally, community-based organizations (CBOs) are the entities that employ health coaches. As noted in the CY 2023 PFS final rule (87 FR 69790) and explained in the CY 2023 PFS proposed rule (87 FR 46102), when we refer to CBOs, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in the community to address the health needs of those populations. They may include community care hubs, community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. Generally, we believe such organizations know the populations and communities they serve and may have the infrastructure or systems in place to assist practitioners to provide these services. We noted that individuals employed by CBOs may operate under general supervision of the billing practitioner, as long as the training and certification guidelines outlined earlier in this section are met.

Finally, we proposed national payment for CPT codes 0591T, 0592T, and 0593T. We proposed to crosswalk work and direct PE inputs for 0591T and 0592T to CPT codes 99490 (Chronic care management) and 99439 (Chronic care management, each additional 20 minutes), respectively, since, like Chronic Care Management (CCM), these visit-based services are performed under general supervision. For 0593T, since it is a group visit billed in 30-minute increments, we proposed to crosswalk the work and PE inputs to CPT code G0109 (Group diabetes self-management training). Therefore, we proposed a work RVU of 1.00 for CPT code 0591T, 0.70 for CPT code 0592T, and 0.23 for CPT code 0593T. Since multiple sessions in the same calendar month may be needed, we did not propose frequency limitations for these codes, as long as they are reasonable and necessary. We will monitor utilization and may re-evaluate these policies in future rulemaking. These services were added to the Medicare Telehealth Services List in the CY 2024 PFS Final Rule (88 FR 78859 through 78860).

We solicited comments on the valuation of these services and the conditions of payment. We also solicited comments on whether we should consider creating HCPCS G-codes to describe these services for CY 2027, rather than actively pricing these Category III CPT codes that describe health coaching services, including what the potential benefits of G-codes would be compared to using the existing codes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters were in support of finalizing national payment for health and well-being services, emphasizing their value in chronic disease prevention, patient engagement, adherence and bridging the gap between clinical advice and sustainable behavior change. A few commenters do not recommend establishing coding or payment for these services under the PFS and suggested testing these concepts through a limited

demonstration or an alternative payment model (APM) first.

Response: We appreciate all input received from commenters regarding national payment for health and well-being services. After consideration of the comments submitted in response to the CY 2026 Request for Information (RFI) on health coaching and comments received on this proposed rule, we are finalizing national pricing for health and well-being coaching, as we recognize the value these services bring to chronic disease prevention. While a few commenters suggested further testing through limited demonstration or APMs, we do not believe this is necessary. These codes have been in effect since January 1, 2020, and are already recognized and used by practitioners. We believe that establishing national pricing at this time best supports the advancement and accessibility of health and well-being coaching services.

Comment: Many commenters were in support of national payment for health and well-being services but raised concerns regarding the proposed valuation for the codes. The commenters indicated that the proposed valuation undervalues the time and professional contribution required for effective health coaching for CPT codes 0591T and 0592T, which would lead to non-utilization of the codes. Commenters noted that the chronic care management codes may provide a reasonable conceptual reference point citing similarities in longitudinal care and general supervision. Several commenters stated that the proposed valuation for the health coaching codes are undervalued because the time used to value the codes are significantly less than what is required. A few commenters, indicated that the proposed crosswalk for the 60-minute initial assessment, CPT code 0591T to CPT code 99490, and the 30-minute follow-up session, CPT code 0592T to CPT code 99439, uses only the first 20-minute increment of the Chronic Care Management (CCM) codes, resulting in both codes being allotted approximately 25 minutes of clinical labor time, such that a 60-minute session and a 30-minute session are valued nearly identically, and both at a fraction of their actual time, leading to payment rates that do not reflect the duration and effort required for these services. A few commenters recommended prorating the CCM crosswalk practice-expense RVUs to reflect the actual time the coaching service requires. Another commenter recommended work RVUs of approximately 3.15, 1.10, and 0.30 for the health coaching services respectively, and if CMS did not adopt this refinement, they recommend at a minimum adopting another commenter's recommended work RVU values of 3.00, 1.05, and 0.29 respectively. Some commenters recommended finalizing national payment as proposed.

Response: We thank the commenters for communicating their concerns, indicating that the time duration of the proposed crosswalk codes would undervalue the health coaching services. Several commenters expressed concerns that our proposed crosswalks for CPT codes 0591T and 0592T did not adequately account for the time required to furnish these services. We agree that the proposed crosswalks do not sufficiently reflect the time associated with furnishing these services. Therefore, in consideration of the comments received, we are valuing the work RVU of CPT code 0591T at 1.81 and CPT code 0592T at 1.00, based on a crosswalk to CPT codes 99487 and 99489. We are crosswalking the work RVUs, work times, and direct PE inputs directly to these complex care management codes that account for more time, specifically, 60 minutes of clinical staff time and each additional 30 minutes, which more closely aligns with the health coaching service CPT codes 0591T and 0592T respectively. We continue to believe crosswalking the work RVU of CPT code 0593T to G0109 is appropriate and were not persuaded that CPT code 0593T required additional time and work valuation. Therefore, we are finalizing it as proposed.

Comment: Many commenters provided feedback on the supervision requirements for health and well-being coaching services (CPT codes 0591T, 0592T, 0593T). The majority of commenters expressed strong support for general supervision, based on operational feasibility, and stated that CMS's proposal was inconsistent because CMS crosswalked the valuation of CPT codes 0591T and 0592T to Chronic Care Management (CCM) codes (CPT codes 99490 and 99439) which are furnished under general supervision, while proposing direct supervision for health coaching itself, and would separately allow health coaches employed by community-based organizations to work under general supervision. Many commenters indicated that direct supervision for health coaching would create unnecessary barriers and would impede access for populations most in need. Some commenters requested adding language that would provide health coaching under general supervision by updating the codes to the designated care management services provision at § 410.26(b)(5), enabling general supervision for health coaching. Nurse organizations and credentialed nurse coaches specifically requested exemption from supervision requirements for licensed professionals, advocating for deference to state scope-of-practice laws and direct billing pathways. A few commenters supported direct supervision. Some commenters recommended that virtual or on-call supervision (real-time audio-video availability) could satisfy the requirements of direct supervision, consistent with recent CMS policy for incident-to services.

Response: We thank the commenters for their feedback regarding the supervision requirements for health coaching. Based on comments received, we now agree that health and well-being coaching should be performed under general supervision of the billing practitioner instead of as proposed with direct supervision. We believe this position is supported by several factors, including that chronic care management services can be delivered under general supervision which offers flexibility for auxiliary personnel to provide services without the billing practitioner being physically present. Additionally, 24/7 access is not necessary for health coaching and is not a required element for similar services such as Community Health Integration (CHI) and Principal Illness Navigation (PIN), which also operate under general supervision. We also want to note that direct supervision is typically reserved for highly clinical services where immediate oversight is needed to reduce potential harm, whereas health coaching is not as directly clinical and aligns more closely with services CMS historically allows under general supervision. As many commenters noted, CMS proposed health coaching codes valuation using a crosswalk to chronic care management codes which permit general supervision, and behavioral health services with similar goals also allow general supervision. We believe that requiring direct supervision would be inconsistent with other chronic care management services and could limit the operability and uptake of health coaching, especially among community-based organizations employing health coaches. Therefore, we are finalizing that health coaching may be furnished under general supervision, ensuring greater workforce capacity, improved patient access, and alignment with CMS's established practices. Additionally, we are making updates to

§ 410.26(b)(5) to specify general supervision for health coaching services accordingly.

Comment: Many commenters provided feedback on qualification and credentialing pathways for health and well-being coaching. Many commenters supported the credentialing pathway of the National Board for Health & Wellness Coaching (NBHWC), citing the rigor of its nationally standardized examination and training process as a quality safeguard. In addition, some commenters advocated for explicit retention of the National Commission for Health Education Credentialing (NCHEC) pathways, including Certified Health Education Specialist (CHES) and Master Certified Health Education Specialist (MCHES), as qualifying credentials for health coaching auxiliary personnel. Some commenters requested for American Holistic Nurses Credentialing Corporation (AHNCC) board-certified Nurse Coaches (NC–BC, HWNC–BC) be explicitly recognized among qualified personnel. Some commenters supported CMS's proposal to recognize training completed through evidence-based health promotion and disease-prevention programs funded under the Older Americans Act and overseen by the Administration for Community Living (ACL), and some commenters recommended aligning the Older Americans Act to HCPCS codes G0108 and G0109 rather than health coaching codes. Several commenters recommended allowing professionals such as occupational therapists, exercise professionals, registered dietitians, pharmacists, community health workers, and social workers to be included as eligible health coaches. They recommended that qualification standards be based on demonstrated skills and competency in evidence-based behavior change principles, allowing these professionals to serve as health coaches, if they can show they have the appropriate education, training and competency to deliver health and well-being coaching services. Several commenters recommended that occupational therapists be recognized as qualified health coach providers without requiring additional certification. Some commenters indicated that credentialing standards should be flexible, avoiding an exhaustive list that could inadvertently exclude qualified professionals as the workforce evolves.

Response: We note that as previously discussed, we are finalizing that CPT codes 0591T, 0592T, and 0593T may be performed under general supervision, as defined by § 410.26(a)(3). In addition, we continue to believe that auxiliary personnel must have received appropriate certification to perform the services, which includes, but is not limited to, fulfilling the National Board for Health and Wellness Coaching National Standards, the National Commission for Health Education Credentialing eligibility for Certified Health Education Specialists, or the American Holistic Nurses Credentialing national standards for Certified Nurse Coaches. In addition, we agree with the comments submitted in response to the RFI in the CY 2026 PFS proposed rule (90 FR 49479 through 49480) that appropriate certification for auxiliary personnel to perform the services can be fulfilled by receiving training from the evidence-based health promotion and disease prevention programs funded under the Older Americans Act and overseen by the Administration for Community Living (ACL) because these programs undergo review, meet significant evidence thresholds, and have training requirements built into the program requirements. Accordingly, we are finalizing as proposed. As such, auxiliary personnel who have received appropriate certification to perform the services, which includes, but is not limited to, fulfilling the National Board for Health and Wellness Coaching National Standards, the National Commission for Health Education Credentialing eligibility for Certified Health Education Specialists, or the American Holistic Nurses Credentialing national standards for Certified Nurse Coaches, and/or have received training from the evidence-based health promotion and disease prevention programs funded under the Older Americans Act and overseen by the Administration for Community Living (ACL) may provide health coaching services under general supervision of a physician or non-physician practitioner. The applicable list of the evidence-based health promotion and disease prevention programs funded under the Older Americans Act and overseen by the Administration for Community Living (ACL) can be found on the *ACL.gov* website (*https://acl.gov/programs/health-wellness/disease-prevention*).

Comment: Many commenters recognized the essential role of community-based organizations (CBOs) in delivering health and well-being coaching services, emphasizing their unique ability to engage local populations and address social drivers of health. Many commenters noted that CBOs are trusted entities within their communities. Credentialed health education specialists, such as CHES and MCHES professionals, frequently work in CBOs and bring expertise in health education, behavior change, communication, and program implementation. Commenters recommended CMS explicitly allow CBOs to employ and furnish health coaching services under general supervision, highlighting that CBOs may lack on-site practitioners but can still provide high-quality, evidence-based coaching through trained personnel.

Response: We thank the commenters for their feedback. CBOs often employ health coaches, and individuals employed by CBOs may operate under general supervision of the billing practitioner as long as the training and certification guidelines outlined earlier in this section are met. Accordingly, auxiliary personnel employed by a CBO, or otherwise affiliated with a CBO that employs health coaches, who have received appropriate training and certification to perform health coaching services, may provide health coaching services under general supervision of a physician or non-physician practitioner.

Comment: Commenters overwhelmingly supported the inclusion of telehealth as an allowable delivery option for health and well-being coaching services, emphasizing its critical role in expanding access for Medicare beneficiaries who face geographic, transportation, mobility, or caregiving barriers. Commenters also recommended flexible delivery as essential for accommodating evening and weekend sessions, and for matching beneficiaries with specialized coaches, such as those fluent in American Sign Language or with expertise in particular health conditions. Several commenters requested CMS to clarify that audio-only telehealth encounters should be permitted when video is not feasible, ensuring accessibility for individuals with sensory, cognitive, or technological limitations.

Response: We thank the commenters for their support. These services were added to the Medicare Telehealth Services List in the CY 2024 PFS Final Rule (88 FR 78859 through 78860). Section 6209(e) of the CAA, 2026 extends the flexibilities to allow audio-only Medicare telehealth services from January 30, 2026 to the extended date of January 1, 2028. Please refer to section II.C. Payment for Medicare Telehealth Services of this final rule for additional information.

Comment: Several commenters supported CMS's proposal to not propose frequency limitations on health and well-being coaching services. The commenters noted that the frequency and duration of coaching sessions

should be determined by clinical need and beneficiary-specific goals, rather than arbitrary caps. Several commenters highlighted that higher-frequency coaching is often necessary during the early period of a new patient relationship.

Response: We thank the commenters for their support in not establishing frequency limits for health and well-being services. Since multiple sessions in the same calendar month may be needed, we are not finalizing frequency limitations for these codes, as long as they are reasonable and necessary. We will monitor utilization and may re-evaluate these policies in future rulemaking.

Comment: Several commenters provided feedback regarding adopting the CPT prefatory language for 0591T, 0592T and 0593T. Commenters expressed the importance of maintaining clear, inclusive, and precise descriptors as established by the AMA CPT Editorial Panel. Several commenters recommended preserving the existing CPT language, which defines the scope, session duration, and credentialing standards for health coaching. Some commenters suggested that CMS revise the CPT code descriptors to clarify minimum session times, such as specifying ''at least 60 minutes'' for the initial assessment (CPT code 0591T), ''at least 30 minutes'' for follow-up (CPT code 0592T), and ''each 30 minutes'' for group coaching (CPT code 0593T), to help ensure consistent billing and proper reimbursement, especially for sessions that may require accommodations or longer durations. Some commenters recommended adopting language that would allow multiple units of CPT code 0593T to be billed for longer group sessions.

Many commenters advocated transitioning from temporary Category III CPT codes to permanent HCPCS G-codes for health and well-being coaching. The commenters stressed the need for payment stability and billing clarity. Conversely, several commenters supported retaining the Category III CPT codes, stating that the existing Category III codes are already recognized nationally, and retaining them would ease dual Medicare-commercial billing, reduce administrative complexity, and provide a clear path for eventual conversion to permanent Category I CPT status. The commenters stated creating new G codes could introduce confusion, duplicative coding, and especially for practices and payers already set up to use the existing CPT codes.

Response: We thank the commenters for their feedback on the adoption of CPT prefatory language for codes 0591T, 0592T, and 0593T. After consideration of comments, we will finalize adopting the CPT prefatory language for these codes and retain the Category III CPT codes, 0591T, 0592T, and 0593T. We agree with commenters that maintaining the established CPT prefatory language and CPT codes, which are recognized nationally, will help ensure clarity and consistency. We believe this approach will help avoid unnecessary confusion and administrative complexity, especially for practices and payers already set up to use the existing CPT codes.

Comment: Many commenters recommended not limiting health coaching services solely to medical conditions, emphasizing the importance of including behavioral health needs within the scope of reimbursable coaching. The commenters stated that health and well-being coaching can play an important role in supporting beneficiaries with stress management, sleep improvement, treatment engagement, and broader health behavior change. The commenters stated that behavioral health and medical health are deeply interconnected, and that coaching interventions often address factors such as motivation, adherence, self-management, and lifestyle modification, which are relevant for both physical and behavioral health outcomes.

Response: We thank the commenters for their feedback regarding including behavioral health needs within the scope of reimbursable health coaching services. Behavioral health needs should not be precluded from being addressed by health coaches when medically necessary.

Comment: Commenters requested that CMS expand recognized delivery settings for the coaching codes (CPT 0591T, 0592T, 0593T) to explicitly include RHCs and FQHCs. A commenter stated the proposed ''employing entity'' provision is limited to community-based organizations and asked CMS to confirm RHCs and FQHCs may report the codes on a fee-for-service basis. Another commenter stated that RHC exclusion under the proposed policy is inconsistent with CMS's goal of aligning payment across settings, and noted that RHCs already employ certified health coaches; this commenter urged CMS to permit RHC billing for coaching services.

Response: We thank the commenters for their comments. Health and well-being coaching services furnished under the general supervision of an RHC or FQHC practitioner, do not constitute a billable RHC or FQHC visit (§ 405.2463).

After consideration of the public comments, we are finalizing our proposal with modifications. Specifically, we are finalizing the valuation for health and well—being coaching, CPT codes 0591T and 0592T based on a crosswalk to CPT codes 99487 and 99489, with work RVUs of 1.81 and 1.00 and finalizing the valuation of CPT code 0593T as proposed. We are also finalizing that health coaching may be furnished under general supervision and updating § 410.26(b)(5) accordingly.

(57) Vascular Embolization or Occlusion Procedure With Use of a Pressure-Generating Catheter (HCPCS Code G0577)

HCPCS code C9797 (*Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction*) was created for the April, 2025 Quarterly Release for the OPPS and Ambulatory Surgical System (ASC) to describe use of a pressure-generating catheter inclusive of imaging guidance for vascular embolization. Subsequently, we also created HCPCS code C8004 (*Simulation angiogram with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the angiogram, for subsequent therapeutic radioembolization of tumors*) to describe the simulation angiogram associated with the use of the pressure-generating catheter described by HCPCS code C9797 for the April, 2025 OPPS Quarterly Release. For CY 2026, HCPCS code C9797 is assigned to APC 5194 with a payment rate of around $18,729 while HCPCS code C8004 is assigned to APC 5193 with a payment rate of around $11,874. Currently both HCPCS codes C9797 and C8004 are only payable in the OPPS and ASC settings, as there is currently no coding for the physician office setting describing use of this technology. Under the PFS, vascular embolization procedures are reported using CPT code 37243 (*Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ*

ischemia, or infarction) regardless of the technology used to perform the service.

Interested parties have indicated that use of this technology has expanded beyond the OPPS and ASC settings and into the physician office setting; however, the resource costs associated with CPT code 37243 do not accurately account for the use of innovative catheter technology. While this technology may not yet be typical and as such is appropriately absent from the valuation of CPT code 37342, we are concerned that the lack of appropriate coding and payment for the use of innovative catheter technology may negatively impact access in the non-facility setting.

Beginning July 1, 2026, we began making separate payment for vascular embolization or occlusion procedure with the use of a pressure-generating catheter through the contractor priced HCPCS code G0577 (*Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction performed in the non-facility setting)* and proposed to nationally price this service for CY 2027. We sought comment on whether there is a need for creation of a HCPCS G-code to mirror HCPCS code C8004 as currently there are no claims for this service in the HOPD setting.

In the CY 2026 PFS final rule, we finalized use of the relationship between the OPPS APC relative weights to inform the PE RVUs for those services under the PFS. We believe a similar policy is necessary here to establish the initial valuation for vascular embolization using a pressure generating catheter given the lack of pricing information in the non-facility setting. Therefore, we proposed to use the relative relationship between the approximate APC payment amounts between CPT code 37243 and HCPCS code C9797 to value the PE portion of HCPCS code G0577 and a direct crosswalk to the work and MP RVUs associated with CPT code 37243 as well as the physician time. We sought comments on these values. We also noted in the proposed rule that this valuation is preliminary and we will consider updates for future rulemaking if use of this technology becomes more widespread in the non-facility setting.

Comment: We received comments requesting clarification on the methodology used to value the PE RVUs for HCPCS code G0577, noting that the reference to approximate APC payment amounts could not be independently replicated. Another comment separately raised a concern that the published PE RVU and total non-facility RVU for G0577 in the proposed rule addenda did not appear consistent with applying the adjustment ratio to the PE RVU alone before adding work and malpractice RVUs and requested that we review the calculation.

Response: We are revising our methodology for the final rule. Rather than relying on a single OPPS-based ratio, we compared the relative payment relationship between CPT code 37243 and HCPCS code C9797 under two measures of OPPS payment: the ratio of the OPPS APC payment amounts for the two codes, and the ratio of the OPPS geometric mean costs for the two codes. We then averaged the resulting ratios to produce a single adjustment factor. We are applying this adjustment factor to the existing non-facility PE RVUs for CPT code 37243 to derive the non-facility PE RVUs for HCPCS code G0577. Consistent with our proposal, we are finalizing a direct crosswalk of the work RVUs, malpractice RVUs, and physician time from CPT code 37243 to HCPCS code G0577. We confirm that the adjustment factor is applied to the PE RVUs only; the work and malpractice RVUs are added afterward to determine total RVUs. We reiterate that this valuation is preliminary.

Comment: We received comments in favor of establishing an office-based G-code analogous to HCPCS code C8004, even though no claims for C8004 currently exist in the hospital outpatient setting. Commenters noted that simulation angiograms are a clinically necessary planning step for radioembolization procedures, and that the absence of a non-facility reporting mechanism may create care fragmentation and access barriers for beneficiaries receiving the corresponding embolization procedure in the office-based setting.

Response: We appreciate the support from commenters for establishing a non-facility analog to HCPCS code C8004. We are not finalizing a new G-code for this service in this final rule, as we believe further utilization experience with HCPCS code G0577 will help inform whether, and how, to value a corresponding non-facility simulation angiogram code. We will consider establishing such a code in future rulemaking as this technology becomes more widely used in the non-facility setting.

Comment: We received a comment expressing broader concern that incorporating the cost of high-cost disposable supplies directly into PFS payment amounts creates budget-neutrality pressure that can erode physician work RVUs over time. The commenter urged the development of a separate, transparent payment pathway for high-cost disposable supplies outside the physician fee schedule.

Response: We appreciate the comment and share the goal of ensuring that payment for innovative technologies is accurate and sustainable. However, establishing a payment pathway for high-cost disposable supplies outside the PFS would require a broader policy change beyond the scope of this final rule. We will continue to consider this feedback as we evaluate our approach to valuing services that rely on high-cost disposable technology in future rulemaking.

Comment: A commenter requested that CMS revise the parenthetical language in the code descriptors for HCPCS codes G0577, C9797, C8004, and C1982 from ''(for example, one-way valve, intermittently occluding)'' to ''(for example, one-way valve or occlusion balloon, intermittently or temporarily occluding)'' to clarify that the descriptor is not limited to a specific device type. Separately another commenter requested that the long descriptor for G0577 be updated to mirror recent updates made to the C9797 descriptor in the October 2026 HCPCS file update.

Response: We appreciate the suggestions regarding the parenthetical language in the code descriptors for HCPCS codes G0577, C9797, C8004, and C1982, as well as the request to align the G0577 long descriptor with the October 2026 update to C9797. Requests to revise HCPCS Level II code descriptors are addressed through the HCPCS Level II coding process, outside of this rulemaking. Information on how to submit a request for a code descriptor change is available on the CMS website at *https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/level-ii-coding-process*.

After consideration of the public comments, we are finalizing our proposal to establish separate payment for HCPCS code G0577, with a revised methodology for determining its non-facility PE RVUs.

(58) Accounting for E/M Resource Overlap Between Stand-Alone Visits and Global Periods

(a) Background

Surgical procedures with a global surgery period include all the necessary services normally provided by the practitioner before, during, and after a procedure. The global surgery payment includes things like pre-operative visits, typical intra-operative services for that procedure, post-operative follow-up visits, supplies, and other services such as dressing changes, and removal of items used during or after surgery like sutures, staples, splints, or casts.[60] The payment and coding structure of global surgery periods includes the same foundational pieces as other codes in the PFS: work RVUs, practice expense RVUs, and malpractice RVUs. The work RVUs include time crosswalked from E/M codes to reflect the valuation of things such as pre-operative and post-operative visits. Given that global surgical packages already account for the resource costs associated with visits, standalone E/M codes are not billable on the same day as a procedure code unless they are significant and separately identifiable from the procedure. These visits are identified through appending of modifier –25 to the claim. This proposal is meant to address the likely overlap and duplication of payment between the E/M services already paid for during the global surgical package, and any additional E/M services billed for through the use of modifier –25 as significant and separately identifiable.

The PFS has other existing policies where we reduce payments if multiple procedures are furnished on the same day for the same patient, the multiple procedure payment reduction (MPPR) policies. MPPR is a longstanding Medicare policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished on the same day to the same patient, largely based on the efficiencies in PE and pre- and post-surgical physician work. Since the implementation of the PFS, MPPR policies were also established on nuclear medicine diagnostic procedures, the professional and technical component of diagnostic imaging, the technical component of diagnostic cardiovascular and ophthalmology procedures, and always-therapy services. In the 2019 PFS proposed rule (83 FR 35840 through 35841), as part of a suite of proposals designed to modify the payment structure of E/M visits, we proposed to reduce payment by 50 percent for the least expensive 0-day global procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier –25.

In the 2019 PFS final rule (83 FR 59638 through 59640), many commenters opposed this proposal, stating that current billing rules allow these services to be billed only when modifier –25 is used, which makes it clear that the visits are significant and separately identifiable. Other commenters described that the RUC review process includes adjustments to account for any costs that the RUC considers duplicative, which means that CMS is making an unnecessary second adjustment. Commenters also stated that CMS provided insufficient rationale for a 50 percent payment reduction instead of other potential adjustments. Some physician organizations and patient advocacy groups also stated concerns that physicians might respond to financial incentives to bring patients back for necessary visits on a different day to avoid triggering the payment reduction. MedPAC, among others, were supportive of the proposal, stating that when a standalone E/M visit occurs on the same day as a procedure, there are efficiencies such as pre- service and post-service clinician work and practice expense, that are not currently accounted for in the system. Other commenters suggested alternative reductions, such as a 5 percent or 25 percent reduction.

In our response to commenters in the CY 2019 final rule (83 FR 59638 through 59640), we stated that we continued to have concerns about 0- and 10-day global periods on the same day as E/M visits. We appreciated the efforts of the RUC to address overlaps when they recognize that a code is often reported with a same day E/M visit, but we also noted that the RUC tends to recommend only minor adjustments to physician time and direct PE inputs to account for overlap. We also discussed that there are several thousand codes with global periods, and while we routinely prioritize review of high-volume services, we believe code-level reviews are not a practical solution to ensuring the accuracy of accounting for these types of efficiencies. We also stated that if practitioners begin deliberately scheduling visits on separate days to avoid the payment adjustment, this could create undue burden and create potential medical risk for beneficiaries.

We did not finalize this proposal in CY 2019 for a few reasons. First, we had concerns related to balancing the appropriate valuation of these codes with potential disruption to patient care. We reiterated that we find the possible practice of scheduling medical services to maximize payment highly problematic, and we invited interested party feedback regarding how to address these challenges. Second, we did not finalize any of the suite of proposals related to the valuation of the E/M code set in CY 2019, as the AMA and the CPT Editorial Panel stated plans to revisit coding for O/O E/M, and we delayed further action to allow that process to play out (83 FR 59638).

(b) Proposed Changes to Payments Using Modifier –25

As we stated in the CY 2019 final rule (83 FR 59638 through 59640), we continue to believe that there are efficiencies when the same physician (or a physician in the same group practice) provides an E/M service for the same patient in conjunction with a procedure with a global period, and that we are likely duplicating payment under the current payment methodology. We proposed to reduce payment, as described later in this section, when a separately identifiable O/O E/M visit is furnished by the same physician (or a physician in the same group practice) on the same day as a 0-, 10-, and 90-day global procedure. Under this proposal, the most expensive service (either surgical or E/M visit) would be paid at 100 percent, and all other surgical procedure(s) or E/M visit(s) would be paid at 50 percent. For example, a patient receives an O/O E/M visit using CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code section, 10 minutes must be met or exceeded*) at a dermatologist's office, and then has two skin lesions removed, one using CPT code 11300 (*Shaving of epidermal or dermal lesion, single lesion, trunk, arms, or legs; lesion diameter 0.5 cm or less*) and one using CPT code 11301 (*Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.6 to 1.0 cm).* Using 2026 RVU values, the total non-facility (NF) RVU of CPT code 99212 is 1.78, the total NF RVU of CPT code 11300 is 2.89, and the total NF RVU of CPT code 11301 is 3.48. Since CPT code 11301 is the highest paid service, CPT code 11301 will be paid at 100 percent (total RVU

[60] *https://www.cms.gov/files/document/mln907166-global-surgery-booklet.pdf.*

of 3.48), and CPT code 11300 and the payment for CPT code 99212 will both be reduced by 50 percent, CPT code 11300 down to 1.445 RVUs and CPT code 99212 down to 0.89 RVUs.

The 50 percent value aligns with our previous proposal from CY 2019 PFS proposed rule (83 FR 35840 through 35841) and matches the longstanding surgical MPPR discussed previously in this section. We welcomed comments on the value of this adjustment, including whether it would be more appropriate to match a different MPPR value, such as 25 percent.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters noted that we proposed but did not finalize this policy for CY 2019. Commenters asked us to explain why we re-proposed this policy for CY 2027, seeking to understand what had changed between 2019 and now. Other commenters had a more general objection, stating that this was the ''wrong policy in 2019'' and ''remains the wrong policy now.''

Many commenters also disagreed with our view that there are existing efficiencies that are currently unaccounted for when an O/O E/M is furnished on the same day as a 0-, 10-, or 90-day global procedure. Many commenters disagreed that we had proven the existence of this overlap, and we received several comments requesting more information on the empiric data CMS used to make this claim. Commenters also stated that the RUC process already takes any overlap into account through the existing process of screening procedures that are furnished with an E/M visit on the same day more than 50 percent of the time. These commenters felt that the RUC process was sufficient and questioned our assertion that it was inadequate. The RUC responded to our claim that the corresponding edits they make to account for overlap are insufficient by asserting that the overlap is small, therefore, the adjustments are accordingly small. Other commenters stated that this proposal was too broad and recommended that we take a more granular code-level approach. Commenters also recommended that we work with the RUC to identify and account for overlap or use other existing processes such as the Potentially Misvalued Code (PMVC) process.

Several commenters supported our proposal. MedPAC noted that they supported this proposal in 2019, and they continue to believe there are efficiencies in providing these services on the same day to the same patient, such as in pre-service and post-service clinician work and practice expense that are not accounted for in the current payment system. They also noted that this policy would have redistributive effects within the PFS, increasing payment rates for many types of services such as primary care and behavioral health services. A few other commenters supported our proposal, with a commenter stating that we struck an appropriate balance between reducing duplicative payment for overlapping services and preserving reimbursement for separately identifiable E/M services that involve additional clinical work beyond what is captured in the procedural payment.

AHIP (America's Health Insurance Plans) provided detailed comments in support of our proposal, citing 2024 Original Medicare claims data which showed that approximately 50 million of the 220 million O/O E/M visits in 2024 were billed with modifier –25, representing approximately $5.7 billion in total Medicare allowed charges. AHIP hypothesized that if one quarter of the resource costs fully overlap with the same resources included in surgical procedures, that would be approximately $1.5 billion in annual Original Medicare PFS payments that are redundant and inappropriate. They went on to emphasize that the potential for redundancy not only extends to physician work and clinical resources, but to indirect practice expense and overhead, which they stated represents approximately 75 percent of the indirect practice expense costs per hour for surgical services. AHIP went on to say that when an E/M visit is performed with a procedure, there is only one professional claim filed, making coding, billing, and revenue cycle management much more efficient, as well as front office staff work and use of the waiting room, exam room, electronic health record, IT equipment, and other administrative costs.

AHIP also discussed that the current methodology that is applied by CMS and the RUC to account for overlap is applied only on a case-by-case basis. The analysis done by AHIP using publicly available RUC documents and the Medicare Carrier 5% standard analytic file dataset indicates that overlap adjustments appear to have only been incorporated into physician time and/or valuation for fewer than 100 global surgical procedures. However, AHIP stated that Medicare claims data indicate that more than 800 procedures are reported with modifier –25 and a same day O/O E/M visit. They went on to state that since this process relies on Original Medicare claims data and a 5% sample of Medicare beneficiaries, this may under-identify overlap associated with newer services, lower-volume procedures, or procedures primarily furnished to non-Medicare populations, and added that this process likely recognizes only a small subset of services impacted and is likely applied inconsistently across the PFS. AHIP also provided a few examples of codes with unaddressed overlap. The first code they cited is CPT code 52000 *(Cystourethroscopy (separate procedure)),* which had over 700,000 Original Medicare claims in 2024 and is reported with an E/M service almost half the time. This code was last reviewed by CMS and RUC in the CY 2018 rulemaking cycle, but no overlap was accounted for in physician work time, medical staff and indirect practice expense resources. AHIP also cited CPT code 17261 *(Destruction, malignant lesion (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), trunk, arms, or legs; lesion diameter 0.6 to 1.0 cm),* which had approximately 130,000 Original Medicare claims in 2024 and occurs with a same-day E/M more than 40 percent of the time. In this code, roughly 30 percent of the procedure's total physician time is pre-service and immediate post-service work, and yet the valuation reflects no overlap adjustment. AHIP also stated that since O/O E/M services are now selected based on either medical decision-making or total practitioner time, it may not always be straightforward for clinicians to distinguish between work attributable to the separately reported E/M service and the work that is already reflected in the procedure's pre-service, intraservice, or post-service valuation, which further supports the need for a systematic approach to overlap adjustments.

AHIP also noted that our proposal would likely improve relativity across services since the current methodology undertaken by the RUC to account for these efficiencies is inconsistent and is not flexible enough to handle individual patient encounters. AHIP also pointed out that for procedures where overlap has already been incorporated into the RVU valuation, providers who furnish the procedure without an associated E/M visit are not receiving payment that reflects the full resources required to perform the service. AHIP agrees with CMS that the code-by-code approach does not fully address the large number of surgical procedures and widespread use of modifier –25.

Response: We thank all the commenters for their comments. Regarding the presence of overlap

between O/O E/M visits and global periods, as we stated in the CY 2019 final rule (83 FR 59640), ''We continue to have significant concerns about the appropriate payment when codes with global periods, especially 0- and 10-day global periods, are billed on the same day as an E/M visit. Generally, we understand that the global codes are valued to include the typical amount of evaluation and management furnished to patients as part of the service.''

We went on to state (83 FR 59640), ''Although many commenters suggested that the overlapping resource costs between global codes and E/M visits billed on the same day have already been accounted for, we are not persuaded by the statements that the RUC process has achieved this goal, and we agree with MedPAC's assessment of the significant problem with valuation of codes that describe global services. We acknowledge and appreciate the efforts of the RUC to address overlaps when they recognize that a code is usually reported with a same day E/M visit. However, as observers to the RUC process, we have noted a general tendency for the RUC to recommend only minor adjustments in physician time and direct PE inputs to account for overlap. We also often make adjustments to the RUC-recommended valuation in cases where the agency believes there is overlap between services frequently billed together that has not been adequately addressed through the RUC process. More importantly, even if the RUC valuation process better accounted for the overlapping resource costs, those adjustments would be made to national valuation of particular codes based on snapshot, national claims data for a given year, and would apply to all physicians reporting the services regardless of whether or not these particular physicians were achieving the efficiencies that occur when visits are reported on the same day as codes with global periods.''

We believe that these concerns have not been adequately addressed in the intervening years. We note that while the RUC continues to assert that this overlap is accounted for, we did not receive a list of codes from the RUC outlining all codes where the RUC has already accounted for overlap. We have also found no other process to validate which specific codes out of the thousands of global procedures for which overlap has been accounted, beyond individually searching through RUC meeting materials. Regarding the comments asking us for a more empiric analysis or data, we welcome additional information from the public to help inform a process for addressing overlapping resources in the future. Additionally, we welcome feedback from the RUC and others regarding particular codes that may be misvalued for consideration through future rulemaking.

We thank MedPAC for their continued support of this policy, and we agree with MedPAC's assertion that there is still overlap that is unaccounted for, such as in pre- and post-service clinician work and practice expense. We also thank the commenters who noted this policy is meant to strike a balance between allowing these services to occur on the same day while recognizing that there are efficiencies that are not currently recognized.

We appreciate the work and data analysis done by AHIP, and we believe that this analysis further supports our point. We note that the current RUC process to account for overlap is only used when the global code is billed more than 50 percent of the time with an O/O E/M visit with modifier –25 appended. Both of the codes provided by AHIP support this assertion, and we note that both codes are frequently billed with O/O E/M visits, but do not meet the 50 percent threshold. We also note that one of those codes, CPT code 17261, was last reviewed by the RUC in 2010, furthering our point that this piecemeal approach to accounting for overlap code by code relies on a RUC process that is not an accurate representation of the current reality, since it represents decades-old data. In the CY 2026 PFS final rule (90 FR 49335), we reiterated similar concerns surrounding the delay and piecemeal approach to RUC data when we finalized the efficiency adjustment. We noted that while there is significant variability in how often codes are reviewed by the RUC, we estimated that there is an average of 17.69 years since the last review of a code. This delay also has an impact on accounting for the overlap of O/O E/M services and global procedures, since any overlap that the RUC takes into account only happens when codes are reviewed.

Comment: We received several comments discussing our proposed application of this policy to services provided by the same physician (or a physician in the same group practice). Commenters representing large multi-specialty group practices and academic medical centers noted that beneficiaries may schedule several appointments the same day with physicians of different specialties, especially if they have to travel for these appointments. Commenters recommended we modify our language to say, ''same physician (or a physician in the same specialty in the same group practice).'' Another commenter recommended that we limit it only to the services provided by the same physician.

Response: We thank the commenters for pointing this out, and we agree with them that our intention was not to target services furnished the same day by practitioners of different specialties. We are amending our application of this policy to services furnished by, ''the same physician (or a physician in the same specialty in the same group practice).'' We note that this is consistent with the Medicare Claims Processing Manual, Chapter 12, § 30.6.5—Physicians in Group Practice (Rev. 1, 10–01–03), where, ''Physicians in the same group practice who are in the same specialty must bill and be paid as though they were a single physician; physicians in the same group practice but in different specialties may bill and be paid without regard to common group membership.''

Comment: We received many comments that discussed the potential impact of our proposed 50 percent reduction in reimbursement, describing diminishing operational margins, staffing cuts, and inability to take on more Medicare patients if we finalize a 50 percent payment reduction. Other commenters stated that this policy would have a compounding impact with other reductions in payment such as the CY 2026 PFS final rule efficiency adjustment, declining Medicare conversion factors over the years, and the impact of inflation on costs such as staffing and supplies. We received comments from across the health care industry, including practitioners, health systems, private practices, and clinical and non-clinical support staff describing the potential impacts of this policy. These commenters reported that the impacts of this policy would directly impact their operational capacity to see Medicare patients and reiterated that this policy would have devastating impacts on the beneficiaries that they serve.

Most commenters stated that there was no payment reduction that would be appropriate. A few commenters stated that if a payment reduction was necessary, 25 percent would be an acceptable alternative. Another commenter stated that 50 percent seemed too steep, but that a 20 percent reduction would be more reasonable. A few other commenters stated that if we proceeded with a payment reduction, it should be below 50 percent. While AHIP supported a 50 percent payment reduction, they recommended that we phase in the policy, with a 25 percent

reduction for CY 2027 and CY 2028, with a 50 percent reduction going into effect for CY 2029 to minimize disruption. Another commenter recommended that we go forward with a 50 percent payment reduction but requested that we create a clear and objective exception process to account for the ''limited'' circumstances in which a beneficiary requires a separate clinical assessment involving distinct decision-making, evaluation, counseling, or examination that goes beyond the work accounted for in the global procedure. A few commenters including the RUC and the AMA also noted that our 2019 proposal only included 0-day global periods, and they questioned our inclusion of 10- and 90-day global procedures in our proposal this year.

Response: We are sensitive to the overwhelming response we received from commenters. We are also sensitive to the potential compounding impacts of many different policies across the healthcare system. Our intention with this proposal was to more accurately pay for the relative resource costs involved in furnishing an O/O E/M visit on the same day as a global procedure. We also appreciate the commenters who put forth suggestions for other percentages, such as 25 percent or 20 percent as alternatives, or those who stated it should be below 50 percent. While we acknowledge that the RUC takes overlap into account in some instances, we continue to believe that the RUC's approach is piecemeal and both underestimates the amount of overlap and does not recognize cases in which overlap exists when both codes are billed in conjunction less than 50 percent of the time.

In response to comments, and in acknowledgement of the overlap that has already been accounted for through the limited current RUC process, we are finalizing a 20 percent reduction in payment to all services except the highest value service when an O/O E/M visit is performed on the same day with the same practitioner (or a practitioner of the same specialty in the same group practice) as a service with a 0-day global period. We believe that a 20 percent reduction in payment is both responsive to commenters and strikes a balance between paying more accurately for services performed on the same day and the real-world impact of this policy. We reiterate that our original proposed reduction of 50 percent was based on long-standing MPPR payment reductions for surgical services. However, there are other MPPRs of 25 percent for the Technical Component (TC) of diagnostic cardiovascular services, as well as a 20 percent reduction to the TC for diagnostic ophthalmology, and a 5 percent reduction for the Professional component (PC) of diagnostic imaging. We reiterate that we welcome feedback and collaboration with the RUC and through the existing PMVC process.

Regarding an exception process, we invite feedback through PMVC nominations, and we welcome code specific recommendations from the RUC. Regarding the inclusion of 10- and 90-day global periods in this proposal, commenters are correct that we did not include these periods in the CY 2019 proposal. As we stated in the proposed rule (91 FR 43908), we believe overlap exists between any global period and an O/O E/M service performed on the same day for the same patient. We agree with commenters that the resources involved in furnishing a 10- or 90-day global service occur throughout the global period, making the overlap that occurs on just one day of a 10- or 90-day global period more difficult to quantify. We are therefore finalizing this policy to apply only to O/O E/M visits billed on the same day as 0-day global procedures. While we proposed to apply this policy only to O/O E/M visits, we sought comments on whether it should also apply to other E/M visits, such as inpatient E/M visits.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments about applying this policy to only O/O E/M visits. A few commenters sought clarification on whether this policy applies to other E/M codes, such as emergency room or critical care codes. Several other commenters asked us not to expand this policy to any other E/M visits, including inpatient E/M visits. A commenter encouraged us to expand this policy to inpatient E/M visits, stating that the overlap that they believe exists in O/O E/M visits also exists in inpatient settings.

Response: We thank commenters for their feedback. We reiterate that we are finalizing that this policy only applies when an office/outpatient E/M visit is performed on the same day as a 0-day global procedure.

After consideration of public comments, we are finalizing the application of this policy to O/O E/M codes (CPT codes 99202, 99203, 99204, 99025, 99211, 99212, 99213, 99214, and 99215).

We also reiterate that we do not find it appropriate to schedule medical services for patients to maximize payment, which would create undue burden and potential medical risk for beneficiaries. We have a number of data analysis tools to monitor for potentially problematic utilization patterns which may be useful in the future, if necessary, for monitoring for this practice, including distinct claims editing to identify problematic utilization patterns, comparative billing reports to identify to providers their outlier status, and medical review capabilities to determine if the patterns are problematic and indicative of waste or abuse. We also sought comment on whether or not it is necessary to revise the conditions of payment to mitigate such payment abuses.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments stating that this proposal would ''require'' patients to come back for a second, separately billed visit, as physicians respond to the reduced payment by scheduling the evaluation and the procedure on separate days. A few commenters expressed concern that practices or health systems may put processes in place that prevent practitioners from performing an O/O E/M visit on the same day as a global procedure. Other commenters stated that we were ''forcing'' practitioners to ''choose between our patients and our own financial viability.'' We received several comments from beneficiaries that included a copy of a letter or outreach they received from their practitioner or practitioner's office. Others included pictures of letters posted in their doctors' offices. These letters either implied or stated directly that Medicare would no longer pay for same day procedures and that beneficiaries would be forced by Medicare to come back another day.

Many commenters requested that CMS monitor utilization to ensure that beneficiaries were not being brought back to maximize payment. Many commenters stated that requiring beneficiaries to come back another day for a surgical procedure would impose a direct burden on beneficiaries through a second copayment, additional transportation and time away from work, have disproportionate impact on rural and underserved beneficiaries, and added difficulty for those who rely on caregiver support.

However, a supportive commenter refuted the claim of higher cost-sharing, noting that beneficiary cost-sharing would decrease under this proposal since beneficiaries are generally responsible for 20 percent coinsurance, and when overlapping expenses are

paid separately for the procedure and the E/M visit, beneficiaries incur additional cost even though those services were effectively only used once during the single encounter. This commenter also noted that this policy would support payment accuracy, program integrity, and the prudent stewardship of Medicare resources.

Response: We would like to clarify that this policy does not prohibit same-day procedures from occurring with an office visit. We see comments received and patient letters that imply a limit on same-day procedures as highly concerning, as we feel that practitioners who are directly misleading their patients are not operating in good faith of the doctor-patient relationship. We would also like to reiterate that we find the possible practice of scheduling medical services to maximize payment problematic. As noted in the proposed rule, we have a number of data analysis tools to monitor for potentially problematic utilization patterns which CMS plans to use to monitor for this practice. These tools include distinct claims editing to identify problematic utilization patterns, comparative billing reports to identify to providers their outlier status, and medical review capabilities to determine if the patterns are problematic and indicative of waste or abuse.

We agree with the commenters who noted that cost-sharing burden would decrease under this policy, and we would like to reiterate that if practitioners bring patients back another day for their procedure, this would actually increase beneficiary cost-sharing.

(c) Intravitreal Eye Injections

We also sought comment on how this policy might apply to an E/M visit reported on the same day as intravitreal eye injection, such as CPT code 67028, a high volume 000-day global code. In recent years, since new injected medications were developed to treat retinal diseases, there has been new focus from auditors (such as the OIG), MACs, professional eye associations and the AMA, to better understand the standard of care for patients receiving these treatments, in terms of when same-day eye examinations are clinically indicated and separately identifiable from the injection procedure, for the injected eye or the fellow eye. We have heard that patients with retinal diseases require examination every one to three months based on their treatment response, and importantly, both eyes are examined at each visit because of the high incidence of bilateral (though often asynchronous) involvement. The associations have written to CMS outside of the rulemaking process, indicating that around 50 percent of the time, a separately reported E/M visit on the same day to examine the eye(s) may be prompted or required by the symptom or condition for which the injection is being provided. The fellow eye could require examination if the patient reports symptoms in that eye when they present for an injection, and same-day exams determine if the type of medication is appropriate and the length of time between injections can be extended.

To help us ensure accurate payment and address questions raised in the most recent OIG audit, we sought to better understand the clinical circumstances involved, and any overlap with resources already accounted for in valuation of the global procedure, such as for (1) established patients without symptoms in the fellow eye; (2) established patients with symptoms in the fellow eye, whether prior or newly reported upon presenting for their injection; (3) new patients; (4) does it vary according to diagnosis and exam findings; (5) are injections in the fellow eye always deferred to another day; and (6) how CMS might be able to confirm or ensure that the visit being reported is significant and separately identifiable absent medical record review, for example, should we expect to see a new or different diagnosis code on the claim. See *https://oig.hhs.gov/reports/all/2025/medicare-payments-for-evaluation-and-management-services-provided-on-the-same-day-as-eye-injections-were-at-risk-for-noncompliance-with-medicare-requirements/*.

We also sought to better understand whether the E/M work associated with new patients is typically included in valuation of the minor procedures, or whether there is extra work for new patients that is significant and separately identifiable enough to always warrant separate payment.

Comments: We received many comments from specialty societies, providers, practitioners and other stakeholders describing the standard of care for patients receiving intravitreal injections, any overlap with resources already accounted for in valuation of the global procedure, and how our proposal to apply an MPPR to same-day visits reported with Modifier 25 on the same day as global procedures might apply to an E/M visit reported on the same day as intravitreal eye injection.

Response: We appreciate all of the detailed information provided by comments and will consider this information for future rulemaking.

(59) Revisions to Teaching Physician Policy Related to the Primary Care Exception

(a) Background

As a general matter, E/M visit codes under the PFS can only be reported when the care is personally provided by a qualified practitioner. Currently, under the primary care exception described at § 415.174, in the case of certain visit codes of lower and mid-level complexity, Medicare contractors may be able to make PFS payment for a service provided by a resident without the presence of a teaching physician, but in specific outpatient primary care centers and when certain conditions must be met. For example, the teaching physician must direct the care from such proximity as to constitute immediate availability (that is, to effectively provide direct supervision).

During the Public Health Emergency (PHE) for the 2019 Novel Coronavirus (COVID–19) pandemic, CMS allowed through an interim final rule (85 FR 19230 through 19292) that all levels of an O/O E/M service provided in specified primary care centers may be provided under supervision of the teaching physician by interactive telecommunications technology (85 FR 19259). At the conclusion of the PHE this flexibility expired, such that only lower and mid-level complexity visits (as specified by CMS in program instructions) could be provided without the presence of a teaching physician under the terms specified in § 415.174.

Additionally, in the CY 2020 PFS final rule (84 FR 62851 through 62854), E/M visits were revised to allow visits to be based on time and medical decision making. According to our claims data, we note that the most commonly billed O/O E/M visit level is now a moderate level visit (level 4), whereas in the past, a mid-level (level 3) visit was most common.

(b) Revisions to Current Policy

We have received multiple requests from interested parties requesting us to allow residents to perform moderate and high (level 4 and 5) E/M visits under the supervision of the teaching physician and to defer to the clinical judgment of that graduate medical education (GME) program as to whether or not these high level visits may be performed without the presence of the teaching physician.

After consideration and evaluation of interested parties' requests, we proposed that all levels of an O/O E/M service provided in primary care centers, and meeting the requirements in § 415.174, may be provided under direct supervision of the teaching

physician in such cases where the teaching physician believes such care is clinically appropriate and without the presence of a teaching physician. Specifically, we proposed modifications to the requirements at § 415.174 Exception: Evaluation and management services furnished in certain centers, to expand coverage of services for teaching physicians as part of a graduate medical education (GME) program. We proposed to modify the requirements for certain E/M codes to allow physician fee schedule payment for a service furnished by a resident provided under direct supervision. We proposed to modify paragraph (a) to state that certain evaluation and management codes (as specified by CMS in program instructions), may be paid by the physician fee schedule and are thus proposing to remove the language ''of lower and mid-level complexity'' to potentially allow for certain moderate and higher-level evaluation and management codes to be billed if the visit meets all the criteria in § 415.174. We proposed § 415.174 (a) to read as follows: ''In the case of certain evaluation and management codes (as specified by CMS in program instructions), Medicare Administrative Contractors (MACs) may make physician fee schedule payment for a service furnished by a resident without the presence of a teaching physician. For the exception to apply, all of the following conditions must be met.''

We believe this proposal would provide some autonomy to residents as well as the teaching physician if the specific GME program would support it. We considered that some visits may take more time in the beginning since residents are still learning and we will continue to monitor the visit levels over time. We welcomed comments on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters were overall in support of our proposal that all levels of an office/outpatient E/M service provided in primary care centers, and meeting the requirements in § 415.174, may be provided under direct supervision of the teaching physician in such cases where the teaching physician believes such care is clinically appropriate and without the presence of a teaching physician. Commenters noted this will improve resident training and allow the program to prepare senior residents to practice autonomously. Other commenters noted this policy would discourage inadvertent downcoding driven by billing constraints and would allow teaching physicians to focus their supervision on residents who need the most guidance. Other commenters noted that residents must develop experience caring for patients across the full spectrum and this policy would support that.

Several commenters noted that expanded resident autonomy should be accompanied by maintaining the current safeguards and appropriate oversight and accountability. The commenters stated that teaching physicians must retain ultimate responsibility for patient care and clinical decision-making, and documentation should continue to demonstrate compliance with supervision requirements and continue to clearly identify the respective roles of the resident and teaching physician. Additionally, commenters supported our proposed regulation text change to 42 CFR § 415.174.

We received many comments asking CMS to make other changes to the primary care exception (PCE) to include adding preventive and whole-person services to the PCE, as well as requests to add specific psychotherapy services when billed with specific E/M visits, to update the language that restricts the PCE to services furnished in centers where the residents are being claimed for GME payments by a hospital, and to update the ''teaching setting'' definition to include Federally Qualified Health Centers. These comments were out of scope for this year's proposal.

Response: We thank the commenters for their support and feedback. We are finalizing as proposed that all levels of an O/O E/M service provided in primary care centers, and meeting the requirements in § 415.174, may be provided under direct supervision of the teaching physician in such cases where the teaching physician believes such care is clinically appropriate and without the presence of a teaching physician. We are also finalizing the proposed changes to 42 CFR § 415.174. We express appreciation for the feedback from commenters on other policies related to the primary care exception and will take the comments into consideration for possible future rulemaking.

(60) Bundled Payments Under the PFS for Substance Use Disorders (HCPCS Codes G2086, G2087, and G2088)

In the CY 2020 PFS final rule (84 FR 62673), we finalized the creation of new coding and payment describing a bundled episode of care for the treatment of Opioid Use Disorder (OUD). Then, in the CY 2021 PFS final rule, we finalized a revision to the code descriptors for HCPCS codes G2086, G2087, and G2088 by replacing ''opioid use disorder'' with ''a substance use disorder'' in response to requests to expand these bundled payments to be inclusive of other substance use disorders (SUDs), not just OUD, stating we agreed that doing so could expand access to needed care.

The codes are:

- HCPCS code G2086: *Office-based treatment for a substance use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code G2087: *Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code G2088: *Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

Interested parties have pointed out disparities in payment for HCPCS codes G2086 through G2088 compared to payment for similar services under the Medicare Opioid Treatment Program (OTP) benefit. They state that both OTPs and non-OTP outpatient addiction treatment settings can provide American Society of Addiction Medicine ASAM Level 1.7's suite of services that include medically managed outpatient treatment services, including evaluation and management of intoxication, withdrawal, biomedical concerns, and common low complexity psychiatric concerns. They state that the only clinical difference between these places of service at ASAM Level 1.7 is that OTPs can provide methadone for the treatment of OUD, and the other cannot due to Federal regulations. OTPs are also governed by extensive Federal and State regulations, unlike office-based practices which are not federally regulated settings but may be subject to extensive State regulations. They note that since the time these codes were created, there is now a new Level 1.0 that describes remission monitoring services or services to patients in stable remission, similar to services described by outpatient E/M codes. The new Level 1.5 provides outpatient counseling and psychotherapeutic services, appropriate for patients with mild SUDs and those in early remission, and a new Level 1.7 that describes medically-managed outpatient treatment, including withdrawal management. They state

that the services described by HCPCS codes G2086–G2088 align with Level 1.5, but that there is no existing coding under the PFS to describe level 1.7.

We welcomed additional information on this topic, including whether we should consider updates to the rates for HCPCS codes G2086 through G2088, and/or whether additional coding is needed to describe the ASAM 1.7 level of care.

We received public comments on this comment solicitation. After consideration of public comments, we express appreciation for the feedback from commenters and will take the comments into consideration for possible future rulemaking.

(61) Software as a Medical Service (SaMS) Laboratory Analyses

In recent years, there have been rapid developments in the use of software-based technologies with novel functionalities to support clinical decision-making in the outpatient and physician office settings. New clinical software, which includes clinical decision support software, clinical risk modeling, and computer aided detection (CAD), is becoming increasingly available to practitioners. These technologies often perform data analysis of diagnostic images from patients, relying on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment planning of a patient's condition. In previous rulemaking, we have referred to these algorithm-driven services that assist practitioners in making clinical assessments or diagnoses as Software as a Service (SaaS). Unlike prescription digital therapeutics (PDTs), for example PDTs that provide cognitive behavioral therapy to treat substance disorders or chronic insomnia, SaaS technologies do not currently treat illnesses or patient injuries. SaaS is also separate from remote patient monitoring (RPM) and remote therapeutic monitoring (RTM), which are digital healthcare tools for tracking patient data outside traditional office settings (90 FR 49394). For CY 2027, we proposed a change in terminology (91 FR 43910). We noted that we now understand that, in other industries, the existing SaaS terminology is used for general cloud-based computing service models outside of a health care context, which may cause confusion as we are using it to describe specific services that provide a medical function for purposes of PFS Medicare payment policy. To dispel any ambiguity and clarify that distinction, we proposed to change our terminology from SaaS to Software as a Medical Service (SaMS) to refer to software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality. We welcomed public comments on the proposed change in terminology.

For further discussion of this terminology and other OPPS SaMS proposals, please see the CY 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Final Rule.

We received public comments on our proposed terminology change from SaaS to SaMS. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed terminology change from SaaS to SaMS. A commenter explained that the proposed terminology would clarify the distinction between clinical algorithms and generic cloud tooling. A commenter requested that we clarify whether the transition to SaMS is intended solely as a naming convention or whether it reflects broader distinctions regarding the scope, classification, valuation or payment treatment of these technologies.

Response: We thank the commenters for their support. The terminology change from SaaS to SaMS seeks to clarify, as a commenter explained, the distinction between clinical algorithms used to furnish these services and generic cloud tooling.

Comment: Some commenters did not support our proposed terminology change, stating that our proposed definition is too broad, and we should limit SaMS to stand-alone software services that analyze previously generated diagnostic information, excluding services that examine a patient specimen and make a new clinical measurement, or should distinguish between a stand-alone software analysis and software that is an integrated component of a laboratory, imaging, or other diagnostic service. Some commenters requested additional clarifications regarding inclusion and exclusion criteria and how our terminology relates to FDA's Software as a Medical Device (SaMD) or CPT's AI terminology.

Response: We thank commenters for the additional information. At this time, our aim is to limit our definition of SaMS to refer to software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality. This also aligns with the definition and terminology discussed in the CY 2027 OPPS final rule. We note that we will consider these comments as we continue to refine this definition and terminology.

Based on the comments received, for CY 2027, we are finalizing our proposal to change the terminology for these algorithm-based software services that are paid under Medicare from ''SaaS'' to ''SaMS.''

In recent years, we have seen an increase in laboratory tests that combine laboratory analyses, such as genomic sequencing or immunoassays, with computer algorithms to produce a clinical test result. The AMA CPT Editorial Panel created a category called Multi-Analyte Assays with Algorithmic Analysis (MAAA's), to categorize test codes that combined laboratory analyses with computer algorithms to generate clinical information. More recently, however, we are seeing the development of distinct algorithmic analyses alone with distinct CPT codes.

For example, when the genomic sequencing of an individual is performed, this sequencing will likely only need to be performed once by a laboratory. However, once the genomic sequence has been generated, the subsequent algorithmic analyses of that sequence data can be performed an infinite number of times to produce a wide range of results and/or diagnostic or risk-related information. These secondary analyses of original genomic sequences can be proprietary and unique to a single laboratory, but could also be conducted at a range of settings. For purposes of this final rule, we are referring to subsequent stand-alone algorithmic analyses as ''SaMS analyses performed on laboratory tests''.

As discussed in the proposed rule, currently, certain SaMS analyses performed on laboratory tests are treated as clinical diagnostic laboratory tests (CDLTs) and paid under the Clinical Laboratory Fee Schedule (CLFS) (91 FR 43911). Section 1861(s) of the Act specifies items and services included as ''medical and other health services'' under Part B, including diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests as described in section 1861(s)(3) of the Act. Sections 1833(h) and 1834A of the Act and the implementing regulations at 42 CFR part 414, subpart G, set forth the CLFS rate setting methodologies for CDLTs. We stated in the proposed rule that we do not believe it is appropriate to consider these secondary algorithmic analyses, when performed alone, to be CDLTs or establish CLFS payment rates for these analyses because we believe these secondary algorithmic analyses may not

currently require laboratory services or entities, to perform them.

Our position, as stated in the proposed rule, is that the secondary analyses, which have distinct CPT codes,[61] are ''other diagnostic tests'' under section 1861(s)(3) of the Act as opposed to ''diagnostic laboratory tests.'' As noted previously, Medicare will not pay for CDLTs on the CLFS unless they are furnished by laboratories that meet applicable certification requirements. Tests that examine materials derived from the human body are assigned to and paid under the CLFS only when furnished by such certified laboratories, in accordance with 42 CFR 410.32(d). Because SaMS analyses performed on laboratory tests are downstream evaluations of the data generated by a prior laboratory test, which are described by distinct CPT codes, an entity that performs only algorithmic analyses of previously sequenced data may not meet the definition of a ''laboratory'' under 42 CFR 493.2 or qualify for payment under CLFS. We believe SaMS that evaluate data generated by a prior laboratory test should not be treated as CDLTs for Medicare payment purposes.

As discussed in the proposed rule, we are also concerned that paying for these analyses based on existing CLFS payment methodologies may create significant vulnerabilities for the Medicare program, due to the lack of data transparency and CDLTs not being subject to beneficiary cost-sharing or budget neutrality. Section 414.508 outlines the rate setting methodologies CMS uses to set payment rates for new tests on the CLFS. Under § 414.508(b), CMS determines the payment amount based on either crosswalking or gapfilling methodologies until applicable information is available to establish a payment amount under the methodology described in § 414.507(b). Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code. Gapfilling is used when no comparable existing CDLT is available. Public consultation for payment for new CDLTs is required in determining payment amounts, receiving public comments and recommendations (and data on which the recommendations are based) as well as recommendations from the Medicare Advisory Panel on CDLTs per 42 CFR § 414.506. A significant challenge to the rate setting process for CMS is in receiving transparent data from laboratories outlining resource costs of a test, particularly for the algorithmic portions of tests that are combined with other analytes. In the past, laboratories have explained to CMS that the algorithmic components of laboratory tests are highly proprietary and details cannot be shared. Thus, CMS has worked with the limited information available on the details of methods or resources for the algorithmic portions of tests or analyses and has thus far relied on the other laboratory methods provided in the CPT descriptor (that is, NGS sequencing, RT–PCR, or DNA methylation analysis). As we have gathered more information on SaMS analyses performed on laboratory tests, we now believe that since these analyses are entirely computer-based, comparison based on laboratory methodologies is not appropriate. We believe that these analyses are substantially similar to other SaMS already paid under the PFS. Additionally, in contrast to the PFS, the CLFS generally does not include beneficiary cost-sharing or budget neutrality adjustments, which limits transparency regarding pricing and creates challenges for ensuring appropriate valuation of these services.

CMS has an interest in ensuring that services that are fundamentally similar are paid for and treated in the same way, regardless of the setting of care in which the service is furnished. Since we believe SaMS analyses performed on laboratory tests perform algorithmic analyses on previously generated data, we believe SaMS analyses performed on laboratory tests are substantively similar to other SaMS technologies that are currently paid under the PFS. Accordingly, we believe that whether the SaMS performs algorithmic analyses of an imaging test (for example, CT scan) or whether it performs an algorithmic analysis on data generated from a laboratory test, all algorithmic analyses should be treated consistently from a payment perspective. We believe that this approach for SaMS technologies would promote stability and predictability in payment for similar services.

Finally, we note that CMS and CDC issued a Request for Information (RFI) on July 16, 2026, regarding CLIA regulations, the results of which may be used to help inform the agencies as to what types of action, if any, should be taken to update the existing CLIA regulations through future notice and comment and rulemaking (91 FR 43586). The RFI closed for comments on September 15, 2026. CMS may refine SaMS payment and policies based on RFI responses and make changes in future rulemaking.

For CY 2027, we proposed to contractor price ten HCPCS codes describing various SaMS analysis performed on laboratory tests under the PFS (91 FR 43911). We note that SaMS analyses performed on laboratory tests would not require FDA marketing authorization in order to receive payment under the PFS. SaMS payment and policies may be refined in future rulemaking. Table A–D8 in the proposed rule (91 FR 43912) shows the list of currently payable SaMS analysis performed on laboratory tests under the CLFS that we proposed to contractor price under the PFS. These ten HCPCS codes were identified by the CPT descriptor for the code. We noted in the proposed rule that, if there were no laboratory methods included in the code descriptor, and only an algorithmic analysis was described, we identified the code as a SaMS laboratory analysis. We referred to the 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Proposed Rule (91 FR 41918) for discussion of payment for these services under the OPPS, where we proposed to assign the same SaMS analysis performed on laboratory tests to new technology APCs.

We invited public comment on this proposed list and any other similar analyses that should be removed from the CLFS and contractor priced under the PFS. We sought comment more broadly on other approaches to payment for these services, including, but not limited to, a direct crosswalk to the proposed OPPS new technology APC dollar amounts for all proposed analyses, a subset of these analyses, or specific analyses as opposed to contractor pricing.

In addition, for CY 2027 and subsequent years, we proposed to assign any new codes that describe SaMS analysis performed on a laboratory test to contractor pricing for payment under the PFS. We requested public comment on these proposals, including the list of ten HCPCS codes that we identified as SaMS analyses performed on laboratory tests, as well as any additional HCPCS codes that we should designate as SaMS analyses performed on laboratory tests and pay under the PFS rather than the CLFS. We stated in the proposed rule that CMS may finalize a policy that includes such payment for additional HCPCS codes in the PFS final rule based on public comment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

[61] We note that the AMA has created Category III CPT codes that describe secondary algorithmic analyses performed on laboratory tests. *https://www.ama-assn.org/system/files/cpt-category3-codes-long-descriptors.pdf.*

Comment: Some commenters, including large cancer treatment centers, supported our proposal to establish a payment methodology for software-based analyses performed on laboratory tests distinct from the underlying laboratory test. These commenters supported migrating software-based analyses performed on laboratory tests from payment under the CLFS to payment under the PFS and agreed that such analyses are better characterized as ''other diagnostic tests.'' Commenters added that this policy correctly recognizes algorithmic re-analysis of previously obtained data as a separately payable clinical service. In addition, commenters expressed support for establishing a consistent, cross-setting payment framework for algorithmic analyses, citing that this policy seeks to adapt and evolve with changing healthcare environments. The commenters noted that it is especially critical that this payment policy evolve to reflect the value and resource costs of these technologies.

Response: We thank the commenters for their support and note that we will consider these comments as we continue to refine this payment policy.

Comment: Some commenters, including independent laboratories, supported our proposal but requested that CMS develop the payment methodology transparently, and ensure the payment for algorithm-driven services rests on evidence of clinical benefit. Commenters requested that CMS establish a payment mechanism for these services when the patient is seen in a place of service not paid under the PFS, noting that as proposed, the framework would leave no payment mechanism for a substantial share of medically necessary testing. Commenters requested CMS establish a defined, confidential process through which laboratories may submit cost and clinical outcomes data to support valuation as CMS develops a more comprehensive payment methodology. One commenter supported the proposal but requested that CMS defer changes to CLFS payment for algorithm-only laboratory analyses until the necessary coding, regulatory, and operational infrastructure has been established.

Response: CMS appreciates the suggestion to be transparent and thoughtful in the implementation of this policy. We believe that publicly proposing this policy in the proposed rule, inviting comments, and addressing those comments in this rule has made this process transparent. We also appreciate the recommendation to evaluate the clinical benefit of a given SaMS analyses performed on laboratory tests. We remind readers that our goal in this rulemaking cycle is to establish the category of SaMS analyses performed on laboratory tests and the general payment mechanism for those services under the PFS. Regarding a request to establish a separate confidential process through which laboratories may submit cost and clinical data, we remind commenters that we are available to meet with interested parties where information may be shared with CMS. However, because payment rates are finalized through the notice-and-comment rulemaking process, which requires providing the underlying reasoning for our proposals and final policy, establishing a separate confidential process would not be compatible with the existing rulemaking process. Further, finalizing this policy would not eliminate Medicare payment for these services, or prohibit certain facilities from billing Medicare, but rather, it would define how these services would be paid under the PFS. We do not believe that it is appropriate to delay the movement of SaMS analyses performed on laboratory tests from the CLFS to the PFS, given the speed at which SaMS technologies are developing and the goal of having a consistent policy across payment systems for similar services. These similar algorithm-based services will be billed and paid for under the same payment system, depending on the hospital or physician setting (that is, OPPS or PFS).

Comment: A few commenters, specifically large laboratory associations, requested that we not finalize the policy as proposed. Commenters generally believed that CMS should engage with the laboratory community more closely prior to finalizing payment changes for SaMS analyses performed on laboratory tests. Commenters specifically expressed concerns that the proposed policy could inadvertently create duplicate or inconsistent payment pathways and fragment integrated laboratory services by separating algorithmic analyses from the laboratory responsible for validation, quality, clinical interpretation, and reporting. Several commenters expressed concerns regarding the implications of introducing beneficiary cost sharing for services that generally are not subject to cost sharing under the CLFS if this policy were to be finalized. Some commenters explained that, if CMS is concerned about unregulated software vendors billing Medicare, CMS should condition Medicare payment for designated SaMS laboratory services on performance by a CLIA-certified, appropriately accredited laboratory.

Response: We acknowledge the commenters' concerns and we will continue to consider them while we implement the policy. Regarding cost sharing, we acknowledge that while cost sharing shifts some costs to beneficiaries, it also encourages greater efficiency by health care providers and more economical delivery of medically necessary items and services, which would contain unnecessary growth in Medicare spending long-term to the benefit of both Medicare and beneficiaries.

We disagree with concerns that this final policy would fragment integrated laboratory services, as this policy would apply to HCPCS codes that already recognize a distinct SaMS analysis component. To ensure that this policy only impacts HCPCS codes describing the secondary analyses, we requested public comment on the list of HCPCS codes we proposed to designate as SaMS analyses performed on laboratory tests. As discussed further in this section, based on public comments received, PFS payment for HCPCS codes describing integrated services, meaning those codes that describe both the wet lab and SaMS secondary analyses, is not being finalized under this policy for CY 2027. These HCPCS codes would continue to be paid under the CLFS.

Concerns about billing and regulations regarding vendors of SaMS analyses performed on laboratory tests are outside of the scope of this final rule.

While we understand the commenters' concerns, we believe that the proposed policy provides a uniform payment pathway for SaMS that should be implemented for CY 2027. We continue to maintain that paying for SaMS analyses performed on laboratory tests under the CLFS may create significant vulnerabilities for the Medicare program, due to the challenges in receiving transparent data regarding the algorithms themselves and CDLTs on the CLFS generally not being subject to beneficiary cost-sharing or budget neutrality. As mentioned previously, we believe SaMS technologies generally should be treated and paid for consistently across the Medicare program because these algorithm-based services are functionally equivalent, despite differences in the type of clinical service or data. For example, both SaMS currently paid under the OPPS and the SaMS analyses performed on laboratory tests that we proposed to pay for under PFS perform algorithm-based analyses on existing data. We anticipate that resource costs may be

similar between these kinds of services. For SaMS analyses performed on laboratory tests, paying for these services under the PFS means similar algorithm-based services will be billed and paid for under the same payment system. We will continue to engage the broader laboratory community in further dialogue as we consider potential refinements to this policy in future rulemaking.

Comment: Some commenters, especially large laboratory associations, asked CMS to not finalize its proposal to reassign SaMS analyses performed on prior laboratory tests to the PFS and to continue paying for these services as CDLTs on the CLFS. A few commenters urged CMS to exempt current and future software-based laboratory tests from this proposed policy and only designate the proposed tests as SaMS analyses performed on laboratory tests.

Response: CMS appreciates these comments but believes it is important for SaMS-based technologies to be treated consistently across the Medicare program, rather than establishing distinct payment policies for similar SaMS, depending on whether the analysis is performed on an imaging service or on a laboratory test.

Comment: Commenters generally expressed concern that the proposed framework to distinguish SaMS analyses performed on laboratory tests from other laboratory tests would be challenging to apply in practice. Commenters stated that these services have generally been classified and paid as CDLTs under the CLFS, reflecting longstanding treatment from CMS, the AMA CPT process, and the FDA. Commenters expressed concern regarding using CPT code descriptors to determine which HCPCS codes should be designated as a SaMS analyses performed on a laboratory test since descriptors do not always indicate whether activities, such as slide preparation or immunostaining, are included in the reported service. Commenters explained that although SaMS analyses performed on laboratory tests are defined as being both separate from specimen examination and entirely computer-based, several of the examples CMS identified appear to involve wet lab components, creating uncertainty regarding how the criteria would be operationalized, and that as a result, interested parties may face difficulty determining whether a given service qualifies as a purely algorithmic analysis or should continue to be treated as a laboratory test incorporating wet lab processes. Commenters requested that CMS provide additional guidance and examples to support consistent classification and payment for these services.

Response: Medicare utilizes the description of services as provided by the HCPCS code descriptors in determining appropriate payment.- For the proposed policy, we identified services listed on the CLFS that indicated algorithmic analysis in the CPT long descriptor and in the description of intraservice work (as provided by AMA in its valuation of CPT codes) and proposed to treat those services as SaMS analyses performed on laboratory tests. Specifically, we considered code descriptors that included phrases such as ''augmentative algorithmic analysis'' or ''previously established sequence,'' as we believed that these indicated that the code described SaMS analyses performed on laboratory tests. We requested public comments on the proposed list of codes, understanding that we may have inadvertently omitted certain codes or included codes that do not solely describe subsequent, computer-based analyses as intended.

We appreciate the comments regarding the proposed list of codes. In this final rule, we have removed a few HCPCS codes from the proposed list, based on an additional understanding of the code descriptors and public comments received, but we retained the HCPCS codes that contained phrases such as ''augmentative algorithmic analysis'' or ''previously established sequence'', which we discuss in further detail later in this section. We believe that the finalized list of HCPCS codes being reassigned from the CLFS to the PFS is limited to those that are entirely computer-based secondary analyses and do not include specimen examination performed as part of the wet lab component.

Comment: Commenters requested that CMS incorporate additional specificity into the SaMS definition to ensure that technologies and services with meaningful differences, such as algorithm-only laboratory-developed tests, laboratory Software as a Medical Device, and imaging Software as a Medical Device, are not treated as equivalent for payment purposes. A commenter proposed that CMS limit the services included in this policy to algorithmic reanalysis of a prior laboratory test's reported results, and exclude any service that examines a patient's specimen, physical or digitized, or that measures a defined analyte from that specimen.

Response: We appreciate the commenters' input. We remind readers that our goal in this rulemaking cycle is to establish the category of SaMS analyses performed on laboratory tests and the general payment mechanism for those services under the PFS, noting that payment alignment is a priority for these technologies. We will take the definitional concerns raised by the commenters, including incorporating additional specificity regarding differences in SaMS service for purposes of Medicare payment, into consideration for future rulemaking. We welcome public engagement from interested parties on these issues, including whether there are additional services that should be designated as SaMS in the future.

Comment: Some commenters, particularly large laboratory associations, disagreed with the premise underlying our proposal, explaining that the diagnostic testing process as a whole, not the physical location where the final computational step occurs, is what defines a CDLT. These commenters did not agree that the absence of a new wet-lab step converts a patient-specific computational analysis of laboratory-derived data into something other than laboratory testing and argued that treating the final analytical step as severable from the laboratory service that produced the underlying data misconstrues how these tests are developed, validated, and clinically interpreted. Relatedly, these commenters requested that CMS confirm in the final rule that a test incorporating a laboratory assay measuring an analyte from the specimen remains a CDLT paid under the CLFS, and that specimen preparation, staining, and digitization are not the ''prior laboratory test'' on which SaMS designation depends.

Response: We disagree with these commenters that the location of the final analytical step is immaterial to the payment classification of these services. While we recognize that the underlying specimen collection, sequencing, or other data-generating steps may require laboratory services, the algorithmic analysis at issue here is a separate step that is performed on data that has already been generated, and may not necessarily require access to the specimen or laboratory equipment. The fact that a service has historically been billed and paid as a single, integrated CDLT on the CLFS does not mean that each component of that service must continue to be paid as such, particularly where the analytical component is distinguishable from the data-generating component as provided by the HCPCS code descriptor, both in the resources required to perform it and in the manner in which its costs are incurred. Accordingly, we are finalizing our

proposal to treat the algorithmic analysis as an ''other diagnostic test'' under section 1861(s)(3) of the Act distinct from the underlying laboratory test for purposes of PFS payment. We will take the definitional concerns regarding SaMS into consideration for future rulemaking.

Comment: Several commenters urged CMS to coordinate this policy with the pending CLIA RFI issued by CMS and the CDC on July 16, 2026, regarding the appropriate level of CLIA oversight of ''dry-lab'' facilities that perform computational analyses without a traditional wet-lab component, so that the two efforts do not produce conflicting outcomes.[62] Commenters noted that CMS and the CDC are actively considering, through that RFI, whether CLIA certification is required to furnish these types of services, and argued that it is premature for CMS to conclude in this rule that such services are not ''laboratory'' services for payment purposes before that RFI is complete. Commenters requested that CMS defer any changes to this PFS payment policy pending the outcome of the CLIA RFI, given the potential for the policies under consideration there to directly conflict with the proposal at issue here. A commenter separately requested that CMS clarify that CLIA's scope includes facilities that produce and examine information obtained through analysis of materials derived from the human body.

Response: CMS appreciates these comments. We plan to coordinate and collaborate across the relevant agencies to ensure oversight and payment policies are consistent.

Comment: Commenters requested that CMS confirm it does not intend, in addressing the Medicare billing of SaMS analyses performed on laboratory tests, to change the regulatory structure under which laboratories and the tests they provide are governed. Commenters noted that the proposal could be read to create ambiguity on this point, and requested that CMS include the following clarifying statement in the final rule: that algorithmic interpretation of specimen-derived pathology data, performed within or under arrangement with a CLIA-certified laboratory, remains subject to CLIA.

Response: This policy does not seek to make changes to the requirements governing CLIA-certified laboratories. We consider these algorithmic analyses as ''other diagnostic tests'' that are performed on an underlying laboratory test. This policy seeks to provide consistency in paying for all SaMS algorithmic analyses in the PFS. We will take the regulatory concerns raised by commenters, including incorporating additional specificity regarding SaMS services and CLIA, into consideration for future rulemaking. We welcome public engagement from interested parties on these issues.

Comment: While we proposed contractor pricing in the proposed rule, many commenters did not support the proposal to contractor price these services, as they stated they did not believe these services have different costs in different Medicare Administrative Contractor (MAC) geographic jurisdictions and that this proposal would place additional burden on MACs. Other commenters asserted that contractor pricing these services would lead to less payment predictability than when they were paid for as CDLTs under the CLFS. Some commenters requested that we crosswalk the PFS payment for these services to the OPPS payment rates, as the OPPS payment rates are using current CLFS payment rates to inform their pricing, in order to encourage site-neutral pricing between payment systems. A few commenters requested that, if contractor pricing is finalized, we communicate with MACs to encourage a published uniform national methodology, so that beneficiary access does not depend on jurisdiction. Some commenters did not agree with our proposal to assign any new codes that describe SaMS analysis performed on a laboratory test to contractor pricing for payment under the PFS in subsequent years.

Response: We thank commenters for the additional information. As discussed in the CY 2027 OPPS Final Rule, this is a first step towards a more comprehensive payment policy. We agree with commenters that contractor pricing these services could lead to less payment predictability than when they were paid for as CDLTs under the CLFS, as contractor priced services could vary between MACs. We agree with commenters that a more predictable payment methodology would be crosswalking OPPS payment rates for these services, as they are using CY 2026 CLFS payment rates to inform their pricing. This payment methodology would also encourage site-neutral pricing between payment systems, which could encourage providers to choose the most clinically appropriate setting based on patient needs rather than financial incentives. Therefore, we are finalizing national pricing for these services under the PFS for CY 2027, based on a crosswalk to the OPPS payment rates. Additionally, we acknowledge that these codes should have been included with a procedure status indicator of ''C'' in Addendum B of the NPRM, however they were inadvertently not included. These services will be included in Addendum B of the CY 2027 PFS Final Rule with a procedure status indicator of A (active). To crosswalk payment rates from the OPPS, we calculated this value by dividing the OPPS payment rate, which is represented in a dollar amount, by the CY 2027 PFS conversion factor in order to convert the OPPS payment rate dollar amount into RVUs. The resulting value will be the PE RVU for the SaMS services detailed later in this section.

Comment: We received comments regarding the specific list of HCPCS codes we proposed to designate as SaMS analyses performed on laboratory tests. Commenters generally agreed that the following CPT codes describe algorithmic analyses and may be designated as SaMS laboratory analyses:

- 0510U—Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced rna whole transcriptome data, reported as probability of predicted molecular subtype
- 0512U—Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) status, formalin-fixed paraffin embedded (ffpe) tissue, reported as increased or decreased probability of msi-high (msi-h)
- 0513U—Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) and homologous recombination deficiency (hrd) status, formalin fixed paraffin-embedded (ffpe) tissue, reported as increased or decreased probability of each biomarker
- 0418U—Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score
- 0376U—Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate

[62] 91 FR 43586, available at *https://www.federalregister.gov/documents/2026/07/16/2026–14358/request-for-information-clinical-laboratory-improvement-amendments-of-1988-clia-regulations.*

Response: We thank the commenters for their support. We are finalizing assigning CPT codes 0510U, 0512U, 0513U, 0418U, and 0376U to active pricing under the PFS as SaMS analyses performed on laboratory tests. Please refer to Table A–D8 for the list of services we are finalizing as SaMS analyses performed on laboratory tests.

Comment: We received a comment noting that CPT codes 81417 and 81427 both describe post-sequencing data analysis but were not included in the proposed list of CPT codes to designate as SaMS analyses performed on laboratory tests for purposes of payment under the PFS. We also received a comment noting that CPT codes 81417 (Exome (*e.g.,* unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (*e.g.,* updated knowledge or unrelated condition/syndrome)) and 81427 (Genome (*e.g.,* unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (*e.g.,* updated knowledge or unrelated condition/syndrome)) both describe post-sequencing data analysis but were not included in the proposed list of CPT codes to designate as SaMS analyses performed on laboratory tests for purposes of payment under the PFS.

Response: We thank the commenter for bringing these codes to our attention. We agree that CPT codes 81417 and 81427 codes should be designated as SaMS analyses performed on laboratory tests for purposes of payment under the PFS because they provide a secondary or subsequent stand-alone algorithmic analysis of a previously obtained exome or genome sequence. Therefore, for CY 2027, we are finalizing assigning CPT code 81417 and 81427 as actively priced under the PFS.

Comment: Some commenters asserted that certain codes that we proposed to designate as SaMS analyses performed on laboratory tests for payment under the PFS should not be finalized as proposed because they possess, or may possess, wet lab components. Per the commenters, the following CPT codes have wet lab components:

- 0511U—Oncology (solid tumor), tumor cell culture in 3d microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug
- 81416—Exome (*e.g.,* unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (*e.g.,* parents, siblings) (list separately in addition to code for primary procedure)

Similarly, a commenter opposed finalizing CPT code 0414U (Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (alk, braf, egfr, erbb2, met, ntrk1–3, ret, ros1), and kras g12c and pd-l1, if performed, formalin-fixed paraffin-embedded (ffpe) tissue, reported as positive or negative for each biomarker) as a SaMS analysis performed on a laboratory test for payment under the PFS because the service includes a wet lab component if performed, as designated in the descriptor. A commenter opposed similarly designating CPT code 0220U (Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score) as a SaMS analysis performed on a laboratory test because the code is ambiguous on whether it includes wet lab steps. A commenter pointed out that CPT code 0208U (Oncology (medullary thyroid carcinoma), mrna, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma) was deleted effective January 1, 2022, and therefore, should not be included on the final list for payment under the PFS.

Response: We agree with commenters that CPT codes 0511U and 81416 both involve wet lab analyses as outlined in each CPT descriptor, and therefore, should not be paid under the PFS. Since the code descriptors integrate both the wet lab and secondary algorithmic analyses, rather than only the computer-based secondary analyses component, we agree to not designate CPT codes 0511U and 81416 as SaMS analyses performed on laboratory tests. These HCPCS codes would continue to be paid under the CLFS.

However, we do not agree with commenters that CPT code 0414U should be paid under the CLFS, as the descriptor characterizes the service as an augmentative algorithmic analysis. Commenters pointed out that the descriptor allows for additional analysis ''if performed,'' if, for example, a slide needs to be redone for the purpose of the analysis. However, our understanding is that the ''if performed'' language does not indicate that the algorithmic analysis is optional, but instead refers to the optional analysis of additional biomarkers. Therefore, we are finalizing assignment of CPT code 0414U to active pricing for payment under the PFS.

Regarding CPT code 0220U, we similarly disagree with the commenters that the code descriptor is ambiguous on whether a wet lab component is included. The descriptor cites ''image analysis with artificial intelligence'', which we believe is similar to other SaMS laboratory analyses of existing images or slides.

Finally, we appreciate the comment noting that CPT code 0208U was deleted, and agree that it should not be included on the final list for payment under the PFS.

Comment: Commenters requested that CMS confirm that super-intelligence enabled diagnostic analyses performed in CLIA-certified independent laboratories after the hospital encounter are eligible for separate payment under the PFS framework. Commenters further requested that CMS permit laboratories to bill Medicare for these services when developed as laboratory-developed tests, noting that if such tests are not billable by laboratories under the PFS laboratories would effectively be prohibited from directly billing and receiving payment for services they perform.

Response: As we stated in the proposed rule, the services that we designate as SaMS, specifically SaMS analyses performed on laboratory tests, will be assigned active pricing when paid for under the PFS. We refer readers to the CY 2027 OPPS final rule for discussion on how SaMS analyses performed on laboratory tests will be paid under the OPPS.

Comment: A commenter requested that CMS confirm the applicable date of service for algorithm-only laboratory analyses, noting that if such services are classified as ''other diagnostic tests'' rather than clinical diagnostic laboratory tests, the laboratory date-of-service policy would not apply.

Response: We confirm that because we are classifying SaMS analyses performed on laboratory tests as ''other diagnostic tests'' under section 1861(s)(3) of the Act, they would not be subject to the date of service policy as outlined in 42 CFR § 414.510.

After consideration of public comments, we are finalizing our proposal for CY 2027 to reassign certain HCPCS codes describing SaMS analyses performed on laboratory tests that are currently paid under the CLFS. We are finalizing that these services be priced using crosswalked OPPS rates. However, we are finalizing the proposed code list with certain modifications, based on public comments received. In total, for CY 2027, we are finalizing assigning 14 SaMS analyses performed on laboratory tests to active pricing under the PFS. We intend to continue to engage with the laboratory community on these finalized changes,

and acknowledge the definitional concerns regarding SaMS services and the applicable payment and regulatory frameworks. We will consider expanding and further clarifying the scope of the policy through future rulemaking. For CY 2027, as provided in the CY 2027 OPPS/ASC final rule, CMS is setting OPPS payment rates for 14 HCPCS codes that describe SaMS analyses performed on laboratory tests. These OPPS rates are based on the CY 2026 CLFS payment rates for the corresponding services, with the codes assigned to new technology APCs whose payment bands align with the applicable current CLFS rates.

Refer to Table A–D8 for the final list of SaMS analyses performed on laboratory tests for CY 2027. The final CY 2027 payment rates can be found in Addendum B to this final rule via the CMS website at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

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TABLE A-D8: FINAL SAMS ANALYSES PERFORMED ON LABORATORY TESTS FOR CY 2027

HCPCS Code	Long Descriptor
0510U	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced rna whole transcriptome data, reported as probability of predicted molecular subtype
0512U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) status, formalin-fixed paraffin embedded (ffpe) tissue, reported as increased or decreased probability of msi-high (msi-h)
0513U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) and homologous recombination deficiency (hrd) status, formalin fixed paraffin-embedded (ffpe) tissue, reported as increased or decreased probability of each biomarker
0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (alk, braf, egfr, erbb2, met, ntrk1-3, ret, ros1), and kras g12c and pd-l1, if performed, formalin-fixed paraffin-embedded (ffpe) tissue, reported as positive or negative for each biomarker

HCPCS Code	Long Descriptor
0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score
0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate
81417	Exome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)
81427	Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)
1106T (placeholder code X623T)	Oncology (breast), augmentative algorithmic analysis of histomorphologic features in digitized hematoxylin and eosin stained slides from formalin-fixed paraffin-embedded (FFPE) breast cancer tissue, algorithm-derived parameters reported as 5-year and 10-year risks of distant metastasis, including digitization of glass microscope slides and hematoxylin and eosin staining of tissue sections, when performed
1107T (placeholder code X624T)	Oncology (prostate), augmentative algorithmic analysis of histomorphologic features in digitized hematoxylin and eosin stained slide(s) from formalin-fixed paraffin-embedded (FFPE) prostate cancer tissue, algorithm-derived parameters reported as 10-year risk of distant metastasis and prostate cancer specific mortality, including hematoxylin and eosin staining of tissue sections and digitization of glass microscope slides, when performed
1097T (placeholder code X614T)	Oncology (pancreas), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded pancreatic cancer tissue, algorithm-derived parameters reported as prediction of response to fluorouracil backbone versus gemcitabine backbone chemotherapy, including hematoxylin and eosin staining of tissue sections and digitization of glass microscope slides, when performed
1063T (placeholder code X568T)	Oncology (bladder), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded (FFPE) bladder cancer tissue (high-grade, non-muscle invasive), with clinicopathologic variables entered by the qualified health care professional; algorithm-derived parameters reported as prognostic of recurrence and progression, including hematoxylin and eosin staining of tissue sections, and digitization of glass microscope slides, when performed

HCPCS Code	Long Descriptor
1064T (placeholder X569T)	Oncology (bladder), augmentative algorithmic analysis of histomorphologic features in digitized slides from formalin-fixed paraffin-embedded (FFPE) bladder cancer tissue (high-grade, non-muscle invasive), with clinicopathologic variables entered by the qualified health care professional; algorithm-derived parameters reported as predictive of response to Bacillus Calmette-Guérin (BCG) therapy, including hematoxylin and eosin staining of tissue sections, and digitization of glass microscope slides, when performed

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(62) Caregiver Training Services (CTS)

In the CY 2025 PFS final rule (89 FR 97817 through 97821), we finalized new G—codes and payment for direct care CTS: HCPCS codes G0541 *(Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; initial 30 minutes),* G0542 *(Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; each additional 15 minutes (list separately in addition to code for primary service) (use g0542 in conjunction with g0541)),* and G0543 *(Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face with multiple sets of caregivers).*

We sought comment on whether the resource costs associated with these services are best reflected through this existing coding or whether these resources costs are reflected in the valuation of other codes paid under the PFS, such as E/M visits.

We received public comments on this comment solicitation. The following is a summary of the comments we received and our responses.

Comment: We received many comments that supported maintaining separate coding and payment for caregiver training services. Commenters were nearly unanimous in recommending that CMS retain separate coding and payment for CTS rather than incorporating these resource costs into E/M valuation. Additionally, commenters noted that caregiver training needs often do not coincide with an E/M encounter, and that requiring CTS to be billed with or incorporated into an E/M visit would unnecessarily restrict when this training could occur, as well as impose more restrictive supervision or location requirements.

Response: We thank the commenters for their feedback on whether the resource costs associated with direct care CTS are best reflected through existing HCPCS codes G0541, G0542, and G0543. We will consider these comments for potential future rulemaking.

(63) Payment for Physician-Patient Clinical Trial Discussions

Despite the U.S. investing over $50 billion annually in biomedical research, fewer than 7 percent of adult cancer patients enroll in clinical trials.[63] A central and modifiable reason is that physicians rarely initiate conversations about clinical trials with their patients. For example, national survey data show that 70 percent of oncologists discuss trials with less than a quarter of their patients,[64] yet more than 50 percent of eligible patients enroll when actively offered a clinical trial.[65]

Time and administrative burden are documented as the top barrier to conversations between physician and patients about participation in clinical trials in virtually every survey.[66] The current valuation of existing visit codes does not account for the additional time and resource costs associated with the structured physician counseling regarding clinical trial eligibility, options, risks and benefits associated with counseling a beneficiary on whether to enroll in a clinical trial.

We therefore sought comment on whether we should effectuate payment for these resource costs through the creation of a HCPCS G-code describing a minimum of 20 minutes of physician or other QHP time spent on clinical trial counseling.

We sought comment on accurate valuation for this service, including inputs for work and practice expense, and whether the service should be available as a Medicare telehealth service. Interested parties suggested a work RVU value between 1.00 and 1.50 RVUs would accurately account for the physician work associated with this service.

We also sought comment on what documentation requirements we might consider for such a service, such as the trial(s) discussed and the patient's decision.

Comment: Commenters broadly supported creating a payment mechanism for physician-patient clinical trial counseling, agreeing that uncompensated time discourages enrollment. Commenters differed on code structure, with some preferring a modifier or add-on to the E/M visit over a standalone HCPCS G-code. On billing eligibility, some commenters supported allowing RNs and other advanced practice providers to bill. Most commenters supported the suggested work RVU range, though some preferred tiered time increments, and several suggested potential crosswalks to

[63] Unger JM, Shulman LN, Facktor MA, Helson H, Fleury ME. National estimates of the participation of patients with cancer in clinical research studies based on commission on cancer accreditation data. J Clin Oncol. 2024;42:2139–2148.

[64] Lee SJC, Murphy CC, Gerber DE, et al. Reimbursement matters: overcoming barriers to clinical trial accrual. Med Care. 2021;59(5):461–466. PMC8026490.

[65] Unger JM, Vaidya R, Hershman DL, Minasian LM, Fleury ME. Systematic review and meta-analysis of the magnitude of structural, clinical, and physician and patient barriers to cancer clinical trial participation. J Natl Cancer Inst. 2019;111(3):245–255.

[66] Kumar A, Bhatt DL, Fonarow GC, et al. Barriers for cancer clinical trial enrollment: a qualitative study of the perspectives of healthcare providers. Contemp Clin Trials Commun. 2022;28:100939. PMC9189774.

existing codes. Commenters unanimously supported telehealth availability to improve access for beneficiaries. Regarding documentation, most commenters favored minimal requirements and some proposed specific elements, generally agreeing on documenting the trial(s) discussed, time spent, and the substance of the conversation.

Response: We thank commenters for their input on this potential HCPCS G-code for physician-patient clinical trial counseling. Commenters supported the policy's goals but offered differing views on code structure, billing eligibility, valuation, telehealth availability, and documentation requirements. We will take these recommendations into account should we propose to establish this code in future rulemaking.

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TABLE A-D9: CY 2027 WORK RVUs FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
0591T	Health and well-being coaching face-to-face; individual, initial assessment	C	1.00	1.81	Yes
0592T	Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes	C	0.70	1.00	Yes
0593T	Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes	C	0.23	0.23	Yes
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	1.42	1.35	1.35	No
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion	0.98	1.00	1.00	No
15006	Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1% of body area of infants and children	NEW	10.97	10.97	No
15007	Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	NEW	0.59	0.59	No
15008	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	NEW	11.28	11.28	No
15009	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	NEW	0.98	0.98	No
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures	2.44	2.44	2.44	No
20988	Placement of localization marker(s) (eg, fiducial marker[s]), intraosseous, percutaneous, including imaging guidance, when performed; first target site	NEW	3.00	3.00	No
20989	Placement of localization marker(s) (eg, fiducial marker[s]), intraosseous, percutaneous, including imaging guidance, when performed; each additional target site	NEW	1.76	1.76	No
20994	Ablation therapy for reduction or eradication of bone tumor, including adjacent soft tissue when involved by tumor extension, cryoablation, open	NEW	2.70	2.70	No
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	24.75	23.12	23.12	No
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	20.47	21.72	21.72	No
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	20.49	19.53	19.53	No
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment	5.88	3.00	3.00	No
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	17.44	13.81	15.60	No
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))	21.58	17.49	19.35	No
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	19.11	15.37	16.70	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
27278	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive, including imaging guidance, unilateral; placement of intra-articular structural bone graft, metal and/or synthetic device(s) without cortical piercing, including use of osteopromotive material and/or obtaining bone graft, when performed	7.66	7.66	7.66	No
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive, including imaging guidance, unilateral; placement of transarticular and/or intra-articular device(s) that engage bone with intrinsic fixation (eg, screw[s], flange[s], blade[s]) piercing the lateral cortex of the sacrum and the medial cortex of the ilium (with or without piercing the lateral cortex of the ilium), including use of osteopromotive material and/or obtaining bone graft, when performed	11.83	11.00	11.00	No
27417	Acellular scaffold(s) (eg, aragonite) implant(s), for osteochondral lesion(s), knee, open	NEW	9.53	9.53	No
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	19.11	15.94	16.70	No
27494	Implantation of medial knee extra-articular shock absorber, including fluoroscopic guidance	NEW	13.16	13.16	No
33290	Insertion of permanent cardiac contractility modulation (CCM) system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; pulse generator and transvenous electrodes	NEW	8.83	8.83	No
33291	Insertion of permanent cardiac contractility modulation (CCM) system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; pulse generator only	NEW	5.66	5.66	No
33292	Insertion of permanent cardiac contractility modulation (CCM) system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; transvenous electrode, single	NEW	6.00	6.00	No
33293	Insertion of permanent cardiac contractility modulation (CCM) system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; transvenous electrode, dual	NEW	6.23	6.23	No
33294	Removal of permanent cardiac contractility modulation (CCM) system; pulse generator and transvenous electrodes	NEW	9.90	9.90	No
33295	Removal of permanent cardiac contractility modulation (CCM) system; pulse generator only	NEW	4.79	4.79	No
33296	Removal of permanent cardiac contractility modulation (CCM) system; transvenous electrode, single	NEW	7.30	7.30	No
33297	Removal of permanent cardiac contractility modulation (CCM) system; transvenous electrode, dual	NEW	8.39	8.39	No
33307	Removal and replacement of permanent cardiac contractility modulation (CCM) system, pulse generator only	NEW	6.00	6.00	No
33308	Repositioning of previously implanted cardiac contractility modulation (CCM) transvenous electrode(s), including fluoroscopic guidance and programming of sensing and therapeutic parameters	NEW	5.00	5.00	No
33309	Relocation or revision of skin pocket for implanted cardiac contractility modulation (CCM) pulse generator	NEW	5.12	5.12	No

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33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation	9.99	9.00	9.00	No
33466	Transcatheter tricuspid valve edge-to-edge repair (T-TEER), percutaneous approach; initial clip	NEW	17.06	17.06	Yes
33467	Transcatheter tricuspid valve edge-to-edge repair (T-TEER), percutaneous approach; each additional clip during same session	NEW	6.34	6.34	No
33469	Transcatheter tricuspid valve replacement (TTVR) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	NEW	17.52	17.52	Yes
33994	Insertion of left heart ventricular assist device (VAD), including radiological supervision and interpretation, open; axillary, subclavian, or innominate artery exposure with creation of conduit by infraclavicular or supraclavicular incision, unilateral	NEW	13.65	13.65	No
33996	Insertion of left heart ventricular assist device (VAD), including radiological supervision and interpretation, open; aorta exposure with creation of conduit by transthoracic (eg, median sternotomy, thoracotomy) incision	NEW	17.52	17.52	No
33998	Removal of left heart ventricular assist device (VAD) with resection and stapling of graft conduit and skin closure (eg, infraclavicular, supraclavicular)	NEW	6.58	6.58	No
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)	2.29	2.29	2.29	No
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg	2.93	2.62	2.62	No
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)	0.73	0.73	0.73	No
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg	1.46	1.18	1.18	No
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated	3.41	3.41	3.41	No
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites	1.71	1.71	1.71	No
38800	Microvascular anastomosis between a single vein opening and any number of lymphatic vessels, per limb; initial anastomosis	NEW	14.00	14.00	No
38801	Microvascular anastomosis between a single vein opening and any number of lymphatic vessels, per limb; each additional anastomosis	NEW	6.00	6.00	No
39540	Repair, diaphragmatic hernia (other than neonatal), via laparotomy; traumatic, acute	14.21	24.00	24.00	No
39541	Repair, diaphragmatic hernia (other than neonatal), via laparotomy; traumatic, chronic	15.36	26.00	26.00	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
39542	Repair, diaphragmatic hernia (other than neonatal), via laparotomy; nontraumatic (ie, Bochdalek, Morgagni)	NEW	25.75	25.75	No
39543	Repair, diaphragmatic hernia (other than neonatal), via thoracotomy; traumatic, chronic	NEW	26.41	26.41	No
39544	Repair, diaphragmatic hernia (other than neonatal), via thoracotomy; nontraumatic (ie, Bochdalek, Morgagni)	NEW	25.94	25.94	No
39545	Plication of diaphragm for eventration or paralysis, via thoracotomy	14.30	18.45	18.45	No
39562	Division of median arcuate ligament and release of celiac trunk, with ganglionectomy, when performed	NEW	26.41	26.41	No
39570	Laparoscopy, surgical, with division of median arcuate ligament and release of celiac trunk, with ganglionectomy, when performed	NEW	25.94	25.94	No
39571	Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, acute	NEW	22.04	22.04	No
39572	Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, chronic	NEW	26.60	26.60	No
39573	Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); nontraumatic (ie, Bochdalek, Morgagni)	NEW	27.00	27.00	No
39580	Thoracoscopy, surgical, with plication of diaphragm for eventration or paralysis	NEW	20.00	20.00	No
39581	Thoracoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, chronic	NEW	25.44	25.44	No
39582	Thoracoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); nontraumatic (ie, Bochdalek, Morgagni)	NEW	25.94	25.94	No
39590	Implantation of mesh or other prosthesis with open, laparoscopic, or thoracoscopic diaphragmatic hernia repair	NEW	3.00	3.00	No
42808	Excision or destruction of lesion of pharynx, without magnification, any method	2.29	2.29	2.29	No
42985	Transoral removal of oropharyngeal and/or pharyngeal neoplasm under magnification (eg, microscope or telescope), includes robotic assistance, when performed; tongue base	NEW	20.00	20.00	No
42986	Transoral removal of oropharyngeal and/or pharyngeal neoplasm under magnification (eg, microscope or telescope), includes robotic assistance, when performed; lateral pharyngeal wall, including tonsil	NEW	20.05	20.05	No
43498	Endoscopic submucosal dissection (ESD) of upper gastrointestinal tract, including mucosal closure, when performed	NEW	15.00	15.00	No
44011	Duodenoduodenostomy or duodenojejunostomy for congenital duodenal obstruction	NEW	50.00	50.00	No
44181	Laparoscopy, surgical; duodenoduodenostomy or duodenojejunostomy for congenital duodenal obstruction	NEW	52.60	52.60	No
45991	Endoscopic submucosal dissection (ESD) of lower gastrointestinal tract, including mucosal closure, when performed	NEW	16.38	16.38	No
48990	Ablation, irreversible electroporation of tumor(s) of the pancreas, open, including imaging guidance	NEW	25.19	25.19	No

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51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck	3.64	3.64	3.64	No
55705	Biopsy, prostate, any approach, nonimaging-guided	1.88	1.88	1.88	No
55707	Biopsy, prostate, transrectal, including imaging guidance, regional	2.63	2.63	2.63	No
55708	Biopsy, prostate, transrectal, including imaging guidance, regional and fusion-targeted lesion(s)	3.39	3.39	3.39	No
55709	Biopsy, prostate, transperineal, including imaging guidance, regional	3.23	3.23	3.23	No
55710	Biopsy, prostate, transperineal, including imaging guidance, regional and fusion-targeted lesion(s)	3.81	3.81	3.81	No
55711	Biopsy, prostate, transrectal or transperineal, including imaging guidance, fusion-targeted lesion(s) without regional; first targeted lesion	2.61	2.37	2.37	No
55714	Biopsy, prostate, including imaging guidance, in-bore CT- or MRI-guided; first targeted lesion	3.62	3.62	3.62	No
55715	Biopsy, prostate, including imaging guidance, in-bore CT- or MRI-guided; each additional targeted lesion	1.05	1.80	1.80	No
55716	Biopsy, prostate, transrectal or transperineal, including imaging guidance, fusion-targeted lesion(s) without regional; each additional targeted lesion (List separately in addition to code for primary procedure)	NEW	0.68	0.68	No
59030	Fetal scalp blood sampling	1.94	0.90	0.90	No
59051	Fetal monitoring during labor by consulting physician (ie, non-attending physician) or other qualified health care professional, with interpretation and report	0.72	0.93	0.93	No
59080	Initial day labor management; straightforward, per day	NEW	4.03	4.03	No
59081	Initial day labor management; complex, per day	NEW	5.18	5.18	No
59082	Subsequent day labor management; straightforward, per day	NEW	3.45	3.45	No
59083	Subsequent day labor management; complex, per day	NEW	4.83	4.83	No
59160	Curettage, postpartum	2.69	2.93	2.93	No
59300	Repair of first or second-degree episiotomy or laceration, by other than attending physician or other qualified health care professional performing vaginal delivery care (separate procedure)	2.35	1.76	1.76	No
59320	Cerclage of cervix, during pregnancy; vaginal	2.42	3.02	3.02	No
59325	Cerclage of cervix, during pregnancy; abdominal	3.96	6.34	6.34	No
59412	External cephalic version	1.71	2.63	2.63	No
59414	Delivery of placenta only (separate procedure)	1.61	1.61	1.61	No
59431	Vaginal delivery, with or without episiotomy;	NEW	9.20	9.20	No
59432	Vaginal delivery, with or without episiotomy; after previous cesarean delivery	NEW	10.35	10.35	No
59433	Repair of episiotomy or laceration; third-degree laceration	NEW	2.47	2.47	No
59434	Repair of episiotomy or laceration; fourth-degree laceration	NEW	4.14	4.14	No

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59502	Cesarean delivery; primary	NEW	13.80	13.80	No
59503	Cesarean delivery; repeat	NEW	16.86	16.86	No
59504	Subtotal or total hysterectomy after cesarean delivery	NEW	15.56	15.56	No
59623	Uterine tamponade (eg, balloon, catheter, vacuum, packing material)	NEW	2.15	2.15	No
59871	Removal of cerclage suture under anesthesia (other than local)	2.08	2.15	2.15	No
61781	Stereotactic computer-assisted (navigational) procedure; cranial, intradural	3.66	3.66	3.66	No
61782	Stereotactic computer-assisted (navigational) procedure; cranial, extradural	3.10	2.06	2.06	No
61783	Stereotactic computer-assisted (navigational) procedure; spinal	3.66	3.66	3.66	No
62287	Decompression, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar	9.03	6.23	6.23	No
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical	17.50	17.25	17.25	No
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; thoracic	16.82	16.71	16.71	No
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar	14.99	14.99	14.99	No
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional vertebral segment, cervical, thoracic, or lumbar	3.38	3.38	3.38	No
64400	Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie, ophthalmic, maxillary, mandibular)	0.73	0.73	0.73	No
64405	Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve	0.92	0.84	0.84	No
70544	Magnetic resonance angiography, head, including image postprocessing; without contrast material(s)	1.17	1.17	1.17	No
70545	Magnetic resonance angiography, head, including image postprocessing; with contrast material(s)	1.17	1.17	1.17	No
70546	Magnetic resonance angiography, head, including image postprocessing; without contrast material(s), followed by contrast material(s) and further sequences	1.44	1.44	1.44	No
70547	Magnetic resonance angiography, neck, including image postprocessing; without contrast material(s)	1.17	1.17	1.17	No
70548	Magnetic resonance angiography, neck, including image postprocessing; with contrast material(s)	1.46	1.46	1.46	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
70549	Magnetic resonance angiography, neck, including image postprocessing; without contrast material(s), followed by contrast material(s) and further sequences	1.76	1.76	1.76	No
70560	Magnetic resonance angiography, head and neck, including image postprocessing; without contrast material(s)	NEW	1.77	1.77	No
70561	Magnetic resonance angiography, head and neck, including image postprocessing; with contrast material(s)	NEW	2.10	2.10	No
70562	Magnetic resonance angiography, head and neck, without contrast material(s) in 1 or both body regions, followed by contrast material(s) and further sequences in 1 or both body regions, including image postprocessing	NEW	2.23	2.23	No
73200	Computed tomography, upper extremity; without contrast material	0.98	1.00	1.00	No
73201	Computed tomography, upper extremity; with contrast material(s)	1.13	1.16	1.16	No
73202	Computed tomography, upper extremity; without contrast material, followed by contrast material(s) and further sections	1.19	1.24	1.24	No
77402	Radiation treatment delivery; Level 1 (eg, single-electron field, multiple-electron fields, or 2D photons), including imaging guidance, when performed	0.00	0.00	0.00	No
77407	Radiation treatment delivery; Level 2, single-isocenter (eg, 3D or IMRT), photons, including imaging guidance, when performed	0.00	0.00	0.00	No
77412	Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (eg, 2D, 3D, or IMRT) or a single-isocenter photon therapy (eg, 3D or IMRT) with active motion management, or total skin electrons, or mixed-electron/photon field(s), including imaging guidance, when performed	0.00	0.00	0.00	No
77520	Proton treatment delivery; simple, without compensation	C	0.00	0.00	No
77522	Proton treatment delivery; simple, with compensation	C	0.00	0.00	No
77523	Proton treatment delivery; intermediate	C	0.00	0.00	No
77525	Proton treatment delivery; complex	C	0.00	0.00	No
90832	Psychotherapy, 30 minutes with patient	1.94	2.02	2.02	No
90833	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service	1.71	1.79	1.79	No
90834	Psychotherapy, 45 minutes with patient	2.56	2.67	2.67	No
90836	Psychotherapy, 45 minutes with patient when performed with an evaluation and management service	2.17	2.26	2.26	No
90837	Psychotherapy, 60 minutes with patient	3.78	3.94	3.94	No
90838	Psychotherapy, 60 minutes with patient when performed with an evaluation and management service	2.86	2.98	2.98	No
90839	Psychotherapy for crisis; first 60 minutes	3.58	3.73	3.73	No
90840	Psychotherapy for crisis; each additional 30 minutes	1.71	1.79	1.79	No

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90845	Psychoanalysis	2.40	2.50	2.50	No
90846	Family psychotherapy (without the patient present), 50 minutes	2.74	2.86	2.86	No
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes	2.86	2.98	2.98	No
90849	Multiple-family group psychotherapy	0.67	0.70	0.70	No
90853	Group psychotherapy (other than of a multiple-family group)	0.67	0.70	0.70	No
90901	Biofeedback training by any modality (eg, EMG, EEG, ECG); initial 15 minutes of direct patient contact by physician or other qualified health care professional	0.41	0.61	0.61	No
90903	Biofeedback training by any modality (eg, EMG, EEG, ECG); each additional 15 minutes of direct patient contact by physician or other qualified health care professional	NEW	0.48	0.48	No
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient	0.90	0.90	0.90	No
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient	0.50	0.50	0.50	No
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder, group, 2 or more individuals	0.33	0.28	0.28	No
92513	Video head impulse testing (vHIT), with recording, interpretation, and report; of lateral semicircular canal function	NEW	0.53	0.53	No
92514	Video head impulse testing (vHIT), with recording, interpretation, and report; of lateral and vertical semicircular canal function	NEW	0.84	0.84	No
92527	Rotational vestibular assessment by sinusoidal harmonic acceleration (SHA) testing with calibrated, computer-controlled chair, with interpretation and report;	NEW	0.92	0.92	No
92528	Rotational vestibular assessment by sinusoidal harmonic acceleration (SHA) testing with calibrated, computer-controlled chair, with interpretation and report; with velocity step testing (VST)	NEW	0.35	0.35	No
92654	Treatment of fluency disorder (eg, stuttering and cluttering), direct (one-on-one) patient contact; initial 30 minutes	NEW	0.92	0.92	No
92655	Treatment of fluency disorder (eg, stuttering and cluttering), direct (one-on-one) patient contact; each additional 15 minutes	NEW	0.44	0.44	No
92656	Treatment of speech sound production disorder (eg, articulation, phonological process, apraxia, dysarthria), direct (one-on-one) patient contact; initial 30 minutes	NEW	0.90	0.90	No
92657	Treatment of speech sound production disorder (eg, articulation, phonological process, apraxia, dysarthria), direct (one-on-one) patient contact; each additional 15 minutes	NEW	0.44	0.44	No
92658	Treatment of language comprehension and expression disorder (eg, receptive and expressive language), direct (one-on-one) patient contact; initial 30 minutes	NEW	1.00	1.00	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
92659	Treatment of language comprehension and expression disorder (eg, receptive and expressive language), direct (one-on-one) patient contact; each additional 15 minutes	NEW	0.48	0.48	No
92660	Treatment of speech sound production disorder (eg, articulation, phonological process, apraxia, dysarthria) and language comprehension and expression disorder (eg, receptive and expressive language), direct (one-on-one) patient contact; initial 30 minutes	NEW	1.00	1.00	No
92661	Treatment of speech sound production disorder (eg, articulation, phonological process, apraxia, dysarthria) and language comprehension and expression disorder (eg, receptive and expressive language), direct (one-on-one) patient contact; each additional 15 minutes	NEW	0.50	0.50	No
92662	Treatment of voice, upper airway dysfunction, and/or resonance disorders, direct (one-on-one) patient contact; initial 30 minutes	NEW	0.98	0.98	No
92663	Treatment of voice, upper airway dysfunction, and/or resonance disorders, direct (one-on-one) patient contact; each additional 15 minutes	NEW	0.48	0.48	No
92922	Percutaneous transcatheter therapeutic drug-delivery by intracoronary drug-delivery balloon (eg, drug-coated, drug-eluting), including mechanical dilation by nondrug-delivery balloon angioplasty, single major coronary artery and/or its branch(es)	NEW	8.05	8.62	No
92976	Percutaneous transcatheter therapeutic drug-delivery by intracoronary drug-delivery balloon (eg, drug-coated, drug-eluting), single major artery and/or its branches	NEW	4.38	4.38	No
92978	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel	1.76	1.40	1.40	No
92979	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel	1.40	1.04	1.04	No
93154	Programming of the cardiac contractility modulation (CCM) system (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report by a physician or other qualified health care professional	NEW	0.90	0.90	No
93155	Interrogation device evaluation (in person) with analysis, review, and report by a physician or other qualified healthcare professional, including connection, recording, and disconnection, per patient encounter, implantable cardiac contractility modulation (CCM) system	NEW	0.80	0.80	No
93156	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation (CCM) system, with interim analysis, review, and report(s) by a physician or other qualified health care professional	NEW	0.59	0.59	No
93157	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation (CCM) system, remote data acquisition(s), receipt of transmissions, technician review, technical support, and distribution of results	NEW	0.00	0.00	No
95843	Unattended sleep study, set-up, data acquisition and technical analysis; low complexity of 3-4 channels that generate at least 3-5 parameter categories	NEW	0.00	0.00	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
95844	Unattended sleep study, set-up, data acquisition and technical analysis; moderate complexity of 5-10 channels that generate at least 6-8 parameter categories	NEW	0.00	0.00	No
95846	Unattended sleep study, set-up, data acquisition and technical analysis; high complexity of 11 or more channels that generate at least 9 parameter categories	NEW	0.00	0.00	No
95847	Unattended sleep study, interpretation and report by a physician or other qualified health care professional; low complexity of 3-4 channels that generate at least 3-5 parameter categories	NEW	0.81	0.81	No
95848	Unattended sleep study, interpretation and report by a physician or other qualified health care professional; moderate complexity of 5-10 channels that generate at least 6-8 parameter categories	NEW	1.05	1.05	No
95849	Unattended sleep study, interpretation and report by a physician or other qualified health care professional; high complexity of 11 or more channels that generate at least 9 parameter categories	NEW	1.42	1.50	No
95921	Testing of autonomic nervous system function, with interpretation and report; cardiovagal innervation (parasympathetic function), including 2 or more of the following: heart rate response to deep breathing with recorded R-R interval, Valsalva ratio, and 30:15 ratio	0.88	0.74	0.74	No
95922	Testing of autonomic nervous system function, with interpretation and report; vasomotor adrenergic innervation (sympathetic adrenergic function), including beat-to-beat blood pressure and R-R interval changes during Valsalva maneuver and at least 5 minutes of passive tilt (ie, tilt table)	0.96	0.96	0.96	No
95923	Testing of autonomic nervous system function, with interpretation and report; sudomotor, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint	0.88	0.88	0.88	No
95924	Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt (ie, tilt table)	1.73	1.50	1.50	No
95944	Testing of autonomic nervous system function, with interpretation and report; use of tilt table	NEW	0.34	0.34	No
95945	Testing of autonomic nervous system function, with interpretation and report; sudomotor, thermoregulatory sweat test	NEW	1.00	1.00	No
95946	Testing of autonomic nervous system function, with interpretation and report; sudomotor, assessing the sympathetic skin response (SSR) potential	NEW	0.50	0.50	No
95947	Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint	NEW	1.17	1.17	No
95948	Testing of autonomic nervous system function, with interpretation and report; combined sympathetic adrenergic with at least 5 minutes of passive tilt (ie, tilt table) and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint	NEW	1.56	1.56	No
95949	Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic, sympathetic adrenergic function with at least 5 minutes of passive tilt (ie, tilt table), and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint	NEW	1.77	1.77	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
96156	Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)	2.40	2.50	2.50	No
96158	Health behavior intervention, individual, face-to-face; initial 30 minutes	1.66	1.73	1.73	No
96159	Health behavior intervention, individual, face-to-face; each additional 15 minutes	0.57	0.60	0.60	No
96164	Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes	0.24	0.25	0.25	No
96165	Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes	0.11	0.12	0.12	No
96167	Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes	1.77	1.85	1.85	No
96168	Health behavior intervention, family (with the patient present), face-to-face; each additional 15 minutes	0.63	0.66	0.66	No
96920	Laser treatment, 308-312 nanometer wavelengths, for inflammatory or autoimmune skin diseases (eg, psoriasis); total area less than 250 sq cm	0.81	1.00	1.00	No
96921	Laser treatment, 308-312 nanometer wavelengths, for inflammatory or autoimmune skin diseases (eg, psoriasis); 250 sq cm to 500 sq cm	0.88	1.24	1.24	No
96922	Laser treatment, 308-312 nanometer wavelengths, for inflammatory or autoimmune skin diseases (eg, psoriasis); over 500 sq cm	1.12	1.50	1.50	No
97148	Behavior identification–supporting assessment of harmful behavior; each 15 minutes of technician time face-to-face with a patient, requiring the following components: • delivered by 2 technicians, • for a patient who exhibits harmful behavior, • conducted in an environment that is customized to the patient's behavior.	NEW	C	C	No
97149	Behavior identification–supporting assessment of harmful behavior; additional technicians present, each 15 minutes	NEW	C	C	No
97151	Behavior identification assessment, administered by a physician or other qualified health care professional (QHP), each 15 minutes of the physician's or other QHP's time face-to-face with patient and/or caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring and/or interpreting the assessment, and preparing the report and/or treatment plan	C	C	C	No
97152	Behavior identification–supporting assessment, administered by technician, face-to-face with the patient, each 15 minutes	C	C	C	No
97153	Adaptive behavior treatment by protocol, administered by technician, face-to-face with 1 patient, each 15 minutes	C	C	C	No
97154	Group adaptive behavior treatment by protocol, administered by technician, face-to-face with 2 or more patients, each 15 minutes	C	C	C	No
97155	Adaptive behavior direction of technician and analysis by physician or other qualified health care professional, face-to-face with a patient, each 15 minutes	C	C	C	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
97156	Family adaptive behavior treatment guidance with analysis, administered by physician or other qualified health care professional (with or without the patient present), including discussing protocols and treatment targets and/or training the caregiver(s) to implement assessment or treatment protocols with the patient, face-to-face with caregiver(s) for 1 patient, each 15 minutes	C	C	C	No
97157	Multiple-family group adaptive behavior treatment guidance with analysis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of caregivers for multiple patients, each 15 minutes	C	C	C	No
97158	Group adaptive behavior treatment with analysis, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes	C	C	C	No
97159	Adaptive behavior treatment of harmful behavior; each 15 minutes of technician time with a patient, requiring the following components: • delivered by 2 technicians, • for a patient who exhibits harmful behavior, • conducted in an environment that is customized to the patient's behavior.	NEW	C	C	No
97160	Adaptive behavior treatment of harmful behavior; each additional technician present, each 15 minutes	NEW	C	C	No
97173	Adaptive behavior treatment with analysis, administered by physician or other qualified health care professional, face-to-face with 1 patient, each 15 minutes	NEW	C	C	No
97180	Adaptive behavior non-face-to-face services, personally performed by a physician or other qualified health care professional, each 15 minutes, with any of the following elements, when performed: • review and analysis of data and session notes on patient treatment targets, • clinical decision-making regarding the need to modify treatment targets, goals, or protocols and/or making those modifications, • clinical decision-making regarding the need for additional assessment and developing or modifying assessment protocols, • developing discharge or transition plan, • training on or reviewing treatment targets and/or revised assessment or treatment protocols with technician(s).	NEW	C	C	No
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	0.39	0.39	0.39	No
97611	Real-time fluorescence wound imaging with clinical darkness to identify presence, location, load of bacteria, and measure wound size, per day	NEW	0.80	0.80	Yes
98963	Lactation care directed by a physician or other qualified health care professional, including history, assessment, training, and report; first 30 minutes	NEW	0.18	0.18	No
98964	Lactation care directed by a physician or other qualified health care professional, including history, assessment, training, and report; each additional 15 minutes	NEW	0.00	0.00	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
98975	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); initial set-up and patient education on use of equipment	0.00	0.00	0.00	No
98976	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 16-30 days in a 30-day period	0.00	0.00	0.00	No
98977	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period	0.00	0.00	0.00	No
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 16-30 days in a 30-day period	C	0.00	0.00	No
98979	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 10 minutes	0.31	0.31	0.31	No
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 20 minutes	0.62	0.62	0.62	No
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes	0.61	0.61	0.61	No
98984	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period	0.00	0.00	0.00	No
98985	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 2-15 days in a 30-day period	0.00	0.00	0.00	No
98986	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 2-15 days in a 30-day period	C	0.00	0.00	No
99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days	1.10	1.10	1.10	No
99406	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes	0.24	0.29	0.29	No
99407	Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes	0.50	0.60	0.60	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
99445	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate); device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period	0.00	0.00	0.00	No
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate); initial set-up and patient education on use of equipment	0.00	0.00	0.00	No
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate); device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period	0.00	0.00	0.00	No
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 20 minutes	0.61	0.61	0.61	No
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes	0.61	0.61	0.61	No
99470	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 10 minutes	0.31	0.31	0.31	No
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration	0.00	0.00	0.00	No
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient	0.18	0.18	0.18	No
99492	Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.	1.88	2.75	3.25	No
99493	Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate	2.05	2.26	2.56	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
	documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.				
99494	Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional	0.82	1.13	1.28	No
G0396	Alcohol and/or substance (other than tobacco) misuse structured assessment (for example, audit, dast), and brief intervention 15 to 30 minutes	0.65	0.77	0.77	No
G0397	Alcohol and/or substance (other than tobacco) misuse structured assessment (for example, audit, dast), and intervention, greater than 30 minutes	1.30	1.55	1.55	No
G0561	Tympanostomy with local or topical anesthesia and insertion of a ventilating tube when performed with tympanostomy tube delivery device, unilateral	C	0.00	0.00	No
G0568	Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies	1.88	2.75	3.25	No
G0569	Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using	2.05	2.26	2.56	No

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
	evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment				
G0572	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), first 20 minutes of clinical staff time with the patient, family member(s), directed by a treating physician or other treating qualified health care professional	NEW	1.00	1.00	No
G0573	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), each additional 20 minutes of clinical staff time with the patient, family member(s), directed by a treating physician or other treating qualified health care professional	NEW	0.70	0.70	No
G0576	Office or other outpatient evaluation and management service(s) for the diagnosis and treatment of vaccine adverse effects, new or established patient; each 15 minutes personally performed by the physician or qualified healthcare professional	NEW	0.61	0.61	No
G0577	Vascular embolization or occlusion procedure with use of a pressure-generating catheter (for example, one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction performed in the non-facility setting	C	11.45	11.45	Yes
G0681	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area	C	C	1.46	Yes
G0682	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	C	C	0.32	Yes
G0683	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	C	C	3.41	Yes
G0684	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)	C	C	0.78	Yes

HCPCS	Descriptor	CY 2026 Work RVU	Proposed CY 2027 Work RVU	Final CY 2027 Work RVU	CMS time refinement
G0686	Group-based medical session involving multiple patients with common medical condition(s) and receiving medical care in a group setting. The voluntary session is billed and led by a physician or other qualified healthcare professional (QHP) and may include services provided by other QHPs, clinical staff, or auxiliary personnel under the direction of the supervising physician or QHP. The voluntary session integrates group education, counseling, and peer support with individualized patient clinical assessment and care, includes 2–10 patients, billed once per patient, first 60 minutes	NEW	1.73	1.73	No
G0687	Group-based medical session involving multiple patients with common medical condition(s) and receiving medical care in a group setting. The voluntary session is billed and led by a physician or other qualified healthcare professional (QHP) and may include services provided by other QHPs, clinical staff, or auxiliary personnel under the direction of the supervising physician or QHP. The voluntary session integrates group education, counseling, and peer support with individualized patient clinical assessment and care, includes 2–10 patients, billed per patient, each additional 30 minutes (list separately in addition to code for primary service)	NEW	-	0.87	No
G0903	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual; for the pediatric population age 21 and under	NEW	1.30	1.30	No
G2011	Alcohol and/or substance (other than tobacco) misuse structured assessment (for example, audit, dast), and brief intervention, 5-14 minutes	0.33	0.39	0.39	No
G2214	Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional	0.77	1.13	1.28	No

TABLE A-D10: CY 2027 DIRECT PE REFINEMENTS

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
10005	Fna bx w/us gdn 1st les	EQ250	ultrasound unit, portable	NF		37	0	G1: See preamble text	-5.97
10005	Fna bx w/us gdn 1st les	ER130	Fine Needle Aspiration portable ultrasound	NF		0	37	G1: See preamble text	11.74
10006	Fna bx w/us gdn ea addl	EQ250	ultrasound unit, portable	NF		17	0	G1: See preamble text	-2.74
10006	Fna bx w/us gdn ea addl	ER130	Fine Needle Aspiration portable ultrasound	NF		0	17	G1: See preamble text	5.39
97611	R-t fluor wound imaging pr d	EF015	mayo stand	NF		0	30	G1: See preamble text	0.03
97611	R-t fluor wound imaging pr d	EF031	table, power	NF		0	30	G1: See preamble text	0.47
97611	R-t fluor wound imaging pr d	EQ137	instrument pack, basic ($500-$1499)	NF		0	36	G1: See preamble text	0.08
97611	R-t fluor wound imaging pr d	EQ168	light, exam	NF		0	30	G1: See preamble text	0.10
97611	R-t fluor wound imaging pr d	ER131	real-time fluorescence wound imaging system	NF		0	30	G1: See preamble text	2.56
97611	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available	0	3	G1: See preamble text	1.62
97611	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Obtain vital signs	0	3	G1: See preamble text	1.62

97611	R-t fluor wound imaging pr d	L037D	RN/LPN/ MTA	NF	Provide education/obtain consent	0	1	G1: See preamble text	0.54
97611	R-t fluor wound imaging pr d	L037D	RN/LPN/ MTA	NF	Prepare room, equipment and supplies	0	2	G1: See preamble text	1.08
97611	R-t fluor wound imaging pr d	L037D	RN/LPN/ MTA	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	0	2	G1: See preamble text	1.08
97611	R-t fluor wound imaging pr d	L037D	RN/LPN/ MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (100% of physician intra-service time)	0	15	G1: See preamble text	8.10
97611	R-t fluor wound imaging pr d	L037D	RN/LPN/ MTA	NF	Clean room/equipment by clinical staff	0	3	G1: See preamble text	1.62
97611	R-t fluor wound imaging pr d	L037D	RN/LPN/ MTA	NF	Clean surgical instrument package	0	10	G1: See preamble text	5.40
97611	R-t fluor wound imaging pr d	L037D	RN/LPN/ MTA	NF	Check dressings, catheters, wounds	0	1	G1: See preamble text	0.54
97611	R-t fluor wound imaging pr d	L037D	RN/LPN/ MTA	NF	Review home care instructions, coordinate visits/prescriptions	0	2	G1: See preamble text	1.08
97611	R-t fluor wound imaging pr d	SA043	pack, cleaning, surgical instruments	NF		0	1	G1: See preamble text	11.09
97611	R-t fluor wound imaging pr d	SB007	drape, sterile barrier 16in x 29in	NF		0	1	G1: See preamble text	0.51
97611	R-t fluor wound imaging pr d	SB019	drape-towel, sterile 18in x 26in	NF		0	1	G1: See preamble text	0.47
97611	R-t fluor wound imaging pr d	SB022	gloves, non-sterile	NF		0	2	G1: See preamble text	0.60
97611	R-t fluor wound imaging pr d	SB028	gown, surgical, sterile	NF		0	1	G1: See preamble text	5.13
97611	R-t fluor wound imaging pr d	SB044	underpad 2ft x 3ft (Chux)	NF		0	1	G1: See preamble text	0.32

97611	R-t fluor wound imaging pr d	SB061	MolecuLight DX Eco Dark Drape	NF		0	1	G1: See preamble text	6.25
97611	R-t fluor wound imaging pr d	SC056	syringe 50-60ml	NF		0	1	G1: See preamble text	1.13
97611	R-t fluor wound imaging pr d	SG018	bandage, Kling, non-sterile 3in	NF		0	1	G1: See preamble text	0.34
97611	R-t fluor wound imaging pr d	SG035	dressing, 3in x 4in (Telfa, Release)	NF		0	2	G1: See preamble text	0.10
97611	R-t fluor wound imaging pr d	SG051	gauze, non-sterile 4in x 4in	NF		0	8	G1: See preamble text	0.24
97611	R-t fluor wound imaging pr d	SG052	gauze, self-adherent roll 0.5in to 2in (Fabco, Gauztex)	NF		0	72	G1: See preamble text	5.76
97611	R-t fluor wound imaging pr d	SG079	tape, surgical paper 1in (Micropore)	NF		0	12	G1: See preamble text	0.12
97611	R-t fluor wound imaging pr d	SH069	sodium chloride 0.9% irrigation (500-1000ml uou)	NF		0	1	G1: See preamble text	3.34

TABLE A-D11: CY 2027 EXISTING INVOICES FOR DIRECT PE INPUTS

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
27278	Dorsal SI Joint Arthrodesis Implant	SD356	$11,500.00	$12,500.00	9%	1	512
36465, 36466	Varithena admin pack	SA125	$40.00	$55.00	38%	1	119,660
36465, 36466	Varithena (foam)	SD324	$3,195.00	$3,495.00	9%	1	119,660
36516	liposorber system	EQ174	$7,800.00	$56,000.00	618%	1	535
51726, 51727, 51728, 51729	catheter, pressure, urodynamic	SD027	$19.35	$86.80	349%	1	115,311
51726, 51727, 51728, 51729, 51797, 91020	transducer dome (pressure)	SD125	$3.58	$17.32	384%	1	197,342
51727, 51728, 51729, 51797	catheter, balloon, rectal pressure	SD017	$35.89	$74.00	106%	1	195,056
86580	purified protein derivative (0.1ml per test) (PPD-Tubersol)	SH059	$26.11	$44.07	69%	5	25,309
88364, 88365, 88367, 88368, 88369, 88373	Universal Detection Kit	SA117	$6.05	$6.38	5%	1	66,767
93241, 93243, 93245, 93247	extended external ECG patch, medical magnetic tape recorder	SD339	$315.00	$365.00	16%	31	675,748
97113	aquatic therapy pool	EQ050	$36,000.00	$192,171.88	434%	3	1,562,410
97610	kit, low frequency ultrasound wound therapy (MIST)	SA119	$320.18	$125.00	-61%	3	179,021
99151, 99152, G0500	pack, moderate sedation	SA044	$19.20	$15.69	-18%	1	158,962
G2082	Esketamine (56 mg vial)	SH109	$834.20	$895.10	7%	1	4,386
G2083	Esketamine (84 mg vial)	SH110	$1,251.31	$1,324.66	6%	1	32,576
No codes	WatchPAT One device	SD362	$98.20	$100.35	2%	800+	-
No codes	Digital mental health device (insomnia)	SD386	$800.00	$400.00	-50%	8	-
111 codes	pack, basic injection	SA041	$12.73	$15.00	18%	-	-
306 codes	pack, cleaning and disinfecting, endoscope	SA042	$25.3600	$28.3250	12%	-	-
4568 codes	pack, minimum multi-specialty visit	SA048	$4.01	$2.99	-25%	-	-
168 codes	pack, ophthalmology visit (no dilation)	SA050	$2.263	$1.807	-20%	-	-
239 codes	pack, pelvic exam	SA051	$14.38	$8.59	-40%	-	-
1079 codes	pack, post-op incision care (staple)	SA052	$6.50	$8.20	26%	-	-
469 codes	pack, post-op incision care (suture & staple)	SA053	$7.49	$9.52	27%	-	-
1708 codes	pack, post-op incision care (suture)	SA054	$6.53	$8.43	29%	-	-
12 codes	pack, post-op incision care, craniotomy	SA055	$10.93	$14.55	33%	-	-
24 codes	pack, post-op incision care, neurosurgical	SA056	$9.48	$12.77	35%	-	-
38 codes	pack, urology cystoscopy visit	SA058	$75.67	$56.65	-25%	-	-
120 codes	pack, drapes, ortho, large	SA080	$33.33	$29.35	-12%	-	-
145 codes	pack, ophthalmology visit (w-dilation)	SA082	$3.12	$2.73	-13%	-	-
119 codes	pack, protective, ortho, large	SA083	$12.16	$13.45	11%	-	-
27 codes	pack, protective, ortho, small	SA084	$6.71	$7.43	11%	-	-
100 codes	guidewire, hydrophilic	SD089	$27.42	$34.29	25%	-	-

TABLE A-D12: CY 2027 NEW INVOICES FOR DIRECT PE INPUTS

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
10005, 10006	Fine Needle Aspiration portable ultrasound	ER130	83,750.00	1	66,742
27279	Dorsal SI joint articular fixation device	SD390	14,451.00	1	41
51715	Urethral bulking agent	SD396	1,175.00	18	1,926
61782	Single Use Instrumentation Wire	SD391	48.40	1	3,565
61782	Patient Tracker	SD392	130.00	2	3,565
61782	Adhesive Pad	SD393	9.50	1	3,565
61782	Cube 4D Navigation system (monitor, 2 mounts, cart, pointer)	ER129	93,850.00	1	3,565
90901	Disposable paper shorts	SB060	0.82	1	51,307
92513, 92514	Face cushion	SD394	1.48	1	2,349
92513, 92514	Monocular Video Frenzel base unit with vestibular software	EQ420	3,424.50	1	2,349
92513, 92514	Lateral VHIT module	EQ421	7,589.70	1	2,349
92514	Larp/Ralp module	EQ422	6,138.90	1	1,565
95921, 95922, 95924, 95947, 95948, 95949	Filtered Mouthpiece	SD387	1.72	1	152,213
95923, 95947, 95948, 95949	Gel Trode 2x2 Return Electrode	SD388	4.95	1	88,241
95923, 95947, 95948, 95949	Meridian Electrode w/Expanding Foam	SD389	13.25	1	88,241
92527, 92528	VNG Open Chair System	EF051	113,900.00	1	36,179

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
95843	Apnea Link Air	EQ418	1,500.00	1	58,431
95844	Apnea Trak Legacy	EQ419	5,623.00	1	222,669
95846	Nox A1 Sensor Kit adult	SA143	22.46	1	6,192
95846	Nox A1s System with SpO2, US	EQ417	14,000.00	1	6,192
97611	MolecuLight DX Eco Dark Drape	SB061	6.25	1	175,391
97611	Real-time fluorescence wound imaging system	ER131	21,500.00	1	175,391
98963, 98964	scale, infant, digital, fine gradation	EF052	1,409.31	5	-
G0561	Automated PE tube delivery device	SD395	511.25	3	3
No codes	Smart Lids	SD397	1000	10	-
No codes	Smart Hub	EQ423	6583.33	6	-
No codes	sinonasal suction irrigation system	SD398	334.27	7	-

TABLE A-D13: CY 2027 NO PE REFINEMENTS

HCPCS	Description
15006	Scsa t/a/l 1st 100 sq cm/<
15007	Scsa t/a/l ea addl 100 sq cm
15008	Scsa f-dgt 1st 100 sq cm/<
15009	Scsa f-dgt ea addl 100 sq cm
20985	Cptr-asst navig px muscsk px
20988	Plmt loclzj mrk ntross prq 1
20989	Plmt loclz mrk ntross prq ea
20994	Abltj ther rdctj/erad b1 tum
22210	Incis 1 vertebral seg cerv
22212	Incis 1 vertebral seg thorac
22214	Incis 1 vertebral seg lumbar
22216	Incis addl spine segment
23470	Reconstruct shoulder joint
23472	Reconstruct shoulder joint
27130	Total hip arthroplasty
27278	Arthrd si jt i-artic b1 grf
27279	Arthrd si jt tartclr&/iatric
27417	Aclr scaf impl ostchndrl les
27447	Total knee arthroplasty
27494	Impl med kne xartic shck abs
33290	Ins perm ccm pg&trnsvn eltrd
33291	Ins perm ccm pulse gen only
33292	Ins perm ccm trnsvns eltrd 1
33293	Ins perm ccm trnsvn eltrd dl
33294	Rmv perm ccm pg&trnsvn eltrd
33295	Rmv perm ccm pulse gen only
33296	Rmv perm ccm trnsvns eltrd 1
33297	Rmv perm ccm trnsvn eltrd dl
33307	Rmvl&rplcmt perm ccm pg only
33308	Repos prv ccm transvns eltrd

HCPCS	Description
33309	Rlc/rev skn pckt impl ccm pg
33340	Perq clsr tcat l atr apndge
33466	T-teer perq initial clip
33467	T-teer perq each addl clip
33469	Ttvr w/prosth valve perq
33994	Insj l hrt vad ax subcl/inom
33996	Insj l heart vad aorta expos
33998	Rmvl l hrt vad rescj&staplg
36465	Njx noncmpnd sclrsnt 1 vein
36466	Njx noncmpnd sclrsnt mlt vn
36470	Njx sclrsnt 1 incmptnt vein
36471	Njx sclrsnt mlt incmptnt vn
36473	Endovenous mchnchem 1st vein
36474	Endovenous mchnchem add-on
38800	Mvasc anast 1vn&lymph vsl 1
38801	Mvasc anast 1vn&lymph vsl ea
39540	Rpr diphrg hrna lapt tr aqt
39541	Rpr diphrg hrna lapt tr chrn
39542	Rpr diphrg hrna lapt ntraumt
39543	Rpr diphrg hrna thrc tr chrn
39544	Rpr diphrg hrna thrcm ntraum
39545	Plctj diaphragm evntrn/palys
39562	Div med arc lig&rls cel trnk
39570	Laps surg div median arc lig
39571	Lap rpr dphrg hrna traum aqt
39572	Lap rpr dphrg hrna traum chr
39573	Laps rpr dphrg hrna nontraum
39580	Thrsc plctj dphrm evnt/palys
39581	Thrsc diphrg hrna traum chr
39582	Thrsc rpr diphrg hrna ntraum
39590	Impl mesh diphrg hrna rpr
42808	Exc/dstr les pharynx wo magn

HCPCS	Description
42985	Trnsorl rmvl neo tongue base
42986	Trnsorl rmv neo lat phrn wal
43498	Esd upper gi tract
44011	Dd/dj cgen duol obstrcj
44181	Laps surg dd/dj cgen duo obs
45991	Esd lower gi tract
48990	Abltj ire tum pancreas open
55705	Bx prst8 any approach nonimg
55707	Bx prst8 trct regional
55708	Bx prst8 trct reg&fus trgt
55709	Bx prst8 tprnl regional
55710	Bx prst8 tprnl reg&fus trgt
55711	Bx prst8 trct/tprn fus trgt1
55714	Bx prst8 in-bore ct/mri 1
55715	Bx prst8 in-bore ct/mr ea
55716	Bx prst8 trc/tprn fus trg ea
59030	Fetal scalp blood sampling
59051	Fetal mntr drg labor w/i&r
59080	Initial day labor mgmt sf
59081	Initial day labor mgmt cplx
59082	Sbsq day labor mgmt sf
59083	Sbsq day labor mgmt complex
59160	D & c after delivery
59300	Rpr 1st/2nd episiotomy/lac
59320	Revision of cervix
59325	Revision of cervix
59412	External cephalic version
59414	Delivery of placenta only
59431	Vag dlvr w/w/o episiotomy
59432	Vag dlvr after prev cesarean
59433	Rpr episio/lac 3rd degree
59434	Rpr episio/lac 4th degree

HCPCS	Description
59502	Cesarean delivery primary
59503	Cesarean delivery repeat
59504	Stot/tot hyst after cesarean
59623	Uterine tamponade
59871	Remove cerclage suture
61781	Scan proc cranial intra
61782	Scan proc cranial extra
61783	Scan proc spinal
62287	Dcmprn pq nuc pul 1/mlt lmbr
63045	Lam facetec & foramot crv
63046	Lam facetec & foramot thrc
63047	Lam facetec & foramot lumbar
63048	Lam facetec &foramot ea addl
64400	Njx aa&/strd trigeminal nrv
64405	Njx aa&/strd gr ocpl nrv
70544	Mra head w/post-pxessing c-
70545	Mra head w/post-pxessing c+
70546	Mra head w/pst-pxessg c-/c+
70547	Mra neck w/post-pxessing c-
70548	Mra neck w/post-pxessing c+
70549	Mra neck w/pst-pxessg c-/c+
70560	Mra h&n w/pst-pxessg c-
70561	Mra h&n w/pst-pxessg c+
70562	Mra h&n w/pst-pxessg c-/c+
73200	Ct upper extremity w/o dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o&w/dye
90901	Biofeedback train any 1st 15
90903	Biofeedback train any ea add
90912	Bfb training 1st 15 min
90913	Bfb training ea addl 15 min
92508	Tx sp lang voice comm group

HCPCS	Description
92513	Vhit lat smcrclr canal funcj
92514	Vhit lat&ver smcrcl cnl func
92527	Rotl vstblr assmt sha tstg
92528	Rotl vstblr assmt sha w/vst
92654	Tx fluency do 1st 30 min
92655	Tx fluency do ea addl 15 min
92656	Tx sp sound production do 1
92657	Tx sp sound production do ea
92658	Tx lang cmpre&xprsn do 1st
92659	Tx lang cmpre&xprsn do ea
92660	Tx sp sound&lang cmpre do 1
92661	Tx sp sound&lang cmpre do ea
92662	Tx voic uairw dysf&/res do 1
92663	Tx voic uairw dys&/res do ea
92922	Prq tcat ther rx ntrac balo1
92976	Prq tcat ther rx dlvr balo 1
93154	Prgrmg ccm sys phys/qhp ip
93155	Interrog ccm sys phys/qhp ip
93156	Interog ccm sys phys/qhp rem
93157	Interrog ccm sys tech remote
95843	Unatn slp std setup lo 3-4ch
95844	Unatn slp st setup mod5-10ch
95846	Unatn slp std setup hi 11+ch
95847	Unatn slp std i&r low 3-4 ch
95848	Unatn slp std i&r mod 5-10ch
95849	Unatn slp std i&r hi 11+ch
95921	Tst ans cardiovagal innervaj
95922	Tst ans vsmtr adrnrgc inrvaj
95923	Tst ans sudomotor qsart
95924	Tst ans parasymp&symp w/tilt
95944	Tst ans use of tilt table
95945	Tst ans sudomotor thermoreg

HCPCS	Description
95946	Tst ans sudomotor ssr pot
95947	Tst ans parasymp&sdmtr qsart
95948	Tst ans symp adrngc w/tilt
95949	Tst ans parasymp symp adrngc
96920	Lsr tx inflam/ai skn<250sqcm
96921	Lsr tx inflam/ai 250-500sqcm
96922	Lsr tx inflam/ai skn>500sqcm
98963	Lactation care 1st 30 min
98964	Lactation care ea add 15 min
G0561	Temp tube delivery, unil

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4. Potentially Misvalued Services Under the PFS

a. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes (PMVC) under the PFS, using the same criteria used to identify PMVC, and to make appropriate adjustments.

As outlined in section II.D. of this final rule, under Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct practice expense (PE) inputs using other data sources, such as the Veterans Health Administration (VHA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recent available data, we assessed the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other interested parties such as from the general medical-related community and the public. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We noted in the proposed rule that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*https://www.medpac.gov/document/report-to-the-congress-2006-medicare-payment-policy/*), MedPAC discussed the importance of appropriately valuing physicians' services, stating that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases, or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*https://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high-cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using current processes for consideration of coding changes), which may involve consolidating individual services into bundled codes for payment under the PFS.

b. CY 2027 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058 through

73059), we finalized a process for the public to nominate PMVC. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and interested parties may nominate PMVC for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of PMVC may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high-cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be PMVC appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a PMVC. The public has the opportunity to comment on these and all other proposed PMVC. In each year's final rule, we finalize our list of PMVC.

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for PMVC by February 10th and we display these nominations on our public website (*https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*), where we include the submitter's name, their associated organization and the submitted studies for full transparency. We sometimes receive submissions for specific PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize later in this section this year's submissions under the PMVC initiative. For CY 2027, we received 15 requests concerning various codes as PMVC.

The nominations are as follows:

(1) Nasal Sinus Irrigation (CPT Codes 31000 and 31002)

We received a request from one nominator to review nasal sinus irrigation codes, CPT 31000 *(Lavage by cannulation; maxillary sinus (antrum puncture or natural ostium))*, and CPT 31002 *(Lavage by cannulation; sphenoid sinus)*, as potentially misvalued. We reviewed this code family for the CY 2026 PFS final rule and our extensive discussion and rationale for finalizing the current values can be found at 90 FR 49310 through 49311.

We appreciate the information we received from the nominator. However, we note the information was the same as last year's submission. Additionally, the aforementioned CY 2026 PFS final rule specifically mentions for nasal sinus irrigation that interested parties were encouraged to submit relevant documentation, such as invoices or other evidence that demonstrates the typical resource costs for providing these services (90 FR 49311). However, we did not receive any invoices from the nominator.

In consideration of the information provided in this potentially misvalued nomination request as well as our previous valuation review and decision stated in the CY 2026 PFS final rule, we sought comments on the typicality and usage of the nasal sinus irrigation codes, CPT codes 31000 and 31002.

Comment: A few commenters recommended CMS increase the price of nasal sinus irrigation codes based on newly submitted invoices. A commenter submitted seven invoices associated with a sinonasal suction irrigation system, at an average price of $334.27, and requested that CPT codes 31000 and 31002 should be referred to the RUC as potentially misvalued so that the associated non-facility direct PE inputs could be reviewed and updated. Another commenter agreed with CMS that the values of these services should not change due to the lack of sufficient evidence.

Response: We thank commenters for their feedback. CMS continues to believe that any revaluation should reflect current clinical practice and reliable evidence regarding service frequency, circumstances of use, and the physician work and practice expense resources required to furnish the services.

After consideration of the public comments, we are not finalizing any changes to the direct PE inputs of CPT codes 31000 and 31002 at this time due to the conflicting information that we received from commenters. However, in light of the invoices that we received from commenters, we do nominate CPT Codes 31000 and 31002 as potentially misvalued. Additionally, we will add a sinonasal suction irrigation system (SD398) supply to the ratesetting database at a price of $334.27 for potential future inclusion in CPT codes.

(2) Urethral Bulking Material (CPT Code 51715)

We received a request from a nominator to review CPT code 51715 *(Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck)* as potentially misvalued. The nominator stated that CPT code 51715 currently does not include a supply for the implant material necessary to properly perform CPT code 51715 in the office setting, which is a clinically desired place of service for this treatment. The nominator requested that CMS create a supply code for a urethral bulking agent sold in 2 mL vials, with a non-facility quantity of 1 priced at an average of $1,175 and incorporate this new supply into CPT code 51715 to appropriately value the service in the non-facility setting.

We appreciate the nominator submitting invoices regarding the pricing of this urethral bulking agent. Given the information provided by the nominator as well as factoring in the amount of time that has passed since CPT code 51715 was last formally reviewed in the 1990s, we proposed to create a new supply code (SD396) for this urethral bulking agent. The SD396 supply is based on a 2 mL vial which we proposed to price at the requested $1,175 based on an average of the submitted invoices. We proposed to add 1 quantity of this supply to CPT code 51715 in the non-facility setting to reflect current clinical practice. Given the cost of this supply and the length of time since last review, we also sought comment on whether CPT code 51715

should be referred to the RUC for review.

Comment: Many commenters were in support of our proposal to price SD396, representing a 2 mL vial, at the requested price of $1,175 based on the average of the submitted invoices. Some of these commenters noted this increase in price is a necessary step as the current reimbursement structure is too low and unsustainable. Additionally, several commenters stated that the proposed price of $1,175 remains too low based on the cost of the product alone, particularly when accounting for geographic variation. However, some commenters, including the AMA, mentioned CPT code 51715 has already been identified by the RUC's RAW on the high-volume growth screen and an action plan will be reviewed at the September 2026 RUC meeting to determine whether the code should be re-reviewed. As a result, these commenters urged CMS to delay finalizing any decision until the RAW's review of the action plan is complete.

Response: We appreciate the considerable support from commenters regarding our proposal. Upon reviewing the submitted invoices, we continue to believe the proposed price is appropriate. Furthermore, while the RUC reviewed these codes at the September 2026 RUV meeting, the nominator submitted invoices, which does support a price increase. CMS will look forward to reviewing the recommendations from the RUC through our standard process.

After consideration of public comments, CMS will finalize its proposal to price SD396, representing a 2 mL vial, at the requested price of $1,175.

(3) Complex Cystometrogram (CPT Codes 51728 and 51729)

We received a request from a nominator to review CPT code 51728 *(Complex cystometrogram (i.e., calibrated electronic equipment); with voiding pressure studies (i.e., bladder voiding pressure), any technique)* and CPT code 51729 *(Complex cystometrogram (i.e., calibrated electronic equipment); with voiding pressure studies (i.e., bladder voiding pressure) and urethral pressure profile studies (i.e., urethral closure pressure profile), any technique).* The nominator submitted invoices to request a pricing increase in the supply codes SD017 (catheter balloon), SD027 (catheter pressure), and SD131 (tubing pressure) for CPT codes 51728 and 51729. The invoices submitted from the requestor are dated from January 2025 to October 2025 and the nominator specifically is requesting an increase in the price of the SD017 supply from $35.89 to $74.00, an increase in the price of the SD027 supply from $19.35 to $86.80, and an increase in the price of the SD131 supply from $2.90 to $25.48.

We appreciate the information submitted from the nominator and note we previously reviewed these supply codes in the CY 2026 PFS final rule and stated, ''Given the differences between the names of the items in question, and the significant increases in requested pricing, we proposed not to update the pricing of these three supplies as we cannot verify that the invoices refer to the same supply items.'' (90 FR 49279) Taking into consideration the invoice for the SD017 supply listed a ''Abdominal Sensor Catheter'', the invoice for the SD027 supply listed a ''Single Sensor Catheter'', and the invoice for the SD131 supply listed a ''Tubing, Pump, Infusion Line'' our rationale that we cannot verify the names of items in question remains the same. Therefore, based on a lack of additional information submitted to explain the differences in names of the supply codes in question, we did not propose to update the pricing of these three supplies as we were still unable to verify that these invoices refer to the same supply items.

Comment: A commenter mentioned that CMS should continue to work with the nominator to confirm product mapping and recognize current costs that are documented. The same commenter also believes that the CMS rationale for declining updates based on an inability to verify the names of items in question was not sufficient. Another commenter did submit documentation to substantiate invoices submitted previously, which they believe provides information that will help connect the commercial invoice terminology and the generic CMS supply descriptions. No new invoices were submitted during this comment period.

Response: We thank commenters for their feedback as well as for the additional documentation. We note that, under the potentially misvalued code review process, CMS must consider whether submitted invoices accurately reflect the supplies being valued. When the invoiced items do not correspond to the supplies in question, their medical relationship alone does not provide an appropriate basis for valuation. Due to the highly technical nature of the product documentation submitted by the commenters, we still cannot establish with certainty that the previously submitted invoices from CY 2026 correspond to the supply items in question. However, after reviewing these new materials, we believe that the preponderance of the available information supports the contention of the commenters that the prior invoices match the supply items in question, and that there is sufficient evidence to support updating their prices.

After consideration of the public comments, we are therefore finalizing an update in the price of the catheter, balloon, rectal pressure (SD017) supply from $35.89 to $74.00, an update in the price of the catheter, pressure, urodynamic (SD027) supply from $19.35 to $86.80, and an update in the price of the transducer dome (pressure) (SD125) supply from $3.58 to $17.32. We are also finalizing CPT codes 51728 and 51729 as potentially misvalued as we believe that these codes would benefit from additional formal review. CPT codes 51728 and 51729 have not been reviewed in nearly two decades, they have reasonably high utilization at more than 50,000 annual services, and we continue to have concerns about the accurate pricing of these supplies which we believe could be more accurately determined through a full review.

(4) Carpal Tunnel Release Procedure (CPT Code 64728)

We received a request from one nominator to review CPT code 64728 *(Decompression; median nerve at the carpal tunnel, percutaneous, with intracarpal tunnel balloon dilation, including ultrasound guidance)* as potentially misvalued. The nominator stated that this code is misvalued due to the following reasons: (1) the anomalous relationship between the valuation for CPT code 64728 and other CPT codes for carpal tunnel release procedures; (2) Incorrect assumptions were made based on the previous valuation of the service, including a misleading survey and flawed crosswalk assumptions; and (3) Analysis of work relative value units (RVUs) from reliable data sources support increased valuation. The nominator requested an increase in work RVUs to appropriately reflect the intensive work associated with this procedure.

This code family was reviewed in the CY 2026 PFS final rule and our extensive discussion for finalizing a work RVU of 2.70 can be found in 90 FR 49374 through 49376. We previously addressed the concerns of the nominator in this preamble and we have received no new data for CY 2027 which would support a higher valuation for CPT code 64728. Based on the lack of new information submitted for CY 2027, we do not believe this code to be potentially misvalued. We sought comment on this issue, including the

submission of new information to support the request.

Comment: A commenter believes CMS should continue to evaluate the valuation of CPT code 64728 due to misalignment in the work RVUs for this code. This commenter specifically mentioned the relative time and intensity of physician work among open, endoscopic, and ultrasound-guided carpal tunnel release techniques are not appropriately reflected in the proposed work RVUs. However, another commenter concurred with the CMS proposal that CPT code 64728 is not potentially misvalued and mentioned that the comparison code the nominator listed as a means of an increase is inappropriate. Additionally, the same commenter also noted that the intensity of work per unit of time for CPT code 64728 already exceeds that of the comparator codes cited as evidence of undervaluation.

Response: We appreciate the feedback from commenters.

After consideration of the public comments, we continue to believe CPT code 64728 is not potentially misvalued. Commenters were unable to provide new cost information which would support a higher valuation for CPT code 64728 and we received support from some commenters who agreed that the code was not potentially misvalued.

(5) Electronic Analysis of Implanted Neurostimulator Pulse Generator/ Transmitter (CPT Codes 95970, 95976, 95977)

We received a request from one nominator to review CPT codes 95970 (*Electronic analysis of implanted neurostimulator pulse generator/ transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/ transmitter, without programming*), 95976 (*Electronic analysis of implanted neurostimulator pulse generator/ transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*), and 95977 (*Electronic analysis of implanted neurostimulator pulse generator/ transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*).

The nominator stated they believe this code family is potentially misvalued due to differing valuations relative to the recently reviewed CPT codes 93150 (*Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming*), 93151 (*Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system*), and 93153 (*Interrogation without programming of implanted phrenic nerve stimulator system*), despite being clinical similar services. The nominator also believed there were discrepancies in equipment used to perform each procedure as opposed to what is included in the current valuation due to inaccurate assumptions about what clinical specialties most commonly furnish these procedures. To support their requests, the nominator shared 2024 utilization data showing an increase in certain clinical specialties furnishing these services. We appreciate the additional information and sought comment on the appropriate valuation of this code family as well as any additional information on the typical specialty and resource costs associated with furnishing these procedures.

Comment: A few commenters appreciated CMS soliciting comment on CPT codes 95970, 95976, 95977 and believe CMS should evaluate this code family as potentially misvalued because these codes are undervalued relative to the required work and practice expense, historical valuations, and comparable analysis and programming codes. A commenter reiterated that for valuation purposes, the resource costs associated with CPT codes 95970, 95976, and 95977 should be compared to the existing peripheral nerve stimulation codes, CPT codes 93150, 93151, and 93153.

Response: We thank the commenters for their feedback and note that in accordance with 1848(c) of the Act we take into account the typical specialty and resource costs associated with furnishing these procedures when assessing if a code family is potentially misvalued.

Comment: Many commenters were in disagreement that CPT codes 95970, 95976, 95977 were potentially misvalued or that they should be valued similarly to CPT codes 93150, 93151, and 93153 only because they involve interrogation and programming of implanted neurostimulation devices. These commenters also stated utilization trends or changes in specialty participation do not establish comparable resource requirements and that valuation should reflect the physician work and practice expense resources required to furnish each service. Furthermore, the AMA noted the RUC will place CPT codes 95970, 95976 and 95977 on the next level of interest (LOI) for review of work and direct practice expenses and submit recommendations to CMS for the CY 2028 Medicare Physician Payment Schedule.

Response: We thank commenters for their feedback. We also support the RUC survey process as a reliable and transparent approach for evaluating PE inputs and determining whether services are appropriately valued.

After consideration of the public comments, we will not finalize any changes to CPT codes 95970, 95976 and 95977 at this time as we were persuaded by the commenters that these codes are not potentially misvalued. We look forward to reviewing any recommendations submitted by the RUC for potential CY 2028 rulemaking.

(6) Scalp Cooling (CPT Codes 97007, 97008, 97009)

We received a request from one nominator to review the mechanical scalp cooling family of services described by CPT codes 97007 *(mechanical scalp cooling, including individual cap supply with head measurement, fitting, and patient education),* 97008 *(mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and pre-cooling period),* and 97009 *(mechanical scalp cooling; each 30 minutes),* as potentially misvalued. We reviewed this code family for the CY 2026 PFS final rule and our extensive discussion and rationale for finalizing the current values can be found at 90 FR 49405 through 49406.

The nominator stated that they believe this code family may be potentially misvalued based on newly available empirical evidence (a Time and Motion Study) that demonstrates incorrect assumptions were made

during our prior valuation decision for the CY 2026 PFS final rule. They reference in their nomination that the August 2024 Time and Motion Study demonstrated that the clinical staff and PE inputs required to furnish this service are materially greater than those reflected in the current valuation and were not made available to CMS prior to our valuation review and decision for CY 2026. Specifically, the nominator recommended an increase in PE clinical staff time to 103 minutes for CPT code 97007, 52 minutes for 97008, and 23 minutes for 97009.

We appreciate the information we received from the nominator. However, we disagree with their assertion that CMS did not have the results of the August 2024 Time and Motion Study when making our valuation decision for CY 2026. The aforementioned CY 2026 PFS final rule discussion outlines the information considered for the valuation decision and specifically mentions the August 2024 Time and Motion Study results as well as the public comments received for the CY 2026 PFS proposed rule, which reflect the requested increase in PE clinical staff time. We assure the nominators and readers of this discussion that all the information provided in this potentially misvalued nomination request was considered when making our previous valuation review and decision for CY 2026. Accordingly, we disagree with the assertion that this family is misvalued. However, we sought comment, particularly updated information that could support a change in valuation for these services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters disagreed that this code family is not potentially misvalued. They believe that the current PE inputs do not adequately account for the clinical labor required to furnish these services. Commenters specifically requested increased clinical staff (oncology nurse OCN) time inputs as well as an increase to the cooling cap supply item, SA141 Scalp Cooling Cap/Kit, which they support with some submitted documentation. A commenter also referenced the Time and Motion study in support of their recommendations.

Response: We thank commenters for their feedback. As mentioned in our previous discussion for the CY 2026 proposed rule, we did review the Time and Motion Study results when making our valuation decisions for CY 2026 and we continue to believe that the current clinical staff time captured in the direct PE inputs for this code family adequately account for the resources involved with furnishing this service. Additionally, we acknowledge the request to update the direct PE supply item, SA141 Scalp Cooling Cap/Kit. We do not believe that updating the supply cost at this time for SA141 is necessary, as this supply was just priced for CY 2026 based on several valid vendor invoices. While we did receive documentation from the commenter, we did not receive a valid invoice for this request.

After consideration of public comments, we are finalizing the work RVUs and direct PE inputs as proposed for CPT codes 97007, 97008, and 97009.

(7) Hyperbaric Oxygen Under Pressure (HCPCS Code G0277)

The RUC has requested the deletion of HCPCS code G0277 *(Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval),* and recommended that CPT code 99183 be revised to be time-based as well to appropriately describe the treatment delivery, attendance and supervision. The RUC concluded that maintaining a separate G-code creates unnecessary coding complexity without adding clinical or administrative value and that one clear and consistent coding structure should exist for this service.

In 2015, CMS created HCPCS code G0277 to describe direct practice expense inputs associated with CPT code 99183 *(Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session).* We noted that under the Outpatient Prospective Payment System (OPPS), the treatment used to be reported using separate treatment code C1300 *(Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval.)* Therefore, we created HCPCS code G0277 to report the treatment delivery and to maintain consistency with the OPPS coding and PFS payment systems.

HCPCS code G0277 was identified as a high-volume growth code that has Medicare utilization of 10,000 or more. High utilization of this magnitude reflects that the code has been broadly adopted across multiple care settings and underscores its operational importance within the Medicare program. Deleting or replacing a high-volume code without an equivalent can disrupt billing practices, create reporting gaps, and impose unnecessary administrative burden on providers who have integrated it into their standard practice. As such, we believe there is a reason to continue to maintain the use of the G-code for hyperbaric oxygen therapy since HCPCS code G0277 is utilized in multiple Medicare payment systems to report the time the patient uses the hyperbaric oxygen therapy. Accordingly, we proposed to maintain HCPCS code G0277.

Comment: Several commenters opposed the AMA RUC's recommendation to crosswalk HCPCS code G0277's direct practice expense (PE) inputs into CPT code 99183 (multiplied by a factor of 4) and delete G0277. These commenters supported CMS's proposal to retain HCPCS code G0277 as a distinct code and preserve separate reporting of CPT code 99183 and HCPCS code G0277. Commenters stated that the two-code structure accurately reflects physician work and treatment-delivery costs as separate resources.

Commenters stated that CPT code 99183 and HCPCS code G0277 describe clinically and operationally distinct services. They explained that CPT code 99183 describes physician attendance and supervision during hyperbaric oxygen therapy, while HCPCS code G0277 describes the resources required to deliver the treatment itself, including the hyperbaric chamber, oxygen-delivery and monitoring systems, trained ancillary staff, and associated safety and maintenance requirements. A commenter stated that physicians who report HCPCS code G0277 understand the existing distinction between HCPCS code G0277 and CPT code 99183, and that deleting HCPCS code G0277 and revising CPT code 99183 would introduce confusion into an area of billing that functions appropriately under the current structure.

Commenters further stated that because HCPCS code G0277 is a HCPCS code rather than a CPT code, the RUC referred CPT code 99183 to the CPT Editorial Panel for possible revision. Commenters explained that the RUC's current recommendation to convert CPT code 99183 into a time-based code incorporating delivery, attendance, and supervision would require either incorporating multiple 30-minute PE segments into CPT code 99183 or substantially redefining the code, neither of which has been adopted through the CPT process. Commenters stated that this approach would also increase administrative burden for small, office-based practices.

Several commenters stated that similar coding changes have previously caused Medicare and commercial payment disruption, citing extended Medicare prepayment review and delayed commercial payer adoption following implementation of HCPCS code G0277 in 2015. Commenters stated

that consolidating HCPCS code G0277 into CPT code 99183 could result in comparable disruption.

Many commenters recommended that CMS retain HCPCS code G0277 as a distinct code, preserve separate reporting of CPT code 99183 and HCPCS code G0277, reject the RUC's recommended crosswalk and deletion of HCPCS code G0277, continue to evaluate physician work and treatment-delivery resources independently, and evaluate the effects of any future restructuring across all applicable sites of service.

Response: We thank the commenters for their feedback and support of retaining CPT code 99183 and HCPCS code G0277 as two distinct codes. We agree that the two codes reflect distinct components of care.

Comment: The RUC stated that the CY 2026 proposed rule did not adopt the RUC's earlier recommendation to establish direct practice expense (PE) inputs for CPT code 99183 or to delete HCPCS code G0277. The RUC reiterated its recommendation that CMS crosswalk the January 2023 direct PE inputs for HCPCS code G0277 to CPT code 99183, multiplied by a factor of four to reflect a full two-hour treatment session, and that CMS delete HCPCS code G0277 on the basis that CPT code 99183, once revalued, could appropriately account for the service.

Response: We thank the commenter for their feedback. However, we continue to believe that two codes represent separate components of care. We also note that HCPCS code G0277 has high utilization and broad adoption across care settings. Deleting such a high-volume code without an appropriate equivalent can disrupt billing practices, creating reporting gaps and imposing an unnecessary administrative burden on providers.

Comment: A commenter took no position on CMS's proposal to retain HCPCS code G0277 or the RUC's recommendation to delete it and revise CPT code 99183. The commenter instead urged CMS to continue collaborating with the RUC and affected specialty societies to develop a coding structure that accurately reflects the service while avoiding duplication and administrative complexity.

Response: We thank the commenters for their feedback.

After consideration of the public comments, we continue to believe the existing coding structure, which distinguishes professional attendance and supervision (CPT code 99183) from treatment-delivery resources (HCPCS code G0277), remains appropriate and should be maintained. Therefore, for CY 2027, we are finalizing the proposal to maintain HCPCS code G0277 as a distinct code and to preserve separate reporting of CPT code 99183 and HCPCS code G0277.

(8) Image-Guided Robotic Linear Accelerator Stereotactic Radiosurgery (HCPCS Codes G0339 and G0340)

Image-guided robotic linear accelerator-based stereotactic radiosurgery services are currently reported by and paid for using HCPCS G-codes established the in CY 2007 PFS final rule HCPCS codes G0339 *(Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment)* and G0340 *(Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment)*. In April 2025, the RAW identified HCPCS code G0340 with 2023 Medicare utilization over 10,000 and Medicare status of ''C'' contractor priced. The Workgroup requested an action plan for G0340 for September 2025. In September 2025, the Workgroup reviewed the action plan and recommended that the RUC request that CMS delete G0339 and G0340 having identified a CPT code 77373 (*Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions)* that is available to report in lieu of G0339 and G0340.

A review of Medicare claims data shows that HCPCS codes G0339 and G0340 are billed frequently. HCPCS code G0339 was billed approximately 3,000 times and HCPCS code G0340 12,000 times in 2024 respectively. As such, we believe there is a reason to maintain the G codes for image-guided robotic linear accelerator-based stereotactic radiosurgery services since both sets of codes are billed so frequently, and we do not want to cause disruption in billing practice. Since the RUC planned on reviewing these codes during its September 2026 meeting if the codes are not deleted for CY 2027, we welcomed the RUC's additional information regarding appropriate coding and payment for these services.

Comment: The RUC recommended that CMS delete HCPCS codes G0339 and G0340 for CY 2027 rather than maintain them. The commenter stated that only 17 centers in 11 states currently offer robotic radiosurgery, and that of 234 physicians who reported these codes in 2023, 68 no longer offer the service and 20 have retired. The RUC further noted that CMS's own provider-and-service data show only 68 practice locations billed HCPCS code G0339 and only 96 billed HCPCS code G0340 in 2024, notwithstanding the higher claims-line counts cited in the proposed rule. The commenter argued this indicates the affected provider population is small and identifiable, such that requiring these practices to report existing CPT code 77373 in lieu of the G-codes would not impose material burden, and would promote uniform payment across all stereotactic body radiation therapy modalities. The commenter indicated the RAW would review action plans for both codes again at its September 2026 meeting to further support deletion.

Other commenters, including a specialty society representing radiation oncology professionals, supported continued use of the G-codes in the near term but urged CMS to treat the coding question as secondary to a broader valuation concern. These commenters stated that stereotactic radiosurgery and stereotactic body radiation therapy share capital-intensive and infrastructure-dependent characteristics with other radiation treatment delivery services for which we have already adopted OPPS-informed practice expense methodologies (for example, CPT codes 77402, 77407, and 77412, and proposed proton beam delivery codes). These commenters recommended that, rather than resolving valuation through the G-code deletion question alone, CMS link SRS/SBRT services to OPPS data beginning January 1, 2028, consistent with the stated rationale for adopting alternative PE methodologies for other radiation oncology services that do not fit the standard non-facility PE framework.

An individual commenter, a practicing radiation oncologist, did not comment specifically on the coding treatment of HCPCS codes G0339 and G0340, but urged CMS broadly to avoid payment reductions affecting stereotactic body radiation therapy and stereotactic radiosurgery services. The commenter stated that these modalities allow patients, including those in rural areas, to complete treatment in as few as five sessions rather than a longer conventional course, and that reduced payment for the planning, physics, and management services supporting these modalities could jeopardize access to this care.

Response: We acknowledge the RUC's data showing that utilization of HCPCS codes G0339 and G0340 is concentrated among a limited number of practice

locations (68 and 96, respectively, in 2024). However, we continue to place significant weight on the high overall claims volume associated with these codes—approximately 3,000 claims for HCPCS code G0339 and over 12,000 claims for HCPCS code G0340 in 2024—which indicates that these services remain a frequently furnished and clinically significant component of radiation oncology care for Medicare beneficiaries, even though they are billed by a comparatively small number of sites. We are concerned that deleting high-volume codes without a transition period could disrupt billing practices, create reporting gaps, and impose administrative burden on the providers who have integrated them into standard practice, regardless of how many distinct locations are affected. We are therefore not finalizing deletion of HCPCS codes G0339 and G0340 for CY 2027.

Comment: A commenter was concerned about the broader importance of maintaining adequate payment for the planning, physics, and management services that support stereotactic body radiation therapy and stereotactic radiosurgery, including the role these modalities play in enabling shorter courses of treatment for patients in rural and underserved areas.

Response: While this comment did not address the coding treatment of HCPCS codes G0339 and G0340 specifically, we considered it alongside the broader comments regarding valuation methodology for these services. We will consider any future recommendations, together with the high utilization of these codes and the comments on OPPS-informed valuation methodology for SRS/SBRT services, in future rulemaking.

(9) Request for Revaluation of Physician Work Time Based on Empiric Data (CPT Codes 15734, 19318,19380, 23472, 27130, 27447, 37227, 37229, 43281, 43644, 47120, 88305, 88307)

An interested party nominated 13 CPT codes as potentially misvalued. These codes are listed in Table A–D14.

TABLE A-D14: CPT CODES NOMINATED FOR REVALUATION BASED ON CHANGES IN PHYSICIAN WORK TIME

CPT Codes	Description
Integumentary system (CPT codes 15734, 19318, 19380)	
15734	Muscle, myocutaneous, or fasciocutaneous flap obtained from the trunk
19318	Breast reduction
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction
Musculoskeletal system (CPT codes 23472, 27130, 27447)	
23472	Arthroplasty, total shoulder (glenoid and proximal humeral replacement (eg, total shoulder)
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
Cardiovascular system (CPT codes 37227 and 37229)	
37227	with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed*
37229	with atherectomy, includes angioplasty within the same vessel, when performed*
Digestive system (CPT codes 43281, 43644, 47120)	
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
47120	Hepatectomy, resection of liver; partial lobectomy
Surgical pathology (CPT codes 88305 and 88307)	
88305	Level IV - Surgical pathology, gross and microscopic examination
88307	Level V - Surgical pathology, gross and microscopic examination

*Deleted as of CY 2026.

The nominator provided evidence that current physician work time values in the PFS do not accurately reflect real-world clinical practice for 13 CPT codes across five code families. Their methodology focused on codes involving large discrepancies between empirically derived intraservice estimates and intraservice times assigned in the PFS. The nominator did not assert that their research provided confirmatory evidence for every intraservice time discrepancy, which is why their analysis focused on coding families related to the 13 CPT codes listed previously (Table A–D14). They provided additional details on their findings related to the 13 CPT codes and other codes included in their coding families in this section.

Using the 2023 Maryland All-Payer Claims Database (MD–APCD), the nominator's analysis indicates that some of these codes are likely to be overvalued. In their nomination, their analysis reveals that the 88305 (Level IV Tissue Exam by Pathologist) code had the highest number of provider days with intraservice time exceeding an 8-hour workday, with more than 1,763 days, which was significantly higher than the other 12 CPT codes. There were 587 instances of physicians billing 88305 so many times in a single day that the total intraservice time exceeded 24 hours. For these 1,763 days, when they added up the total time spent on services (including other codes billed in a day, and pre-services times as well), the average time that services were billed for during these days was 2,217 minutes (approximately 37 hours). Additionally, despite the name of the code being ''Tissue Exam by Pathologist,'' they found that gastroenterologists and dermatologists

frequently billed this code while exceeding eight hours of work in a single day. According to the nominator, data from a 2016 Urban study [67] indicated that the median intraservice time for 88305 was only 2 minutes, compared to 25 minutes in the PFS, which is a 1,250 percent difference—larger than any of the empiric differences between NSQIP and the PFS intraservice times.

They also reviewed additional codes outside of the Urban study that are in the Level IV tissue exam by pathologist coding family, specifically CPT codes 88302, 88304, 88307, and 88309, to conduct a thorough check. As a result, they found that CPT code 88307 had 40 provider days where the total intraservice time exceeded 8 hours. The nominator suggested that CMS should consider reviewing the physician time for all codes within this family to address the existing PFS intraservice times.

In addition, they stated that several codes from the integumentary systems—CPT codes 15734 (*Muscle, myocutaneous, or fasciocutaneous flap; trunk*), 19318 (*Breast reduction*), and 19380 (*Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)*)—are likely overvalued as clinicians spend 34, 90 and 14 days, respectively, performing these services, where the intraservice times of these codes themselves were more than 8 hours. Over these days, clinicians spent an average of 32, 17, and 41 hours when the PFS times for all services they billed on these days were summed (including pre-service times). The RAND study [68] identified that 21 codes in the integumentary system had PFS intraservice times that were likely too long, and 3 codes had PFS intraservice times that were likely too short.

In the musculoskeletal system, they identified specific procedures with extended service times. For CPT codes 23472 (*Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (e.g., total shoulder))*), 27130 (*Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft*), and 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*), there were 12, 10, and 26 Provider Days, respectively, that exceeded the 8-hour intraservice thresholds. These instances resulted in average total service times of 19, 19, and 21 hours, respectively. The NSQIP RAND study found that 97 musculoskeletal codes had intraservice times that were likely too long, while 14 had intraservice times that were likely too short.

According to the nominator, CPT codes 43281 (*Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh*), CPT 43644 (*Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)*), and CPT code 47120 (*Hepatectomy, resection of liver; partial lobectomy*) were found to have 15, 14, and 10 practitioner days, respectively, where the intraservice time exceeded 8 hours. On these days, the providers recorded average total service times of 25, 33, and 52 hours, respectively. Additionally, the nominator stated that the 2015 NSQIP RAND study identified 86 digestive system codes that were likely too long and 12 codes that were likely too short.[69]

In the proposal rule, we stated that we appreciated the detailed information provided to us by external interested parties and welcomed comments from the public regarding any potential actions for CY 2027 or for future rulemaking. We acknowledged the limitations associated with NSQIP data in terms of its applicability to other settings, as it is representative of the hospital setting, however we believe this empirical data may be a better input than limited survey data. Therefore, we sought comment on whether we should make these changes for CY 2027, or for future rulemaking, and whether we should consider making corresponding changes to the work RVUs for these services or if changes to the physician time would be sufficient.

Comment: The RUC and many commenters requested that CMS not rely on data from the Maryland Health Care Commission (MHCC). The RUC noted that 5 of the 13 codes do not warrant further action: CPT codes 37227 and 37229 were deleted for CY 2026, and CPT codes 23472, 27130, and 27447 were resurveyed for CY 2027 with RUC-recommended decreases to physician time, work RVUs, and post-operative visits, as reflected elsewhere in this final rule. The RUC raised concerns about the reliability of the MHCC methodology, including limited sample size, failure to account for specialty-specific billing patterns, and use of claims data that may not reflect actual physician work time. Commenters requested that CMS not rely on this data and, if CMS proceeds with review, that we defer action on the remaining 8 codes to the CY 2028 PFS rulemaking cycle.

Many commenters urged CMS not to revalue these codes based on data from the MHCC, and instead to refer any valuation question to the RUC process. First, they stated that MHCC's methodology was flawed (for example, it mistakenly assumes the billed date equals the date the physician actually performed the work). Second, they stated that only about 2.9% of CPT code 88305 provider-days exceeded MHCC's 8-hour threshold, which is not typical. Also, multiple commenters stated that the 2016 Urban Institute pilot study's 2-minute time estimate for CPT code 88305 (versus the current 25-minute PFS value) relied on a convenience sample. Many commenters noted that a pure time-based claims analysis misses the real intensity of the pathology work.

A couple of commenters supported the use of empirical, claims-based data to revalue potentially misvalued codes. A commenter stated that such data are more reliable than survey data submitted through the RUC process, and recommended that CMS collect such data on an ongoing basis rather than through isolated or one-time efforts. Another commenter recommended that CMS adopt empirically derived operative times from the National Surgical Quality Improvement Program (NSQIP) in place of current PFS time estimates when valuing potentially misvalued codes, noting that NSQIP data, while skewed toward complex cases at academic medical centers, offer a more reliable empirical basis and a more gradual transition than other data sources. This commenter further recommended that CMS evaluate and revalue entire families of related codes, rather than individual codes in isolation, to avoid rank-order anomalies and unintended distortions in clinical practice. Finally, the commenter re-examined Maryland's all-payer claims database and found that the discrepancy

[67] *https://www.urban.org/research/publication/collecting-empirical-physician-time-data-piloting-approach-validating-work-relative-value-units.* Stephen Zuckerman, PhD, Katie Merrell, BA, Robert A. Berenson, MD, Susan Mitchell, RHIA, Divvy Upadhyay, MD, MPH, Rebecca Lewis, MPH, Collecting Empirical Physician Time Data: Piloting an Approach for Validating Work Relative Value Units. *https://www.urban.org/sites/default/files/publication/87771/2001123-collecting-empirical-physician-time-data-piloting-approach-for-validating-work-rel.ative-value-units_0.pdf.*

[68] *https://www.rand.org/pubs/research_reports/RRA3470-1.html.*

[69] *https://www.rand.org/content/dam/rand/pubs/research_reports/RR600/RR662/RAND_RR662.pdf.*

persisted, confirming its statement that CPT code 88305 is overvalued. Given this result, the commenter reiterated its recommendation that CMS adopt the Urban Institute's empirically derived intraservice time of 2 minutes.

Response: We thank the commenters for their feedback, and we appreciate the commenter's follow-up analysis regarding CPT code 88305. The majority of commenters opposed this approach to revaluing the potentially misvalued codes using empirical data and recommended referring any valuation questions to the RUC process. We must also note a range of concerns about using empirical data for revaluation, including the representativeness of the underlying data sources, the methodology used to translate empirical data into revised time and work values, and the potential effects of the proposed changes on affected specialties and on beneficiary access to care.

After considering public comments, we are neither revaluing the cited codes based on the empirical data provided nor finalizing any changes to these codes. However, we may take these comments into consideration in future rulemaking and welcome additional studies and data submissions on this topic.

(10) Request for Reassessment of Assigned RVUs for ''Harvard-Valued'' Codes (CPT Codes 24515, 22216, 22210, 64721, 29824, 20610, and 20680)

We received notification from concerned interested parties about the ''Harvard-valued'' codes from 1992 that have not undergone a reassessment of assigned RVUs for over 20 years in some cases (see Table A–D15). We share their concerns about whether the current values for the CPT codes accurately reflect the resource inputs associated with furnishing the services. Because the CPT codes have not been recently reviewed and potentially significant technological changes have occurred during this time, we proposed these CPT codes as potentially misvalued and requested that the RUC and other interested parties review these services in terms of appropriate work RVUs, work time assumptions and direct PE inputs.

TABLE A-D15: CPT CODES NOMINATED FOR REVALUATION BASED ON ASSIGNED RVUS FOR "HARVARD-VALUED" CODES

CPT Codes	Description
24515	Open treatment of humeral shaft fracture, with or without internal fixation, includes repair of fracture fragments
22216	Spine, posterior or posterolateral technique, 3–6 vertebral segments, cervical or thoracic; includes all decompression and fusion work
22210	Spine, posterior or posterolateral technique, single vertebral segment, cervical or thoracic; includes all decompression and fusion work
64721	Neuroplasty and/or transposition; median nerve at carpal tunnel
29848	Endoscopy, wrist, surgical, with release of transverse carpal ligament
29824	Arthroscopy, shoulder, distal claviculectomy, includes debridement, limited capsular release as needed
20610	Arthrocentesis, large joint(s) (eg, shoulder, elbow, hip, knee, or wrist); with or without injection, including ultrasound guidance if performed
20680	Removal of deep implant, includes incision, dissection, and closure; eg, plates, rods, screws, or nails

Comment: The majority of commenters, including the RUC and several specialty societies, disputed the factual basis for including these codes on the list of potentially misvalued services. Commenters stated that seven of the eight identified codes have, in fact, been surveyed and revalued by the RUC subsequent to the original 1992 Harvard valuation, in some instances as recently as the January 2026 RUC meeting, and provided documentation of survey dates and corresponding rule cycles for each code. A commenter noted that CPT code 29824 was created in 2002, a decade after implementation of the Harvard-based RBRVS and therefore cannot reflect an unrevised Harvard value. Commenters stated they were unable to identify a rationale supporting the nomination because the nomination letter was not included in the public use files accompanying the proposed rule. Commenters requested that we remove these codes from consideration as potentially misvalued.

Another commenter representing urologic surgeons did not dispute that certain services within this category may warrant review, but expressed concern regarding the methodology by which any resulting revaluation would occur. The commenter stated that changes in surgical technique, particularly the adoption of minimally invasive approaches, have altered physician work in more than one direction simultaneously, reducing intraoperative time in some cases while increasing equipment complexity, intraoperative decision-making, and preoperative optimization associated with treating an older and more medically complex patient population. The commenter recommended that CMS rely on specialty society input and published survey data before proposing any revised values, rather than assuming that a reduction in operative time corresponds to a proportional reduction in physician work. An additional commenter supported the inclusion of long-unreviewed 1992-era codes for reassessment and recommended that CMS extend the same reasoning to legacy gynecologic surgical codes of comparable age, which the commenter stated reflect a documented and sustained valuation disparity relative to comparably complex procedures.

Response: We acknowledge commenters' documentation that seven of the eight codes have undergone subsequent RUC survey and revaluation since 1992, and that CPT code 29824 was established in 2002. However, our proposal was not premised on these codes retaining unrevised 1992 Harvard values; rather, our concern is whether the currently assigned work RVUs, time assumptions, and direct PE inputs still

accurately reflect the resources involved in furnishing these services in light of technological and practice changes. A prior RUC survey does not foreclose the need for further review where subsequent changes in technique or technology may warrant it, and we do not believe the revaluation history identified by commenters is sufficient basis to remove these codes from consideration.

We recognize commenters' concerns regarding the absence of nomination documentation in the public use files and will consider whether additional transparency is appropriate in future rulemaking.

Regarding the methodology concern, we agree that changes in surgical technique may affect physician work in more than one direction and that revaluation should not assume operative time and physician work decline proportionally. We will take this into account, in coordination with the RUC, as these codes proceed through review.

We note, however, that section 1848 of the Social Security Act assigns CMS the responsibility for establishing relative values for physicians' services. We are not in a position to commit to adopting specialty society recommendations in every instance or to treat survey data as dispositive; there are cases in which claims data, internal consistency across the fee schedule, or other evidence leads us to propose a value that differs from the RUC-recommended value. We believe this approach is consistent with our statutory obligation to ensure that relative values reasonably reflect the relative resources involved in furnishing a service.

We will continue to consider specialty society input and published survey data as important components of our valuation process in this and future rulemaking cycles, and we encourage continued engagement from specialty societies and other stakeholders in this process.

With respect to legacy gynecologic surgical codes, we did not propose such codes as potentially misvalued in this cycle and are not identifying them as such in this final rule. Interested parties may nominate potentially misvalued services, including these, through our established annual nomination process.

After consideration of public comments, we are finalizing the identification of CPT codes 20610, 20680, 22210, 22216, 24515, 29824, 29848, and 64721 as potentially misvalued, as proposed.

(11) Allergy Immunotherapy (CPT Code 95165)

In the CY 2001 PFS final rule (65 FR 65393), we discussed the direct PE inputs for CPT code 95165 *(Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)).* As in the case of venoms, some non-venom antigens cannot be mixed together, that is, they must be prepared in separate vials. An example of this is mold and pollen. Therefore, some patients will be injected at one time from one vial—containing in one mixture all of the appropriate antigens—while other patients will be injected at one time from more than one vial. We extensively discussed how the practice expense component for mixing a multidose vial of antigens was computed, and how we observed that the most common practice at the time was to prepare a 10 cc vial; we also observed that the most common use was to remove aliquots with a volume of 1 cc. Therefore, a physician's removing 10 1cc aliquot doses captured the entire PE component for the service.

Recently we have received interested parties' communication from relevant specialties on the definition of a dose as it pertains to an allergy immunotherapy. They are concerned that clinical practice is not using this method of dosage to treat patients and the definition that Medicare is using is causing general confusion. They note that Medicare's 1 cc aliquot dose is now creating reimbursement-driven changes to medical practice, rather than changes that align with clinical practice and is increasingly adopted by commercial payers and Medicaid plans, thereby negatively impacting the delivery of medically necessary and cost-effective patient care to Medicare beneficiaries. According to the specialty societies, when this Medicare policy was implemented, few Medicare beneficiaries received allergy immunotherapy—most practices report that less than 5 percent of patients receiving treatment at that time were Medicare beneficiaries. Today, specialty societies report, Medicare beneficiaries often comprise more than 20 percent of an individual practice's allergy immunotherapy patients.

We invited comment from the wider medical community, including analyses or studies, regarding CPT code 95165 and the definition of an allergy immunotherapy dose. In particular, we stated in the proposed rule, we are interested in how these concepts are interpreted and implemented within clinical practice.

Additionally, Medicare utilizes a medically unlikely edit (MUE) of 30 doses per claim to flag potential overutilization. Specialty societies claim a more appropriate policy should use common clinical practice, by having an annual limit on doses of medically necessary treatment. For example, the annual limit of up to 160 doses per year during the first year of therapy would be higher to account for the build-up phase, then reduced to 130 or fewer doses per year thereafter when the beneficiary is receiving maintenance doses.

We welcomed comments, including research or opinions from the medical community, on appropriate annual dose limits billed for CPT code 95165 based on clinical practice.

Comment: Commenters were nearly unanimous in urging CMS to rescind the current definition of a dose for CPT code 95165 as a 1 cc aliquot and instead align with the definition used for the companion CPT codes 95115 and 95117, under which a dose is a single injection from a multidose vial. They argued the 1 cc standard, unchanged since 2000, does not reflect current practice, since maintenance doses are typically prepared at approximately 0.5 cc—meaning the existing definition effectively pays for only about half of clinically prepared doses. Building on this, commenters noted that certain allergens, such as molds, cockroach antigen, and pollens, cannot be safely combined due to proteolytic activity and cross-reactivity, requiring multiple separately prepared vials that the current definition does not account for. A commenter added historical context, citing a 2002 HHS OIG report that found the original 1 cc definition was based on inaccurate dosing data at the time of adoption, a finding never addressed through subsequent rulemaking.

Commenters further argued that the stakes of this definition have grown over time, since Medicare beneficiaries now make up a much larger share of immunotherapy patients than when the policy was adopted—reportedly over 20 percent today compared to under 5 percent historically—and Medicaid programs and commercial payers increasingly mirror Medicare's definition, extending its effects well beyond the Medicare population.

Closely related to the dose definition, commenters addressed the 30-unit per-claim MUE applied to CPT code 95165, asking CMS to eliminate it in favor of an annual, per-beneficiary parameter that reflects higher utilization during the buildup phase and lower utilization

during maintenance, paired with an exception process for documented medical necessity. Recommended annual limits varied: two national societies proposed up to 150 doses in the first year and 120 during maintenance; a multistate alliance and a regional society recommended up to 160 doses in the first year and 130 during maintenance, consistent with figures referenced in the proposed rule; and one individual commenter recommended a higher limit of 200 doses, citing patients on accelerated buildup protocols requiring four or more separately prepared vials.

Several commenters extended these concerns into related payment methodology requests, recommending that CMS recognize preparation of dilution vials during the buildup phase as a separately payable component, recalculate the direct practice expense input for antigen supply costs using a representative mix of invoice data across vial sizes rather than the largest available vial, and exclude any resulting valuation correction from the proposed 5 percent practice expense stabilization limit, or alternatively allow accelerated implementation of such a correction.

To illustrate the practical scope of these issues, several commenters offered supporting data. A commenter representing a large practice reported thousands of patients actively receiving immunotherapy, drawn from a Medicare-related population exceeding 8,000 individuals over an18-month period, and stated that its standard preparation methodology uses 2 cc per unit—twice the volume recognized under the current definition. Other commenters, particularly those in rural and medically underserved areas, reported that Medicare and Medicaid beneficiaries make up a disproportionate share of their immunotherapy patients, in some cases exceeding 60 percent, and expressed concern that inadequate reimbursement could lead to discontinuation of immunotherapy services where few or no alternative providers exist.

Commenters also tied these access concerns to patient safety, stating that maintaining separate dosing conventions for Medicare and non-Medicare patients introduces variability into dosing and labeling that may increase the risk of medical error, and that MUE-driven delays in preparing multiple vials on separate dates could compound this risk, particularly for patients with severe allergic disease, including venom hypersensitivity.

Finally, commenters situated these recommendations within the broader clinical and economic significance of allergen immunotherapy, noting that it remains one of the few disease-modifying treatments available for allergic rhinitis, allergic asthma, and related conditions, and that reduced access could increase downstream use of medications, emergency care, and other services. A commenter cited a published cost-effectiveness analysis suggesting that reimbursement reductions causing access reductions beyond a modeled threshold would not be cost-effective from either a societal or health-system perspective.

Response: We agree that the current volume-based definition, unchanged since 2000, no longer reflects contemporary clinical practice, under which maintenance doses are routinely prepared in volumes smaller than 1 cc. We further agree that this discrepancy has had the practical effect of valuing only a fraction of the doses actually prepared and administered. We also recognize that certain allergen combinations cannot safely be consolidated into a single vial due to proteolytic activity and cross-reactivity, and that the revised definition better accommodates the use of multiple, separately prepared vials in these clinical circumstances. With respect to the 2002 HHS OIG findings regarding the data underlying the original 1 cc standard, we acknowledge that this definitional change addresses a long-standing inconsistency between Medicare policy and current clinical practice.

The recommendation to eliminate the 30-unit per-claim MUE for CPT code 95165 in favor of an annual, per-beneficiary utilization parameter—including the specific thresholds proposed for buildup and maintenance phases and the associated medical necessity exception process—is outside the scope of this rulemaking. MUE values are established and maintained through a subregulatory process administered separately from the annual PFS rulemaking cycle. We will refer this recommendation to the appropriate subregulatory process for further consideration.

The recommendations regarding payment methodology, including separate payment for dilution vial preparation, recalculation of the direct practice expense input for antigen supply costs based on a representative mix of vial-size invoice data, and an exclusion or accelerated correction relative to the proposed 5 percent practice expense stabilization limit, raise substantive questions about current valuation inputs that merit further review beyond the scope of this rule. We intend to consider these recommendations, along with the supporting utilization and practice-cost data submitted, in future rulemaking.

We appreciate the data provided regarding the growing share of Medicare beneficiaries within the immunotherapy patient population and the extension of Medicare's dose definition into Medicaid and commercial coverage policies. We also appreciate the concerns raised regarding access in rural and medically underserved areas, and the patient safety considerations associated with maintaining divergent dosing conventions across payers. We recognize the clinical and economic significance of allergen immunotherapy as a disease-modifying treatment and will take the broader cost-effectiveness and access considerations raised into account as we evaluate the remaining payment methodology questions in future rulemaking.

After consideration of the public comments received, we are finalizing our proposal to revise the definition of a dose for CPT code 95165 from a 1 cc aliquot to a single injection from a multidose vial, consistent with the definition used for CPT codes 95115 and 95117. The recommendation to adopt an annual, per-beneficiary utilization parameter in place of the current MUE will be referred to the appropriate subregulatory process for further consideration.

(12) Ultrasonic Wound Assessment (CPT Code 97610)

An interested party nominated CPT code 97610 (*Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day*) as potentially misvalued due to an inflated supply costs direct PE input. The nominator stated that this inflation causes a site of service disparity where CMS pays significantly more for the non-facility practice expense compared to the hospital outpatient (OPPS) payment rate. The CY 2026 non-facility PE RVU of 11.51 for CPT code 97610 results in a payment of $384, compared to an OPPS payment rate of $205, representing a payment differential of $179. The nominator stated that this disparity is primarily driven by the $320 direct PE input, SA119 (kit, low frequency ultrasound wound therapy (MIST)). The nominator provided a hyperlink to the UltraMIST® system manufacturer's Investor Presentation [70] from December 2025 which states that ''consumable costs = ~$100/procedure (list price).'' On slide 13 of the

[70] *https://sanuwave.com/investors/presentations.*

presentation, it states that the single use applicators are $100 and that the pricing reflects manufacturer's suggested retail price (MSRP). The nominator also estimated an implied sales price of $86 per disposable kit on average using publicly available manufacturer disclosures and Medicare claims data. The nominator stated that the manufacturer reported $21.0 million in U.S. consumable and parts net revenue for CY 2024. The nominator was able to estimate the total volume of kits sold by the manufacturer by assuming each of the 745 unique billing NPIs in Medicare claims have approximately one of the ~1,000 UltraMist® systems in the field, such that the 181,851 Medicare claim lines account for 74.5 percent of total volume ($21.0 million/[181,851/{745/1,000}] = $86), noting that actual sales price would vary due to volume-based or other supplier discounts, commercial utilization, and other factors.

We agree with the nominator and proposed CPT code 97610 as potentially misvalued. Additionally, we proposed to change the cost of supply code SA119 to $100 in the direct PE database. We sought comment on this proposal and invited interested parties to submit paid invoices for supply code SA119 (kit, low frequency ultrasound wound therapy (MIST)). We also noted that physician time may be currently overstated for CPT code 97610, as the December 2025 Investor Presentation asserts that the procedure takes about 3 to 20 minutes, with an average of 6 minutes. The current total physician time is nearly 26 minutes, with a work RVU of 0.39. Because the current intraservice time is over double the time asserted by the supply manufacturer in the Investor Presentation, we sought comment on whether the typical physician time to perform this service is closer to the manufacturer's assertion of 6 minutes or the current intraservice time of nearly 15 minutes.

Comment: Several commenters stated that an input price of $100 for supply code SA119 does not reflect the wide range of costs across different device manufacturers and technologies used to furnish CPT code 97610 (such as Vaporox, Sanuwave, and Arobella). Commenters reported supply costs ranging from $20 to $250 in some geographic areas, and specifically requested that CMS evaluate costs across all technologies rather than relying on data from a single manufacturer's investor presentation. The most common cost for SA119 that commenters referenced was $125, particularly among small practices and individual providers. Most commenters requested that CMS rely on paid invoice data rather than pricing derived from an investors presentation. Several commenters stated they would provide invoices for the device and applicator upon request, though a couple of commenters submitted an invoice to substantiate alternative costs for SA119. The commenters submitted invoices for a per-use device fee ranging from $60 to $125 discussed later in this section, and a disposable treatment kit specific to Vaporox ranging from $35 to $50.

Response: We note that commenters gave us a range of costs for SA119, but no commenters asserted that they pay the current $320.18 for SA119. We appreciate commenters' input regarding the range of costs across different technologies used to furnish CPT code 97610. We appreciate the commentators' submission of invoices and note in response to commentors who stated they would submit invoices upon request, that we specifically requested invoice submission in the proposed rule. However, consistent with our standard ratesetting methodology, we establish direct PE inputs and their values to reflect the typical cost of furnishing a service, not the costs associated with any one product, manufacturer, or business arrangement.

Comment: The AMA RUC indicated that they intend to review an action plan at their September 2026 meeting to determine whether this code should be re-reviewed. The RUC and several other commenters requested that CMS delay finalization of changes to CPT code 97610 pending this RUC review process. Other commenters raised coding concerns, noting the code lacks depth, size, wound quantity, or anatomic-site distinctions, and same-day billing restrictions with other wound care codes, and requested referral back to the RUC on these grounds as well.

Response: While we recognize that the RUC may consider resurveying and revaluation for a future rulemaking cycle, we do not believe it is appropriate to delay finalization on the individual supply cost concern identified through our misvalued code initiative, considering no commenters asserted that they pay the current $320.18 for SA119 and we believe it is significantly overvalued. In the event that there is a new RUC review of this service, we would look forward to receiving any additional information, invoices, or new data about the broader coding structure, specifically regarding depth, size, wound quantity, or anatomic-site distinctions, and same-day billing restrictions.

Comment: A commenter stated that they pay $97 for the single use UltraMIST applicator but requested that CMS maintain the current $320.18 price for the kit because it carried the cost of other consumables (such as saline, dressings, PPE, and clinician travel between homes) and created a margin for practices to recover the $27,500 device cost.

Several commenters stated that CMS conflated the cost of the single-use applicator with the cost of the SA119 kit. A commenter stated that the kit includes the applicator and tubing, plus saline and dressings purchased separately. The commenter also stated that their members report kit pricing above and below our proposed $100 depending on purchase volume. Several commenters requested that CMS include saline in CPT code 97610's supplies, with a commenter specifically requesting the inclusion of SH069 (sodium chloride 0.9% irrigation (500–1000ml uou)).

Response: We can clarify that the proposed $100 price for supply code SA119 is intended to reflect the cost of the kit, consistent with the cited manufacturer's investor presentation describing $100 in consumable costs. Supply code SA119 is separate and distinct from the other direct PE supplies included in CPT code 97610 which are not affected by our proposal. We note that the valuation of CPT code 97610 already accounts for multiple different bandages, dressings, gauzes, and PPE. We encourage commenters to review the direct PE input public use files, available on the CMS website, which detail all supply, equipment, and clinical labor direct PE inputs. We note that a couple of commenters provided invoices and they indicated the single-use disposable treatment kit specific to Vaporox ranges from $35 to $50. We do not believe that this range is representative of the typical kit cost across all technologies and devices. Additionally, we agree with the commenters that saline should be a supply input for CPT code 97610 and we are therefore adding 1 quantity of supply code SH069 to CPT code 97610 in the non-facility setting for the final rule.

Comment: Several commenters stated that they did not agree with the proposed $100 for SA119 because they use the Vaporox system and pay a per-treatment operating or rental charge for the device, in addition to a separate $50 device-specific disposable kit cost. Commenters stated that this per-treatment cost of $160 in total, rather than the $100 figure derived from a competing manufacturer's disclosed consumable price, should be used to value supply code SA119 because they made no capital equipment investment

and pay per use instead. A couple of commenters provided invoices, but they corroborated the commenters' prices. Another commenter stated that some of their members use an alternative system with higher capital acquisition cost but reusable applicators that are autoclaved between patients rather than discarded. The commenter stated that those practices have significantly lower supply costs, while capital acquisition, equipment, and clinical labor costs are higher. A few commenters stated that the MIST Therapy system acquisition cost is significantly higher than cost indicated in the investors presentation, but did not provide invoices to substantiate their figures for consideration in updating the device cost in the direct PE database.

Response: We do not agree that a pay-per-use operating charge should be used to set the direct PE supply input for SA119. As we have stated in rulemaking as recent as CY 2025 (89 FR 97798), while we understand that there may be alternative business models, we do not believe a rental, subscription, or per-use fee of an equipment item that is still available to be purchased and is already accounted for with our equipment methodology is appropriate. Similarly, while we appreciate the submissions of per-use invoices for the Vaporox device, we believe that the typical cost of the device is appropriately and adequately accounted for in the equipment formulas for EQ372 (MIST Therapy System) and EQ368 (MIST Therapy Cart) (based on our standardized formula which accounts for years of useful life, utilization rate, purchase price, and minutes per year of use, outlined in detail in section II.B. of this final rule, Determination of PE RVUs). We do not believe that CPT code 97610 should be valued based on a significantly more expensive pay-per-use business model when the same treatment is cheaper and available as a purchasable form of equipment.

Comment: Some commenters requested that, if CMS must finalize a price of $100 for SA119, it should phase in the reduction over time.

Response: As discussed in section II.B. of this final rule, we note that the proposed changes to the supply code SA119's price decreased CPT code 97610's PE RVU. Because this reduction was the result of revaluation of the code's supply input, CPT code 97610 is exempt from the proposed PE stabilization adjustment, but the statutory phase-in of significant total RVU decreases will apply because its total RVU decrease is greater than 19 percent. Therefore, we agree with commenters and note that the reduction in total RVUs that resulted from the updated price for SA119 will be phased in, not due to a staggered implementation of the SA119 supply price, but rather due to the preexisting phase-in transition policy (see the CY 2016 PFS final rule 80 FR 70927 through 70929 for additional details).

Comment: Many commenters provided feedback in response to our comment solicitation about physician time, mostly stating that our current physician time is not overstated or, in some cases, possibly understated. A few commenters stated that service is performed primarily by clinical staff under supervision, and that physician time may be overstated for the wound assessment and documentation portions of the service that are performed by a physician. Some commenters provided detailed clinical labor activities and times, some indicating undervaluation. A commenter highlighted possible clinical labor anomalies and stated they planned to survey its membership for corrected clinical labor inputs prior to the PFS final rule. Another commenter provided empirical times: a single wound takes 24.9 minutes of physician time and 4.1 minutes of clinical staff time, and each additional wound adds 12 minutes of physician time and 3 minutes of clinical staff time. The commenter stated that treating 2 wounds per encounter is typical. Another commenter provided aggregated data over 41 months and 110,237 recorded treatments that showed machine-recorded active device runtimes averaged 43.4 minutes, with a median of 42 minutes and a range of 14 to 56 minutes.

Response: We thank the commenters for the detailed feedback. We reiterate that we did not propose any changes to physician time, work RVU, or clinical labor time but appreciate the commenters feedback that the current physician and clinical labor times are not overstated.

After consideration of public comments, we are finalizing the addition of 1 quantity of SH069 to CPT code 97610 in the non-facility setting, and a supply cost of $125 for SA119. We note that we are finalizing $125 despite the lack of an invoice to substantiate that price because we believe the current price of $320.18 is significantly overpriced based on commenters' feedback, and $125 was the most common price commenters referenced for SA119. We believe this strikes a balance between the few invoices we received for the single-use disposable treatment kit specific to Vaporox that ranges from $35 to $50, the lack of consensus and clarity about what is included in the SA119 kit, the range of technologies used to furnish CPT code 97610, and the absence of any support or indication from commenters that the current price of $320.18 for SA119 is accurate. We continue to invite interested parties to submit paid invoices reflecting actual costs for supply code SA119 and information about what is included in the kit for consideration in future rulemaking.

(13) Autologous Platelet Rich Plasma (HCPCS Code G0465)

We received a request from a nominator to review HCPCS code G0465 *(Autologous platelet rich plasma (PRP) or other blood-derived product for diabetic chronic wounds/ulcers, using an FDA-cleared device for this indication, (includes as applicable administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)* as potentially misvalued. The nominator requested that CMS update the work RVUs for HCPCS code G0465 from 1.78 to 5.50 based on the results of an independent survey of physicians and qualified health professionals who have training and experience treating chronic, non-healing diabetic wounds that was performed by a third party in the Fall of 2025. The nominator also requested that CMS update its policy to state that multiple procedure payment adjustments do not apply to HCPCS code G0465. Additionally, in the CY 2025 PFS Final rule, we finalized crosswalking G0465 to CPT code 15275 (*Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area*), however, the nominator believes this is not an appropriate crosswalk for G0465.

We thanked the nominator for submitting the information, including the survey conducted by the third party. However, we note the sample size of the survey shows only 34 respondents and so we have concerns as to whether this is a representative sample size of practitioners furnishing this service. Additionally, we continue to believe that the MPPR payment adjustment is applicable to multiple units of this service billed to the same beneficiary on the same day due to overlapping resource costs. Given that no additional information was submitted to support the increase in work RVU, we did not propose this code as potentially misvalued.

Comment: Many commenters urged CMS to reconsider HCPCS code G0465 as potentially misvalued. A few

commenters referenced the concern with the sample size of the submitted survey and recommended CMS to reconsider based on their updated survey results that included an expanded sample size of 21 new respondents, bringing the total to 54 respondents. Additionally, many commenters disagreed with the decision to keep the MPPR payment adjustment for HCPCS code G0465. Some commenters mentioned that the MPPR payment adjustment causes a direct financial disincentive for physicians to treat every wound patient within a single visit because chronic diabetic wound patients frequently present with more than one active wound. Some commenters requested CMS to instead change the MPPR indicator from 2 to 0 or establish a wound-specific modifier for HCPCS code G0465, similar to the A1–A9 modifiers used under the surgical dressings policy article. Some commenters also noted they believe the crosswalk code, CPT code 15275, is not appropriate as it describes fundamentally different services and the work is not comparable.

Response: We thank commenters for their feedback and for submitting the newly submitted survey results that include an expanded sample size. However, we continue to believe that a payment reduction is warranted when this service is furnished more than once during the same encounter, as certain resources are shared or are not incurred independently with each additional unit.

After consideration of public comments and given the new information submitted, we nominate HCPCS code G0465 as potentially misvalued.

E. Request for Information: Redesigning Primary Care To Make America Healthy Again

1. Introduction

Primary care is an essential component of the HHS Secretarial priority to ''Make America Healthy Again'' commonly known as MAHA.[71] Relatively and accurately valuing primary care is essential. It is the cornerstone of a high-functioning health care system, helping enable the shift in U.S. health care toward a focus of preventive rather than reactive medicine—for health care rather than ''sick care.''[72] Critical to this transition is incentivizing investment in high-value care that reduces health care costs (especially from chronic disease) in the long term. Building off recent HHS rulemaking that established such incentives for commercial health plans,[73] we are interested in how Original Medicare may similarly be able to incorporate more robust incentives to invest in high-value care, which will reduce costs of care in the long-term within the Physician Fee Schedule (PFS). More specifically, the agency solicited comment on how we might reconsider primary care service valuation to better support this objective amidst what may be a meaningful shift in how primary care is delivered given more recent technological innovation.

Primary care services delivered in the physician office were the locus for continuous, coordinated, and comprehensive care when the PFS was established in 1992. This definition of primary care as a beneficiary's first point of contact with the health care system[74] has been increasingly challenged by broader access to medical information through digital resources. This may accelerate as the increasing adoption of technology reshapes access to increasingly sophisticated sources of medical information before beneficiaries ever show up in the doctor's office.[75] Advances in technology, including generative and agentic superintelligence (SI)[76], are poised to transform both beneficiary experience[77] and the role of the primary care clinicians.[78] These were not anticipated when defining the relative value units and time and intensity of services delivered by physicians, which are essential inputs to the PFS.[79]

To both support broader MAHA priorities and to reconcile with how technology is reshaping primary care delivery for beneficiaries and clinicians, we are seeking comment on how to re-imagine and improve the relative valuation of primary care services. We are focused on understanding how that re-imagination might occur within the current construct of office/outpatient (O/O) evaluation and management (E/M) services as well as via alternatives to fee-for-service payment, including through outcomes-based payment and/or the expansion of prospective primary care payment (PPCP). The latter, in particular, has long been a goal of external policy experts, including as a recommendation from the 2021 National Academy of Science, Engineering, and Medicine report '*Implementing High Quality Primary Care,'* which recommends team-based delivery supported by 'hybrid' payment models that combine prospective monthly and visit-based payments.[80] Over the past decade, the CMS Innovation Center tested PPCP in Medicare using a series of increasingly sophisticated hybrid payment approaches from the Comprehensive Primary Care initiative (CPC) to Primary Care First (PCF). The lessons learned from these Innovation Center model tests led Medicare to establish advanced primary care management (APCM) codes in the CY 2025 PFS final rule as a first step towards PPCP.[81] The potential changes to primary care practice with increasing adoption of technology also raises concerns for increasing opportunity for fraud, waste, and abuse from malicious actors.[82] For these and other reasons, as the agency thinks about the re-imagination of primary care payment in the PFS, we considered first establishing PPCP permanently in the Medicare

[71] U.S. Department of Health and Human Services. *Make America Healthy Again (MAHA).* HHS.gov, *https://www.hhs.gov/maha/index.html.* Accessed 29 Apr. 2026.

[72] Kennedy, R. F., Jr. (2025). Remarks on the U.S. ''sick-care system.'' *Fox News interview. https://www.foxnews.com/health/rfk-jr-likely-confirmed-health-secretary-dr-siegel-says.* Accessed May 31, 2026.

[73] ''Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2027; and Basic Health Program.'' **Federal Register**, vol. 91, 2026, p. 29683. U.S. Government, *https://www.federalregister.gov/d/2026-10050/p-1540.*

[74] O'Connor, S. M. ''Citing Primary Care.'' *British Journal of General Practice,* vol. 61, no. 586, 2011, pp. 361–362. *https://pmc.ncbi.nlm.nih.gov/articles/PMC3133574.*

[75] Rastogi, Namrata. ''Healthcare's New Frontier: The Digital Front Door.'' *BMJ Innovations,* vol. 8, no. 2, 2022, *https://doi.org/10.1136/bmjinnov-2021-000874.*

[76] The terms ''Super Intelligence'' and ''SI'' are used herein to refer to what was formerly called Artificial Intelligence or AI. *See* Exec. Order No. 14434, *Inaugurating the Era of Super Intelligence,* 91 Fed. Reg. 63,129 (Oct. 2, 2026).

[77] Yang, Betsy, et al. ''Transforming the Primary Care Journey with Generative AI: A Foundation Model to Boost Efficiency, Quality, and Engagement.'' *Journal of General Internal Medicine,* 2026, *https://doi.org/10.1007/s11606-025-09716-y.*

[78] Sarkar, Urmimala, and David W. Bates. ''Using Artificial Intelligence to Improve Primary Care for Patients and Clinicians.'' *JAMA Internal Medicine,* vol. 184, no. 4, 2024, pp. 343–344. *https://doi.org/10.1001/jamainternmed.2023.7965.*

[79] Berenson, Robert A., and Kevin J. Hayes. ''Could Artificial Intelligence Affect Physician Payment for Nonprocedural Services? Part 1.'' *Health Affairs Forefront,* Health Affairs, 2025, *https://www.healthaffairs.org/content/forefront/could-artificial-intelligence-affect-physician-payment-nonprocedural-services-part-1.*

[80] National Academies of Sciences, Engineering, and Medicine. ''Designing Interprofessional Teams and Preparing the Future Primary Care Workforce.'' *Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care,* National Academies Press, 2021.

[81] Agarwal, Sumit D., et al. ''The Underuse of Medicare's Prevention and Coordination Codes in Primary Care: A Cross-Sectional and Modeling Study.'' *Annals of Internal Medicine,* vol. 175, no. 8, 2022, pp. 1100–1108. *https://doi.org/10.7326/M21-4770.*

[82] Gray, Jacob. ''Strengthening Healthcare Program Integrity with AI.'' *ICF,* 2026, *https://www.icf.com/insights/health/healthcare-fraud-waste-abuse-ai.*

Shared Savings Program. We also sought to better understand if there are suggestions on how to implement PPCP within the broader Original Medicare program with appropriate guardrails.[83]

We sought comment on three main topics:

- *Reconsidering relative primary care payment in the Medicare PFS:* We are increasingly concerned about the relative undervaluation of primary care services. We would like feedback on how to reconsider this relative undervaluation in the PFS under the current paradigm of O/O E/M visits, the Annual Wellness Visit (AWV), and care management codes. We seek comment on updating this code set, and how or if CMS should consider a 'two-track' approach to care management services with one track focused on technology enabled care and the other track focused on 'traditional' care management.

- *The payment implications of technology-enablement of primary care:* We are seeking comment on how technology and clinical AI are impacting primary care, both broadly and more narrowly within the care management codes and the AWV. We also would like to better understand how CMS might update its approach to paying for technology-enabled care given the potentially transformative effects on the beneficiary and clinician experience. If we were to approach paying for technology-enabled primary care differently, how should we consider the relative valuation, in terms of time and intensity of services? How else could these services be valued? How should we consider evidence of the impact or outcome of technology-enabled services in primary care?

- *Establishing Prospective Primary Care Payment in the Medicare Shared Savings Program:* Given the series of CMS Innovation Center PPCP model tests, how should CMS approach establishing PPCP in the Shared Savings Program, and more broadly across Original Medicare?

In short, this RFI sought comment on how we should evaluate which of the payment models discussed previously in this section (FFS payment models, outcomes-based payments, or prospective payment) makes the most sense for primary care given the rapid changes that may arise for recent technological innovation.

[83] Centers for Medicare & Medicaid Services. *Accountable Care Organization Operational System (ACO–OS).* CMS, *https://security.cms.gov/pia/accountable-care-organization-operational-system.*

2. Reconsidering Relative Primary Care Payment in the Medicare Physician Fee Schedule

a. O/O E/M Visits

Under the PFS, in accordance with section 1848 of the Social Security Act (''the Act''), we establish payment amounts for covered physicians' services and update payment policies to address changes, including those in medical practice, coding, or new data on relative value components. Original Medicare's fee-for-service payments for primary care services are overwhelmingly made through traditional O/O E/M visit codes. E/M codes describe a broad range of physician services that occur in an office setting, and do not distinguish between a one-time consultative visit and care that is part of a longitudinal care relationship, which may require additional time, coordination, and resources. We have previously described our concern that the complexity of services required to provide longitudinal care is not fully incorporated as part of the valuation of the work RVUs when the E/M code itself is used as the primary way to report the work of the professional (88 FR 78972). The physician community had previously supported this view when they highlighted that the existing E/M services, such as office visits, do not adequately describe the typical non-face-to-face care management work required by certain categories of beneficiaries most often served by primary care practitioners (78 FR 43337).

As a result, specialties that do not routinely furnish procedural interventions or diagnostic tests and for which E/M visits represent a greater share of total allowed services are paid differently and generally less than their counterparts who routinely furnish procedural interventions and diagnostic tests. Section 1848 of the Act prohibits specialty-specific payment under the PFS, so we cannot vary the conversion factor or the number of relative value units for a physician's service based on the specialty type of the physician. Instead, in CY 2021, we adopted the RUC's recommendations for increased E/M work RVUs, based on their review of physician time for the E/M visit code set (84 FR 62851 through 62854). Next, in the CY 2024 PFS final rule, we took steps to better recognize the inherent complexity of visits associated with primary and longitudinal care of patients by finalizing Healthcare Common Procedure Coding System (HCPCS) code G2211 *(Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management service, new or established)).* HCPCS code G2211 is used by practitioners furnishing services as the continuing focal point for all the patient's needed health care services, including but not limited to primary care practitioners (88 FR 78969). In the CY 2026 PFS final rule (90 FR 49462 through 49464), we finalized our proposal to allow HCPCS code G2211 to be billed as an add-on code with the home or residence E/M visits, in addition to office/outpatient E/M visits. We are proposing changes to HCPCS code G2211 for CY 2027; see section II.D of this proposed rule for further discussion.

The current O/O E/M code set may still insufficiently reflect differences in the nature and intensity of care provided. As such, we are considering establishing distinct categories of O/O E/M visits in future rulemaking. Potential categories could be longitudinal care, acute care, or consultative visits, with distinctions based on the clinical purpose of the encounter and the associated resource costs of furnishing care. Longitudinal care visits involve care delivered both during and between encounters as part of an ongoing comprehensive care relationship. During these visits, a beneficiary establishes, maintains, or updates that relationship. For example, a beneficiary returns to the clinic 3 months after their AWV for ongoing management of their diabetes, which requires an oral medication titration, and elevated blood pressure and hyperlipidemia, which includes a discussion about lifestyle modification. The practitioner also notices that they are overdue for an immunization, schedules them for a necessary screening test, and updates their plan of care accordingly. We would distinguish this visit (including the valuation of the pre- and post-service time and proximity to prior visits) from the care delivered in an acute care visit. In the future, we may consider valuing these visits as a combination of the E/M service furnished during the encounter and certain between-visit care management activities. In contrast, acute care visits are focused on the evaluation and management of a discrete, episodic problem that is generally resolved after treatment. For example, a beneficiary may seek care for a sore throat and suspected streptococcal pharyngitis, with no

expectation of an ongoing care relationship related to that condition once it is resolved. While consultative visits are distinct from longitudinal and acute care visits because they are furnished in response to a referral to address a specific clinical question, consultative services could be considered similar in complexity to acute care, distinguished largely by consultative services typically including an evaluation of the patient and communication of findings or recommendations back to the referring practitioner.

We also noted that CPT codes exist and are paid by private payers for consultative services (for example, CPT codes 99242 through 99245), although they are not paid by Medicare. We are seeking comment on whether to consider the complexity of these services to be closer to the acute care services versus the longitudinal care services. As a general matter, we expected to consider consultative visits to be less complex than longitudinal care visits. We sought feedback on further actions we could take around appropriate valuation of primary care services:

- What updates to the HCPCS code G2211 policy (or the proposed modifiers, MOD1 and MOD2) should CMS consider to ensure the clinician billing HCPCS code G2211 (or proposed modifiers, MOD1 and MOD2) is serving as the focal point for beneficiaries, and that the practitioner is also considering preventive care, risk factor reduction, and other services necessary for coordinating the care of beneficiaries who have a complex condition?

Comment: Commenters broadly agreed that clinicians serving as the 'focal point' in care is best expressed through the ongoing relationship and the clinical responsibility taken for patients, not through a documentation checklist. Commenters were mixed on whether the current specialist utilization of HCPCS code G2211 is appropriate or if there additionally needs to be required coordination of care with primary care clinicians to ensure preventive services and risk factor reduction is addressed. Commenters agreed that supporting longitudinal care is the priority and that discrete or time-limited care should not qualify.

Response: We will consider these comments for future rulemaking.

- Given the broad range of changes CPT makes annually, we recognize updates to the CPT code set to reflect distinctions among O/O E/M visits by the function of the visit (longitudinal, acute, or consultative) may have significant advantages within the current billing and coding ecosystem. However, absent a change in CPT coding, should we consider the possibility of creating G codes to better recognize distinction between and among these kinds of visits? If so, what categories should we consider? How could we effectively differentiate longitudinal care visits from acute care visits? What number of levels would be needed and for which settings of care? Should we use existing CPT codes as templates? How should we consider valuing these potential G-codes under the PFS, including the basis for the standard inputs: work RVUs, time values, specialty mix for utilization crosswalks, direct PE inputs, etc.? How would practitioners balance and manage the increasing number and complexity of these codes?
- If CMS were to propose longitudinal or primary care visit types, what should the service period be? Should subsequent care management services be bundled in? If so, for what period of time? Which care management services might be included?

Comment: Commenters stated the importance of appropriately valuing longitudinal work and the current challenges with limited differentiation in O/O E/M services. A few commenters endorsed revisiting consultative visits through existing CPT codes. Commenters highlighted that the current coding structure of E/M visits billed along with HCPCS code G2211 and/or APCM can potentially address the differences in the physician work conducted within an existing E/M visit and highlighted that the flexibility of addressing acute and longitudinal concerns in the same visit is an important flexibility. Commenters also suggested that rather than creating functional visit categories, CMS may consider simplifying E/M visits to fewer levels alongside a per-beneficiary per-month (PBPM) payment in a hybrid payment structure.

Response: We will consider these comments for future rulemaking.

- Are there specific data on the resources used in furnishing longitudinal care, acute care, or consultative services CMS should consider for potential categorization of O/O E/M services?

Comment: Commenters generally highlighted the challenges associated with differentiating the resource costs associated with longitudinal, or consultative services, and suggested potential 'empiric' data sources to identify gaps in the resource requirements currently identified.

Response: We will consider these comments for future rulemaking.

Comment: Commenters broadly agreed that the PFS structurally undervalues primary care. Primary care organizations, payers, and policy groups urged rebalancing payment away from fee-for-service, while FQHCs asked that any changes preserve their existing payment structure. Specialty organizations agreed primary care is undervalued but opposed funding it through cuts to specialty services, citing their own longitudinal and cognitive care needs; hepatology and cardiology groups specifically warned against disrupting specialty access. Many commenters favored voluntary, risk-adjusted, hybrid prospective payment for predictable revenue, with primary care groups preferring hybrid/sub-capitation over full capitation over access concerns. Others argued primary care should formally include behavioral health and lifestyle support.

Response: We will consider these comments for future rulemaking.

3. Care Management Code 'Family'

We have for the last 14 years sought to unbundle services previously considered bundled into E/M services through separate coding and payment for care management services. In 2013, the agency implemented a transitional care management code for post-discharge care (77 FR 68978). This was then followed by the creation of a broader family of codes for care management, including for beneficiaries with multiple chronic conditions or chronic care management (CCM) (78 FR 74414), for those requiring complex medical decision-making (for example, complex CCM, 81 FR 80349), and for those with a single or principal condition (principal care management (PCM), 85 FR 84697). In total, the CCM and PCM code families now include five sets of codes which are reported monthly on a timed basis, each set with a base code of 20 to 60 minutes and an add-on code for each additional 30 minutes. In the CY 2025 PFS final rule (89 FR 97859), we finalized three APCM codes (HCPCS codes G0556, G0557, and G0558) to recognize the evolving way primary care practices manage prevention and chronic condition management through interprofessional care teams. See Table A–E1 for more specificity on the purpose of each of the codes.

Despite these important steps to pay separately for care management services, uptake of the care management

codes has been limited.[84] Interested parties cite cost-sharing and non-trivial documentation requirements as the primary barriers to broader adoption.[85] In response to these considerations, we removed the CCM requirement to count and document the minutes of care management services provided in the patients' medical record when billing APCM services. Interested parties had stated this was so burdensome it limited their use of the CCM Current Procedural Terminology (CPT) codes. At the same time, the agency was concerned about program integrity and therefore code auditability. In the absence of medical record documentation, we required that if a practitioner billed the APCM codes, they must report the Value in Primary Care MIPS Value Pathway (89 FR 97864). Despite these changes, uptake in the first year was less than anticipated. We seek feedback on whether a different payment structure might be more appropriate as well as what might be done to further simplify the code set and associated requirements.

TABLE A-E1: CARE MANAGEMENT SERVICES PAID UNDER THE PFS

Service	Description
Care Management Services	
Chronic Care Management (CCM) (CPT Codes 99487, 99489, 99490, 99491, 99439, 99437)	Management of all care for patients with two or more serious chronic conditions, timed, per month.
Principal Care Management (PCM) (CPT Codes 99424, 99425, 99426, 99427)	Management of all care for patients with one serious chronic condition, timed, per month.
Transitional Care Management (TCM) (CPT Codes 99495, 99496)	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit (bundled into payment for the code), once per patient within 30 days post-discharge.
Advanced Primary Care Management (APCM) (HCPCS G0556, G0557, and G0558)	Management of all care for patients with or without chronic conditions, not timed, per month.
Communication Technology-Based Services	
Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) (CPT codes 99453, 99445, 99454, 99470, 99457, 99458, 99091)	Remote monitoring and assessment of physiologic data or adherence and response to therapeutic treatment, timed, per month.

We also sought comment on how to reconfigure the care management code 'family' to better establish effective relative payment options for between visit care management services and how supervision requirements may need to change in technology-enabled care models where patients may initially engage with digital tools or receive care entirely in a digital environment. In addition, given our concerns about fraud, waste, and abuse in the care management code families, we would like to better understand how to ensure care management services are impacting care.

To improve the utilization of care management services where it is clinically appropriate, we sought comment on the following questions:

- What additional requirements should CMS consider to reduce fraud, waste, and abuse in care management services? Specifically on the following:

++ What is the appropriate 'trigger' or initiating visit for care management services? How would this change if it were an initiating visit vs. another event?

++ Should CMS consider changing supervision requirements in care management services to prevent fraudulent billing of care management services? What is the appropriate supervision requirement for care management services?

++ How should data submission to CMS change to verify services are received?

++ What guardrails should CMS consider to prevent inappropriate billing?

++ What proportion of care management services must be delivered by the supervising provider, versus auxiliary personnel?

Comment: Commenters cautioned that CMS may be overstating FWA concern among 'ordinary' physician practitioners who are personally furnishing care management services, and a broader concern may be the underreporting of care management services due to cost-sharing and documentation requirements. For the FWA that does exist, commenters highlighted the importance of using claims analytics to identify outliers and potential FWA, or require 'time-stamped, user-attributed' audit records to be produced on request for care management services. Many commenters suggested that the central solution for reducing FWA in care management is making the care plan and accountable practitioner the center of program-integrity verification.

Response: We will consider these comments for future rulemaking.

- Are there specific data on the resources used in furnishing advanced primary care, which incorporates population health management, enhanced communication technology, and longitudinal care management? We welcome submission of any such data.

Comment: Commenters highlighted a series of existing resources to understand the resource costs associated with delivering advanced primary care, including a series of reports from the National Academies of Science, Engineering, and Math (NASEM) and from the State of Rhode Island. Commenters highlight a series of resource costs not currently accounted for in O/O E/M services, including members of the clinical workforce, EMR and HIE platforms and population

[84] Agarwal SD, Basu S, Landon BE. The Underuse of Medicare's Prevention and Coordination Codes in Primary Care: A Cross-Sectional and Modeling Study. Ann. Intern. Med. 2022 Aug;175(8): 1100–1108. doi: 10.7326/M21–4770. Epub 2022 Jun 28. PMID: 35759760; PMCID: PMC9933078.

[85] Agarwal SD, Barnett ML, Souza J, Landon BE. Adoption of Medicare's Transitional Care Management and Chronic Care Management Codes in Primary Care. *JAMA.* 2018;320(24):2596–2597. doi:10.1001/jama.2018.16116

health registries and platforms to support advance primary care functions like 24/7 access, referrals and scheduling workflows, as well as clinical governance and operational oversight.

Response: We will consider these comments for future rulemaking.

• To what extent are the current care management codes duplicative? Are there efficiencies to be gained in simplifying the current care management code 'family' into a more efficient code set? To what extent would this improve appropriate utilization of care management services?

Comment: Commenters agreed there was substantial overlap in the activities conducted by current care management codes but often differed on the clinical purpose for such activities being duplicative. Commenters differed on whether APCM, CCM, PCM, or TCM were most duplicative.

Response: We will consider these comments for future rulemaking.

• If reducing the number of care management codes would not increase efficiency or utilization of appropriate services, how else can CMS standardize the requirements across the care management codes?

Comment: Commenters agreed on the importance for 'harmonizing' or creating common standards for requirements across the services, such as the initiating visit requirements, beneficiary consent, supervision, responsibility for updating the care plan, and documentation of meaningful activity.

Response: We will consider these comments for future rulemaking.

• As care management becomes increasingly technology-enabled, how should CMS consider changing the code family and their relative valuations? How can CMS ensure that automated billing leveraging technology reflects actual care delivered to beneficiaries by care teams or practitioners?

Comment: Commenters largely did not agree with a differentiation of care management services by technology requirement or between 'technology-first' and 'traditional' care management services.

Response: We will consider these comments for future rulemaking.

• Should CMS create 'technology-enabled care management' codes or a 'two-track' approach to care management? How should we ensure these codes are appropriately differentiated?

Comment: Commenters largely did not accept a ''technology-first vs. traditional'' differentiation for care management, citing cost sharing, overlapping billing rules, and infrastructure costs as the real barriers. Some commenters favored clinically based differentiation instead. Other commenters discussed the importance of embedding care management in accountable, outcomes-based care regardless of delivery mode. Most commenters agreed that clinical integration should be a priority, and aligning requirements matters more than cutting the number of codes.

Response: We will consider these comments for future rulemaking.

4. Payment Implications of Technology Enablement of Primary Care

a. Changes to Primary Care and Care Management Due to Technology and Clinical AI

Adoption of new technology and AI tools in primary care has the potential to transform clinical care to such a degree that it may challenge how we traditionally think about care delivery. However, clinician-facing AI tools that are currently in widespread use are more focused on administrative burden reduction and clinical decision-support. For example, tools focused on *reducing clinician documentation burden* (for example, AI scribes) have perhaps been the most widely taken up by clinicians,[86] with an estimated 25% penetration among all US physicians.[87] Early system-level evaluations demonstrate generally increased productivity among adopters along with decreases in perceived documentation burden.[88] The most widely used AI tool in primary care is likely a *clinical decision-support* application, Open Evidence, which more than forty percent of US physicians have self-reported using as of the CY 2027 Proposed Rule.[89] This software allows clinicians to ask an AI chat interface a wide variety of clinical questions and receive answers based on a large language model only drawing from well-known peer reviewed journals and guidelines (that is, not the entire internet). *AI-assisted care delivery* agents have been deployed in a number of health systems but have not yet reached widespread use, to the best of CMS' knowledge.[90] In general, we note greater technological adoption may support a shift in care management from reactive, manual processes to proactive, data-driven, and personalized care.

In short, we believe technology is being used in increasingly innovative ways throughout primary care but would like to better understand that usage. Given this changing backdrop, we sought comment on how we develop a comprehensive and consistent approach to payment for technology-enabled care given likely lower cost-to-serve but potentially higher quality of care delivered. There are challenges in establishing appropriate valuation methodologies, due to the rapidly evolving nature, accuracy, impact, and scope of these technologies as well as the limited transparency into underlying costs and effect of these tools in primary care and other specialties.

One potential approach may be to link payment more directly to demonstrated clinical outcomes. We sought additional information on how to best structure payment for these technologies in a way that aligns with our agency's mission to increase quality, improve health, reduce costs, and strengthen the healthcare system. Clinical technology tools of interest would include those that provide clinical decision-making support that deliver AI-assisted (or augmented, etc.) primary care, or that are otherwise of note. We sought input on the following:

• Our understanding is that clinical documentation and clinical decision-support tools are currently the most commonly used applications of AI in primary care. Does this reflect current practice? In particular, are there additional *clinical* AI tools and new technologies that are frequently being used in primary care settings with high accuracy, demonstrated safety, and clinical outcomes reported? If so, please describe how they impact the clinical workflow and the beneficiary experience.

• If you are a physician furnishing primary care services, how has your practice been impacted or how do you

[86] Littrell, A. (2026, May 19). *The AI tool physicians actually love: A conversation with Robert Wachter, M.D., chair of UCSF Medicine.* Medical Economics. *https://www.medicaleconomics.com/view/the-ai-tool-physicians-actually-love-a-conversation-with-robert-wachter-m-d-chair-of-ucsf-medicine.*

[87] Doximity. (2026). *State of AI in medicine report 2026. https://www.doximity.com/reports/state-of-ai-medicine-report/2026.*

[88] Holmgren AJ, Fenton CL, Thombley R, et al. Ambient Artificial Intelligence Scribes and Physician Financial Productivity. JAMA Netw Open. 2026;9(1):e2553233. doi:10.1001/jamanetworkopen.2025.53233.

[89] OpenEvidence. (2025, July 15). *OpenEvidence, the fastest-growing application for physicians in history, announces $210 million round at $3.5 billion valuation. https://www.openevidence.com/announcements/openevidence-the-fastest-growing-application-for-physicians-in-history-announces-dollar210-million-round-at-dollar35-billion-valuation.*

[90] Examples include ''Cedars-Sinai Connect'', from *https://www.cedars-sinai.org/csconnect.html* or 'Hartford Healthcare GPT' *https://www.aha.org/aha-center-health-innovation-market-scan/2026-05-19-hartford-healthcare-embraces-ai-patientgpt.* Retrieved May 31, 2026.

expect it will be impacted by clinical AI tools?

- How has incorporating technology and AI tools impacted the resource costs associated with primary care practice, in terms of the time and intensity of services delivered?
- How has the implementation of clinical AI tools led to improvements in the quality of care, or reduced downstream costs? In general, please cite any evidence available for your comments.
- If these tools are increasing productivity, what are clinicians and other health professionals doing with the additional time/bandwidth created? Are you seeing more patients in visits, engaging more with population-health management or care management, accomplishing administrative tasks, or something else?
- How do you ensure patient data and privacy is adequately protected during use of these tools?
- Please describe areas *where clinical AI tools in primary care are not well captured* in the current coding and payment system and suggest how these may be incorporated to facilitate *high-value,* technology-enabled primary care.

What lessons can CMS learn and adopt from private payors with respect to clinical AI? More specifically, we asked the following:

- What can CMS learn from how private payors have approached payment and coverage of clinical AI in primary care? How are they monitoring for beneficiary safety, privacy, fraud, waste, and abuse?
- How could private payor coverage of clinical AI in primary care streamline or otherwise facilitate CMS coverage or payment?
- From an outcomes-based perspective, how should CMS evaluate and monitor the impact of technology-enabled care in primary care?
- What outcomes would accurately capture whether these technologies have improved or negatively affected primary care practice for both clinicians and beneficiaries? Are there different outcomes for short-term and long-term impacts?

What type of outcomes data should be shared with CMS? For example, to what extent would submission via Fast Healthcare Interoperability Resources (FHIR)-based APIs of clinical outcomes or activity sets be an appropriate approach by which to tie payment?

- What submission frequency and formats would be most appropriate?
- How can we collect those outcomes in a way that minimizes administrative burden?
- Are there other payment structures, beyond outcomes-based and prospective (which will be discussed in the next section), that would be more suited to the unique nature and impact of these technologies? If so, please describe.

Comment: Many commenters were broadly skeptical of AI use in health care, citing current problems with AI models, and asked us to ensure that any care we pay for in the future has proven value in the clinical setting. Other commenters reminded us that health care is driven by human compassion and clinical judgement, expressing concern that increased use of technology does not always equal improved outcomes. Commenters broadly support AI-enabled tools that help clinicians synthesize longitudinal patient information, identify gaps in screenings and vaccinations, flag risk factors, and generate clinically meaningful summaries from health risk assessments, prior visits, wearable data, and test results. Many note that these tools are especially valuable for automating repetitive, non-clinical tasks like questionnaire administration and documentation, freeing physicians to better focus on direct patient interaction, care planning, and shared decision-making. Regarding privacy, commenters argued existing HIPAA and HITECH protections already govern AI-enabled tools and cautioned against a duplicative AI-specific regime, while others called for better data infrastructure and standardization to support broader adoption.

Response: We will consider these comments for future rulemaking.

5. Technology and AI-Augmentation in Primary Care Via the Medicare AWV

As we at CMS endeavor to shift US health care toward a focus on preventive rather than reactive medicine—for health care rather than 'sick care'—there may be no more obvious starting place for Medicare than the Initial Preventive Physical Exam (IPPE) and Medicare Annual Wellness Visits (AWVs). The IPPE is a one-time preventive check-up where practitioners review the beneficiary's medical history, make sure they are up to date on important screenings and vaccines, and talk with the beneficiary about their family history and how to stay healthy.[91] Then every year following, beneficiaries have a conversation-focused visit to create a personalized prevention plan, called an AWV.[92]

The IPPE was established under section 611 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), and the AWV was established under section 4103 of the Affordable Care Act (Pub. L. 111–148), which requires Medicare to cover an AWV in which a personalized prevention plan is created. The payment for AWVs has been updated to reflect the resource costs associated with advanced care planning (80 FR 70956), review of opioid use (85 FR 84713), and optionally physical activity and nutrition (90 FR 49483). The current requirements for the IPPE and AWV can be found on the CMS website.[93]

Section 1861(hhh)(1) of the Act establishes the requirements for 'personalized prevention plans' and the subsequent subsection 1861(hhh)(4)(F) directs the Secretary to encourage the use of, integration with, and coordination of health information technology in the AWV, and gives the Secretary the authority to experiment with the use of personalized technology focusing on health behavior change. We sought comment on whether advances in technology, including clinical AI, could improve the effectiveness, personalization, and both beneficiary and clinician experience for the AWV. Despite the importance of prevention and early identification of risk factors, evidence regarding the impact of the AWV on outcomes is mixed. Some studies have found that an AWV visit is associated with increased use of preventive services[94] but may not sufficiently close gaps in preventive care.[95] However, other studies have found no substantive association between AWV adoption and improvements in evidence-based screening, acute care utilization, or spending,[96] or potentially increasing

[91] ''Welcome to Medicare Preventive Visit.'' *Medicare.gov,* Centers for Medicare & Medicaid Services, *https://www.medicare.gov/coverage/welcome-to-medicare-preventive-visit.* Accessed 16 June 2026.

[92] ''Yearly 'Wellness' Visits.'' *Medicare.gov,* Centers for Medicare & Medicaid Services, *https://www.medicare.gov/coverage/yearly-wellness-visits.* Accessed 16 June 2026.

[93] Centers for Medicare & Medicaid Services. ''Medicare Wellness Visits.'' *Centers for Medicare & Medicaid Services,* U.S. Department of Health and Human Services, *https://www.cms.gov/medicare/coverage/preventive-services/medicare-wellness-visits.* Accessed 7 July 2026.

[94] Beckman AL, et al. The effect of Medicare's Annual Wellness Visit on preventive care for the elderly. *Prev Med.* 2018;116:126–133.

[95] Camacho F, Yao N, Anderson R. The Effectiveness of Medicare Wellness Visits in Accessing Preventive Screening. *Am J Health Promot.* 2017.

[96] Ganguli I, Souza J, McWilliams JM, Mehrotra A, et al. Association of Medicare's Annual Wellness Visit with Cancer Screening, Referrals, Utilization, and Spending. *Health Affairs.* 2019.

downstream low-value services.[97] Given the heterogeneity of these findings, we are interested in whether technology-enabled AWVs can improve not only the proportion of Medicare beneficiaries completing an AWV but also meaningful outcomes.

We sought comment on whether clinical adoption of technology including clinical AI tools may facilitate transformation of the AWV from a point-in-time assessment to a more continuous, data-driven, and beneficiary-specific preventive care function. The function of these tools may support AWV completion from pre-visit activities as well as activities during and after the clinical encounter. As examples, clinical AI tools may support pre-visit collection of beneficiary reported information such as in the health risk assessment, adapting questions to a beneficiary's language or health literacy level.[98] For reviewing the medical and family history, AI tools have demonstrated superiority to human experts in summarizing health information from structured and unstructured fields.[99] During the clinical encounter, AI tools may also support standardized clinical workflows embedded in the electronic health record environment,[100] identify beneficiaries who may warrant additional assessment, and generate suggested follow up steps for clinicians to review.[101] Following the encounter, AI tools may assist with developing post-encounter instructions in the language and health literacy level of the patient.[102]

We believe much of this can occur under current CMS billing guidance, and reiterate that under the statute and regulations, the AWV must be performed by a physician or other health professional, or team of medical professionals directly supervised by a physician currently enrolled as a Medicare provider. We are interested in what barriers—if any—these requirements create to innovative AWV delivery models in which an AI technology company develops or operates these clinical AI tools and affiliates with a Medicare enrolled provider or supplier. We sought comment on the following:

- How can CMS improve the effectiveness, efficiency, personalization, and beneficiary experience of the IPPE and Medicare AWV?
- Which, if any, AWV components are being delivered (or could be) more efficiently delivered through technology and clinical AI-enabled tools? Please comment on how technology is being used today within the AWV, how that has changed over the last year, and how the community sees that changing over the next couple of years. Which activities require direct involvement by a physician, qualified non-physician practitioner, or medical professional under physician supervision?
- Could AI-enabled AWVs improve health outcomes that prior studies have found to be inconclusive?
- What evidence should CMS consider regarding whether technology or clinical AI-enabled AWVs improve clinical usefulness of visit and clinical outcomes, beneficiary reported outcomes, or utilization? In particular, research around changes in the use of preventive services, the application of preventive services to individual clinical risk factor assessment or in low-value downstream utilization are of specific interest.
- What existing statutory, regulatory, enrollment, billing, supervision, documentation, data-sharing or other requirements may create barriers to an AI technology company delivering AWV-related services while employing or contracting with appropriately licensed physicians or other medical professionals to perform AWVs? To what extent may program integrity concerns exist with these models?
- In what circumstances should CMS consider payment or policy changes that would allow technology-enabled organizations, including AI technology companies, to participate in AWV delivery models, either directly or through partnerships with Medicare-enrolled providers or suppliers?
- How should CMS evaluate whether AI-enabled AWVs are improving outcomes rather than merely increasing AWV volume, documentation completeness, coding intensity, or low-value care follow 'cascades' of services? Specifically, for which outcomes should CMS hold technology companies accountable?
- How could CMS optimize information sharing from AWV throughout the duration of the primary care relationship? Where could AI-enabled tools facilitate this process?

Comment: Commenters supported using technology to help make the prevention plan developed through the AWV more dynamic and longitudinal, including by supporting follow-through after the visit. Commenters noted that technology could support specific AWV elements, including with health risk assessment, history reconciliation, provider lists, medication review, screenings, and even drafting prevention plans. At the same time, commenters agreed interpretation, judgment, counseling, and plan approval must stay with the practitioner under current regulations. Commenters identified digital cognitive assessment tools as one area not yet ready for reliable use in the AWV. Most opposed separate payment or valuation for AWV technology, viewing its use instead as an enhancement to the existing AWV service.

Response: Section 1861(hhh) of the Act and 42 CFR § 410.15 establish the requirements for the Medicare AWV. In light of commenters' interest in how technology could support completion of the AWV and enhance its impact, we take this opportunity to clarify how AI/SI could be used within those existing statutory and regulatory requirements. We emphasize at the onset of this discussion that any use of AI/SI in connection with the Medicare AWV must preserve clinician autonomy in the practice of medicine, consistent with the role of the health professional in furnishing the AWV as set forth in the statute and regulations. We may also propose additional improvements to the AWV in future rulemaking, including establishing opt-out procedures for beneficiaries who do not wish to utilize new technology.

As set forth in the statute, the elements of the 'personalized prevention plan' include a health risk assessment, collecting information on beneficiaries' individual and medical family history, measuring objective health indicators (for example, vital signs, BMI), detecting cognitive impairment, and establishing a screening schedule.

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[97] Ganguli I, Lupo C, Mainor AJ, et al. Assessment of Prevalence and Cost of Care Cascades After Routine Testing During the Medicare Annual Wellness Visit. *JAMA Netw Open.* 2020;3(12):e2029891. doi:10.1001/jamanetworkopen.2020.29891.

[98] Swisher AR, Wu AW, Liu GC, Lee MK, Carle TR, Tang DM. Enhancing Health Literacy: Evaluating the Readability of Patient Handouts Revised by ChatGPT's Large Language Model. Otolaryngol Head Neck Surg. 2024 Dec;171(6):1751–1757. doi: 10.1002/ohn.927. Epub 2024 Aug 6. PMID: 39105460.

[99] Van Veen D, Van Uden C, Blankemeier L, et al. Adapted large language models can outperform medical experts in clinical text summarization. *Nature Medicine.* 2024;30:1134–1142.

[100] Perkins SW, Muste JC, Alam T, Singh RP. Improving Clinical Documentation with Artificial Intelligence: A Systematic Review. Perspect Health Inf Manag. 2024 Jun 1;21(2):1d. PMID: 40134899; PMCID: PMC11605373.

[101] Yao, X., Rushlow, D.R., Inselman, J.W. *et al.* Artificial intelligence-enabled electrocardiograms for identification of patients with low ejection fraction: a pragmatic, randomized clinical trial. *Nat Med* 27, 815–819 (2021). *https://doi.org/10.1038/s41591-021-01335-4.*

[102] Young, Albert T., et al. ''Patients and Dermatologists Are Largely Satisfied with ChatGPT-Generated After-Visit Summaries: A Pilot Study.'' *JAAD International,* vol. 15, 2024, pp. 33–35. Elsevier, *https://doi.org/10.1016/j.jdin.2023.12.004.*

In particular, this personalized prevention plan is meant to support the ''furnishing of personalized health advice and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.''

We reiterate that section 1861(hhh)(4)(F) directs the Secretary to encourage the use of health information technology and ''experiment with the use of personalized technology'' focusing on developing self-management skills and adherence to provider recommendations in order to improve or maintain the health status of beneficiaries, which we view as encouraging technology to support health behavior change. The list later in this section identifies the AWV components and 'elements' reflected in section 1861(hhh) of the Act and 42 CFR § 410.15, and describes how clinical AI/SI tools could assist in furnishing them. We reiterate that the AWV must be conducted by a health professional, and we believe these clarifications may help those health professionals use technology to support a 'personalized prevention plan,' including for certain functions that may occur outside the clinician encounter or asynchronously, consistent with existing requirements:

++ Health Risk Assessment (HRA): The statute and regulations identify the HRA as an evaluation tool that collects self-reported information, may be completed prior to the visit, and may be administered independently by the beneficiary. The statute further contemplates that the HRA may be furnished through an ''interactive telephonic or web-based program'' or other means the Secretary determines appropriate, provided that beneficiary privacy is protected. Consistent with these provisions, clinical AI/SI could administer the health risk assessment questionnaire, collect updated medical history or current care provider information, and summarize clinical information prior to the clinician encounter, where the HRA is reviewed and augmented by the clinician.

++ Medical/Family History: AI/SI may extract information from the electronic medical record for review and verification by the clinician, who establishes or updates the medical and family history during the encounter.

++ Current Providers/Suppliers: AI/SI may reconcile the current providers and suppliers list for review and verification by the clinician, who establishes or updates the list during the encounter.

++ Use of Medications, Supplements, and Other Substances: AI/SI may reconcile the current list of medications/supplements/other substances used, for review and verification by the clinician.

++ Routine Measurements: Under current technology, we are not aware of how AI/SI could be used to measure weight or waist circumference, blood pressure, or other routine measurements, and do not clarify a role for using AI/SI in furnishing this element at this time.

++ Cognitive Impairments: The regulations require assessment of cognitive function by direct observation, with due consideration of information obtained from the beneficiary and others. We are not aware of how AI/SI could be used to conduct a cognitive assessment under the current regulatory standard.

++ Depression Risk Review: AI/SI may administer an appropriate screening instrument selected by the clinician and flag or escalate responses *prior* to the clinician encounter, for review by the clinician.

++ Functional Ability and Safety Review: AI/SI could conduct appropriate screening questions or a screening questionnaire selected by the clinician *prior* to the clinical encounter, the results of which may be reviewed by the clinician during the encounter.

++ Written 5–10 year screening schedule: AI/SI may generate a list of recommended screenings to be reviewed and prioritized by the clinician during the encounter.

++ Personalized Prevention Plan: AI/SI may support generation of a draft personalized prevention plan including individualized health advice and referrals to health education or preventive counseling services or programs, for review and approval by the clinician. This personalized prevention plan is meant to support patients' overall health goals and risk factor reduction and self-management, in areas such as fall prevention, nutrition, physical activity, substance avoidance, social engagement, weight loss, or cognition.

++ Advanced Care Planning: AI/SI may, at the *discretion* of the beneficiary, support prompting patient discussions on preparing an advance directive, future care decisions, caregiver identification, and other priorities to support an advance care planning discussion as part of the AWV, conducted by the clinician.

We anticipate there may be resource requirement shifts associated with the technology-enablement of the AWV as well as potentially other physician services. While we reiterate that we are providing payment for the physician service, we are aware of many beneficiary-facing applications which patients may use to support their health, and these novel technologies could support beneficiaries in *implementing* the personalized prevention plan as developed between the Medicare beneficiary and their physician or non-physician practitioner as part of the Medicare AWV.

To ensure beneficiaries have access to the best possible care including novel technologies should beneficiaries elect to do so, and acknowledging the Secretary's authority to ''experiment with the use of personalized technology'' to support beneficiary self-management skills and adherence to provider recommendations to improve the health status of beneficiaries, we further clarify that should organizations provide a software application to a Medicare beneficiary to support their implementation of a personalized prevention plan, such remuneration may implicate both the Federal Anti-Kickback Statute and the Beneficiary Inducements Civil Monetary Penalty Law (that is, ''Beneficiary Inducements CMP'') and would need to be evaluated on a case by case basis.

We reiterate that in future rulemaking we may provide additional clarifications or flexibilities on how the Medicare AWV is conducted, however under current regulations these physician or non-physician practitioner functions may be enhanced by clinical AI/SI, and while we pay for the furnishing of the service to develop a personalized prevention plan, organizations may choose to provide beneficiaries with applications to support their self-management skills and implement these personalized prevention plans. These clarifications, we reiterate, are intended to support beneficiaries adopting technology to improve their health and do not constitute the practice of medicine or replace the beneficiary and physician or non-physician practitioner relationship.

6. Developing Prospective Payment in the Shared Savings Program

a. Background

We stated at the beginning of this request for information that we are interested in further developing prospective primary care payment (PPCP) in Original Medicare, beginning with the Shared Savings Program. There

is growing recognition that the fee-for-service (FFS) payment model has inherent limitations as a primary care payment mechanism, as it is not designed to support the comprehensive, coordinated care that primary care requires. In 2015, the Medicare Payment Advisory Commission (MedPAC) recommended a per beneficiary payment for primary care providers to support additional care coordination activities for Medicare beneficiaries.[103] MedPAC explained that while a per beneficiary payment in itself will not guarantee an increase in care coordination activities or even an increase in compensation for eligible primary care practitioners, it would be a first step in transitioning from FFS to a beneficiary-centered payment approach that encourages care coordination, including the non-face-to-face activities that are a critical component of care coordination.[104]

In a 2021 report on implementing high-quality primary care, the National Academies of Sciences, Engineering, and Medicine (NASEM) recommended that health care payers ''pay for primary care teams to care for people, not doctors to deliver services'' and encouraged payers to adopt a hybrid reimbursement model that combines FFS and capitation over time with an overarching goal to eventually pay for the majority of primary care services through risk-adjusted prospective payment.[105] NASEM recommended that a hybrid reimbursement model—with a mix of FFS and lump-sum or per-person payments—become the default method for paying for primary care teams.[106] NASEM found that with time, hybrid reimbursement models show improvements in care and reductions in use, particularly for people with multiple complex chronic conditions.[107]

Over the past 13 years, the CMS Innovation Center has tested a number of models that have progressively moved away from FFS billing, including: CPC, Comprehensive Primary Care Plus (CPC+), PCF, Next Generation ACO (NGACO), Global and Professional Direct Contracting (GPDC) Model, ACO REACH, and ACO Primary Care (PC) Flex. These models have focused on testing whether Medicare payment for primary care services through hybrid payments (a mix of FFS and capitated payments), population-based payments (PBPs), or total care capitation (TCC) improves quality of care for beneficiaries and reduces Medicare spend. Evidence from these models suggests that primary care capitation (PCC) is most effective when it is embedded in an accountable care framework, such as the Shared Savings Program.[108] Model design and evaluations are available on the model-specific websites that can be found on *https://www.cms.gov/priorities/innovation/models#views=models*.

Previous Innovation Center primary care model tests have yielded lessons that shape current and future work, including the development of codes and payment for APCM services. Participants, namely clinicians, in primary care models have indicated, however, difficulties with investing in and maintaining primary care redesign activities due to a range of challenges. First, additional non-visit-based primary care payments have been generally layered upon base payments that are still predominantly FFS in structure. While payment for APCM services represents a meaningful step toward non-visit-based payments in concept, we do not view APCM as the end goal of primary care payment reform. The payment amounts associated with APCM are predicated on furnishing and billing APCM services. As such, APCM retains the fundamental structure of FFS billing and may not provide sufficient incentives for practices to focus on proactive, population-based non-visit care management activities.

Second, Innovation Center model funding that supports salaries for clinical and administrative staff, who are needed for advanced primary care coordination and population health functions, is contingent on continued participation in these models. Unlike APCM codes,[109] which are billing codes paid under the PFS and can be used to support ongoing primary care workforce investments, once the models end, practices are left without the funding that they received under the models for the clinical and administrative staff that had supported population health functions. Based on a review of internal CMS data related to billing for APCM services, billing for APCM services is higher for Shared Savings Program ACO-assigned beneficiaries compared to Medicare beneficiaries outside of an ACO. This finding suggests that the accountability and care management infrastructure associated with ACOs may support more robust adoption of non-visit based primary care payment mechanisms.

Table A–E3 identifies recent Innovation Center models that tested capitated payment arrangements. As outlined in the table, the payment arrangements tested across these models reflect a progression from hybrid (FFS + capitation) payment structures to PBPs and TCC, with each successive model designed to build upon the experience of previous models. CPC+ and PCF relied on care management fees, performance-based incentive payments, and PBPs that partially replaced traditional FFS billing. While neither model reduced total Medicare expenditures or achieved net savings, the CPC+ evaluation found that independent practices who spent a longer time in the model, and those participating in the Shared Savings Program tended to have more favorable results.[110] This finding underscores the importance of embedding primary care

[103] Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare Payment Policy,* page 106 Washington, DC: MedPAC. *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-mar2015_entirereport_revised-pdf/.*

[104] Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare Payment Policy,* page 106 Washington, DC: MedPAC. *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-mar2015_entirereport_revised-pdf/.*

[105] National Academies of Sciences, Engineering, and Medicine. ''Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care,'' pages 7–8. Washington, DC: The National Academies Press, 2021. *https://doi.org/10.17226/3393 https://www.nationalacademies.org/read/25983/chapter/3#8.*

[106] National Academies of Sciences, Engineering, and Medicine. ''Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care,'' page 8. Washington, DC: The National Academies Press, 2021. *https://doi.org/10.17226/3393 https://www.nationalacademies.org/read/25983/chapter/3#8.*

[107] National Academies of Sciences, Engineering, and Medicine. ''Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care,'' page 301. Washington, DC: The National Academies Press, 2021. *https://doi.org/10.17226/3393 https://www.nationalacademies.org/read/25983/chapter/3#8.*

[108] *See, for example,* O'Malley A, Singh P, Fu N, et al. Independent Evaluation of the Comprehensive Primary Care Plus (CPC+): Final Report. Mathematica, page xviii. December 2023. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

[109] Three APCM codes and payment amounts were established in the CY 2025 Physician Fee Schedule final rule (89 FR 97859 through 97902). In the CY 2026 PFS final rule, CMS established three new G-codes (HCPCS codes G0568, an add-on code based on CPT code 99492, G0569, an add-on code based on CPT code 99493 for CoCM services delivered to patients also receiving APCM services, and G0570, an add-on code for general behavioral health integration services based on CPT code 99484) to be billed as add-on services to APCM base codes: HCPCS codes G0556, G0557, and G0558 (90 FR 49464 through 49471).

[110] O'Malley A, Singh P, Fu N, et al. ''Independent Evaluation of the Comprehensive Primary Care Plus (CPC+): Final Report,'' page 209. Mathematica. December 2023. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

payment reform within an accountable care framework.

Other Innovation Center models that have tested different kinds of cash flow and primary care capitated payments have focused on ACOs in models that build on the foundation of the Shared Savings Program. For example, ACOs in the NGACO model could select from four payment mechanisms: (1) traditional FFS; (2) FFS with a fixed per beneficiary per month (PBPM) infrastructure payment; (3) PBPs that gave ACOs a fixed percentage of expected FFS claims reductions in prospective monthly payments; or (4) all-inclusive PBPs, in which the ACO received expected FFS claim reductions in prospective monthly payments. Three quarters of NGACOs primarily chose FFS-based payment mechanisms such as the FFS or FFS with infrastructure payment (FFS+ISP). NGACOs electing PBP mechanisms had larger spending reductions of 3 percent ($409.1 per beneficiary per year (PBPY), p<0.01), compared with 1.3 percent ($172.9 PBPY, p<0.01) for NGACOs electing FFS-based payment mechanisms. Additionally, NGACOs, particularly the 35 that remained through PY 6, showed improvements in model reported quality measures over time for prevention and screening and for chronic disease management. Further, 25 of 35 NGACOs had reduced cumulative Medicare spending while maintaining or reducing rates of ambulatory care-sensitive conditions-related hospitalizations or 30-day unplanned readmissions, tended to reduce outpatient spending and Emergency Department visits, and tended to reduce skilled nursing facility spending and utilization. Over the course of the model, NGACOs invested in initiatives to better manage their patient populations, toward the goals of reduced spending and improved quality.[111]

Under the GPDC Model [112] (the successor to the NGACO model) and the ACO REACH model,[113] we offered two capitation options: (1) TCC (a PBPM capitated payment for all Medicare Part A and Part B services) and (2) PCC for primary care services equal to seven percent of the estimated total cost of care and composed of both a base amount and an enhanced amount designed to provide upfront revenue. Direct contracting entities and ACOs that selected PCC could also select an advanced payment option (APO), which provided upfront payments for services beyond primary care.

The ACO PC Flex model extends capitated payment arrangements to ACOs participating in the Shared Savings Program. The model is designed to test how prospective payments and increased funding for primary care in ACOs affects health outcomes, quality, and costs of care within the Shared Savings Program.[114] Model participants are limited to ACOs that participate in the Shared Savings Program and qualify as a ''low revenue ACO'' as defined by § 425.20.[115] ACOs participating in the ACO PC Flex Model receive two payments: a monthly PPCP and a one-time advanced shared savings payment. The PPCP is a PBPM payment for primary care services that replaces FFS payments for eligible primary care services with a monthly prospective payment composed of a county base rate (based on a county's average primary care spending), an ACO enhanced amount, and a population adjustment.[116] ACOs are required to spend at least 90 to 95 percent (depending on the performance year) of the total PPCP payment on the provision of care.[117] The ACO enhanced amount includes three types of payment enhancements: (1) the county enhancement, which is applied at the county level in counties designated as low spending counties relative to standardized spending nationally; (2) the flex enhancement, which is applied at the ACO level to all PC Flex ACOs, regardless of location or utilization, and (3) the enhancement add-on, which is a fixed amount PBPM for a performance year that may be used to increase the ACO enhanced amount for underlying changes in the Medicare PFS that are not reflected in the rate book. The enhanced amount will not be subject to recoupment in full by CMS based on the PC Flex ACO's performance in achieving shared savings.[118] Although interest in the ACO PC Flex model was robust, many eligible ACOs that expressed initial interest in the model ultimately did not submit applications, citing challenges associated with the application timeline. Additionally, several interested parties shared that concurrent interest in the Making Care Primary model was a factor in their decision not to participate in ACO PC Flex.

The Innovation Center recently announced the Long-term Enhanced ACO Design (LEAD) model,[119] which is scheduled to begin on January 1, 2027. As currently designed, LEAD's capitated payment architecture builds directly on the framework used in ACO REACH and ACO PC Flex. Similar to ACO REACH and the ACO PC Flex model, participating ACOs will be required to select from either: (1) TCC payment or (2) PCC payment. The LEAD model plans to offer ACOs that elect PCC the option to receive additional payments to extend value-based arrangements beyond primary care. Specifically, ACOs may elect the non-primary care capitation (NPCC) or the APO to support alternative payment arrangements for non-primary care providers. It is anticipated that these options would allow ACOs to incrementally expand capitation beyond primary care without adopting full TCC.

[111] Lowell, K.H., and contributing authors. ''Evaluation of the Next Generation Accountable Care Organization (NGACO) Model, Final Report,'' page 10. Bethesda, MD: NORC at the University of Chicago, 2024. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/nextgenaco-sixthevalrpt.*

[112] Lowell, K.H., and contributing authors. ''Evaluation of the Global and Professional Direct Contracting Model, Annual Report 2.'' Bethesda, MD: NORC at the University of Chicago, 2024. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/gpdc-2nd-ann-report.*

[113] ''ACO REACH Model, PY 2026 Financial Operating Policies: Capitation and Advanced Payment Mechanisms.'' Baltimore, MD: RTI International, 2025. *https://www.cms.gov/priorities/innovation/files/aco-reach-py26-financial-ops-capitation-payment-mechanisms.pdf.*

[114] ACO PC Flex (ACO Primary Care Flex) Model website: *https://www.cms.gov/priorities/innovation/innovation-models/aco-primary-care-flex-model.*

[115] Under § 425.20, a ''low revenue ACO'' is an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available, is less than 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available.

[116] ACO Primary Care Flex Model Financial Methodology: Rate Book Development, Calculation of Monthly Prospective Primary Care Payment, and Financial Settlement, June 2025, version 2, pages 1–2. *https://www.cms.gov/files/document/aco-pc-flex-fin-meth-ratebook-dev.pdf.*

[117] ACO Primary Care Flex Model Financial Methodology: Rate Book Development, Calculation of Monthly Prospective Primary Care Payment, and Financial Settlement, June 2025, version 2, page 56. *https://www.cms.gov/files/document/aco-pc-flex-fin-meth-ratebook-dev.pdf.*

[118] ACO Primary Care Flex Model Financial Methodology: Rate Book Development, Calculation of Monthly Prospective Primary Care Payment, and Financial Settlement, June 2025, version 2, page 33. *https://www.cms.gov/files/document/aco-pc-flex-fin-meth-ratebook-dev.pdf.*

[119] *https://www.cms.gov/priorities/innovation/innovation-models/lead.*

TABLE A-E2: CAPITATED PAYMENT ARRANGEMENTS IN SELECT CMS INNOVATION CENTER MODELS

Model	Type	Capitated Payment Arrangement Options
Comprehensive Primary Care Plus (CPC+) 2017-2021	Hybrid (OM+ capitation)	FFS base + care management fees + performance-based incentive payments. Alternative payments to partially replace FFS billing available to Track 2 practices.
Primary Care First (PCF) 2021-2025	Population-based payments	Quarterly population-based payments that exceed FFS rates + flat visit fees replaced E/M billing + performance-based adjustment (based on performance measures) of -10 percent to 50 percent + payment accuracy adjustment to account for primary care furnished outside participating PCF practices.
Next Generation ACO (NGACO) 2016-2021	OM + Hybrid + Population-based payments	Four options: (1) FFS; (2) FFS + fixed per-beneficiary per-month infrastructure payment; (3) population-based payments as fixed percent of expected FFS claims; (4) all-inclusive population-based payments (prospective monthly payments based on expected FFS claim reductions).
Global and Professional Direct Contracting (GPDC) 2021-2022	Primary care capitation or Total Care Capitation	Two monthly payment options: (1) primary care capitation (PCC) payment or (2) total care capitation (for all Medicare Part A and Part B services). PCC includes a base primary care capitation amount + enhanced primary care capitation amount. Advanced payment option available for ACOs that select PCC.
ACO REACH 2023-2026	Primary care capitation or Total Care Capitation	Two monthly payment options: (1) primary care capitation (PCC) payment or (2) total care capitation. PCC consists of base primary care capitation amount + enhanced primary care capitation amount. Advanced payment option available for ACOs that select PCC.
ACO PC Flex 2025-2029	Primary Care Capitation	Monthly prospective primary care payment (PPCP) to replace FFS for eligible primary care services + one-time $250,000 advance shared savings payment. PPCP consists of: county base rate + ACO enhanced amount + population adjustment. Enhanced amount consists of: county enhancement + flex enhancement.
Long-term Enhanced ACO Design (LEAD) 2027-2036 (planned)	Primary Care Capitation or Total Care Capitation	Two monthly payment options are planned: (1) primary care capitation (PCC) payment or (2) total care capitation. As currently designed, PCC consists of: a base primary care capitation amount + enhanced primary care capitation amount. As currently designed, Advanced payment option and non-primary care capitation payment may be available for ACOs that select PCC.

b. Primary Care Capitated Payment Arrangements Considerations for the Shared Savings Program

The goal of capitated payments is to give health care providers additional flexibility in how they deliver care and to reduce the volume-based incentives of Original Medicare (OM) payment. With capitated payments, health care providers receive steady, predictable cash flow that is not tied to the number of services they provide. This flexibility frees health care providers to deliver care in innovative and flexible ways, such as non-face-to-face care management, telehealth, and electronic messaging, without worrying about foregone OM revenue, tying these services to overall outcomes. We are interested in building on the experience of previous Innovation Center models that tested capitated payment arrangements. Section 1899(i)(2) of the Act authorizes the Secretary to use partial capitation in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B, provided that the partial capitation payments for a year made under the partial capitation model do not result in additional program expenditures than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not implemented. The Secretary may limit a partial capitation model to ACOs that are highly integrated systems of care and to ACOs capable of bearing risk, as determined to be appropriate by the Secretary. Additionally, section 1899(i)(3) of the Act authorizes the Secretary to use other payment models instead of the one-sided model described in section 1899(d) of the Act as long as the Secretary determines that the other payment model will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures.

We have previously described how primary care teams are central to the relative success of Shared Savings Program ACOs.[120] [121] In 2024, as in previous years, ACOs comprised of larger proportions of primary care clinicians had significantly higher net per capita savings than ACOs comprised of smaller proportions of primary care clinicians (with $403 vs $224 in net per capita savings).[122] In recent years, we have received significant input from interested parties regarding opportunities to increase participation in ACO initiatives. One such option to increase participation would be to identify ways that the Shared Savings Program can support ACOs' efforts to strengthen primary care, such as by providing prospective monthly primary care capitated payments to primary care practices, to reduce reliance on OM payments and support innovations in care delivery that better meet beneficiary needs.

In the CY 2026 PFS proposed rule (90 FR 32502), we solicited comments on whether CMS should consider new payments to Shared Savings Program ACOs for prospective monthly APCM payments to be delivered to primary care practices that satisfy the APCM billing requirements, with the payments reconciled under the ACO benchmark. Nearly all commenters supported giving ACOs the option to receive prospective APCM payments. Only one commenter opposed prospective APCM payments, arguing that APCM delivery solely through ACOs risks undermining the core principles of CCM.

In the CY 2027 PFS proposed rule, we sought feedback about developing prospective primary care payment arrangements in the Shared Savings Program. Specifically, we requested input on the following questions:

ACO and ACO Participant Readiness

- To what extent are Shared Savings Program ACOs and ACO participants, and their associated health care providers (referred to herein as ''ACO providers/suppliers''), ready to take on capitated payment arrangements? Please

[120] ''Medicare Shared Savings Program Continues to Deliver Meaningful Savings and High-Quality Health Care'', October 29, 2024, Press Release. *https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-continues-deliver-meaningful-savings-high-quality-health-care.*

[121] ''Medicare Shared Savings Program Saves Medicare More Than $1.8 Billion in 2022 and Continues to Deliver High-quality Care'', August 24, 2023, Press Release. *https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-saves-medicare-more-1–8-billion-2022-continues-deliver-high-quality.*

[122] Medicare Shared Savings Program Accountable Care Organizations Updated Performance Year 2024 Financial and Quality Results Fact Sheet, September 29, 2025. *https://www.cms.gov/files/document/fact-sheet-ssp-py24-financial-quality-results.pdf.*

describe ACO and ACO participant level of readiness for each of the following:

++ Hybrid capitation (a combination of capitated and OM payments).

++ Full capitation for primary care services (that could enable ACOs to provide downstream payments to ACO participants).

++ PBPs as a fixed percentage of expected OM claims.

We are interested in understanding what operational changes ACOs would need to undertake to effectively receive, manage, and distribute capitated payments. Please describe any barriers or conditions—legal, financial, or operational—that could affect an organization's readiness to participate in each type of arrangement.

• If an ACO received capitated payments for primary care services furnished by ACO providers/suppliers billing through the TIN of an ACO participant (as defined in § 425.20), what organizational and programmatic goals would the ACO seek to advance with those payments? For example, we are interested in understanding whether ACOs would use capitated payments to expand the scope or capacity of existing care coordination and population health programs, or whether capitated payments would instead enable ACOs to operationalize new care delivery initiatives. Please describe the specific types of initiatives that ACOs would seek to implement, and how ACOs would ensure that these payments went to support primary care practices directly.

Eligibility for Participation

• Should CMS limit access to capitated payment arrangements exclusively to ACOs participating in two-sided risk tracks (BASIC tracks C, D, E or the ENHANCED track), or should all ACOs be eligible to receive some form of capitated payments, regardless of the ACO's participation track? ACOs participating in two-sided risk tracks must establish a repayment mechanism prior to the start of an agreement period, and we are interested in whether similar proof that an ACO could repay losses should be required as a condition for receiving capitated payments, even for ACOs in one-sided risk tracks.

• Should CMS limit capitated payment arrangements to ACOs with prior risk-bearing experience—either through participation in a previous Shared Savings Program agreement period in a two-sided risk track (BASIC tracks C, D, E or the ENHANCED track) or through prior participation in a risk-bearing track in an Innovation Center model, such as ACO REACH—or should risk-bearing ACOs in their first Shared Savings Program agreement period also be eligible to participate in capitated payment arrangements? Why would commenters support one approach over the other? We are interested in whether prior experience with risk-bearing should be an explicit prerequisite for capitated payment eligibility or whether risk-bearing ACOs in their first agreement period should also be eligible to participate in capitated payment arrangements.

• Should CMS permit some, but not all, ACO participants within an ACO to participate in capitated payment arrangements, or should CMS require all ACO participants within an ACO to participate in capitated payment arrangements?

• Should CMS establish a minimum percentage of attributed beneficiaries for whom eligible primary care practices must be furnishing care management services to receive capitated payments, either at the ACO level or at the individual ACO participant level?

• To what extent should the payment design and structure differ based on the level of risk or participation track of an ACO?

Payment Design and Structure

• What percentage of base year OM payments should be replaced by PCC, and what factors should guide this determination? For example, under the ACO REACH model, the PCC payment—including both the base PCC and the enhanced PCC—is set at 7 percent of the REACH ACO's prospective monthly performance year benchmark, a level designed to provide ACOs with a predictable, non-visit-based revenue stream for primary care services.

• What services should be included in primary care capitation (and reciprocally, in a fee reduction) to accurately capture an appropriate scope of primary care services furnished to beneficiaries, balancing the importance of providing up-front flexible payments, with the potential for risk to practices if service utilization grows? For example, under both the ACO REACH and ACO PC Flex models, the set of services eligible for primary care capitated payments is based on a specific list of CPT and HCPCS codes billed by primary care specialists (health care providers with specific specialty codes). In both models, the PCC bundle includes certain E/M office visits along with CCM, behavioral health integration, transitional care management, AWVs, advance care planning, and virtual communication services.

• We are interested in feedback about whether and in what form we should establish an enhanced primary care payment amount—in addition to the base primary care capitated payment amount—as a feature of primary care capitated payment arrangements in the Shared Savings Program. Specifically, we are interested in:

++ Calculation: For example, in ACO REACH, the enhanced primary care payment is calculated as a fixed percentage of the ACO's performance year benchmark, while in ACO PC Flex, the Flex Enhancement component of the primary care payment is calculated as a fixed dollar amount ($125) per eligible beneficiary per year, with additional enhancements (that is, the County Enhancement) derived from county-level or regional spending benchmarks.

++ Reconciliation: In ACO REACH, enhanced primary care capitation (EPCC) is subject to recoupment at the end of the performance year. In ACO PC Flex the enhanced amount is included in total cost of care, subject to offsets from the prior savings adjustment and/or the regional adjustment.

• We are interested in whether CMS should consider offering an advanced payment option (APO) within the Shared Savings Program, similar to the APO offered by the ACO REACH model, to ACOs that have elected PCC. Specifically, we are interested in:

++ Does the availability of an APO enhance an ACO's ability to align specialist financial incentives with the ACO's total cost of care goals, or do the structural and administrative requirements of implementing an APO within the Shared Savings Program present barriers that outweigh the potential benefits?

++ Do Shared Savings Program ACOs have access to sufficient data—shadow bundles, claims data, public use files, and data from arrangements with other payers—to support the development and ongoing administration of an APO? If not, what data would be necessary?

• The ACO REACH model has offered TCC as a payment option for ACOs assuming the highest level of financial risk. The LEAD model also plans to offer TCC as a payment option for ACOs assuming the highest level of financial risk. We are interested in whether CMS should provide a full capitation option to Shared Savings Programs ACOs. Specifically, we seek feedback on:

++ Should CMS consider offering a full capitation option to Shared Savings Program ACOs that have demonstrated readiness to administer prospective payments, under which all Medicare Part A and Part B services furnished to assigned beneficiaries by ACO providers/suppliers billing through the TIN of ACO participants—but not

services furnished to assigned beneficiaries by providers that are not on the ACO's participant list—would be paid through a TCC payment?

++ Should CMS limit full capitation to ACOs in tracks with the highest level of risk—ENHANCED track or BASIC track Level E—on the basis that full capitation should be reserved for ACOs that have already assumed downside financial risk and the organizational readiness to manage prospective payment for Medicare Part A and Part B services?

++ Are there other flexibilities that CMS should give ACOs to make TCC effective?

++ How should CMS calculate the per-beneficiary, per-month payment amount under a full capitation arrangement in the Shared Savings Program? Under ACO REACH, the monthly TCC payment amount paid to the ACO equals 1/12 of the performance year benchmark, adjusted by the TCC withhold.

• Should CMS issue prospective capitated payments on a monthly or quarterly basis? Please describe the potential advantages, disadvantages, and operational implications of each approach.

• Should capitated payments be paid to ACOs and distributed downstream to ACO participants, or should CMS make payments directly to ACO participants that provide primary care services, similar to how CMS makes payments for APCM services, and what are the implications of each approach? Should CMS consider alternative mechanisms for delivering capitated payments directly to ACO Participants that are also primary care practices participating in Shared Savings Program ACOs? If so, what payment design, infrastructure, and policy considerations should guide the development of such alternative payment mechanisms?

• If capitated payments are issued directly to ACOs, should CMS require ACOs to provide a specific percentage of those payments to ACO participants that provide primary care services? How might this be audited? Additionally, should CMS require ACOs to have written capitated payment agreements with ACO participants to specify that a minimum percentage of the capitated payment will flow to ACO participants?

Care Delivery Requirements

• Should CMS require ACOs seeking to participate in capitated payment arrangements to make commitments to specific care delivery goals as a condition for participation? If so, what goals should be required and how should compliance be assessed and enforced? For example, we are interested in whether we should require ACOs to submit a primary care transformation plan—similar to the care delivery requirements under the CPC+ model, which required participating practices to demonstrate progress across five comprehensive primary care functions, including access and continuity, care management, comprehensiveness and coordination, patient and caregiver engagement, and planned care and population health—that specifies measurable targets for care delivery improvements, such as expanding after-hours access, increasing care management for high-risk beneficiaries, or reducing avoidable emergency department utilization.

• How should CMS balance meaningful capitated payment levels with reduced administrative and reporting burdens for participating ACOs, and what primary care delivery requirements should CMS establish as conditions of eligibility for capitated payment arrangements in the Shared Savings Program? Should compliance with any care delivery requirements be monitored on a quarterly or annual basis, with the potential for payment recoupment in cases of noncompliance?

• Should CMS require that ACOs and ACO participants receiving capitated payments demonstrate the use of data-driven risk stratification methods to identify high-risk beneficiaries and target enhanced care management resources toward those beneficiaries? CMS provides Shared Savings Program ACOs with data that could be used for risk stratification, such as claims-based beneficiary data, risk scores, and quality performance reports. We are interested in whether CMS should require ACOs and ACO participants to use these data as a baseline input for their risk stratification methodologies or whether ACOs and ACO participants should be given the flexibility to design their own risk stratification approaches.

• Should care delivery requirements for capitated payment eligibility increase depending on the level/type of capitated payment selected by the ACO or ACO participants? For example, should ACOs that are receiving a higher percentage of capitated payments be subject to more comprehensive care delivery requirements or should a uniform set of care delivery requirements apply to all ACOs, regardless of the percentage of capitated payments they receive?

Comment: Most commenters responding to the RFI on developing prospective payment in the Shared Savings Program were generally supportive of developing primary care capitated payment arrangements within the Shared Savings Program, although views were mixed on design details, ACO readiness, eligibility criteria, payment structure, and mechanisms for ensuring payment adequacy. Commenters encouraged CMS to evaluate an ACO's operational readiness as a criterion to determine whether an ACO is qualified to receive primary care capitated payments and otherwise recommended allowing all risk-bearing ACOs to participate in capitated payment arrangements, without imposing restrictive eligibility criteria or minimum participation thresholds. Commenters provided specific recommendations about payment design, such as: (1) offering primary care capitation similar to the options offered by ACO REACH, along with a CMS-administered hybrid option to provide predictable prospective revenue while retaining a portion of FFS payments; (2) per-member-per-month payments covering care management and preventive services; (3) building on the ACO Primary Care Flex Model; (4) developing FQHC/RHC-specific enhancements and true-up mechanisms, and (5) pairing monthly capitated payments for care-coordination with FFS payments for patient-facing services. To ensure payment adequacy, a few commenters emphasized that any capitated payments must meaningfully increase Medicare's historically inadequate investment in primary care and urged CMS to provide monthly practice and beneficiary-level data, along with technical assistance on cash flow, claims, and reconciliation. One commenter recommended preserving encounter-level FFS claims data to protect attribution, clinician identification, and other essential Shared Savings Program and Innovation Center model functions.

Response: We will consider these comments for future rulemaking.

c. Primary Care Capitated Payment Arrangements Considerations Outside of the Shared Savings Program

Though CMS is first exploring the development of PPCP within the guardrails of accountable care discussed in the third section of this RFI, we are also considering extending these efforts in future years to develop a bundled or capitated approach, called a 'global period' in the broader Original Medicare program (OM). In OM, many services, including surgical and maternity care services, are managed as 'global' periods by OM, where reasonable and necessary medical services are delivered throughout an episode. Primary care, once an initiating visit has occurred,

could also be reimbursed over an interval of care consistent with the development of a trusting, longitudinal relationship between clinician and patient. We have not previously proposed a primary care 'global' period, in part because of the difficulty to ascertain where a primary care relationship starts, and where it stops, through claims data or other information readily obtained by CMS. We do attribute beneficiaries to organizations participating in alternative payment models, such as ACOs in the Medicare Shared Savings Program, based on a plurality of primary care services delivered and also maintain the possibility for beneficiaries to voluntarily align to a Shared Savings Program ACO through Medicare.gov where beneficiaries select a primary care provider.

To establish a primary care global period would require a number of services to be 'bundled' within the primary care global code family, including the IPPE or AWV, O/O E/M services, and care management services such as advanced primary care management services. Central to the challenge inherent in bundling together previously disparate services is ensuring beneficiaries would maintain access to care. CMS could monitor for any potential denials or limitations in care associated with the transition to a global period. We also would like to seek public input on which and how many of the services should be bundled, if they should be bundled entirely or through a 'hybrid' capitation with reduced FFS model, and how best to establish the payment levels for this global period. We seek input on the following:

- What would be the appropriate services to bundle in such a primary care global period (for example, E/M, care management codes, AWV, etc.)? How should the agency consider the benefits and drawbacks regarding quality of care, patient safety, and evidence regarding care delivery changes in a fully or globally capitated approach with no per-visit payment vs. a hybrid payment approach with reduced per-visit payment and per-member per-month payment?
- For both a fully capitated and hybrid payment approach, CMS has in past considered patient complexity (for example, number of chronic conditions or HCC level) in our alternative payment models for primary care. How should CMS approach defining these levels or stratum for payments in a fully capitated or hybrid payment model for primary care? How many levels should be considered?
- In the absence of an encounter, is there another appropriate 'trigger' or initiation for a primary care global period? How long should it last? Is beneficiary receipt of an AWV in the previous 12 months sufficient?
- What necessary reporting requirements and accountability should CMS require for clinicians receiving primary care capitated payments? For example, should there be explicit minimum visit requirements for a clinician to be eligible to receive primary care capitated payments for their Original Medicare patients? Should we require specific clinical outcomes-based reporting? If so, what clinical outcomes should we measure?
- Broadly, to what extent should the approach Original Medicare takes to primary care payment differ between the Shared Savings Program and the broader program? If yes, how?
- In so much as the agency considers a prospective primary care payment (PPCP) for primary care, to what extent should the IPPE/AWV be the initiating visit for that global period? *Comment:* Commenters strongly endorsed the development of a hybrid payment for primary care in the Physician Fee Schedule, and many emphasized the importance of developing a hybrid payment for primary care in the PFS distinct from any action CMS takes on ACO prospective payment. Commenters highlighted that there are many physician services priced in a 'global' period of various numbers of days, however commenters highlighted that hybrid primary care payments, which include both per service (e.g., visit) and global period payments, may require additional steps like attribution to ensure payments are made to the correct entities. Commenters highlighted some services, such as vaccinations, should remain paid on a per service basis, but agreed most services can be priced based on 'typical' monthly utilization. For longitudinal primary care services, many commenters believe these can be priced on the basis of a 'visit fee' and 'typical' monthly care management services expected to be received that can be bundled together. Other commenters specifically highlighted the importance of building on the advanced primary care management (APCM) services as a 'natural starting point' for developing a typical monthly bundle of between-visit care or care management. Other commenters emphasized cost sharing will be a barrier (as it is for APCM) if it persisted in this future care management bundle for a hybrid payment. Commenters suggested that as primary care is undervalued in the Physician Fee Schedule that hybrid payment should increase primary care resources rather than simply bundling together the existing services. Commenters highlighted the importance of 'attribution' for monthly bundled care coordination services to reflect the primary care relationship, and specifically recommended against the monthly payment having a 'trigger' for a specific visit. Further, commenters emphasized the importance of administrative simplification to reduce clinician burden.

Response: We will consider these comments for future rulemaking.

F. Comprehensive Outpatient Rehabilitation Facility (CORF) Services and KX Modifier Threshold, and Medical Review Threshold

1. Technical Corrections of CORF Regulations

During rulemaking for CY 2008 (72 FR 66399), we made several regulation text revisions and redesignations at § 410.100 without changing a related regulatory provision of § 410.105 for the requirements for coverage of CORF services. We also created a new subpart M at 42 CFR 414.1105 for payment of CORF items and services that includes references to § 410.100 without making the corresponding revisions to the sections that were amended during CY 2008 PFS rulemaking.

We proposed to revise § 410.105(b)(3)(ii) for the home environment evaluation to indicate that the home environment evaluation is specified at § 410.100(l) and not § 410.100(m) as it currently reads.

We proposed to amend the regulation at § 414.1105(c) for CORF supplies and durable medical equipment to indicate that the supplies and durable medical equipment that are CORF services is specified at § 410.100(k) instead of § 410.100(l), as it currently reads. At the same time, we also proposed to remove from § 414.1105(c) language that relates to CORF drugs and biologicals because the provisions relating to payment for drugs and biologicals that are CORF services are at § 414.1105(d), which was added in the CY 2008 PFS final rule.

We requested comments on these proposals.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

2. KX Modifier Thresholds

The KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) (BBA) and were formerly referred to as the therapy cap amounts. These per-beneficiary

amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the percentage increase in the Medicare Economic Index (MEI). Specifically, these amounts are calculated by updating the previous year's amount by the percentage increase in the MEI for the upcoming calendar year and rounding to the nearest $10.00. Thus, for CY 2027, we proposed to increase the CY 2026 KX modifier threshold amount by the most recent forecast of the 2017-based MEI. For CY 2027, the proposed MEI increase was estimated to be 2.5 percent and was based on the expected historical percentage increase of the 2017-based MEI. We also proposed to update the MEI increase for CY 2027 based on historical data through the second quarter of 2026, and we proposed to use such data, if appropriate, to determine the final MEI percentage increase and the CY 2027 KX modifier threshold amounts in the CY 2027 PFS final rule.

Section 1833(g)(7)(B) of the Act describes the targeted medical review (MR) process for services of physical therapy, speech-language pathology, and occupational therapy services. The threshold for targeted MR is $3,000 through CY 2027. Effective beginning with CY 2028, the MR threshold levels will be annually updated by the percentage increase in the MEI, per section 1833(g)(7)(B) of the Act. Consequently, for CY 2027, the MR threshold is $3,000 for physical therapy and speech-language pathology services combined and $3,000 for occupational therapy services. Section 1833(g)(5)(E) of the Act states that CMS shall identify and conduct targeted medical review using factors that may include the following:

- The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.
- The therapy provider has a billing pattern for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.
- The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.
- The services are furnished to treat a type of medical condition.
- The therapy provider is part of a group that includes another therapy provider identified using the factors described previously in this section.

We track each beneficiary's incurred expenses for therapy services annually and count them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable multiple procedure payment reduction (MPPR) amount for services of CMS-designated ''always therapy'' services (see the CY 2011 PFS final rule at 75 FR 73236). We also track therapy services furnished by critical access hospitals (CAHs), applying the same PFS-rate accrual process, even though they are not paid for their therapy services under the PFS and may be paid on a cost basis (effective January 1, 2014) (see the CY 2014 PFS final rule at 78 FR 74406 through 74410).

When the beneficiary's incurred expenses for the year for outpatient therapy services exceed one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. Using the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services exceeding the KX modifier thresholds without the KX modifier included are denied.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for the proposal to increase the therapy threshold to $2,540 for physical therapy and speech-language pathology services combined, and to establish a separate $2,540 threshold for occupational therapy. They also supported increasing the targeted medical review threshold to $3,000, stating that these updates better reflect the current health care environment while maintaining appropriate program integrity safeguards.

Response: We appreciate the commenters' support for the increase to the KX modifier threshold amounts based on the CY 2027 MEI update. We also want to clarify that the targeted medical review threshold has been $3,000 since CY 2018 and that it will be increased annually by the percentage increase in the MEI effective January 1, 2028.

After consideration of public comments, we are finalizing the CY 2027 increase to the KX modifier threshold amount based on the most recent percentage increase in the 2017-based MEI reflecting historical data through the second quarter of 2026 of 2.6 percent. Therefore, for CY 2027, multiplying the CY 2026 KX modifier threshold amount of $2,480 by the final CY 2027 percentage increase in the MEI of 2.6 percent ($2,480 × 1.026) and rounding to the nearest $10.00 results in a final CY 2027 KX modifier threshold amount of $2,540 for physical therapy and speech-language pathology services combined and $2,540 for occupational therapy services.

G. Supporting Beneficiaries Planning for Future Medical Decisions

1. Advance Care Planning (ACP) Services (HCPCS Codes G0572 and G0573)

a. Background

Medicare currently pays for ACP services as an optional element of the annual wellness visit (AWV) or a Part B medically necessary service (see 80 FR 70955 and *https://www.cms.gov/files/document/mln-advanced-care-planning.pdf*). While the Social Security Act covered a similar service as a voluntary part of the initial preventive physical exam under section 1861(ww)(3) of the Act since CY 2012, in CY 2016 we adopted new coding developed by the American Medical Association for payment of ACP services as a separate Part B medically necessary service or an optional element of the annual wellness visit (AWV). In the proposed rule, we proposed to create additional codes in this family that more explicitly describe and value the contributions of clinical staff in the provision of ACP services. We emphasized, and reiterate here, that clinicians must not, under any circumstances, attempt to influence their patients' decisions for ACP.

For CY 2015, the CPT Editorial Panel created two new codes describing ACP services by physicians and other qualified healthcare professionals (QHPs): CPT code 99497 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate*) and an add-on code, CPT code 99498 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; each additional 30 minutes (List separately in addition to code for primary procedure))* (80 FR 70955).

In the CY 2015 PFS final rule with comment period (79 FR 67670), we assigned a PFS interim final status indicator of ''I'' (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services. This code is not subject to a 90-day grace period.) to CPT codes 99497 and 99498. We had received many public comments in response to the CY 2015 proposed rule recommending that we recognize and make separate payment for both CPT codes, in view of the time required to furnish the services and their importance for the quality of care and treatment of the patient. In the CY 2015 PFS final rule with comment period we responded that we would consider paying for CPT codes 99497 and 99498 after we had the opportunity to go through notice and comment rulemaking (80 FR 70955).

The following year, in the CY 2016 PFS final rule, we finalized our proposal to assign CPT codes 99497 and 99498 a PFS status indicator of ''A'' (Active) with RVUs based on the RUC recommended values. We adopted the RUC-recommended work RVU, physician time and direct PE inputs: 1.5 work RVUs and 1.4 work RVUs for CPT codes 99497 and 99498, respectively. We also added ACP as an optional element, at the beneficiary's discretion, of the AWV and made conforming changes to our regulations at § 410.15 that describe the conditions for and limitations on coverage for the AWV (80 FR 70959). In addition to adopting both CPT codes, we adopted CPT provisions regarding the reporting of timed services (80 FR 70956). We have also instructed practitioners that when reporting ACP as part of managing a beneficiary's illness, the condition discussed with the beneficiary is reported on the claim, whether or not an E/M visit is billed the same day (*https://www.cms.gov/files/document/mln-advanced-care-planning.pdf*). When ACP services are part of an AWV and furnished on the same day by the same practitioner as the AWV, an administrative exam or exam diagnosis is reported along with modifier 33 indicating the ACP services are preventive and not subject to cost sharing (*https://www.cms.gov/files/document/mln-advanced-care-planning.pdf*). In the CY 2016 PFS final rule, we also adopted CPT's coding guidance for ACP performed in conjunction with an E/M visit. CPT prefatory language indicates that when using CPT codes 99497 and 99498, no active management of the problem(s) is undertaken during the time period reported, and these codes may be reported separately if performed on the same day as most E/M visits.[123] We cited a clinical vignette from the RUC recommendations, illustrating when the services described by CPT codes 99497 and 99498 could be reasonable and necessary for the diagnosis or treatment of illness or injury, stating that this could occur in conjunction with the management or treatment of a patient's current condition, such as a 68 year old male with heart failure and diabetes on multiple medications seen by his physician for the E/M of these two diseases, including adjusting medications as appropriate (80 FR 70955). In addition to discussing the patient's short-term treatment options, the patient might express interest in discussing long-term treatment options and planning, such as the possibility of a heart transplant if his congestive heart failure worsens, and advance care planning including the patient's desire for care and treatment if the patient suffers a health event that adversely affects the patient's decision-making capacity (80 FR 70956). In this case the physician would report a standard E/M CPT code for the E/M service and one or both of the CPT codes describing ACP, depending upon the duration of the ACP service (80 FR 70956). Moreover, the ACP service would not necessarily have to occur on the same day as the E/M service (80 FR 70956).

The CPT Codebook published by the American Medical Association contains prefatory language that describes CPT codes 99497 and 99498 as a ''face-to-face service between a physician or other qualified health care professional and a patient, family member, or surrogate in counseling and discussing advance directives, with or without completing relevant legal forms.'' [124] While this code descriptor language indicates that the time being billed is personally spent by the physician/QHP and the codes are valued accordingly, we finalized a provision in the CY 2016 PFS final rule that allowed the time of clinical staff to be counted if the billing physician or other billing practitioner managed, participated and meaningfully contributed to the provision of the services, because public commenters persuaded us that ACP was performed at times by a team of a treating physician or other treating practitioner and their staff. Therefore, in the CY 2016 PFS final rule (80 FR 70957), we stated that we believed the services described by CPT codes 99497 and 99498 could be appropriately provided by physicians or using a team-based approach where ACP would be provided by physicians, non-physician practitioners (NPPs), and other staff under the order and medical management of the beneficiary's treating physician or treating practitioner. To provide clarity on who could report the new codes, we noted that the CPT code descriptors described the services as furnished by physicians or other qualified health professionals, which for Medicare purposes, has been consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore, we finalized that only these practitioners may report CPT codes 99497 and 99498, and ''incident to'' rules in § 410.26 would apply when these services would be provided incident to the services of the billing practitioner under a minimum of direct supervision. We stated that we expected the billing physician or NPP, in addition to providing a minimum of direct supervision, to manage, participate and meaningfully contribute to the provision of the services. Also, we noted that PFS payment rules would apply when ACP is furnished incident to other physicians' services, including where applicable, that State law and scope of practice must be met (80 FR 70959). Accordingly, even though CPT codes 99497 and 99498 describe (and are valued as) services performed only by the billing practitioner, we finalized a policy allowing the time of clinical staff to be included since we did not have G codes at that time that would have provided coding specific to that situation.

b. Updates for CY 2027

Since 2016, we have heard from interested parties that ACP services may be under-utilized because some practitioners believe that only time they personally spend can count. While growth in ACP services utilization has been increasing, interested parties have communicated to CMS that the increase in utilization is not commensurate with the need for ACP services. Utilization of ACP services has increased since 2016 from about 650,000 services to about 2.5 million per year in 2025. We note that for patients in critical care, advance care planning is bundled into payment for the critical care service codes (CPT codes 99291–2) and is therefore not separately billed, so these patients may receive ACP services that is not

[123] Current Procedural Terminology, (CPT®) 2026 (CPT Codebook), Professional Edition, American Medical Association, page 61.

[124] CPT Codebook 2026, AMA, page 61.

identifiable in the claims data. We believe that new coding could more accurately distinguish and value the work of the billing practitioners from time that is spent by their clinical staff in the provision of ACP services. Therefore, we proposed to create two new HCPCS codes to describe ACP services furnished by clinical staff under the direct supervision of the billing physician or other practitioner (and incidental to their professional services), and proposed that the existing CPT codes 99497 and 99498 would only be used to report time personally spent by the billing practitioner. The new codes would be: HCPCS G-code GACP1 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), first 20 minutes of clinical staff time with the patient, family member(s), surrogate directed by a treating physician or other treating qualified health care professional) and* GACP2 *(Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), each additional 20 minutes with the patient, family member(s),* surrogate *directed by a treating physician or other treating qualified health care professional (List separately in addition to code for primary procedure)).*

We proposed a work RVU of 1.00 for HCPCS code GACP1, based on a crosswalk to the work time of CPT code 99490 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*). For direct PE, we proposed 20 minutes of clinical labor (L037D) in the service period. We proposed a work RVU of 0.7 for HCPCS code GACP2, based on a crosswalk to the work time of CPT code 99439 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)).* For direct PE, we proposed 20 minutes of clinical labor (L037D) in the service period.

As proposed, the new G codes and CPT codes 99497 and 99498 could be reported together, if time thresholds by the billing practitioner and clinical staff were each met with these respective code sets. We sought public comment on whether it would be better for the new G codes to represent, and be valued for, the combined time of a billing practitioner and their clinical staff within a single code, in case, for example, the billing practitioner and staff did not meet time thresholds for separate reporting of their respective times, but might meet the threshold for a code combining their time. For both the existing codes (describing physician time but allowing use for clinical staff time, as discussed previously) and new ACP codes (describing clinical staff time) to be paid ''incident to,'' the reporting practitioner must furnish a prior professional service to which the services of the clinical staff are incidental, such as a prior E/M visit or ACP services personally performed by the billing practitioner the same day. Our manual provides that ''[s]uch a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment'' (Medicare Benefit Policy Manual, Chapter 15, Section. 60.1.B, available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf*).

We received many public comments on our proposal to create two new HCPCS codes to describe ACP services furnished by clinical staff under the direct supervision of the billing physician or other practitioner (and incident to their professional services). We thank all public commenters, including those who responded in depth about their typical clinical practice and team structure. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the proposal to create two new HCPCS codes to describe ACP services furnished by clinical staff. However, many recommended that we reconsider the supervision level. Many favored allowing payments for ACP services furnished under general supervision. Some of the commenters who recommended general supervision recommended direct supervision by audio visual technology in lieu of general supervision. Some commenters wrote that there are rural areas where audio visual technology is not reliable. Several commenters opposed the new coding noting that currently, our policy permits counting clinical staff time in reporting ACP services if the billing practitioner managed, participated and meaningfully contributed to the provision of the service. They stated concern that the new coding could increase documentation and billing burden and potentially discourage collaborative ACP workflows. A commenter surmised that the primary challenge appeared to be provider awareness and understanding of existing billing guidance rather than a deficiency in the current code structure.

Response: We are finalizing HCPCS code G0572, formerly GACP1, (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), first 20 minutes of clinical staff time with the patient, family member(s), surrogate directed by a treating physician or other treating qualified health care professional)* as proposed. We are making a technical correction to and finalizing HCPCS G-code G0573, formerly GACP2, *(Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), each additional 20 minutes of clinical staff time with the patient, family member(s), surrogate directed by a treating physician or other treating qualified health care professional (List separately in addition to code for primary procedure))* by inserting '*of clinical staff time'* after ''*minutes*''. This technical correction is for clarity and consistency with HCPCS code G0572. At the outset, we acknowledge that there is room to increase provider awareness and understanding of existing billing guidance. To that end we will update our Advance Care Planning MLN Fact Sheet in the near future. We reiterate here, as we did in the proposed rule, that direct supervision may be satisfied by use of audio-visual technology. While we acknowledge the limitations of audio visual technology in rural areas addressing those limitations is beyond the scope of this rule. We are persuaded

by commenters that the proposed coding better recognizes their team structures and clinical practices.

Comment: Most commenters supported the proposal that the new G codes and CPT codes 99497 and 99498 could be reported together, if time thresholds by the billing practitioner and clinical staff were each met with these respective code sets.

Response: We are finalizing the proposal that HCPCS codes G0572 and G0573 and CPT codes 99497 and 99498 could be reported together, if time thresholds by the billing practitioner and clinical staff are each met with these respective code sets. Additionally, when counting time for HCPCS codes G0572 and G0573, we are also permitting the counting of practitioner time in combination with clinical staff time to meet the time threshold if clinical staff time otherwise would not meet the time threshold to report the code.

We sought clarity from interested parties about whether ''incident to'' criteria (the requirement for the billing practitioner to perform initial and subsequent services reflecting their participation in and management of the course of treatment) are typically met for beneficiaries needing ACP services, by a separately billed E/M visit (whether the same day as the ACP services or prior), or might best be included in a new code inclusive of combined time spent by both a reporting practitioner and their clinical staff. If the billing practitioner is by definition participating and managing by performing part of the ACP code itself, there would not be a need to require a prior initiating visit as we do for care management services provided ''incident to.'' To help us craft new coding in a manner that reflects typical clinical practice as well as ''incident to'' rules governing payment for services by clinical staff, we sought public comments that specify or clarify for the alternative new coding, the typical care team structure; how much time is typically spent by the billing practitioner and spent by their staff, and when; and the clinical circumstances of patients, for example, the care settings and whether the patient is typically a well patient or is doing advance care planning in conjunction with a particular illness. This would inform how the coding structure reflects work that is personally performed by the billing practitioner in conjunction with ACP.

We received many public comments on these ''incident to'' requirements and possible alternative coding. The following is a summary of the comments we received and our responses.

Comment: Many commenters noted a lack of clarity about 'incident to' requirements as applied to ACP services. Some recommended that we incorporate clinical staff training requirements into the code descriptors. Some took the opportunity to advocate for general supervision analogizing ACP services and their delivery to care management coding. Some requested that we do not finalize a same-day E/M or other unnecessary initiating-visit requirement. Others asked whether the new ACP clinical staff coding could be reported in institutional settings such as skilled nursing facilities and nursing facilities.

Response: First, it is important to note that ACP services are not care management services. ACP services, as a voluntary component of a Part B annual wellness visit, can be described as a preventive benefit under Medicare benefit categories. As such, AWV services may not be furnished 'incident to' the services of a physician's professional services. These are two distinct Medicare benefit categories. Furthermore, the Social Security Act § 1861(hhh)(3) specifies limited types of ''health professionals'' who may furnish AWV services. The health professionals included in this definition are codified at § 410.15, Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage. As physician services, ACP services are required to be reasonable and necessary for the diagnosis or treatment of illness or injury. As physician services, ACP services may be furnished 'incident to' the services of a physician. In part relevant to commenter's recommendations about qualifications, § 410.26, Services and supplies incident to a physician's professional services: Conditions, provides for the qualifications of auxiliary personnel who can provide services incident to a physician's professional services by deferring to States, noting in part that auxiliary personnel means an individual who ''meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.'' As such, we are not prescribing qualifications for clinical staff who may furnish ACP services. Section 410.26 also generally requires incident to services under the direct supervision of the physician or other practitioner, except specifically for designated care management services and behavioral health services.

Second, as physician services, ACP services are required to be reasonable and necessary for the diagnosis or treatment of illness or injury. As such, we have stated that ACP services occur in conjunction with the management or treatment of a patient's condition. While we have not stated that an initial visit is required for ACP services, a prior visit for the patient's diagnosis or treatment is presumed. However, we have also stated that while an ACP service is furnished in conjunction with the management or treatment of a patient's condition the ACP service does not have to occur on the same day as the E/M service (80 FR 70956). We did not propose and are not finalizing otherwise. As for reporting in institutional settings, consolidated billing rules apply to services furnished by clinical staff in institutional settings.

Comment: Some commenters stated a desire for alternative coding that would be additional and optional and would allow combining time spent by both a reporting practitioner and their clinical staff. They desired this option to meet time thresholds or comport with their existing clinical and billing practice.

Response: At this time, we are not finalizing additional coding that would combine time spent by billing practitioners and their clinical staff. Many commenters stated that the additional combined coding would create confusion and administrative burden. We note that we will apply CPT provisions regarding the reporting of timed services to HCPCS code G0572 that we have previously adopted for existing ACP services (80 FR 70956). We also note that HCPCS code G0573 can be reported once the full 20 minutes of clinical staff time or clinical staff time plus practitioner time has been spent under G0572.

Comment: Most commenters described ACP services as team-based and led by physicians and other practitioners, with clinical staff continuing the services under supervision. Nearly all commenters stated concern about documentation burden and requested guidance.

Response: Consistent with existing documentation requirements, billing practitioners should ensure that for timed services, they should include sufficient notes in the medical record to support the time spent furnishing the service that would permit correct billing of timed services. The time counted for reporting one service code must not also be counted to meet the time requirements of another service code being reported.

Finally, for CY 2027 we are finalizing the addition of both HCPCS codes

G0572 and G0573 to the Medicare Telehealth list.

2. Request for Information (RFI) on Community-Based Palliative Care

a. Background

In the FY 2027 Hospice proposed rule, we solicited comment on the development of community-based palliative services outside of the hospice benefit (90 FR 17360). By community-based palliative care, we are broadly considering where palliative services can be delivered outside of the hospital, in outpatient clinics, in patients' homes, and other non-hospital settings. In this request for information we sought feedback on whether current evaluation and management (E/M) services, care management services, and ACP services reflected current billing and payment practices for physicians and other health professionals delivering palliative services, as well as on whether challenges in meeting documentation requirements, issues with compliance, or enhancements to current services could be considered to better enhance palliative care service delivery. In addition, in the 2027 ESRD proposed rule, concurrently, we are requesting information to advance payment policy and better understand the differences between maintenance dialysis and dialysis delivered in a comfort-focused context. Comments regarding either of these subjects are best delivered to their respective rules.

In coordination with these requests for information, we are additionally seeking comment on the specific requirements we should consider given the prior CMS Innovation Center model tests focused on complex and serious illness care. The evaluation findings from these prior tests are best summarized in the CMS Innovation Center white paper on '*Palliative care projects: Synthesis of Evaluation Results 2012–2021'*.[125] These results indicate that a comprehensive approach to palliative care services, including access to interdisciplinary teams, home visits, and shared-decision-making may improve care for Medicare beneficiaries.

We continue to prioritize reducing fraud, waste, and abuse throughout CMS programs, and have prioritized reducing fraud, waste, and abuse in hospice programs. While hospice care is not palliative care, in related disciplines and sites of care we are very interested in how to better address fraud, waste, and abuse.

Where should CMS focus on potential fraud, waste, and abuse in community-based palliative care? Please support your statements with peer-reviewed evidence or evidence from your institution with sufficient detail for review.

b. Eligibility for Serious Illness Care

Defining which beneficiaries are eligible for serious illness care is a principal challenge in palliative and supportive care. While many Medicare beneficiaries may benefit from additional supportive care to manage pain and symptom burden, understanding which beneficiaries should be eligible for this service is of central importance to Medicare. For example, complex chronic care management services require two or more chronic conditions placing the beneficiary at high risk for hospitalization, decline, or death, and requires moderate to high complexity medical decision-making. To elect the Medicare Hospice Benefit, two or more physicians must certify a beneficiary is within 6 months to the end of their life (or, if a beneficiary does not have an attending physician, then the hospice physician alone is permitted to provide the certification).

We are requesting feedback on eligibility and care management services, and for all comments please support your statements with peer-reviewed evidence or evidence from your institution (in sufficient detail for review):

- For any future supportive or palliative care service for Medicare beneficiaries, should eligibility be restricted to certification of a likely life expectancy duration?
- If eligibility is restricted to those beneficiaries with a terminal prognosis, is there evidence to suggest a reasonable interval (that is, less than 1 year of life expectancy as in some States' Medicaid programs)?

c. Eligibility for Palliative Services

Defining eligibility for palliative services beyond the potential criterion of a terminal prognosis is likely necessary to better understand who is eligible for serious illness care.[126] While for complex care management services we restrict eligibility to beneficiaries requiring moderate to complex medical decision making as well as a count of chronic conditions, common definitions of serious illness include not just chronic condition counts but also indicators of the impact on a person's daily function or excessive caregiver strain.[127]

We are requesting feedback on the following:

- For any future supportive or palliative care service for Medicare beneficiaries, how could we consider impact on the daily functions of life or activities of daily living as part of who is eligible for the service?
- Would eligibility best be based on impact on daily function, on caregiver strain, or both?
- How can we avoid overly burdensome requirements for defining eligibility for services?

d. The Future of the Care Management Services

In section II.E. of this proposed rule, we are explicitly reconsidering the future of the care management services that form the basis for payment adequacy for important between visit care (in addition to E/M services for outpatient or home visits). Care for the seriously ill involves interdisciplinary care teams and involves even greater coordination and between visit care than primary care services.[128]

We are requesting feedback on the following:

- How should we differentiate the care management requirements for seriously ill beneficiaries from other Medicare beneficiaries?
- What are the essential service elements that must be included? For example(s), continuity with a designated team member, access to timely clinical support, comprehensive symptom and caregiver assessment, electronic care plans, coordination with treating physicians, patient/caregiver education, timely follow up after ED/discharge. What other service elements should be included? Should any not be included?

e. Advanced Primary Care Management

Currently, for Advanced Primary Care Management (APCM) services (HCPCS codes G0556 through G0558), we require physicians to report to the MIPS Value Pathway for primary care as part of our safeguards for high quality primary care. If we elect to develop additional care management services for seriously ill beneficiaries, however we

[125] *https://www.cms.gov/priorities/innovation/data-and-reports/2022/palliative-care-synthesis-2012-2021.*

[126] Kelley AS, Covinsky KE, Gorges RJ, McKendrick K, Bollens-Lund E, Morrison RS, Ritchie CS. Identifying Older Adults with Serious Illness: A Critical Step toward Improving the Value of Health Care. Health Serv Res. 2017 Feb;52(1):113–131. doi: 10.1111/1475–6773.12479. Epub 2016 Mar 18. PMID: 26990009; PMCID: PMC5264106.

[127] *https://pmc.ncbi.nlm.nih.gov/articles/PMC5756466/pdf/jpm.2017.0548.pdf.*

[128] *https://www.capc.org/toolkits/building-and-supporting-effective-palliative-care-teams/.*

may define serious illness in the future, determining how best to report quality of care safeguards will be essential to ensure high quality care delivery.

We are requesting feedback on the following:

- Should care management services for seriously ill beneficiaries also require reporting to a MIPS Value Pathway? Which quality measures should be reasonably included?
- If no viable MIPS Value Pathway reporting mechanism is found, what are the essential quality elements required for palliative care management? Is sole reporting of ambulatory palliative care patients feeling heard and understood (CBE 3665) sufficient? Should other measures be considered?

Comment: Commenters broadly supported the development of community-based palliative services in Original Medicare. Commenters also noted concern about establishing prognosis as an eligibility criterion, given the clinical uncertainty of prognosis, and reasoned instead for the use of criteria to define serious illness needs such as symptom burden, functional decline/frailty, cognitive impairment, complex care needs, utilization, and/or caregiver strain. Commenters emphasized the importance of defining palliative care services for beneficiaries *prior to* hospice election while beneficiaries continue curative or disease-modifying treatment. Commenters suggest any future community palliative services in the PFS support interdisciplinary team-based care and recognize intensive longitudinal and between-visit work, highlighting the inadequacy of current E/M payments and the existing care management codes. Commenters differed on whether home-based capabilities should be required for community palliative services. For quality measurement, commenters emphasized addressing 'what matters' rather than focusing on documentation, and 'what matters' according to commenters is goal-concordant care, symptom management, caregiver experience/support, days at home and fewer hospitalizations. While commenters acknowledge our important actions to safeguard against fraud, waste, and abuse in hospice, they emphasize that these concerns may be less prominent in defining potential future community-based palliative services in the Physician Fee Schedule.

Response: We will use these comments to advise future rulemaking.

3. Request for Information on Intensive Lifestyle Interventions To Slow Progression of Alzheimer's Disease

a. Background

In the CY 2026 Physician Fee Schedule proposed rule, CMS sought comment in a 'Prevention and Management of Chronic Disease' Request for Information (90 FR 32507), addressing management and self-management of chronic disease, services that address root causes of disease, social isolation and loneliness, improving physical activity, intensive lifestyle interventions, enhancing uptake of the annual wellness visit (AWV), supporting partnerships with AAAs and community care hubs, and addressing motivational interviewing and health coaching. For some topics, responses were of adequate depth for CMS to consider further action, addressed elsewhere in this rule, but as is not uncommon when CMS requests information across a broad range of topics, in other areas responses were limited in the depth and granularity necessary for CMS to address the resource costs to establish coding and payment options. Because of the overwhelming priority for CMS to support the aging processes, given that American older adults commonly cite their fear of Alzheimer's as an even greater health related fear than the development of cancer,[129] and the growing evidence base for using lifestyle changes to slow the progression of cognitive decline and the development of Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD), CMS is requesting additional information to better understand the resource costs and requirements for developing intensive lifestyle interventions to reduce the risk of AD/ADRD for Medicare beneficiaries. Intensive lifestyle interventions would be in concert with but would not specifically include risk factor reduction in modifiable behaviors such as controlling contributing conditions (for example, hypertension, diabetes), eliminating tobacco use (in any form), and addressing hearing loss.[130] In other countries, there is randomized controlled trial evidence that multi-domain approaches can slow cognitive decline amongst at-risk older adults,[131] which appear to be superior to individual domain interventions such as physical activity programming or diet changes.[132] In the U.S. there have also been a number of studies demonstrating the potential impact of diet changes on cognition (for example, the MIND trial demonstrated improved cognition for both groups undergoing diet changes, however one diet was not shown to be superior).[12 13 14 133] To support high-value care, the payer assuming financial risk for an individual's health would do so over a long-term to give that payer an incentive to invest in high-value care that reduces health care costs over that long-term. As discussed in the recent HHS Notice of Benefit and Payment Parameters for 2027,[134] creating these incentives for payers throughout the healthcare system is an HHS priority. Outside of these needed incentives exists Medicare fee-for-service, which has historically employed price-setting regimes that are not market-based and are slow to change with improvements and health innovations. As HHS continues to improve incentives for private payers to invest in preventive health care, we are interested in how to ensure fee-for-service Medicare is similarly able to benefit from better incentives to invest in high-value care.

To better understand resource costs associated with intensive, multi-domain interventions:

- Given the discussion of the evidence to date on the effectiveness of intensive lifestyle interventions for CMS to pursue, we are particularly interested in demonstrations of cost-savings associated with these and other interventions. Please cite any evidence available in your discussion.
- Given CMS' concern for addressing fraud, waste, and abuse throughout the Medicare program, please comment on any potential or observed FWA in

[129] Ornish, Dean, et al. ''Effects of Intensive Lifestyle Changes on the Progression of Mild Cognitive Impairment or Early Dementia Due to Alzheimer's Disease: A Randomized, Controlled Clinical Trial.'' *Alzheimer's Research & Therapy,* vol. 16, 2024, p. 122. *https://link.springer.com/article/10.1186/s13195-024-01482-z.*

[130] National Institute on Aging. ''*Cognitive Health and Older Adults.*'' National Institutes of Health, *https://www.nia.nih.gov/health/brain-health/cognitive-health-and-older-adults.* Accessed 30 Apr. 2026.

[131] Ngandu, Tiia, et al. ''*A 2 Year Multidomain Intervention of Diet, Exercise, Cognitive Training, and Vascular Risk Monitoring versus Control to Prevent Cognitive Decline in At-Risk Elderly People (FINGER): A Randomised Controlled Trial.*'' *The Lancet,* vol. 385, no. 9984, 2015, pp. 2255–2263. *https://doi.org/10.1016/S0140-6736(15)60461-5.*

[132] ''2024 Lancet Commission Underscores the Potential for Dementia Risk Reduction, Identifying 14 Modifiable Risk Factors across the Life Course.'' *Alzheimer Europe,* 31 July 2024, *https://www.alzheimer-europe.org/news/2024-lancet-commission-underscores-potential-dementia-risk-reduction-identifying-14-modifiable.*

[133] Barnes, Lisa L., et al. ''*Trial of the MIND Diet for Prevention of Cognitive Decline in Older Persons.*'' *The New England Journal of Medicine,* vol. 389, no. 7, 2023, pp. 602–611. *https://www.nejm.org/doi/10.1056/NEJMoa2302368.*

[134] *https://www.govinfo.gov/content/pkg/FR-2026-05-20/pdf/2026-10050.pdf.*

diagnosis, treatment, or management of AD/ADRD.

- Given the emerging role of biomarker diagnostic testing (for example, p-tau217, et al.) for AD/ADRD leading to early diagnosis, please provide any evidence supporting earlier detection and its role in supporting improving AD/ADRD care and any potential role in identifying eligibility for an intensive lifestyle intervention focused on AD/ADRD.
- What are the essential domains to address in a multi-domain intensive lifestyle intervention to reduce the risk of cognitive decline for older adults at risk for developing AD/ADRD that would be appropriate to include under Medicare?
- Should these interventions be made available as a one-time service (that is, to teach older adults how to make changes in their lifestyle to help reduce AD/ADRD risk) or on a recurring (for example, annual) basis?
- Should the eligibility for these services be restricted to beneficiaries with a diagnosis of mild cognitive impairment (MCI), or early-stage dementia? If so, how should this diagnosis be made or confirmed?

Respondents to the general intensive lifestyle intervention question in the prior RFI focused on the differentiation between intensive lifestyle interventions (ILIs) and intensive behavioral therapy (IBT) where ILIs are more multi-domain, longitudinal, and comprehensive and typically incorporate a multi-disciplinary team and are delivered in a community setting, and noting these are needed flexibilities that current IBT coding does not currently accommodate. To better understand the resource costs and requirements for future AD/ADRD ILI services:

- Given ILI's are multi-domain, and likely include physical activity, nutrition, potentially additional domains such as sleep and stress management, who are the essential interdisciplinary team members that CMS should account for in developing appropriate resource costs for future services?
- How should supervision be determined for AD/ADRD ILI's? Is general supervision sufficient for ensuring clinical safety and oversight? Is direct supervision required?

While there are many variations of ILI's focusing on AD/ADRD that are delivered, the essential 'dose' of intervention or minimum frequency and duration of a future service, as well as the modality (that is, must this intervention be delivered purely in person, can it be delivered virtually) are all important to consider:

- What is the minimum frequency of sessions for an AD/ADRD ILI per week? What is the minimum number of weeks that will be necessary?
- Should CMS require a future AD/ADRD ILI to be delivered in person? Can it be delivered virtually?

Finally, while we are currently accepting applications for a CMS Innovation Center payment model to generate evidence associated with lifestyle interventions (MAHA ELEVATE),[135] including potentially intensive lifestyle interventions focused on reducing risk and/or slowing progression of AD/ADRD, currently CMS has no endorsement process for specific interventions. In development of the CMS Health Technology Ecosystem[136] and the library of applications:

- How should CMS support the development of our Health Technology Ecosystem to support older adults reducing their risk for developing AD/ADRD using intensive lifestyle changes?

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

We received public comments in response to this request for information.

Comment: Commenters generally view the evidence on intensive lifestyle interventions as a promising opportunity to continue to develop potential PFS services, and recommend focusing interventions early in the disease trajectory, such as for beneficiaries with mild cognitive impairment (MCI) or early-stage Alzheimer's Disease (ADRD) and where cognitive decline is identified through a validated assessment. Commenters endorse the use of a multi-domain model (versus a single-intervention) in the design of future intensive lifestyle intervention services, and many commenters recommended domains such as physical activity, nutrition, cardiovascular and other chronic disease management, and social engagement and provided mixed responses on sleep and stress management. Many commenters also recommend a structured, longitudinal intervention, using flexible, team-based services (including hybrid and virtual services) which may be furnished with other existing dementia services. For biomarker testing, commenters were mixed on the role of biomarker testing and emphasized it may be one component to early ADRD detection and diagnostic confirmation but cautioned against unvalidated or unnecessary biomarker testing.

Response: We will consider this for potential future rulemaking.

H. Current Procedural Terminology (CPT) Request for Information (RFI)

The Current Procedural Terminology (CPT®) coding system is owned and copyrighted by the American Medical Association (AMA) and CMS uses CPT® under a royalty-free licensing agreement with the AMA.[137] The CPT® coding system was introduced by the AMA in 1966,[138] in part to ''encourage the use of standard terms and descriptors to document procedures in the medical record'' and ''help communicate accurate information on procedures and services to agencies concerned with insurance claims,'' and it ''provided the basis for a computer oriented system to evaluate operative procedures and contributed basic information for actuarial and statistical purposes.''[139] The CPT® coding system went through a series of early version changes and in 1977 the AMA established the CPT–4 or 4th edition which established the current five-digit numeric structure of the CPT® coding system still used

[135] Centers for Medicare & Medicaid Services. ''*MAHA ELEVATE (Make America Healthy Again: Enhancing Lifestyle and Evaluating Value-Based Approaches Through Evidence) Model.*'' *CMS.gov*, 2026, *https://www.cms.gov/priorities/innovation/innovation-models/maha-elevate.*

[136] Centers for Medicare & Medicaid Services. ''*Health Technology Ecosystem.*'' *CMS.gov, https://www.cms.gov/priorities/health-technology-ecosystem/overview.* Accessed 30 Apr. 2026.

[137] Centers for Medicare & Medicaid Services. *AMA Terms and Conditions.* Centers for Medicare & Medicaid Services, n.d., *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/AMA-Terms-Conditions.pdf.*

[138] American Medical Association. *History of CPT® Content.* American Medical Association, 5 Dec. 2025, *https://www.ama-assn.org/practice-management/cpt/history-cpt-content.*

[139] American Medical Association. *The Purpose of the CPT® Coding System & the CPT® Editorial Panel.* American Medical Association, 10 Sept. 2025, *https://www.ama-assn.org/about/cpt-editorial-panel/purpose-cpt-coding-system-cpt-editorial-panel.*

today.[140] The Health Care Financing Administration or HCFA, later renamed CMS,[141] in 1983 required the use of the Healthcare Common Procedure Coding System (HCPCS) for physician services and expanded to non-physician services in 1991.[142] and since this time HCPCS Level I services have been considered synonymous with CPT, where Level II HCPCS refers to additional products, supplies, and services not included in the CPT® codes.[143]

Following the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) the Department of Health and Human Services (HHS) in subsequent regulation defined the combination of HCPCS, as maintained and distributed by HHS, and CPT–4, as maintained and distributed by the AMA, as the nationally required medical data code sets for physician services, physical and occupational therapy services, radiologic procedures, clinical laboratory tests, other medical diagnostic procedures, hearing and vision services, and transportation services including ambulance services (45 CFR 162.1002(a)(5)). This is commonly understood as a regulatory requirement for CPT–4 codes to be used to define physician services. While this is HHS' current regulatory interpretation of the HIPAA (Pub. L. 104–191), it is important to note that HHS has only specified in regulation that HCPCS and CPT–4 to be used in combination. There is no specification in the HIPAA statute regarding the manner in which these national coding sets may be used or how they may be combined, and only HHS interpretation, not the Act itself, mentions CPT®.

New CPT® codes are introduced by the CPT® Advisory Committee. This committee was established following the initial publication of the CPT® coding system in 1966, which provides advice on procedure coding and appropriate nomenclature as relevant to the committee member's specialty and consists of ''members of national medical specialty societies seated in the AMA House of Delegates.''[144] When a new CPT® code is defined by the CPT® Advisory Committee, it is then assigned a payment value by the AMA Relative Value Scale Update Committee or RUC.[145]

The AMA RUC was established in 1992, after CMS transitioned to the resource-based relative value scale (RBRVS), to provide recommendations on the valuation of physician services. As established in section 1848 of the Act, CMS began paying for physician services in 1998 on the basis of a product of the relative value of the physician service, incorporating the physician work, the practice expense, and the malpractice component. These elements form the basis for the RBRVS. The components of physician services were originally established by a team of Harvard researchers (William Hsiao, et al.) and CMS has occasionally referenced the 'Harvard' valuations making reference to these original contributions.[146] According to the AMA, the AMA RUC ''*provides medicine a voice in shaping Medicare relative values,*'' and by all published estimates this has been an effective mechanism.[147]

There has also been longstanding concern expressed over the Federal reliance on a private organization with such an obvious conflict of interest providing information on the time and resource requirements to conduct physician services when this information may influence their own payment. For nearly 20 years, MedPAC has expressed concern over the influence of the AMA RUC to value services, specifically noting that CMS has ''*over-relied on specialty societies with a financial stake in the process*'' and has recommended that CMS establish a separate group of experts to make payment recommendations.[148] Further, we note the historic reliance on the CPT and RUC process as a potential contributor to the development of US health care as a 'sick care' system with limited emphasis on prevention and lifestyle modifications and which may inhibit progress on the Secretarial priority to Make America Healthy Again. Additionally, we note a recent National Academies of Sciences, Engineering, and Medicine (NASEM) report recommending RUC alternatives for establishing primary care payment valuation and recommendations for alternative sources for data collection.[149]

Given these longstanding concerns, we sought comment on a number of areas regarding the influence of the CPT® coding system and the AMA process on physician payment policy as part of the Secretarial priority to Make America Healthy Again.

(1) What, if any, evidence is there for CMS to consider regarding the harms or challenges associated with AMA's monopoly over CPT–4 licenses for health care entities? We sought comments on potential improvements to patient care diverted or delayed due to AMA'S monopoly over CPT codes, including inhibited innovations and acquisition or maintenance costs of CPT® licensure.

Comment: Commenters identified issues with the AMA's CPT® licensure process, but many commenters shared their concerns with the challenges associated with introducing alternative coding standards to CPT® and highlighted the importance of having a unified national coding standard. Very few commenters agreed with removing royalties from the CPT process. Issues identified by commenters included the perceived legal discrepancy between the CPT–4 code set being federally mandated and the fact that it is owned privately.

Response: We thank commenters for their feedback, and we will use these comments to advise us for future rulemaking.

(2) What, if any, evidence is there that the generation of CPT–4 codes follows a process of identification of medical

[140] American Medical Association. *The Purpose of the CPT® Coding System & the CPT® Editorial Panel.* American Medical Association, 10 Sept. 2025, *https://www.ama-assn.org/about/cpt-editorial-panel/purpose-cpt-coding-system-cpt-editorial-panel.*

[141] Centers for Medicare & Medicaid Services, Department of Health and Human Services. *Statement of Organization, Functions, and Delegations of Authority.* **Federal Register**, 5 July 2001, *https://www.federalregister.gov/documents/2001/07/05/01-16800/centers-for-medicare-and-medicaid-services-statement-of-organization-functions-and-delegations-of.*

[142] *Medicare Program; Fee Schedule for Physicians' Services; Proposed Rule.* **Federal Register**, vol. 56, no. 108, 5 June 1991, pp. 25792–25978. U.S. Government Publishing Office, *https://www.govinfo.gov/content/pkg/FR-1991-06-05/pdf/FR-1991-06-05.pdf.*

[143] Centers for Medicare & Medicaid Services. ''Healthcare Common Procedure Coding System (HCPCS).'' *Centers for Medicare & Medicaid Services,* U.S. Department of Health and Human Services, *https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system.* Accessed 7 July 2026.

[144] American Medical Association. *CPT® Nominations & Opportunities.* American Medical Association, 11 Feb. 2025, *https://www.ama-assn.org/about/cpt-editorial-panel/cpt-nominations-opportunities.*

[145] American Medical Association. *RVS Update Committee (RUC).* American Medical Association, 4 Mar. 2026, *https://www.ama-assn.org/about/rvs-update-committee-ruc/rvs-update-committee-ruc.*

[146] Hsiao WC, Braun P, Kelly NL, Becker ER. Results, Potential Effects, and Implementation Issues of the Resource-Based Relative Value Scale. *JAMA.* 1988;260(16):2429–2438. doi:10.1001/jama.1988.03410160105013.

[147] American Medical Association. *RVS Update Committee (RUC).* American Medical Association, 4 Mar. 2026, *https://www.ama-assn.org/about/rvs-update-committee-ruc/rvs-update-committee-ruc.*

[148] Medicare Payment Advisory Commission. *Testimony: Options to Improve Medicare's Payments to Physicians.* 8 May 2007, *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/congressional-testimony/051007_Testimony_MedPAC_physician_payment.pdf.*

[149] National Academies of Sciences, Engineering, and Medicine. *Improving Primary Care Valuation Processes to Inform the Physician Fee Schedule.* National Academies Press, 2025, *https://doi.org/10.17226/29069.*

necessity? What opportunities or examples from other populations, sites of care, or international health systems could instruct a process of identification of medical necessity in the CPT–4 code development process?

Comment: Commenters generally answered this question by highlighting the importance of differentiating between the AMA's process for CPT–4 code development and the subsequent and distinct process for the RUC to assign relative payment recommendations. Commenters emphasized the role of CPT® as a nomenclature system and that medical necessity decisions are left to payors.

Response: We thank commenters for their feedback, and we will use these comments to advise us for future rulemaking.

(3) A combination of CPT–4 and HCPCS codes were formally adopted by HHS as the legal standard for national coding for physician and other services as part of implementing HIPAA (45 CFR 162.1002(a)(5)). If CMS were to revisit this standard in future rulemaking, which if any alternatives exist to CPT–4 for CMS to consider as part of the national coding standard for physician services? Would CMS need to specify a separate legal standard, or could CMS allow for private competition to supplement the existing CPT–4 coding standard?

Comment: Many commenters expressed concern about transitioning to alternative or multiple coding standards, and advocated for CMS to improve the current standard. Others highlighted that while there is no unified national standard the CPT functions can decompose across a number of code sets (for example, inpatient procedures may utilize the CMS ICD–10–PCS coding system, general clinical services may utilize SNOWMED CT®, labs may utilize LOINC®, etc.) and highlighted where CMS has already begun to make progress on this mapping through CMS' development of HCPCS codes such as chronic care management or principal illness navigation.

Response: We thank commenters for their feedback, and we will use these comments to advise us for future rulemaking.

(4) What objective alternatives exist, or could be developed, to maintain a more objective process to the current AMA CPT and RUC committee processes? How would these alternatives support or inhibit innovation?

Comment: Many commenters suggested opportunities to improve the AMA CPT® Editorial Panel process of developing new CPT® codes and the AMA Relative Value Update Committee or RUC process of making recommendations to CMS on the valuation, or relative resources involved in, furnishing a physician service. In addition to specific suggestions for improvements, commenters also highlighted a perceived bias against 'cognitive' in favor of 'procedural' services (including several examples of cognitive work that was 'invisible' such as managing patient portal messages) and the challenges in measuring and attributing resources of diffuse longitudinal work, especially regarding the undervaluation of primary care services. Commenters also highlighted the contribution of the AMA RUC towards creating a shortage of primary care practitioners.

Commenters made many more recommendations to improve the AMA RUC process than the CPT® Editorial Panel process. On the CPT process, commenters suggested methods to improve transparency, such as by publishing a formula to define 'widespread use' to better keep pace with advances in technology. On the AMA RUC process, commenters suggested improvements to the data sources used, improvements to the composition of the committee, and suggestions for reducing the conflict of interest inherent in a group of physicians recommending how they or their colleagues will be reimbursed for their services. Many commenters made additional recommendations for AMA RUC improvements, including incorporating more objective or 'empiric' data in their recommendations, such as incorporating EMR or registry data rather than surveying practicing physicians. Commenters suggested a series of structural reforms to the AMA RUC, including changing the specialty composition of the committee members (*e.g.* more geriatrics and primary care representation, or representation proportional to the number of practicing physicians rather than a single representative for each specialty). Commenters suggested a series of recommendations to make the AMA RUC process more transparent, including that the AMA RUC make public their methodology in a public repository which would include the standards and data used in their valuation recommendations for physician work. Other commenters recommended CMS independently verify RUC recommendations before accepting them. Commenters also recommended CMS establish an external advisory body (for example, using a technical expert panel or an existing Federal Advisory Committee) that may work alongside the RUC to supplement the existing process, although commenters differed on their recommendations for who should constitute this external advisory body (i.e. non-physician experts or physician and non-physician experts) or if it should supplement, or replace, the AMA RUC. Commenters recommending an AMA RUC replacement suggested it may be modeled on the Medicare Payment Advisory Committee (MedPAC) which advises Congress on the Medicare program.

In addition to providing suggestions related to the data used for making valuation recommendations, the committee composition, potential solutions for addressing conflicts of interest, and potential supplemental or alternative committee structures, commenters also made recommendations on how the AMA RUC could make recommendations to CMS beyond the relative resource costs or valuation for physician services, to also include other areas of importance to CMS, such as value-based payment or outcomes-based payment. Commenters also suggested the AMA identify a process for retiring low-value services.

Response: We thank commenters for their feedback. While the original intent of this request for information was for CMS to better understand potential harms associated with the AMA's monopoly on CPT–4 licensing and solicit comments on alternative coding standards for physician services, to adequately describe the CPT–4 code development process required us to describe both the CPT® Editorial Panel and the AMA Relative Value Scale Update Committee (RUC). We will consider comments received on the CPT® process for future rulemaking. The overwhelming majority of public comments focused on the AMA RUC.

Given the robust public response focused on improvements to the AMA RUC, CMS is considering a number of potential avenues for improving this process that could take into consideration commenters' recommended changes to the RUC that could enhance transparency, improve data used for making payment recommendations, modify committee composition, take steps to become more independent, or evaluate retirement of low-value services.

It is in both CMS and the public's interest to consider input from doctors and front-line medical health professionals about the medical services they perform in their daily patient care,

and we reiterate that CMS considering the relative resource costs associated with services in accordance with 42 U.S.C. 1395w–4(c) when setting payment for physician services. CMS reiterates the RUC or other organizations may submit data to support valuation of physician services, and we encourage all organizations to do so.

Any organization providing recommendations on the relative resources required for furnishing a physician service should consider using empiric data to establish their recommendations. This may include use of empiric data sources such as statistically valid sampling of clinicians, auditable cost reports in physician settings or other government or non-government payment systems, and other information relevant to assessing both supply- and demand-side factors relevant to assessing the value of a given item or service, including data on market prices.

For examples of using empiric data and data on market prices, in recent rulemaking CMS has proposed and finalized use of data for specific services in the Medicare Outpatient Prospective Payment System that we believe are applicable for clinician rate setting in the Physician Fee Schedule as well. As part of CMS' broader strategy of considering market-based data to inform rate setting, we welcome more information about negotiated rates between clinicians and private payors in a number of specific contexts (for example, rates negotiated by Medicare Advantage plans caring for a comparable population to Original Medicare, self-insured employers, or commercial payors both within and outside of other government health programs). Such feedback will help to advance CMS's priority of aligning program spending with the value of health care items and services by adopting relevant best practices from market contexts.

In addition to providing resource recommendations on the basis of empiric data and market-based information, CMS is also very interested in information on the clinical outcomes the service would be reasonably expected to achieve, including information on distribution or clinical variation in outcomes that would be reasonably expected (or not expected) to occur. We believe that considering application of outcomes-based payment within Medicare is an important factor in progressing towards more accountable and value-based care that is a longstanding priority of CMS.

We highly value the expertise of volunteer groups of physicians who submit relative resource recommendations and reaffirm the crucial role for physicians to provide input to the federal government based on their firsthand expertise regarding complex medical procedures and non-procedural services. CMS also reiterates that we have sole authority to establish payment rates for physician services for the Medicare program, and we strongly encourage any group submitting data to support rate setting for physician services to both utilize empiric data and further submit information on the clinical outcomes that may be expected based on the physician service being furnished. We may in future rulemaking establish these or additional requirements for organizations providing information on the relative resources involved in furnishing physician services.

To describe what information would be helpful for CMS regarding the outcomes expected upon furnishing a physician service, to use an example from the 2027 Physician Fee Schedule, CPT code 27447 describes a total knee arthroplasty (TKA). In addition to understanding the relative resources associated with furnishing the service, which are typically provided by the RUC, CMS would like to better understand the expected outcomes. After a total knee arthroplasty, what proportion of Medicare beneficiaries would have improved range of motion of the affected joint? What proportion would not? What proportion would have improvements in pain, either total or partial resolution? What is a typical recovery time from surgery? What proportion of patients in an orthopedic surgeon's practice would expect to have complications from the procedure, should they be a surgical site infection, venous thromboembolism (or many other potential complications)? What proportion of TKA recipients may eventually require revision of the joint, and on what time horizon? CMS sees clear value in understanding these expected outcome distributions to understand 'typical' practice or practice within commonly clinically accepted standards and practices as we seek to accurately value physician services.

(5) What are the benefits and drawbacks of paying for physician procedural services on the basis of the underlying International Classification of Diseases, 10th Revision (ICD–10) procedure code, as an alternative to CPT–4 code? How could the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) services be grouped or bundled into payment categories, similar to Medicare Severity Diagnosis Related Groups (MS–DRGs), or Outpatient Prospective Payment System (OPPS) Ambulatory Payment Classifications (APCs)? What other alternatives exist for bundling or grouping procedural services?

Comment: Commenters highlighted that while CPT–4 codes and ICD–10 procedure codes may overlap, there are differences, and suggested there may be potential drawbacks to considering physician payment on the basis of ICD–10 procedure codes. There were few commenters specifically addressing bundling services in methods analogous to the MS–DRGs or OPPS APCs.

Response: We thank commenters for their feedback, and we will use these comments to advise us for future rulemaking.

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts (§§ 414.902 and 414.940)

a. Background

Section 1847A(h) of the Act requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter referred to as ''refundable drug'') for calendar quarters beginning January 1, 2023.

The calculation of the refund is codified at § 414.940(c). For a new refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

- The product of the total number of units of the billing and payment code for such drug that were discarded during such new refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such new refund quarter.
- Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the new refund quarter.

Section 1847A(h)(3)(B)(i) of the Act establishes an applicable percentage of 10 percent, but provides that, in the case of a refundable drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary, through notice and comment rulemaking, may increase such applicable percentage as determined

appropriate by the Secretary. Section 1847A(h)(8)(B)(ii) of the Act describes a drug or biological approved by the Food and Drug Administration (FDA) for which dosage and administration instructions included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process. Drugs with an increased applicable percentage are listed on the CMS website.[150]

For previous rulemaking in which we finalized to increase the applicable percentage of a drug with unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, we explained specifically why the loss of product met the statutory requirements. In the CY 2023 Physician Fee Schedule (PFS) final rule (87 FR 69729), we finalized an increase in the applicable percentage for a drug reconstituted with a hydrogel and administered via ureteral catheter or nephrostomy tube into the kidneys, where a substantial amount of reconstituted hydrogel adheres to the vial wall during preparation and cannot be withdrawn for administration. Because this unavoidable preparation-related loss is similar to the loss described in section 1847A(h)(8)(B)(ii) of the Act, we stated that such a drug that is reconstituted with a hydrogel and has variable dosing based on patient-specific characteristics (for example, Jelmyto® (mitomycin for pyelocalyceal solution)) should be considered to have unique circumstances as described in section 1847A(h)(3)(B)(ii) of the Act that would warrant an increased applicable percentage.

In the CY 2024 PFS final rule (88 FR 79057), we increased the applicable percentage for certain drugs with low volume doses and stated that such drugs have unique circumstances because certain FDA-labeled amounts on the vial or package are unused and discarded after administration of the labeled dose and these amounts are not available to be administered. The unique circumstances described for such drugs are similar to loss of product from filtration described in section 1847A(h)(8)(B)(ii) of the Act because in both circumstances, such amounts lost are amounts that are not part of the recommended dose and are not available to be administered to the patient (one being loss due to labeled amounts remaining in the filter and the other due to labeled amounts remaining in other areas such as the vial or syringe).

In the CY 2024 PFS final rule, we also finalized an increased applicable percentage for certain orphan drugs furnished to fewer than 100 unique beneficiaries per calendar year. We explained (88 FR 79053 through 79057) that because of the substantial statistical variation (based on demonstrated JW modifier claims data from 2021 and 2022) from quarter to quarter for such drugs, we believe it would be difficult to optimize the presentation of the drug to consistently minimize the discarded amounts to less than 10 percent given the small number of patients receiving the drug. We considered the higher percentage of unused and discarded amounts from such drugs as unavoidable loss due to both the low number of unique beneficiaries receiving the drug contributing statistically higher variability in discarded amounts. Also, due to the low numbers of patients available to study for rare disease, it may be more difficult to determine the most efficient vial size for the patient population who receive the drug post-marketing. We stated this is similar to the loss of product due to filtration described in section 1847A(h)(8)(B)(ii) of the Act because the loss is unavoidable in both circumstances. In the case of filtration described in statute, the loss is unavoidable because certain amounts of product will be left within the filter and unavailable for administration; in the case of rarely utilized orphan drugs, the loss is unavoidable because of the variability of potential doses (and low number of patients receiving the drug) leading to an inability to develop a package size that will result in a consistent average percentage of discarded units.

We stated in the CY 2024 PFS final rule (88 FR 79057) that we do not consider the following to be unique circumstances warranting an increased applicable percentage at this time: weight-based doses, body surface area (BSA)-based doses, varying surface area of a wound, loading doses, escalation or titration doses, tapering doses, and dose adjustments for toxicity because we believe manufacturers can optimize the availability of products for these circumstances to limit the percentage of discarded units for a drug, unlike the circumstances of manufacturers of drugs that require filtration during the preparation process, as described in section 1847A(h)(8)(B)(ii) of the Act.

We also explained in the CY 2024 PFS final rule (88 FR 79060) that, while we cannot anticipate future drug development or what unique circumstances might arise, we can offer our analysis of the unique circumstances we consider involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act for drugs that are reconstituted in hydrogel and with variable dosing based on patient-specific characteristics (87 FR 69727 through 69731), drugs with low volume doses, and rarely utilized orphan drugs (88 FR 79052 through 79057). Regarding examples of evidence, we noted minimum vial fill studies and dose preparation studies in the CY 2024 PFS proposed rule, both of which are suitable for justifying increased applicable percentages because they can establish that certain unusable amounts of a product are necessarily included in a container to safely and consistently administer the labeled therapeutic dose to a patient.

b. Application for Increased Applicable Percentage

Section 1847A(h)(3)(B)(ii) of the Act permits the Secretary to increase the applicable percentage for a refundable drug that has unique circumstances through notice-and-comment rulemaking. In the CY 2024 PFS final rule (88 FR 79057 through 79060), we finalized an application process (CMS–10835, OMB 0938–1435) by which manufacturers can apply for an increased applicable percentage for a drug and may request that we consider an individual drug to have unique circumstances for which an increased applicable percentage is appropriate. Under § 414.940(e)(2), an application must be submitted by February 1 of the CY prior to the year the increased applicable percentage would apply; for a drug that is not FDA-approved by February 1, the application must have FDA approval by August 1, and the manufacturer must notify CMS and submit the FDA-approved label by September 1 of that year. The application must include a written request that the drug be considered for an increased applicable percentage based on its unique circumstances; FDA-approved labeling for the drug (or, if the drug is not approved by the February 1 application deadline described in paragraph (e)(2) of this section, documentation of FDA acceptance of the application for review); justification for the consideration of an increased applicable percentage based on such unique circumstances; and justification for the requested increase in the applicable percentage. Following review of timely applications, CMS will summarize its analyses of applications and propose

[150] *https://www.cms.gov/medicare/payment/part-b-drugs/discarded-drugs.*

appropriate increases in rulemaking. If adopted, the increased applicable percentage will be the applicable percentage beginning January 1 of the following calendar year.

In the CY 2027 PFS proposed rule (91 FR 43954 through 43956) we discussed the one application we received requesting an increased applicable percentage for consideration for CY 2027 from the manufacturer of Leukine® (sargramostim),[151] who resubmitted a request for a 72 percent applicable percentage after applying the previous 2 years. The applicant submitted the information required at § 414.940(e)(1), including, as applicable, FDA-approved labeling for the drug, justification for consideration of an increased applicable percentage, and justification for the requested applicable percentage.

Leukine® is a leukocyte growth factor with five FDA-approved indications related to hematological conditions and hematopoietic recovery, as well as one indication to increase survival following acute exposure to myelosuppressive doses of radiation. The applicant's submitted FDA-approved labeling for the drug does not include the adjuvant uses described in the application (further described later in this paragraph) due to ongoing cancer vaccine adjuvant trials. The applicant reemphasized that multiple sponsors are in late-stage development, with a total of 27 Phase II and Phase III clinical trials, an increase from 22 reported in the previous year, investigating Leukine® as a vaccine adjuvant for oncology indications, specifically to stimulate the immune response of dendritic cells when used alongside these vaccines. We note that cancer treatment vaccines differ from the vaccines that protect against viruses, such as the influenza virus. Instead of preventing disease, cancer treatment vaccines aim to stimulate the immune system to attack existing cancer cells in the body.[152] The applicant stated that it has no ownership stake in the development of these cancer treatment vaccines and does not possess control or influence over the design and execution of the clinical trials. The applicant further explained that the estimated completion dates for Phase III clinical trials vary, with the earliest expected in late 2026 [153] [154] and the latest in March 2029.[155] Since the publication of proposed rule (91 FR 43842), we identified that the estimated completion date for one of the three Phase III clinical trials has been updated to December 2031.[5]

The adjuvant use of Leukine® in predetermined dosage is distinct from its six FDA-approved indications, all of which have dosages that are based on body weight or BSA. The adjuvant use dosages of Leukine® in clinical trials are generally much smaller than dosages for indications in the FDA-approved labeling. The smallest dose of Leukine® used for vaccine adjuvant purposes of which the applicant is aware (that is, 70 mcg) would lead to as much as 72 percent of the drug being discarded from a single-dose 250 mcg lyophilized vial, which is the only size available commercially. The applicant suggests that if use of these small doses were to become more common for an approved indication, the percentage of discarded units could increase the discarded drug refund amount that could be owed by the applicant, even though the applicant lacks control or knowledge of the potential variability of the discarded amounts that may occur if Leukine® were used for such purposes. The applicant notes that if another manufacturer were to seek FDA approval for adjuvant use of sargramostim but was not involved in its production, the available single-dose 250-mcg vial presentation of Leukine® would likely not be optimized for the small doses being studied in these trials. The applicant also expresses concern about potential refund liability if small-dose adjuvant use becomes more common.

The application builds on prior submissions by reiterating that Leukine® appears on FDA's list of essential medicines,[156] that the Administration for Strategic Preparedness and Response (ASPR) has documented a requirement to procure and stockpile Leukine® as a medical countermeasure for neutropenia resulting from acute radiation syndrome,[157] and that the applicant continues to collaborate with the Biomedical Advanced Research and Development Authority (BARDA). In this application, the applicant also newly states that Leukine® has been designated a ''Medical Product Priority'' by the Department of Defense (DoD) under Public Law 115–92 (enacted December 12, 2017).[158] DoD maintains a Medical Product Priority list as part of the DoD–FDA coordination framework established following Public Law 115–92 and formalized in the FDA-DoD Memorandum of Understanding.[159] Under this framework, DoD identifies and maintains a list of its highest-priority medical products to support focused, recurring engagement with FDA; however, we could not corroborate a Leukine® designation using resources available for public review. The applicant's 2022 public announcement of an Other Transaction Agreement with the DoD references Leukine® as a potential medical countermeasure for sulfur mustard gas exposure,[160] but it does not reference a ''Medical Product Priority'' designation. Additionally, a study published in 2025 comparing essential medicines across U.S. Federal agencies and the World Health Organization did not identify Leukine® on DoD's operational medicines list. The study noted that the DoD operational medicines list is a subset of FDA's essential medicines list—meaning medicines on the DoD list also appear on FDA's list, but not all medicines on FDA's list appear on the DoD list.[161] Nevertheless, these emergency-response and preparedness-related listings or designations do not, by themselves, demonstrate unique circumstances related to discarded amounts for purposes of an increased applicable percentage because they are designed to support Federal planning, procurement, and interagency coordination to ensure adequate supply of essential products, rather than to provide evidence of drug-specific, unavoidable product loss similar to loss of product as described in section 1847A(h)(8)(B)(ii) of the Act.

In the CY 2027 PFS proposed rule (91 FR 43955), we explained as part of CMS's review of the application, we analyzed existing claims data from the first quarter of 2018 through the last quarter of 2025 and found the percentage of units discarded for Leukine® (HCPCS code J2820) ranged from 1.1 percent to 4.9 percent, which

[151] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/103362s5249lbl.pdf.*

[152] *https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/cancer-vaccines.html.*

[153] *https://clinicaltrials.gov/study/NCT04229979.*

[154] *https://clinicaltrials.gov/study/NCT05232916.*

[155] *https://clinicaltrials.gov/study/NCT05100641.*

[156] *https://www.fda.gov/media/143406/download?attachment.*

[157] *https://sam.gov/opp/f4735f1f235847a0bb138c13333097de/view.*

[158] To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, Public Law 115–92, 131 Stat. 2023 (2017).

[159] *https://www.fda.gov/about-fda/domestic-mous/mou-225-19-001.*

[160] *https://www.partnertx.com/partner-therapeutics-announces-contract-with-u-s-department-of-defense-for-advanced-development-of-leukine-to-treat-sulfur-mustard-gas-hd-exposure/.*

[161] ML Janvrin, A Kanagaratnam, VA Suarez et al. A comparison of the essential medicines lists of the U.S. Department of Health and Human Services, the U.S. Department of Defense, the U.S. Food and Drug Administration, and the World Health Organization, Journal of the American Pharmacists Association, 65(5), 2025.

is below the applicable percentage of 10 percent. The quarterly discarded percentages during this time frame were stable, with a standard deviation of less than 1 percentage point and values tightly clustered around a mean of approximately 2.4 percent. We noted that this is lower than the 6.21 percent average standard deviation observed for rarely utilized orphan drugs, as reported in the CY 2024 PFS final rule (88 FR 79053). Accordingly, the applicant's requested applicable percentage relies on assumptions about hypothetical future dosing and utilization that are not evident in Part B claims data available to date.

At the time of the CY 2026 PFS proposed rule, the impact of a potential adjuvant indication with a type of immunotherapy commonly referred to as cancer vaccines [162] on the current percentage of units discarded was uncertain. Additionally, it was not yet known whether sargramostim would be approved for additional indications and dosages described by the applicant, and the available data was insufficient for CMS to determine whether Leukine® had unique circumstances prompting an increase in the applicable percentage. Therefore, we did not propose to increase the applicable percentage in the CY 2026 PFS proposed rule. The applicant agreed with CMS's rationale for this decision.

Although the applicant agreed with CMS's rationale in the CY 2026 PFS proposed rule, they submitted a new application for CY 2027 with updated information on oncology vaccine-adjuvant clinical trials and projected timing for potential FDA approvals, as well as an asserted DoD ''Medical Product Priority'' designation. However, the core uncertainties identified in the CY 2026 PFS proposed rule persist: the absence of FDA-approved labeling for the asserted adjuvant indication(s) or dosage(s) and uncertainty regarding whether such uses would be utilized to an extent that discarded amounts would exceed the applicable percentage in a calendar quarter.

The existing claims data and trends for discarded amounts of sargramostim discussed earlier do not support a determination that Leukine® has qualifying unique circumstances that would support an increased applicable percentage under section 1847A(h)(3)(B)(ii) of the Act. Unlike the analysis leading to an increased applicable percentage for certain orphan drugs which relied on evidence indicating that certain orphan drugs have unavoidable loss of drug similar to the loss of product described in section 1847A(h)(8)(B)(ii) of the Act, the justification presented by the applicant for an increased applicable percentage for their product is based largely on projections regarding potential future oncology vaccine-adjuvant use at smaller doses. These projections assume a utilization scenario in which sargramostim use would shift predominantly to the studied indications at the lowest study dose discussed earlier in this section, rather than remaining primarily under the FDA-approved indications, for which claims data currently demonstrate very low discarded amount percentages with no trending increase. In the absence of qualifying unique circumstances, we did not reach the question of whether the requested applicable percentage would be appropriate.

Accordingly, we did not propose an increase in the applicable percentage for Leukine® for CY 2027. We stated that the applicant may reapply in a future application cycle when more information, such as FDA-approved labeling reflecting new indications or dosages, becomes available.

The following is a summary of the comments we received and our responses.

Comment: We received one comment related to the single application we received for an increased applicable percentage beginning in CY 2027. The manufacturer of Leukine® acknowledged CMS's rationale that there was insufficient information to determine whether Leukine® had unique circumstances warranting an increased applicable percentage and stated that it intends to reapply in a future rulemaking cycle when additional data are available.

The commenter further stated that, beyond the circumstances presented in its original request in the proposed rule, the current 250-mcg vial represents the optimal vial size for Leukine®'s current FDA-approved indications and for additional treatment indications under development. The commenter reiterated that it should not bear discarded drug refund liability attributable to utilization decisions made by unrelated third-party manufacturers over which it has no ownership interest, control, or influence. In support of its request, the commenter also cited Leukine®'s federal designations, marketing authorization in the European Union, and role in the Strategic National Stockpile, stating that refund liability affecting continued production or availability of the product could carry broader public health and national security implications.

Response: We appreciate the commenter's feedback and intent to submit additional data supporting its request in a future application cycle for Leukine®. With respect to the commenter's concern that it should not bear discarded drug refund liability attributable to utilization decisions made by unrelated third-party manufacturers, we note that, based on the claims data described previously, the percentage of discarded units for Leukine® has remained well below the applicable percentage of 10 percent. Because Leukine®'s discarded amounts have not exceeded the applicable percentage, no refund has been owed under the discarded drug refund program for Leukine® to date.

With respect to vial size and indications under development, the commenter provided insufficient data showing that the projected small-dose use or resulting discarded amounts are indicative of unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act. Absent sufficient evidence demonstrating such unique circumstances, these considerations do not warrant an increased applicable percentage.

Regarding federal designations, marketing authorization in the European Union, and the Strategic National Stockpile, the manufacturer has not shown that these facts provide evidence of drug-specific, unavoidable product loss similar to loss of product as described in section 1847A(h)(8)(B)(ii) of the Act in order to demonstrate unique circumstances related to discarded amounts for purposes of an increased applicable percentage. As discussed in the proposed rule (91 FR 43955), the federal designations and stockpile requirement are designed instead to support federal planning, procurement, and interagency coordination to ensure adequate supply of essential products. Similarly, marketing authorization in the European Union does not demonstrate that a refundable drug has unique circumstances involving loss of product similar to that described in section 1847A(h)(8)(B)(ii) of the Act that would support an increased applicable percentage under section 1847A(h)(3)(B)(ii) of the Act. Such authorization also does not substitute for the FDA approval and labeling requirements specified in § 414.940(e)(1)(ii) and (e)(2).

Accordingly, we continue to find that there is insufficient information at this time to determine that Leukine® has unique circumstances warranting an increased applicable percentage. The

[162] *https://www.cancerresearch.org/treatment-types/cancer-vaccines.*

manufacturer may submit a new application for consideration in a future rulemaking. As described at § 414.940(e), the application (including reapplication) for an increased applicable percentage is due by February 1 of the calendar year prior to the year in which the increased applicable percentage would apply.

Comment: A commenter requested CMS reconsider the policy discussed in the CY 2024 PFS final rule that weight-based doses, BSA-based doses, loading doses, escalation, or titration doses, tapering doses, and dose adjustments for toxicity are not unique circumstances. The commenter stated that discarded amounts may be unavoidable when continuously variable, patient-specific doses must be prepared from a discrete set of available vial sizes and compared such loss to the loss associated with required filtration described in section 1847A(h)(8)(B)(ii) of the Act. The commenter stated that vial-size optimization has not adequately reduced discarded amounts for BSA-dosed products and recommended that, if CMS maintains its current policy, that CMS should publish data on discarded amounts for BSA-dosed Part B oncology drugs with a high volume of claims to provide greater transparency into that policy. The commenter also requested that CMS ensure the discarded drug refund policy does not influence clinicians to select doses or products based on vial economics rather than clinical considerations, while recognizing dose rounding within clinically validated parameters.

Response: We thank the commenter for describing the challenges associated with matching patient-specific and variable dosing regimens, including weight-based doses, BSA-based doses, loading doses, escalation, or titration doses, tapering doses, and toxicity-related dose adjustments, to available vial or container sizes. These comments are out of scope for this final rule, as we did not make proposals or discuss these topics in the proposed rule.

We previously discussed similar dosing circumstances in the CY 2023 PFS final rule (87 FR 69715). For example, we explained that when an induction or loading dose is administered, a larger amount of drug may subsequently be left in the single-dose container compared with the amount of drug left in the container if a typical dose had been administered. Nevertheless, we explained that amounts left in the vial were considered unused and discarded because they were not part of the dose intended to produce a therapeutic effect.

With respect to vial-size optimization that has not adequately reduced discarded amounts for BSA-dosed products, we continue to believe that manufacturers can use vial-size optimization studies to identify a set of container sizes for which less than 10 percent of the labeled amount, while recognizing that introducing or modifying vial sizes may present operational and economic challenges for manufacturers and may impose additional burdens on providers that must stock and administer those vial sizes, as discussed in the CY 2023 PFS final rule (87 FR 69713). Notwithstanding these operational considerations, section 1847A(h) of the Act requires manufacturers to pay refunds calculated under the statutory formula when the amount of discarded units exceeds the applicable percentage of estimated total allowed charges. Consistent with the 2020 data discussed in the CY 2023 PFS final rule, data collected since implementation of the program indicate that Medicare Part B spending on discarded amounts remains concentrated among a relatively small number of products. We note that § 414.940(e) provides a process through which a manufacturer may request an increased applicable percentage for a refundable drug with product-specific unique circumstances and supporting information.

With respect to the request that CMS publish data on discarded amounts for BSA-dosed Part B oncology drugs, CMS issues annual discarded drug refund reports through the Manufacturer Payment Portal. These reports include quarterly information on discarded billing units and the refund amount for a manufacturer's refundable drugs, including those dosed based on BSA. Oncology drugs account for about half of all refundable drugs that owed a refund in the first two program years. Manufacturers of refundable drugs for which no refund is due also receive reports reflecting a zero-refund amount. Separately, CMS publishes prior program-year refund information and quarterly Part B spending by drug on its website.

Finally, the discarded drug refund policy does not require clinicians to change a clinically appropriate dose, select a different product, or round a dose based on a manufacturer's refund liability. The refund requirement applies to manufacturers after Medicare claims are processed and does not affect Medicare's payment to providers for administered and discarded amounts. Consistent with CMS policy, discarded amounts are identified using the JW modifier; the JZ modifier is required on claims when there are no discarded amounts.

Comment: A commenter stated that CMS should improve flexibility under the discarded drug refund policy by recognizing additional unique circumstances in which discarded amounts may exceed the 10 percent threshold. The commenter indicated that therapies such as cell and gene therapies and other personalized treatments have complex, time-sensitive manufacturing and administration processes that may necessitate additional product availability at the time of treatment, resulting in unavoidable discarded drug. The commenter further suggested that drugs undergoing post-market optimization (for example, changes to vial size or fill volume) require extended regulatory and manufacturing timelines that exceed the 18-month exemption period and that a categorical unique circumstance is warranted for such products.

Response: The establishment of additional categorical unique circumstances is out of scope for this final rule. We do not address in this rulemaking whether the therapy types or product characteristics identified by the commenter would, as categories, satisfy the standard in section 1847A(h)(3)(B)(ii) of the Act. Manufacturers may request consideration of an increased applicable percentage for an individual drug through the application process at § 414.940(e), which requires justification for consideration of an increased applicable percentage based on the drug's unique circumstances and justification for the requested applicable percentage. The existing application process remains available for CY 2028 and subsequent years in accordance with the requirements and deadlines at § 414.940(e).

Comment: A commenter recommended improvements to the administration of the discarded drug refund policy. A commenter stated that drugs with multiple indications and varied dosing requirements may require flexibility in vial sizing and urged CMS to amend the Medically Unlikely Edit (MUE) policy so that discarded units identified with the JW modifier are not counted toward unit-of-service calculations. The commenter suggested that CMS standardize and enhance the completeness and accuracy of discarded drug refund report, noting frequent data gaps (such as missing total allowed units or newly launched drugs in the exemption period) that hinder manufacturers' ability to verify refund

obligations or reduce discarded amounts.

Response: We appreciate the commenter's recommendations regarding the content of the discarded drug refund reports and providing additional examples regarding report completeness and consistency. Comments requesting enhancement of data elements in the report for standardization and data accuracy, including for drugs not eligible for refunds under the discarded drug refund policy (for example, drugs that are within the 18-month exclusion period), and comments requesting exclusion of JW modifier-identified discarded units from MUE unit-of-service calculations, are out of scope for this final rule. However, we may take this information into consideration for future policy development and potential operational enhancements.

Comment: Several commenters provided feedback regarding the interaction between the discarded drug refund policy and the Maximum Fair Price (MFP) for selected drugs payable under Part B. Several commenters questioned whether the current discarded drug refund policy's calculation for selected drugs under the Medicare Drug Price Negotiation Program is aligned with CMS's policy requiring manufacturers to provide access to the MFP for both administered and discarded units. A commenter stated that using an ASP-based payment limit for discarded drug refund calculation may create inconsistencies for selected drugs payable under Part B reimbursed at the MFP. Another commenter urged CMS to exclude selected drugs payable under Part B from the discarded drug refund program during their price applicability period, drawing an analogy to CMS's policy of excluding discarded unit for which a discarded drug refund is owed from Part B inflation rebate reconciliation and asked CMS to apply that same non-duplication principle to MFP-eligible discarded units. As an alternative, several commenters requested that CMS confirm the discarded drug refunds for selected drugs payable under Part B will be calculated using the MFP-based payment amount so that manufacturers can plan for MFP effectuation, with a commenter specifically requesting clarification before January 1, 2028.

Response: We appreciate the commenter's recommendations and concerns. The proposed rule did not address the methodology for calculating estimated total allowed charges for selected drugs subject to MFP, and we did not propose or solicit comments on these issues. We are therefore not finalizing any policies with respect to these comments in this final rule. However, we note that the statutory framework governing the discarded drug refund requirement, including the definition of a refundable drug, the exclusions specified in section 1847A(h)(8)(B) of the Act, and the refund calculation methodology under section 1847A(h)(3)(A) of the Act, is set forth in statute and discussed later in this section.

Section 1847A(h)(8)(A) of the Act defines a refundable drug and section 1847A(h)(8)(B) of the Act specifies the categories excluded from that definition. In the CY 2023 PFS final rule, we implemented section 1847A(h) of the Act and finalized at § 414.902 the definition of a refundable single-dose container or single-use package drug, including the statutory exclusions for radiopharmaceuticals and imaging agents, certain drugs requiring filtration during preparation, and certain drugs approved or licensed on or after November 15, 2021, for which payment has been made under Part B for fewer than 18 months (87 FR 69710 through 69724). In the CY 2025 PFS final rule (89 FR 97973 through 97974), we further clarified the implementation of the 18-month exclusion and the identification of single-dose containers and single-use packages for purposes of this definition. The exclusions specified in section 1847A(h)(8)(B) of the Act and implemented at § 414.902 apply to drugs that meet the conditions specified in those provisions. We are not establishing additional exclusions in this final rule.

Section 1847A(h)(3)(A) of the Act and § 414.940 provide that the refund amount is an amount equal to the estimated amount (if any) by which the product of the number of discarded units and the amount of payment determined under either section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological product or section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, as applicable, exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug during the calendar quarter. Section 1847A(b)(1)(B) specifies that in the case of a single source drug or biological product that is a selected drug (as referred to in section 1192(c) of the Act), with respect to a price applicability period (as defined in section 1191(b)(2) of the Act), the amount of payment determined under such section is 106 percent of the MFP for such drug and year during such period.

Comment: A commenter expressed support for the discarded drug refund policy as a means of reducing payment for excessive discarded amounts. The commenter stated that the current modifier-based approach to identifying discarded amounts, including use of the JW and JZ modifiers, imposes administrative burden and does not directly address incentives associated with vial size. The commenter recommended that Medicare instead base payment on the quantity of drug actually administered, using electronic medication administration record data or claims reconciliation where feasible, rather than relying on manual modifier reporting. The commenter also stated that manufacturers should bear the cost of discarded amounts attributable to product packaging beyond clinically unavoidable levels.

Response: We appreciate the commenter's support for the discarded drug refund policy, including the commenter's concern that incentives associated with vial size can contribute to excessive discarded amounts. The discarded drug refund policy addresses that concern directly, by requiring manufacturers to provide refunds for discarded amounts of refundable single-dose container or single-use package drugs for which payment is made under Part B exceeding an applicable percentage of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter.

Section 1847A(h) of the Act establishes the manufacturer refund at issue for certain discarded amounts and does not alter Medicare's longstanding payment policy. When a provider or supplier must discard an unused portion of a separately payable drug from a single-dose container or single-use package after administering a dose to a Medicare beneficiary, Medicare provides payment for both the administered amount and the appropriately discarded amount, up to the amount indicated on the product labeling. Section 1847A(h) of the Act further provides for determining discarded amounts using a mechanism such as the JW modifier (or any successor modifier that includes the same data) and under the JW and JZ modifier policy finalized in the CY 2023 PFS final rule, the JZ modifier is required when there are no discarded amounts from single-dose containers or single-use packages payable under Part B (87 FR 69718 through 69719). This claims-based reporting of administered and discarded amounts is the mechanism CMS uses to identify discarded amounts for purposes of

calculating refunds under section 1847A(h) of the Act. The commenter's recommendations to limit Medicare payment to the quantity administered and to replace the JW and JZ modifier requirements with an electronic medication administration record-based or other claims-reconciliation mechanism would involve changes to existing Medicare Part B payment and claims reporting policies and are out of scope for this final rule.

As explained in the CY 2023 PFS final rule regarding provider burden (87 FR 69716), we continue to believe providers are the only party that can obtain complete and accurate information on used and discarded amounts of variably dosed drugs. While we acknowledge that, in some situations, it may be difficult to quantify discarded quantities of drugs and associate the specific amount with a single beneficiary, we believe that, in most situations, there are no practical impediments that would prevent billing providers or other staff, such as nurses or pharmacists, from incorporating the measurement of discard amounts into the process of preparing and administering the drug. We also believe that the observation and recording of no discard amounts using the JZ modifier does not add additional burden beyond the existing requirement of measuring discarded amounts by use of the JW modifier. If a provider is already required to determine whether there are discarded amounts from single-dose packages, then they are already assessing and documenting what is needed for the JZ modifier.

Regarding the commenter's recommendation to shift to manufacturers the cost of amounts attributable to product packaging beyond clinically unavoidable levels, this recommendation is also out of scope for this final rule. Section 1847A(h) of the Act requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable drug. The refund is based on the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent of total charges for the drug in a given calendar quarter. Accordingly, to the extent the commenter's recommendation that manufacturers be responsible for discarded amounts beyond clinically unavoidable levels would result in an applicable percentage below 10 percent, that recommendation would not be consistent with the statutory requirement that the applicable percentage be at least 10 percent under section 1847A(h) of the Act. Section 1847A(h)(3)(B)(ii) of the Act permits the Secretary, through notice-and-comment rulemaking, to increase the applicable percentage for a refundable drug with qualifying unique circumstances.

Comment: A commenter recommended that CMS establish a national Medicare Part B payment framework for radiopharmaceuticals furnished outside the hospital outpatient setting, citing variation across MACs in payment amounts, documentation requirements, and claims-processing practices that may create uncertainty for providers and affect beneficiary access. The commenter recommended that such a framework include a national quarterly payment file, a standardized pricing hierarchy using ASP, WAC, or acquisition-cost data, as appropriate, limited use of invoice pricing, consistent treatment across MAC jurisdictions, greater payment transparency, and a timely correction process. The commenter also requested that CMS initiate rulemaking and convene a technical advisory group to develop a national framework.

Response: We note that these comments are out of scope for this final rule because the proposed rule did not include any proposals regarding a national Medicare Part B payment framework for radiopharmaceuticals furnished outside the hospital outpatient setting. We appreciate the commenter's feedback and may consider these comments in future notice-and-comment rulemaking regarding broader policies for payment of radiopharmaceuticals in the physician office.

Comment: A commenter recommended payment stability for biologicals and protection access to infusion-based therapies and stated that women veterans rely heavily on biologics for autoimmune disease, osteoporosis, and cancer.

Response: We appreciate the commenter's concerns regarding access to biologicals and infusion-based therapies, including the concerns raised regarding women veterans. We recognize the importance of beneficiary access to medically necessary Part B drugs and biologicals. However, the commenter's recommendations regarding broader payment stability for biologics and access to infusion-based therapies are out of scope for this final rule.

In summary, after consideration of public comments, we are not increasing the applicable percentage for Leukine®.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background on RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405, subpart X of our regulations, RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, nurse practitioners (NPs), physician assistants (PAs), Certified Nurse Midwives (CNMs), clinical psychologists (CPs), licensed marriage and family therapists, mental health counselors, and clinical social workers, and, subject to certain conditions, a registered nurse or licensed practical nurse that is furnishing care to a homebound RHC or FQHC patient in an area verified as having shortage of home health agencies. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) services furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel acting under the supervision of the RHC or FQHC practitioner, are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount per visit. As of April 1, 2021, all RHCs are subject to statutory upper payment limits determined in accordance with section 1833(f) of the Act, as amended by section 130 of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116—260).

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning on that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, March 23, 2010)), FQHCs began to transition to the FQHC

PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV). Section 1834(o)(2)(B)(ii) of the Act requires the FQHC PPS base rate be updated annually by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the Medicare Economic Index (MEI) (as defined in section 1842(i)(3) of the Act) for the year involved. See section III.B.4 of this final rule, for the final CY 2027 updates.

Under the general authority of section 1834(o) of the Act, CMS codified at §§ 405.2462 and 405.2464 to pay historically excepted tribal FQHCs using the Medicare outpatient per visit rate established annually by IHS, rather than the FQHC PPS rate (80 FR 71089). These rates are set by IHS under sections 321(a) and 322(b) of the Public Health Service (PHS) Act based on prior-year cost reports. The outpatient per visit rate applies only to provider-based IHS or tribal facilities (see § 413.65(m)) and historically excepted tribal FQHCs. For CY 2026, the outpatient per visit rate is $733 per visit in the lower 48 States.

Both the RHC AIR and FQHC PPS payment rates were initially designed to reflect the cost of all services and supplies that an RHC or FQHC furnished to a patient in a single day. These nearly all-inclusive rates are not adjusted at the individual level for the complexity of individual patient health care needs, the length of an individual visit, or the number or type of practitioners involved in the patient's care. Instead, for RHCs, all costs for the facility over the course of the year are aggregated, and an AIR is derived from these aggregate expenditures. For FQHCs, the FQHC PPS base rate is updated annually by the percentage increase in a market basket of Federally qualified health center goods and services as discussed in section III.B.4 of this final rule.

RHCs and FQHCs are also paid for non-face-to-face care management work involved in coordinating care outside of the RHC AIR and FQHC PPS (§ 405.2464(c)). That is, payment is based on the PFS national non-facility payment rate and is made in addition to the otherwise billable visit for patients utilizing chronic care management (CCM), principal care management (PCM), general behavior health integration (BHI), chronic pain management (CPM), remote physiologic monitoring (RPM), remote therapeutic monitoring (RTM), community health integration (CHI), principal illness navigation (PIN), PIN-peer support services, advanced primary care management (APCM), and psychiatric collaborative care model (CoCM). In addition, payment is based on the PFS national non-facility payment rate and is made in addition to the otherwise billable visit for communication technology-based services (CTBS) and remote evaluation services (§ 405.2464(e)).

In the CY 2026 PFS final rule (90 FR 49556 through 49558), we finalized a policy that effective January 1, 2026, services that are established and paid under the PFS and designated as care management services would be considered ''care coordination services'' for purposes of separate payment for RHCs and FQHCs. The care coordination codes can be found in the PFS table entitled ''Designated Care Management Services'', which is published annually with the PFS Final Rule Addenda on the CMS website.

2. Payment for Certain Preventive Services

a. Background

Medicare Part B covers a comprehensive set of preventive services aimed at promoting early detection and reducing the risk of chronic disease.[163] These services include wellness visits (such as the IPPE and AWV), evidence-based screenings for cancer and chronic conditions, behavioral health and risk factor screenings, certain vaccinations, and preventive counseling interventions. Coverage for many of these services was expanded under sections 4103 and 4104 of the Patient Protection and Affordable Care Act (Pub. L. 111–148); the services are covered without beneficiary cost-sharing when furnished according to Medicare requirements. Collectively, they are designed to support proactive, patient-centered care and improve long-term health outcomes, particularly when delivered in primary care settings. CMS has implemented these statutory provisions through regulations at 42 CFR part 410, which define, among other things, the coverage, eligibility, and frequency requirements for preventive services.

CMS also establishes and updates coverage of preventive services through the National Coverage Determination (NCD) process, if such services are recommended with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF). These processes specify the conditions under which preventive services are considered reasonable and necessary for Medicare beneficiaries.

Payment for preventive services is made in accordance with applicable Medicare payment systems, for example, the PFS under 42 CFR part 414. CMS provides additional operational guidance through subregulatory instructions, including manuals and program transmittals, to ensure consistent implementation of coverage and payment policies. Beneficiary copayment and deductible (where applicable) is waived by the Affordable Care Act for the IPPE and AWV, and for Medicare-covered preventive services recommended by the USPSTF with a grade of A or B.

When statutorily permissible, we pay for covered preventive services under Medicare Part B to RHCs and FQHCs pursuant to such facilities' encounter-based payment methodologies, rather than as PFS separately billable services, except where the statute specifies otherwise.

RHCs are paid under the AIR methodology for a limited number of qualified preventive health services furnished by an RHC practitioner. FQHCs are paid under the FQHC PPS for qualified preventive health services and preventive primary health services required under section 330 of the PHS Act.[164] A qualified preventive health service refers to a Medicare-covered preventive service that also meets the requirements for a billable RHC or FQHC visit, including a face-to-face encounter with a RHC or FQHC practitioner (that is, the service is at a level that requires the expertise of a RHC or FQHC practitioner).

[163] *https://www.cms.gov/medicare/prevention/prevntiongeninfo/medicare-preventive-services/mps-quickreferencechart-1.html.*

[164] Section 1861(aa)(3) of the Act (42 U.S.C. 1395x(aa)(3)) defines Federally Qualified Health Center (FQHC) services to include services and supplies furnished by an FQHC, including preventive primary health services required under section 330 of the Public Health Service Act (42 U.S.C. 254b).

Specifically, RHCs and FQHCs are paid for the professional component of allowable preventive services when the program requirements are met and frequency limits (where applicable) have not been exceeded.[165] In this context, professional component refers to the practitioner's clinical service associated with a preventive service, as opposed to the technical or ancillary elements of the service. Preventive services furnished in other settings, for example, physician offices, are generally paid on a service-by-service basis. However, preventive services that do not constitute a separate billable RHC or FQHC visit must be furnished as part of a qualified RHC or FQHC visit (for example, an evaluation and management (E/M) visit) to be billable to Medicare. If a preventive service that is not part of a billable RHC or FQHC visit is furnished to a beneficiary, it may not be payable under Medicare.

b. Federal Initiatives To Improve Health Outcomes and Access to Care

(1) The Make America Healthy Again (MAHA) Commission

On February 13, 2025, the President signed an Executive Order establishing the MAHA Commission within the Department of Health and Human Services (HHS).[166] The Commission is chaired by the Secretary of HHS and includes representatives from multiple Federal agencies. The Commission was directed to assess contributing factors to chronic disease and to develop a coordinated Federal strategy to improve population health outcomes, with an initial focus on pediatric populations.

In 2025, the Commission released an assessment identifying a range of factors associated with chronic disease, including dietary patterns, environmental exposures, physical inactivity, and other behavioral and upstream drivers of health. The Commission subsequently issued a strategy outlining potential Federal actions to address these factors through cross-agency coordination, research, and programmatic initiatives.[167]

Although the Commission's initial focus is on childhood health, its findings are relevant to Federal health programs serving other populations, including Medicare beneficiaries. Chronic conditions associated with the factors identified by the Commission are prevalent among Medicare beneficiaries and are significant drivers of program expenditures.

(2) The Rural Health Transformation (RHT) Program

The RHT Program was authorized by section 71401 of Public Law 119–21 (July 4, 2025), which CMS refers to as the Working Families Tax Cut (WFTC) legislation, and empowers States to strengthen rural communities across America by improving healthcare access, quality, and outcomes by transforming the healthcare delivery ecosystem. The RHT Program represents a $50 billion Federal investment over five Federal fiscal years (FY 2026 to FY 2030), with $10 billion available annually, intended to strengthen health care infrastructure, expand access to care, and improve health outcomes in rural communities across the United States.

The program has five strategic goals, grounded in the permissible uses of funds under the statute: Make Rural America Healthy Again—Support rural health innovations and new access points to promote preventive health and address the root causes of disease; Sustainable Access—Improve the efficiency and long-term sustainability of rural health care providers as enduring access points for care; Workforce Development—Strengthen recruitment and retention of qualified health care professionals in rural communities; Innovative Care—Advance innovative care models that improve health outcomes, coordinate care, and promote flexible care arrangements; and Technology Innovation—Foster the adoption of innovative technologies that promote efficient care delivery, data security, and access to digital health tools for rural facilities, providers, and patients.[168]

c. Increasing Access to Diabetes Self-Management Training (DSMT) and Medical Nutrition Therapy (MNT) Services in RHCs

Section 4105 of the Balanced Budget Act of 1997 (Pub. L. 105–33) added section 1861(qq) of the Act to permit Medicare coverage of outpatient DSMT services when these services are furnished by a certified provider who meets certain quality standards. This program is intended to educate beneficiaries in the successful self-management of diabetes. The program includes instructions in self-monitoring of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin dependent; and motivation for patients to use the skills for self-management. DSMT services may be covered by Medicare only if the treating physician or treating qualified non—physician practitioner who is managing the beneficiary's diabetic condition certifies that such services are needed. The referring physician or qualified non-physician practitioner must maintain the plan of care in the beneficiary's medical record and documentation substantiating the need for training on an individual basis when group training is typically covered, if so ordered. A designated certified provider bills for DSMT provided by an accredited DSMT program. Certified providers must submit a copy of their accreditation certificate to the contractor. The statute states that a ''certified provider'' is a physician or other individual or entity designated by the Secretary that, in addition to providing outpatient self-management training services, provides other items and services for which payment may be made under title XVIII of the Act, and meets certain quality standards.

We designated all providers and suppliers that bill Medicare for other individual services such as hospital outpatient departments, renal dialysis facilities, physicians and durable medical equipment suppliers, as eligible to be certified providers. All suppliers/providers who may bill for other Medicare services or items and who represent a DSMT program that is accredited as meeting quality standards can bill and receive payment for the entire DSMT program.

Registered dietitians are eligible to bill on behalf of an entire DSMT program on or after January 1, 2002, if the provider employing or contracting with the dietitian has obtained a Medicare provider number. A dietitian may not be the sole practitioner of the DSMT service.[169] Under our regulations at § 410.144(a)(4)(ii), there is an exception for dietitians working in rural areas. In a rural area, an individual who is qualified as a registered dietitian and as a certified diabetic educator who is currently certified by an organization approved by us may furnish training and is deemed to meet the multidisciplinary team requirement. DSMT requirements for coverage, beneficiary eligibility, services and frequency of services and provider certification and accreditation are

[165] Public Law 100–02, Chapter 13, Section 220—Preventive Health Services.

[166] Exec. Order No. 14212, Establishing the Make America Healthy Again Commission, 90 FR 9833 (Signed, February 13, 2025).

[167] *https://www.usda.gov/about-usda/news/press-releases/2025/09/09/maha-commission-unveils-sweeping-strategy-make-our-children-healthy-again.*

[168] *https://www.cms.gov/priorities/rural-health-transformation-rht-program/overview.*

[169] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/b02062.pdf.*

codified in 42 CFR 410 subpart H and the National Coverage Determination (NCD) 40.1.[170]

Section 1861(s)(2)(V) of the Act authorizes Medicare Part B coverage of MNT for certain beneficiaries who have diabetes or a renal disease. Regulations for MNT were established effective January 1, 2002, at 42 CFR 410 subpart G (66 FR 55246 and 55331). The NCD 180.1 establishes the duration and frequency limits for the MNT benefit and coordinates MNT and DSMT.[171] MNT services are defined in section 1861(vv) of the Act as nutritional diagnostic, therapy, and counseling services provided by a registered dietitian or nutrition professional for the purpose of disease management under a referral by a physician. The provider qualifications for registered dieticians and nutrition professionals are defined in § 410.134.

Effective January 1, 2022, coverage of MNT, for the first year a beneficiary receives MNT, with either a diagnosis of renal disease or diabetes as defined at 42 CFR 410.130, is 3 hours of administration. Coverage in subsequent years for renal disease or diabetes is 2 hours. The dietitian/nutritionist may choose how many units are administered per day as long as all of the other requirements of the NCD and §§ 410.130 through 410.134 are met. Under the exception at § 410.132(b)(5), additional hours are considered to be medically necessary and covered if the physician determines that there is a change in medical condition, diagnosis, or treatment regimen related to diabetes or renal disease that requires a change in MNT and orders additional hours during that episode of care. If the physician determines that receipt of both MNT and DSMT is medically necessary in the same episode of care, Medicare will cover both DSMT and MNT initial and subsequent years without decreasing either benefit as long as DSMT and MNT are not provided on the same date of service.

In the CY 2027 PFS proposed rule (91 FR 43958) we stated that section 5114 of the Deficit Reduction Act of 2005 amended section 1861(aa)(3) of the Act to add DSMT and MNT services as covered and paid under the FQHC benefit, effective January 1, 2006. Then the Affordable Care Act further expanded the scope of FQHC services to include preventive services defined under section 1861(ddd)(3) of the Act; however, RHCs were not similarly addressed. Under this statutory authority, DSMT and MNT services furnished by certified providers are stand-alone billable visits in FQHCs when all of the requirements are met. If DSMT or MNT services are provided on the same day as another qualified visit, the FQHC is paid for one visit, and the charges associated with DSMT or MNT are waived from coinsurance obligations (79 FR 25447). We noted in the CY 2027 PFS proposed rule, group DSMT is not payable in FQHCs because Medicare payment is limited to individual, face-to-face encounters under the FQHC PPS, and group training does not meet the definition of a billable visit.

We explained in the CY 2027 PFS proposed rule, for RHCs, DSMT services and MNT services rendered by registered dietitians or nutrition professionals are included under the RHC benefit, if all relevant program requirements are met. Separate payment under Part B to RHCs for these services provided by these practitioners is precluded as set forth in regulations at §§ 414.63 and 414.64. However, RHCs are permitted to become certified providers of DSMT and MNT services and bundle the cost of such services into their clinic payment rates. The provision of these services would not generate an RHC visit, though their costs may be included in the cost report and used for determining the AIR.[172] Consequently, RHCs are not paid for encounters where only DSMT or MNT services are provided.

We also explained in the CY 2027 PFS proposed rule that interested parties have expressed concern about access to DSMT and MNT services in RHCs for several years (91 FR 43958). Those commenters stated that, because these are preventive services, not treating these services as a separate encounter is impacting access to care for rural beneficiaries. They stated that there are additional concerns regarding the payment for DSMT and MNT services between RHCs and FQHCs and rural interested parties have requested aligning payment for these services. They believe that we should recognize DSMT and MNT services as a qualified visit for RHCs when these services are provided by a certified provider and all the requirements are met. They believe that the utilization rate is low for beneficiaries receiving care in RHCs and explained that if we allow RHCs to receive payment for furnishing DSMT and MNT services, then this rate may increase.

In the CY 2027 PFS proposed rule (91 FR 43959) we discussed recent studies that highlight a continued need for DSMT and MNT services in rural areas, driven by rising diabetes prevalence and significant access disparities. Some of the barriers identified for people living in rural communities, especially for getting access to diabetes education and prevention programs, include limited number of providers, longer distance to medical facilities, higher costs, outdated cultural beliefs, lack of transportation, and limited community resources. More efforts to reduce these barriers may help reduce the overall high burden of diabetes in the rural US.[173] We explained that the necessity of DSMT and MNT in rural areas is supported by findings such that, they are clinically essential, diabetes control is improved, complications are reduced, lower costs, rural populations have equal or greater need, there are higher diabetes burden (widely established in rural health literature), access is systematically worse in rural areas, there are fewer providers, geographic maldistribution, and lower utilization despite need. Therefore, we opined that expanding DSMT and MNT in rural areas is not just beneficial, it is necessary to address documented health differences in access and outcomes.[174] In addition, we stated that we have observed low utilization for these services in rural settings. That is, we provided an analysis of Medicare claims data from 2024 that indicated that utilization of DSMT and MNT in RHC settings is substantially lower than in comparable care settings. In CY 2024, DSMT services were furnished to approximately 125 RHC beneficiaries, representing 0.005 percent of the total RHC beneficiary population of approximately 2.3 million. MNT services were furnished to approximately 439 RHC beneficiaries, representing 0.019 percent of the total RHC beneficiary population. On a claims basis, DSMT accounted for 0.002 percent and MNT for 0.007 percent of total RHC claims in CY 2024. By comparison, FQHCs showed DSMT utilization rates approximately 22 times higher and MNT utilization rates

[170] *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=251&ncdver=1&keyword=DSMT&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1.*

[171] *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=252.*

[172] *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/a03021.pdf.*

[173] Khavjou O, Tayebali Z, Cho P, Myers K, Zhang P. Rural-Urban Disparities in State-Level Diabetes Prevalence Among US Adults, 2021. Prev Chronic Dis. 2025 Jan 16;22:E05. doi: 10.5888/pcd22.240199. PMID: 39819894; PMCID: PMC11870018.

[174] Rhudy, C., Schadler, A., & Talbert, J. C. (2020). *Rural/urban disparities in utilization of diabetes self-management training to the fee-for-service Medicare population.* Rural and Underserved Health Research Center, University of Kentucky.

approximately 28 times higher than RHCs on a per-beneficiary basis. On a claim basis, FQHC utilization of DSMT and MNT exceeded RHC utilization by approximately 31 times and 32 times, respectively. Rural physician offices, whose patients share the geographic and demographic characteristics of RHC patient populations, showed DSMT and MNT utilization rates approximately 17 times and 7 times higher than RHCs, respectively, on a per-beneficiary basis. We observed that the analysis further demonstrated that within the PFS setting, where DSMT and MNT are most readily identifiable in claims data, these services represent a very small share of total Medicare spending less than 0.01 percent and 0.02 percent of total PFS line item payments, respectively, in CY 2024. We stated that these findings could suggest that beneficiaries receiving care in RHCs may have disproportionately lower participation due to potential provider shortages and structural payment barriers when compared to other settings of care.

As such, we explained that we believed we should attempt to align access and payment for RHCs and FQHCs to the extent possible, given the statutory differences in benefit design between the two settings of care. Because DSMT and MNT are affirmatively covered Medicare Part B benefits under sections 1861(s)(2)(S) and 1861(s)(2)(V) of the Act, respectively, and are defined under sections 1861(qq) and 1861(vv) of the Act, we stated there is a compelling basis for ensuring these clinically essential services are payable under the RHC benefit. We stated that continuing to exclude these services from RHC payment limits access for rural Medicare beneficiaries and would be inconsistent with both the statutory coverage framework and the foundational purpose of the RHC program (91 FR 43959). We explained that reducing differences between RHCs and other settings in which DSMT and MNT are furnished and paid, such as in FQHCs and physician office, may help expand access to care for Medicare beneficiaries in rural areas. We also stated that this policy would strengthen access to services that address chronic conditions prevalent among Medicare beneficiaries which are significant drivers of program expenditures.

In the CY 2027 PFS proposed rule (91 FR 43959), we stated that since DSMT and MNT services may be furnished by certified providers other than RHC practitioners as defined in §§ 410.141 and 410.134, respectively, these services could be furnished by certified providers under the direct supervision of an RHC practitioner. Direct supervision does not require the physician (or other supervising practitioner) to be present in the same room. However, the physician (or other supervising practitioner) must be present in the RHC or FQHC and immediately available to provide assistance and direction throughout the time the incident to service or supply is being furnished. See definitions at § 405.2401(b) ''Direct Supervision.''

For the reasons discussed previously, we proposed to recognize DSMT and MNT services as qualified preventive services that are covered and paid the AIR as stand-alone billable visits under the RHC benefit (91 FR 43959). We proposed that to constitute as a billable RHC visit, these services would need to be furnished by a certified provider under the direct supervision of RHC professional staff. We stated that we believe aligning payment policies in RHCs with other settings, for example FQHCs and physician offices, would help expand access to care for Medicare beneficiaries in rural areas while supporting Federal initiatives to strengthen rural healthcare. As such, we proposed to revise § 405.2463(a) and (b)(2) to allow DSMT and MNT services to be stand—alone billable visits in RHCs. We proposed that, similar to FQHCs, when DSMT or MNT is furnished on the same day as another qualified visit, the RHC would be paid one AIR for that encounter. We explained that we considered these policies to align an incongruency between FQHC and RHC access to preventive services and that we did not expect in future rulemaking to propose additional preventive services beyond those which are currently paid for in FQHCs and physician offices. We invited public comments on these proposals.

We received approximately 130 comments on this proposal from a broad range of commenters, including national physician and nurse practitioner associations, registered dietitian and nutrition professional organizations, disease-specific advocacy organizations, rural health clinic and health center representation organizations, individual RHCs and health systems, state and regional primary care associations, medical device and pharmaceutical industry commenters, and individual clinicians, dietitians, nurses, and students practicing in rural and underserved communities. The following is a summary of the comments we received and our responses.

Comment: The majority of the commenters were supportive of the proposal to recognize DSMT and MNT services as qualified visits for RHCs when these services are provided by a registered dietician or nutritional professional. Commenters stated that they believe providing separate reimbursement for DSMT and MNT encounters furnished in RHCs will strengthen the ability of rural practices to offer comprehensive, patient-centered care and improve access to services that are essential for the prevention and management of chronic disease. Most commenters framed the proposal as correcting a long-standing inconsistency: DSMT and MNT have been separately billable in FQHCs since the Deficit Reduction Act of 2005, and in physician offices for even longer, but RHCs have been able only to absorb these costs into their cost report and have not been able to generate a separately payable visit. Commenters characterized this as an unnecessary inconsistency or a structural payment barrier that CMS is now proposing to close, and specifically credited CMS's own stated rationale—that aligning RHC policy with FQHCs and physician offices would expand rural access.

A large subset of commenters went further than general endorsement and cited CMS's claims data from the CY 2027 PFS proposed rule (91 FR 43959) directly as evidence the current structure suppresses utilization rather than reflects a lack of need. Several of these commenters explicitly argued that this gap cannot be explained by differences in clinical need, since rural Medicare beneficiaries carry a disproportionate burden of diabetes and chronic kidney disease—the very conditions MNT is intended to treat.

Many commenters pointed to structural barriers specific to rural beneficiaries, that is, longer travel distances, clinician and registered dietitian nutritionist (RDN) workforce shortages, and limited specialty access—arguing that bundling DSMT/MNT into another visit compounds rather than accommodates these constraints. A smaller number of commenters supplied concrete, clinic-level accounts as indication that the barrier is payment structure, not clinical capability or willingness. One commenter reported it had previously offered DSMT and MNT at its RHCs but could not sustain clinician coverage once the services proved unpayable as stand-alone visits and stated it would restore and expand both services if separate payment were finalized. Another commenter cited a member poll finding that 23.5% of responding RHCs already furnish DSMT/MNT today but are unable to generate payment for doing so under current rules.

Response: We thank commenters for their support of this proposal to recognize DSMT and MNT services as qualified visits for Rural Health Clinics (RHCs) when furnished by a registered dietitian or nutrition professional. We appreciate the clinic-level experience commenters shared illustrating the practical effect of the current payment structure, including accounts of discontinued services and of RHCs that currently furnish DSMT and MNT without generating separate payment. We believe this information supports our expectation that this policy would enable RHCs to sustain and, in some cases, restore or expand access to these services for their patients. We believe that the commenter feedback received underscores the importance of aligning payment policies across care settings to expand access and address longstanding inconsistencies.

Comment: One commenter did not dispute the clinical value of DSMT and MNT but opposed making them stand-alone billable visits, cautioning that per-visit billing risks recreating an encounter-counting dynamic. The commenter recommended incorporating DSMT/MNT into a Primary Care Month or diabetes episode-based payment, with incentives tied to clinical outcomes rather than visit volume.

Response: We thank the commenter for their suggestion and appreciate the commenter's support for the clinical value of DSMT and MNT and their broader concern about avoiding payment structures that incentivize volume over outcomes. However, RHCs are paid on the basis of an all-inclusive rate and subject to a payment limit per visit (§ 405.2462(a)). Our proposal to recognize DSMT and MNT as stand-alone, qualified visits under the RHC AIR payment methodology is consistent with how these services are already recognized and paid in other settings, such as physician offices and FQHCs. Under current policy, RHCs cannot bill for DSMT and MNT when it is the only service furnished in a day, which we believe may have limited beneficiary access to these services. We believe that making DSMT and MNT stand-alone, qualified visits removes this access barrier and aligns payment incentives with furnishing medically necessary diabetes education and nutrition counseling.

We recognize the commenter's broader point about episode-based or population-based payment models that tie payment to clinical outcomes rather than visit counts. We agree that such models may hold promise for chronic disease management, including diabetes care, and note that Medicare has several programs that tie payment to diabetes-related care and clinical outcomes. RHCs can participate in Accountable Care Organizations (ACOs) under the Medicare Shared Saving Program, a value-based care initiative which allows ACOs that reduce healthcare costs while meeting quality benchmarks, including diabetes management metrics, to earn a share of the savings they generate. However, the RHC benefit as structured under current statute and regulations does not provide for incentives tied to clinical outcomes.

Comment: Several commenters asked CMS to confirm that DSMT and MNT may be furnished in a group or shared format. One commenter recommended that CMS remove its general limitation on group visits in RHCs, or at minimum establish a DSMT/MNT-specific exemption similar to the exemption previously adopted for intensive outpatient services furnished in RHCs, noting that DSMT in particular is often delivered in a group education format.

Response: We recognize that the Medicare DSMT and MNT benefit permits training to be furnished in both individual and group settings under the requirements applicable to that benefit. However, whether a service is covered under the Medicare DSMT or MNT benefit is distinct from whether the service constitutes a payable visit under the RHC or FQHC payment methodology. The RHC and FQHC payment methodologies are generally based on a qualifying visit between an individual beneficiary and a qualified practitioner. Consistent with this longstanding framework, group services generally do not constitute payable RHC or FQHC visits, as detailed in § 405.2463.

We also do not agree that the payment policies for intensive outpatient program services provide a basis for establishing a comparable exception for DSMT or MNT. Effective January 1, 2024, Medicare coverage and payment for IOP services furnished by RHCs and FQHCs were established pursuant to section 4124 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328). The payment policies applicable to group therapy furnished as part of an IOP implement that distinct statutory benefit and payment framework. Accordingly, the availability of payment for qualifying group therapy under the IOP benefit does not alter the requirements that otherwise apply in determining whether a service constitutes a payable RHC or FQHC visit.

Comment: Several commenters would like CMS to remove the direct supervision requirement. They noted that requiring direct supervision which they understood to mean that the supervising physician or practitioner would have to be physically present in the RHC and immediately available throughout the entire DSMT or MNT encounter—is inconsistent with how these services are furnished in every other Medicare setting. These commenters noted that FQHCs and physician offices require only a physician referral and provider certification, with no supervision requirement and RDNs bill independently under their own provider number once a referral is made. Commenters stated that importing a direct-supervision standard for RHCs alone runs counter to CMS's own stated objective of reducing payment and operational differences between RHCs and other settings, and that it would recreate, in a different form, the access barrier the proposal is intended to resolve: in rural clinics where the supervising physician or NP is typically fully scheduled, requiring that practitioner to remain immediately available for the full duration of a DSMT or MNT encounter would mean the service either displaces physician visit time or does not occur. Two commenters submitted specific proposed regulatory text, recommending that CMS collapse proposed § 405.2463(a)(2) into paragraph (a)(1) and list qualified MNT and DSMT providers, as defined under 42 CFR part 410, subparts G and H, directly among the practitioners whose face-to-face encounters constitute a billable RHC visit—without a separate supervision clause. One commenter recommended a different resolution: transitioning DSMT and MNT from direct to general supervision, which they believe would allow RHCs to contract with external or telehealth-based RDN networks rather than requiring an on-site supervising practitioner, an approach they stated is particularly important for small, resource-constrained rural clinics that cannot staff a full-time RDN.

Other commenters, generally representing physician and nursing professional associations, supported the direct supervision requirement as an appropriate mechanism for team-based care and practitioner oversight. One commenter supported the requirement and specifically noted that it appropriately includes nurses among the RHC professional staff who may provide supervision. Another commenter characterized the requirement as appropriately recognizing the value of team-based care while allowing RHCs to leverage the

expertise of qualified health professionals such as registered dietitians under practitioner oversight. A third commenter supported the proposal's approach of supervision by RHC professional staff, such as a nurse practitioner.

Response: With respect to the supportive comments, we agree that this policy would recognize team-based care models. Allowing RHCs to bill for DSMT and MNT encounters furnished by a registered dietitian or nutrition professional, under practitioner oversight, reflects the role these professionals already play in furnishing these services in other settings and allows RHCs to make full use of this expertise without requiring a billing practitioner to furnish the service directly.

We also acknowledge the other commenters' concerns regarding workforce limitations and access barriers associated with direct supervision in rural clinics, and their observation that MNT and DSMT are furnished and paid without a comparable supervision requirement in FQHCs and physician offices under §§ 410.130 through 134 and 410.140 through 146. However, as discussed above, DSMT and MNT are separately identified Part B benefits, with payment available under the physician fee schedule when applicable requirements are met. Congress also specifically expanded the FQHC benefit to include these services, and we recognize DSMT and MNT encounters as billable FQHC visits. The RHC benefit was not similarly amended. Under existing RHC policy, DSMT and MNT services may be included in clinic costs, but they do not independently generate an RHC visit payment. To receive payment for an encounter in an RHC, the service furnished must be at the skill level of an RHC practitioner. To be in compliance with the regulation at § 405.2463, we required direct supervision for DSMT and MNT services furnished by certified providers in RHCs

We have, however, considered commenters' concerns about the operational burden of requiring the supervising practitioner's continuous, on-site presence for the full duration of the encounter and offer clarification. Under § 405.2401(b), direct supervision means that the physician (or other supervising practitioner) must be present in the RHC or FQHC and immediately available to furnish assistance and direction throughout the performance of the service. It does not, however, mean that the physician (or other supervising practitioner) must be present in the room when the service is performed. We clarify that, consistent with § 405.2401(b), the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only). We believe this clarification addresses much of the concern about scheduling conflict commenters described, without requiring a change to the underlying practitioner scope of service requirement.

For the recommendation to adopt general, rather than direct, supervision for DSMT and MNT services in RHCs, we decline to make this change in this final rule. We continue to believe direct supervision, as clarified above to include virtual presence, is necessary to maintain the connection to RHC practitioner services required under § 405.2463. We recognize the appeal of a general supervision model for enabling RHCs to contract with external or telehealth-based RDN networks, particularly for clinics unable to staff a full-time RDN, and we will continue to evaluate this feedback in consideration of statutory authority for potential policy refinements.

We clarify one point raised by a commenter who supported the direct supervision requirement on the understanding that it includes nurses among the RHC professional staff who may provide the required supervision. The direct supervision requirement for DSMT and MNT services is satisfied only by an RHC practitioner. Registered nurses and other RHC professional staff who do not meet the skill level of an RHC practitioner may not serve as the supervising individual for purposes of this requirement.

Comment: A recurring concern across several supportive comments was that the proposal, while expanding access to DSMT and MNT, did not clearly define or protect the role of the RDNs who are the specialists trained to deliver these services. One commenter supported the proposal but asked that the Academy of Nutrition and Dietetics be included as an interested party in implementation discussions and separately opposed any accompanying restrictions on physicians that might come at RDNs' expense.

Other commenters focused less on payment parity and more on whether RHCs will have access to qualified nutrition professionals. One commenter noted that many rural clinics lack in-house dietitians, and that the proposal does not clearly specify that an RDN (in person or virtual) must be the one furnishing the service. Similarly, the commenter asked CMS to be explicit about the RDN clinical role providing clear guidance on staffing, referral, documentation, and care coordination arguing that nutrition policy too often names the intervention but leaves the clinician vague, which risks leaving the workforce question unaddressed even if the payment pathway is finalized.

Response: We thank commenters for their support for expanding access to DSMT and MNT services in RHCs. We recognize the important clinical role of RDNs and agree that recognizing these services as billable visits should not obscure the qualifications of the professionals who furnish them. This proposal addresses payment for qualifying DSMT and MNT encounters under the RHC benefit; it does not replace the service-specific requirements governing who may furnish these services. For MNT, provider qualifications for RDNs and nutrition professionals continue to be governed by § 410.134. For DSMT, instructor and multidisciplinary team qualifications, including the existing rural exception permitting a dually qualified registered dietitian and certified diabetes educator to satisfy the multidisciplinary team requirement in rural areas, continue to be governed by § 410.144(a)(4). This proposal does not alter, narrow, or supersede those qualification standards in RHCs. We also did not propose any restriction on physician billing for other services as a condition of, or offset to, this proposal.

We acknowledge commenters' concerns regarding the availability of qualified nutrition professionals in rural communities. We believe that recognizing DSMT and MNT services as stand-alone billable visits under the RHC benefit will help address a payment barrier and support RHCs in making these services more readily available, creating greater opportunities for rural Medicare beneficiaries to benefit from the expertise of RDNs and other qualified professionals.

We appreciate the recommendation to include the Academy of Nutrition and Dietetics in implementation discussions and welcome input from the Academy, RDNs, RHCs, and other interested parties. Our objective is to improve access to these covered services while maintaining the professional qualifications and program requirements applicable to their delivery.

Comment: Several commenters requested CMS permit separate payment when DSMT or MNT is furnished on the same day as another qualifying RHC visit. They cited continuity of care, the complementary nature of these services, and the burden rural beneficiaries face when required to make multiple trips.

One commenter specifically recommended extending the FQHC same-day multiple-visit exception in § 405.2463(c)(3) to RHCs.

Other commenters stated that the one-AIR-per-day limit could eliminate the financial incentive to furnish DSMT or MNT during the same visit as medical care, particularly when patients cannot return on another day. They recommended separate, stackable AIR payments or a carve-out similar to existing RPM and RTM payment policies. A commenter relatedly requested a supplemental payment mechanism in the FQHC PPS context.

Some commenters sought only implementation guidance, asking CMS to clarify payment when DSMT or MNT is furnished on the same day as another qualified RHC visit. Another commenter asked CMS to confirm whether RHCs would follow the same one-visit-per-day treatment currently applicable to FQHCs.

Response: We thank the commenters for their feedback regarding same day billing for DSMT and MNT services furnished in RHCs. One commenter's recommendation relied on § 405.2463(c)(3) as a provision currently permitting FQHCs paid under the reasonable cost system to receive payment for more than one visit per day when DSMT or MNT is furnished alongside another visit. We note that FQHCs no longer bill Medicare under the reasonable cost system for most services; all FQHCs bill under the FQHC PPS. Under the FQHC PPS, DSMT or MNT furnished on the same day as another qualified visit results in payment for one visit, unless the exception under § 405.2463(c)(4) is applicable.

Consistent with the RHC AIR payment methodology's existing treatment of multiple same-day services (§ 405.2463(c)(1)), and with the comparable FQHC treatment under the FQHC PPS described above, when DSMT or MNT is furnished on the same day as another qualified RHC visit, the RHC will be paid one AIR for that encounter, rather than separate, stackable AIR payments for each service. This approach maintains consistency between RHC and FQHC treatment of same-day visits, which has been the general organizing principle of encounter-based payment under both the RHC AIR and FQHC PPS methodologies. That is, encounters with more than one RHC or FQHC practitioner on the same day, or multiple encounters with the same RHC or FQHC practitioner on the same day, constitute a single RHC or FQHC visit and are payable as one visit. This policy applies regardless of the length or complexity of the visit, the number or type of practitioners seen, whether the second visit is a scheduled or unscheduled appointment, or whether the first visit is related or unrelated to the subsequent visit. This would include situations where an RHC or FQHC patient has a medically necessary face-to-face visit with an RHC or FQHC practitioner and is then seen by another RHC or FQHC practitioner, including a specialist, for further evaluation of the same condition on the same day, or is then seen by another RHC or FQHC practitioner, including a specialist, for evaluation of a different condition on the same day.

We understand commenters' concern that this approach may limit the near-term financial incentive for RHCs to furnish DSMT or MNT alongside an existing medical visit, particularly given that rural beneficiaries may consolidate care into a single visit for reasons of distance, cost, and transportation. We did not propose a stackable or supplemental payment mechanism, or a carve-out of DSMT or MNT from the AIR, however, as such a change would be a substantial departure from the per-diem, encounter-based structure of the AIR methodology generally and was outside the scope of this proposal as presented in the proposed rule.

Comment: One commenter requested CMS to clarify whether the stand-alone DSMT/MNT billing treatment would extend to ''historically excepted Tribal FQHCs'', which are paid under a separate methodology—the IHS outpatient per-visit rate under §§ 405.2462(f) and 405.2464(d)—rather than the standard FQHC PPS rate the proposed rule's discussion references. The commenter asked whether a DSMT or MNT encounter would count as a qualifying visit at these centers on the same terms as RHCs and FQHCs. The commenter supported the request by noting that AI/AN adults have the highest diagnosed diabetes prevalence of any tracked group, concentrated in the same rural areas this proposal targets.

Response: We thank the commenter for this clarifying question. Historically excepted Tribal FQHCs are paid at the lesser of the Medicare outpatient per-visit rate as set annually by the IHS, or the actual charge for the service, under §§ 405.2462(g)(1)(ii) and 405.2464(d). The proposal does not change that payment methodology, and historically excepted Tribal FQHCs are paid this way for all covered services, including DSMT and MNT. We note, as finalized in the CY 2016 PFS final rule, historically excepted Tribal FQHCs are paid for services included in the FQHC benefit (80 FR 71089 through 71096). Under this authority, DSMT and MNT services furnished by certified providers are stand-alone billable visits in FQHCs when all of the requirements are met, without a supervision requirement.

For whether a DSMT or MNT encounter constitutes a qualifying visit, we confirm that DSMT (G0108 Diabetes outpatient self-management training services, individual, per 30 minutes) is a qualifying visit for both FQHC payment codes G0466 (FQHC visit, new patient) and G0467 (FQHC visit, established patient). We also confirm that MNT (97802 Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes) is a qualifying visit for both FQHC payment codes G0466 (FQHC visit, new patient) and G0467 (FQHC visit, established patient). Also, MNT (97803 Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes) and (G0270 Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease), individual, face to face with the patient, each 15 minutes) are each a qualifying visit for FQHC payment code G0467 (FQHC visit, established patient).[175]

We acknowledge the commenter's observation that American Indian and Alaska Native adults have the highest rate of diagnosed diabetes of any racial or ethnic group tracked by CDC, underscoring the importance of ensuring clarity on this point for historically excepted Tribal FQHCs and confirm that, when Tribal FQHCs provide DSMT or MNT services, these services qualify as an FQHC visit.

Comment: Several commenters requested CMS clarify whether DSMT and MNT may be furnished through telecommunication technology, including in group or shared formats, by all personnel otherwise qualified under the existing benefits. They emphasized that virtual access is particularly important for rural beneficiaries who may have limited access to RDNs and diabetes educators.

Other commenters recommended making telehealth payment permanent, eliminating geographic and originating-site restrictions, paying RHC telehealth services at the full AIR rather than the

[175] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/fqhcpps/downloads/fqhc-pps-specific-payment-codes.pdf.*

lower physician fee schedule rate, and using CMMI or other demonstration authority to test accredited virtual or asynchronous DSMT models in RHCs and FQHCs.

Commenters also noted that, while in-person DSMT and MNT would qualify for the full stand-alone AIR, virtually delivered services would be paid at a lower and declining physician fee schedule rate. They stated that this disparity could discourage virtual care in rural clinics with limited on-site staffing and undermine access for beneficiaries least able to travel. One commenter therefore recommended extending the in-person-visit waiver under section 6209(c) of the CAA, 2026 to DSMT and MNT, allowing virtually delivered services to receive the same stand-alone AIR through at least 12/31/2027.

Response: We appreciate commenters' support for expanding access to DSMT and MNT services for beneficiaries receiving care in RHCs and FQHCs, including through the use of telecommunications technology. As discussed in section III.B.3. of this final rule, the Congress has extended through December 31, 2027, the authority for RHCs and FQHCs to furnish certain non-behavioral health services as Medicare telehealth services. As HCPCS codes 97802 and G0108 are listed in the Medicare telehealth services list, they are eligible for payment under the payment policy for non-behavioral services when furnished via telecommunications technology in RHCs and FQHCs. Under the current framework, non-behavioral health services furnished by an RHC or FQHC using telecommunications technology are paid under the methodology set forth in § 405.2464(g), rather than the RHC AIR or FQHC PPS. This methodology bases payment on the national average payment rates of the list of services available as Medicare telehealth services under the Physician Fee Schedule. DSMT and MNT services furnished through telecommunications technology remain subject to the applicable RHC and FQHC telehealth requirements and payment methodology and do not qualify for AIR payment solely because the same service would be payable as a stand-alone visit if furnished in person.

We also acknowledge commenters' concerns that differences between payment for in-person and telehealth services may affect RHCs' ability to invest in or expand virtual care arrangements. Similar concerns were raised in response to our broader proposals concerning RHC and FQHC telehealth policy, including requests to pay for non-behavioral health telehealth services at the RHC AIR or FQHC PPS rate. As explained in section III.B.3. of this final rule, revisions to the payment methodology for non-behavioral telehealth services are outside the scope of the conforming changes finalized in this rulemaking. We will consider commenters' views, as appropriate, in the context of future rulemaking addressing RHC and FQHC telehealth payment policy.

For requests concerning expansion or permanent extension of telehealth flexibilities, elimination of geographic or originating-site requirements, and use of Innovation Center or other demonstration authority to test virtual or asynchronous models, these recommendations concern broader Medicare telehealth, benefit, payment, or demonstration policies that are outside the scope of this rulemaking. We therefore are not addressing those recommendations substantively in this final rule but may take them into consideration in future policy development.

After consideration of public comments, we are finalizing our proposal to recognize DSMT and MNT services as qualified preventive services that are covered and paid the AIR as stand-alone billable visits under the RHC benefit. To constitute as a billable RHC visit, these services would need to be furnished by a certified provider under the direct supervision of an RHC practitioner. As we clarified above, consistent with the definition of ''direct supervision'' in § 405.2401(b), the presence of the physician (or other supervising practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only). We believe this clarification mitigates the burden of workforce limitations that may exist in RHCs since it offers a virtual direct supervision option. We believe aligning payment policies in RHCs with other settings, for example FQHCs and physician offices, would help expand access to care for Medicare beneficiaries in rural areas while supporting Federal initiatives to strengthen rural healthcare. We are also finalizing our proposal to revise § 405.2463(a) and (b)(2) to allow DSMT and MNT services to be stand—alone billable visits in RHCs, as proposed. Similar to FQHCs, when DSMT or MNT is furnished on the same day as another qualified visit, the RHC would be paid one AIR for that encounter.

Comment: In addition to the comments addressed previously, several commenters offered recommendations that, while related to DSMT and MNT generally, go beyond the specific scope of this proposal. We summarize these comments below but do not address them substantively in this final rule, as they concern separate statutory or regulatory provisions, or policy changes not proposed in the CY 2027 PFS proposed rule.

Expanding Eligible Diagnoses/Populations Beyond Diabetes and CKD: Several commenters recommended that CMS broaden MNT and DSMT eligibility beyond the current diabetes and chronic kidney disease diagnoses to include obesity, hypertension, dyslipidemia, cardiovascular disease, malnutrition, and other chronic conditions, or extend DSMT to beneficiaries with pre-diabetes.

Diabetes Prevention Program (MDPP) Alignment: One commenter stated that the rural-access rationale supporting this proposal should also support recognizing the Medicare Diabetes Prevention Program (MDPP) within the RHC and FQHC benefit structure, and separately requested CMS to allow MDPP suppliers to use their existing NPI rather than obtain a second one.

Referral Pathway: One commenter requested CMS amend § 410.132(c) to permit MNT referral by nonphysician practitioners (NPs and PAs) authorized to refer for DSMT, noting that most RHCs are staffed predominantly by mid-level practitioners who currently cannot generate a qualifying MNT referral.

A small number of additional recommendations fell outside the scope of this proposal: removing the one-year expiration on the initial 10 hours of DSMT; reconsidering CMS's general valuation methodology for low-intensity preventive services; requiring state Medicaid programs to recognize RDNs as eligible MNT providers, and revisiting the 85 percent-of-PFS payment cap for RDN-furnished MNT; encouraging referral pathways from DSMT/MNT to medically tailored meal programs; and addressing the effect of the proposed CY 2027 conversion factor reduction on PFS-billed MNT codes.

Response: We appreciate the commenter's feedback however these comments are outside the scope of this proposal.

3. Services Furnished Using Telecommunication Technology

a. Background

Section 3704 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020) directed the Secretary to establish payment for RHC and FQHC services that are provided as Medicare telehealth services by RHCs and FQHCs

serving as a distant site (that is, where the practitioner is located) during the PHE for COVID–19. Specifically, section 1834(m)(8)(B) of the Act, as added by section 3704 of the CARES Act, required that, for the duration of the PHE for COVID–19, the Secretary develop and implement payment methods for FQHCs and RHCs that serve as a distant site. The payment methodology outlined in the CARES Act requires that rates be based on rates that are similar to the national average payment rates for comparable telehealth services under the Medicare PFS. Accordingly, we established payment rates for these services furnished by RHCs and FQHCs based on the average PFS payment amount for all Medicare telehealth services, weighted by volume in a Special Edition Medicare Learning Network Article (SE20016). Congress has extended this payment flexibility beyond the PHE for COVID–19 through a series of statutory amendments, most recently under section 6209(c) of the CAA, 2026, which extended this payment flexibility through December 31, 2027.

We codified this payment policy at 42 CFR 405.2464(g). As amended in the CY 2025 PFS final rule (89 FR 98554), § 405.2464(g) states that for an encounter furnished using interactive, real-time, audio/visual telecommunications technology or for certain audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology services that are not described in § 405.2463(b)(3), payment to RHCs and FQHCs are subject to the national average payment rates for comparable services under the PFS and costs associated with these services shall not be used in determining payments under the RHC all-inclusive rate or the FQHC prospective payment system.

In the CY 2022 PFS final rule (86 FR 65210 and 65211), we revised payment for mental health visits in RHCs and FQHCs furnished via interactive, real-time, audio/visual or audio-only telecommunications technology. Instead of paying for these services under the national average payment rates for comparable services under the PFS, as is done for non-behavioral health services, we amended the regulation at § 405.2463 to permit mental health visits in RHCs and FQHCs furnished via audio/visual or audio-only telecommunication to be paid under the RHC AIR and FQHC PPS rates. In addition, to align with the Medicare telehealth statutory requirements for mental health services, we finalized at §§ 405.2463(b)(3) and 405.2469(d) that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

However, beginning with section 304 of Division P of the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022), the in—person visit requirements for mental health visits were delayed. These requirements were further delayed through various laws that included extension of the telehealth flexibilities. Following the publication of the CY 2026 PFS final rule, section 6208 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37, November 12, 2025) extended the delay until January 30, 2026. Most recently, section 6209(d) of the CAA, 2026 extended the abeyance of the RHC/FQHC mental health in-person requirements through December 31, 2027.

b. Conforming Regulatory Text Changes

In the CY 2027 PFS proposed rule (91 FR 43960), we explained that because section 6209(c) of the CAA, 2026 extended authority for CMS to pay for FQHC and RHC non-behavioral health telecommunication technology services as Medicare telehealth services, we did not propose any modifications for this provision to § 405.2464(g).

We also explained that because section 6209(d) of the CAA, 2026 extended the abeyance of the RHC and FQHC mental health in-person requirements through December 31, 2027, we proposed to make conforming regulatory text changes at §§ 405.2463(b)(3) and 405.2469(d). We stated that this provision, as proposed, would require that the in-person visit requirements not apply to any services furnished through December 31, 2027.

We received public comments on our proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to make regulatory changes to conform to statutory requirements. Commenters stated that telehealth-related flexibilities in general improve access to behavioral health and other services for beneficiaries in rural and underserved areas, where provider shortages, transportation barriers, mobility limitations, and long travel distances may make in-person care difficult to obtain. A commenter noted that these flexibilities may facilitate access to substance use disorder treatment, including the initiation and continuation of treatment through telehealth. Another commenter described the importance of telehealth for individuals with significant mobility, respiratory, communication, and other functional limitations and encouraged CMS to preserve flexible access to telehealth, including audio-only services when clinically appropriate.

Response: We appreciate commenters' support for our proposed conforming changes. The regulatory revisions proposed in this rulemaking are conforming changes intended to reflect statutory requirements.

Comment: Several commenters also urged that the telehealth flexibilities be made permanent rather than extended for limited periods. These commenters stated that successive temporary extensions create uncertainty for RHCs and FQHCs and may discourage investment in telehealth infrastructure, staffing, and other resources necessary to sustain telehealth services over the long term.

Response: We acknowledge commenters' concerns regarding the effects of temporary extensions on RHCs' and FQHCs' ability to plan for and invest in telehealth services. The amendments addressed in this section are conforming changes intended to reflect current statutory requirements, including the statutory extension through December 31, 2027, of the delay of the in-person visit requirements for RHC and FQHC mental health services furnished using telecommunications technology. Because the duration of that extension is established by statute, making the extension permanent is beyond the scope of these conforming amendments.

Comment: Some commenters expressed concerns regarding payment for non-behavioral health services furnished by RHCs using telecommunications technology. Commenters asserted that payment under HCPCS code G2025 is lower than the payment RHCs would receive under the RHC AIR for an in-person visit and,

in some cases, lower than Medicare Physician Fee Schedule payment for comparable services. Commenters stated that this payment methodology may create a financial disincentive for RHCs to furnish or expand telehealth services and requested that CMS reconsider the payment methodology, establish payment parity, or align payment for RHC telehealth services with the RHC AIR. A commenter described the use of RHC telehealth to furnish specialty services, including pulmonology, gastroenterology, and neurology services, and stated that higher payment would support expansion of specialty care in rural communities.

Response: We appreciate commenters' concerns regarding the potential effects of the current payment methodology on RHCs' and FQHCs' ability to furnish or expand telehealth services, including specialty care. The proposed changes concerning payment for non-behavioral health services furnished using telecommunications technology were limited to conforming and technical changes to reflect current statutory authority. Accordingly, broader revisions to the payment methodology, including requests to establish payment parity or align payment for these services with the RHC AIR or FQHC PPS, are outside the scope of this rulemaking. We may consider commenters' views, as appropriate, in the context of future rulemaking addressing RHC and FQHC telehealth payment policy.

Comment: A commenter reiterated their support for an alternative approach that CMS considered in the CY 2026 PFS final rule (90 FR 49561) whereby CMS would change the definition of an RHC or FQHC medical visit to include visits furnished using telecommunications technology so that such services would be paid under the RHC AIR or FQHC PPS, similar to how we previously revised the regulations for mental health visits. The commenter stated that the current payment differential between in-person and medical telehealth visits limits RHCs' ability to invest in telehealth technology and incorporate telehealth into their care delivery models. The commenter acknowledged that the special payment rule for RHC and FQHC telehealth services was established by statute but urged CMS to further consider whether it has authority to adopt an alternative approach or work with Congress to address the payment differential. The commenter also requested that CMS further explain statements made in prior rulemaking regarding potential unintended consequences, program integrity concerns, and administrative burden associated with the alternative payment approach discussed in the CY PFS 2026 final rule. The commenter questioned whether such concerns would arise in practice and suggested that CMS could address potential program integrity concerns through claims modifiers or other safeguards rather than maintaining the current payment methodology.

Response: The regulatory revisions proposed in this rulemaking are conforming changes intended to reflect statutory requirements, and revisions to the payment methodology for non-behavioral services furnished using telecommunications technology are out of scope for purposes of this rulemaking. We note that our proposed changes concerning payment for non-behavioral health services furnished using telecommunications technology were limited to conforming and technical changes to reflect current statutory authority. We may consider commenters' views, as appropriate, in the context of any future rulemaking addressing RHC and FQHC telehealth payment policy.

After consideration of public comments, we are finalizing as proposed conforming amendments to §§ 405.2463(b)(3) and 405.2469(d). These amendments reflect the statutory extension through December 31, 2027 of the delay of the in-person visit requirements for RHC and FQHC mental health services furnished using telecommunications technology. Other technical amendments to § 405.2469(d) proposed in the CY 2027 PFS proposed rule are addressed separately in section III.B.5.c. of this final rule.

4. CY 2027 FQHC PPS Market Basket Update

Section 1834(o)(2)(B)(ii) of the Act requires the FQHC PPS base rate be updated annually by the percentage increase in a market basket of Federally qualified health center goods and services as issued through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1842(i)(3) of the Act) for the year involved. For CY 2027 (that is, January 1, 2027, through December 31, 2027), we proposed to use an estimate of the percentage increase in the 2022-based FQHC market basket to update payments to FQHCs based on the best available data (91 FR 43960). Additionally, as finalized in the CY 2025 final rule (89 FR 98032), a productivity adjustment is included in the 2022-based FQHC market basket.

For CY 2027, we proposed to update the CY 2026 FQHC PPS base rate by the historical percentage increase through the second quarter of 2026 of the productivity-adjusted FQHC market basket (which we refer to as the FQHC market basket update). For CY 2027, the proposed FQHC market basket update was estimated to be 2.5 percent and was based on the expected historical percentage increase of the FQHC market basket update. Multiplying the CY 2026 FQHC PPS base rate amount of $207.72 by the proposed CY 2027 FQHC market basket update of 2.5 percent ($207.72 × 1.025) resulted in a proposed CY 2027 FQHC PPS base rate amount of $212.91. In the CY 2027 proposed rule, we proposed that the CY 2027 market basket update and the productivity adjustment would be updated to reflect historical data through the 2nd quarter of 2026 (91 FR 43960).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters noted appreciation for the proposed CY 2027 market basket update for Federally Qualified Health Centers (FQHCs), also referred to as community health centers (CHCs). These commenters stated that while the proposed 2.5 percent increase is appreciated, it does not resolve their underlying concern that Medicare payments have not kept pace with the actual cost of furnishing comprehensive care in FQHCs.

Commenters stated that the CY 2027 update relies on the 2022-based FQHC market basket, which reflects a cost structure several years removed from CY 2027, and noted that general inflation has grown at a faster rate than the FQHC market basket updates between 2022 and 2026. Commenters also described concurrent cost pressures facing CHCs, including workforce recruitment and retention costs, health information technology and cybersecurity investments, administrative and compliance requirements, anticipated Medicaid coverage losses, and instability affecting the 340B Drug Pricing Program.

Commenters stated that annual market basket adjustments alone cannot correct an underlying prospective payment system (PPS) methodology that was established more than a decade ago and may no longer adequately capture the cost and complexity of contemporary care provided by these facilities. These commenters requested CMS undertake a comprehensive evaluation of the FQHC PPS using current Medicare cost report data and identify opportunities to simplify Medicare cost reporting while preserving the information needed to accurately assess FQHC costs.

Response: We appreciate the commenters' concern regarding inflationary pressure facing FQHCs/CHCs and the proposed CY 2027 market basket update.

The 2022-based FQHC market basket is a fixed-weight, Laspeyres-type index that measures price changes over time. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

Since the inception of the FQHC PPS, the FQHC payment rates (with the exception of statutorily-mandated updates) have been updated by the FQHC market basket percentage increase.

Additionally, the market basket updates appropriately differ from other payment updates (such as increases in the Consumer Price Index) that are not consistent in concept with the statutory requirement for the index to reflect the relative costs associated with furnishing FQHC visits.

We appreciate commenters' concerns regarding the adequacy of the FQHC PPS methodology and the suggestion that we undertake a comprehensive evaluation of the system using current Medicare cost report data. We recognize that FQHCs continue to face evolving operational and financial pressures, and we value the ongoing feedback we receive through the rulemaking process on how well the FQHC PPS reflects current costs of care.

We agree that the annual market basket update described in this rule is required by section 1834(o)(2)(B)(ii) of the Act and is intended to adjust the FQHC PPS base rate for input price inflation; however, it is not intended to serve as a mechanism for broader structural revisions to the payment methodology itself. A comprehensive reevaluation of the FQHC PPS, including the underlying cost reporting requirements and payment structure, would require a more extensive process involving consideration of statutory authority, detailed analysis of current Medicare cost report data, and opportunity for additional interested parties input beyond the scope of this annual update. Regarding the monitoring of trends in FQHC costs and operations, including the impact of the factors commenters raised, we may take these concerns into account as we consider future policy development.

Final Rule Action: As is our general practice, we proposed in the CY 2027 PFS proposed rule that if more recent data became available, we would use such data, if appropriate, to derive the final CY 2027 FQHC market basket update for the final rule. Therefore, for this final rule, based on historical data through the second quarter 2026, the final 2022-based FQHC market basket update for CY 2027 is 2.6 percent, which is 0.1 percentage point higher than the projected CY 2027 market basket update in the proposed rule. Multiplying the CY 2026 FQHC PPS base rate amount of $207.72 by the final CY 2027 FQHC market basket update of 2.6 percent ($207.72 × 1.026) results in a final CY 2027 FQHC PPS base rate amount of $213.12.

5. Technical Changes

a. Section 405.2464(b)(1) and (2)

In the CY 2027 PFS proposed rule (91 FR 43960), we proposed revisions at § 405.2464(b)(1) and (2) to correct the references within these paragraphs so that they reference the appropriate paragraph or sections under subpart X of part 405. We also proposed to revise § 405.2464(b)(1) by replacing ''paragraphs (d) and (e)'' with ''paragraphs (c) and (h)'' since the payment discussed under these paragraphs are not based on the FQHC PPS per diem rate. In addition, we proposed to revise § 405.2464(b)(2)(i) and (ii) to reference § 405.2462(e), explaining that this reference should have been revised when we redesignated this section in the CY 2022 PFS final rule (86 FR 65660).

b. § 405.2464(g)

In the CY 2025 PFS final rule (89 FR 98015 through 98017) we discussed medical visit services furnished via telecommunications technology. We revised § 405.2464 by adding new paragraph (g) to reflect our payment policy for these services. That is, for non-behavioral health services, an encounter furnished using telecommunications technology, payment to RHCs and FQHCs are subject to the national average payment rates for comparable services under the PFS and costs associated with these services shall not be used in determining payments under the RHC AIR or the FQHC PPS. During a recent review of our regulation, we noticed that we inadvertently used the term ''an encounter'' instead of ''services.'' Therefore, in the CY 2027 PFS proposed rule (91 FR 43960 and 43961), we proposed to revise § 405.2464(g) to be consistent with the authority under section 1834(m)(8) of the Act.

c. Section 405.2469(d)

In the CY 2022 PFS final rule (86 FR 65210 and 65211), we explained that § 405.2469(d) was revised to describe the same in-person mental health visit requirement applicable under § 405.2463. In subsequent PFS rulemaking, we described revisions to both provisions as technical changes intended solely to conform the regulations to the applicable statutory delay of the in-person requirement. Because the current text of § 405.2469(d) separately restates the technology modalities and in-person requirement language, it creates an unnecessary risk of divergence from § 405.2463(b)(3). Accordingly, in the CY 2027 PFS proposed rule (91 FR 43961), we proposed to revise the regulatory text at § 405.2469(d) to align the description of permissible telecommunications modalities with the language used in § 405.2463. Specifically, § 405.2469(d) currently refers to audio-only interactions in cases where beneficiaries do not wish to use, or do not have access to, devices that permit two-way, audio/video communication. In contrast, § 405.2463 permits the use of audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology. To ensure consistency across these provisions we proposed to revise the descriptions to match what is described at § 405.2463, namely that the use of audio-only interactions is permissible in cases where the patient is not capable of, or does not consent to, the use of video technology. We also proposed to revise § 405.2469(d) to align the description of the in-person visit requirement for mental health services with the requirements set forth in § 405.2463(b)(3). We explained that these amendments are non-substantive and clarifying because they do not alter payment policy; they merely align duplicative regulatory text and eliminate any potential internal inconsistency.

We did not receive public comments on these technical changes, and therefore, we are finalizing them as proposed.

6. Miscellaneous Comments

We received comments that were out of scope from what we proposed in the CY 2027 PFS final rule for RHCs and FQHCs. A summary of these comments organized by subject area, and our response follow.

Comments: Workforce and Scope of Practice. Several commenters requested that CMS expand the range of practitioners recognized or permitted to independently order and bill certain services. Commenters requested that lactation consultants be permitted to enroll as independent Medicare Part B

practitioners; that pharmacists be explicitly recognized as RHC and FQHC practitioners; and that CMS establish a billing mechanism to reimburse Community Health Workers (CHWs) or their supervising practitioners for travel time associated with home and community-based visits.

Group Visits and the RHC ''Group Services'' Prohibition. Commenters requested that CMS revisit or remove the longstanding prohibition on billing for ''group services'' in RHCs, noting that this limitation restricts the ability of newly recognized practitioners—including Marriage and Family Therapists and Mental Health Counselors—to bill for group, family, or couples therapy.

Behavioral Health Access and Parity. Commenters asked CMS to adopt less restrictive, non-stigmatizing regulatory terminology for mental health and substance use disorder (SUD) services; to permit clinically appropriate combinations of behavioral health services on the same day without arbitrary exclusions; to promote payment parity across CMHCs, RHCs, FQHCs, and hospital outpatient departments; and to reconsider the current interpretation limiting RHCs to providing no more than 49 percent of services as behavioral health services.

Qualifying Visit List Modernization. Commenters stated that the CHC and FQHC qualifying visit lists have not kept pace with changes in Medicare-covered services since 2017, and recommended that CMS establish a regular process for reviewing and updating these lists, including recognition of standalone visits furnished by psychiatric nurse practitioners and clinical pharmacists.

Separate Payment for Part B Drugs and Biologicals. Commenters requested that CMS establish separate payment, outside the FQHC PPS bundled rate, for Part B drugs and biologicals administered by injection, similar to existing exceptions for preventive vaccines. Commenters cited the growing share of high-cost biologics and the risk that acquisition costs for certain injectables may approach or exceed the PPS base payment.

Annual Wellness Visits. Commenters requested that CMS allow RHCs to bill an Annual Wellness Visit (AWV) and a same-day medical visit as two separately reimbursed encounters, consistent with existing FQHC policy, and that CMS permit Registered Nurses to independently furnish AWVs in the RHC setting, consistent with policy in traditional office settings.

Response: We appreciate these comments. However, these suggestions are outside the scope of the proposed rule. We may consider them for future rulemaking.

C. Clinical Laboratory Fee Schedule (CLFS): Consolidated Appropriations Act (CAA), 2026

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS) under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) the amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U), and reduced by a productivity adjustment and other statutory adjustments, but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. In a final rule that appeared in the June 23, 2016 **Federal Register** (81 FR 41036), entitled Medicare Clinical Diagnostic Laboratory Tests Payment System (hereinafter referred to as the CLFS final rule), we established requirements to implement section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016, through June 30, 2016. The first data reporting period occurred from January 1, 2017, through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information with respect to the initial data reporting period.[176]

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850, 35855 through 35862). First, we excluded Medicare Advantage plan payments under Part C from the denominator of the Medicare revenues threshold calculation to broaden the types of laboratories qualifying as an applicable laboratory. Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data, we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced

[176] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

as compared to the payment rates for the preceding year. Under the original provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction could not be more than 10 percent per year. For the next 3 years after implementation (CY 2021 through CY 2023), section 216(a) of PAMA stated that the reduction could not be more than 15 percent per year. Under sections 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update were to occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs was originally scheduled to take place from January 1, 2019, through June 30, 2019, and the next data reporting period was originally scheduled to take place from January 1, 2020, through March 31, 2020, with the next update to the Medicare payment rates for those tests based on that reported applicable information scheduled to take effect on January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. The definition of an ADLT is set forth in section 1834A(d)(5) of the Act and implemented at § 414.502. Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial period of 3 calendar quarters. After the new ADLT initial period, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101) and is available on the CMS website.[177]

3. Previous Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Beginning in 2019, Congress repeatedly extended the data reporting periods for CDLTs that are not ADLTs and revised the phase-in of CLFS payment reductions through multiple laws, including: section 105 of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, December 20, 2019); section 3718 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020); section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, December 10, 2021); section 4114 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117—328, December 29, 2022); section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (FCAOEA, 2024) (Pub. L. 118–22, November 17, 2023); and section 221 of the Continuing Appropriations and Extensions Act, 2025 (CAEA, 2025) (Pub. L. 118–83, September 26, 2024). For a detailed discussion of these statutory revisions, please see the CY 2025 PFS final rule (89 FR 98038 through 98043) and the prior PFS rules referenced in the CY 2025 discussion.

4. Additional Statutory Revisions to the Data Reporting Period, Phase-In of Payment Reductions, and Data Collection Period

Section 6209 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37, enacted November 12, 2025) made further revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 6209(b) of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 delayed the next data reporting period for CDLTs that are not ADLTs so that reporting would be required during the period of February 1, 2026 through April 30, 2026, instead of the data reporting period of January 1, 2025 through March 31, 2025 established under the FCAOEA, 2024.

Section 6209 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 did not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (February 1, 2026, through April 30, 2026) continued to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502.

Section 6209(a) of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2029. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2026 was 0 percent, meaning that the payment amount determined for a CDLT for CY 2026 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2025. Section 6209(b) of this law further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2026 (January 31, 2026 through December 31, 2026), 2027, and 2028.

Most recently, section 6226 of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75, February 3, 2026) amended section 1834A of the Act to revise the data reporting period, data collection period, and requirements for the phase-in of payment reductions. Specifically, section 6226 of the CAA, 2026 revised the next required data reporting period for CDLTs that are not ADLTs to be May 1, 2026 through July 31, 2026, and specified that the applicable data collection period is January 1, 2025 through June 30, 2025.

Section 6226 of the CAA, 2026 also amended section 1834A(b)(3) of the Act to specify that the applicable percent was 0 percent for all of CY 2026, meaning that the payment amount determined for a CDLT for CY 2026 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2025, and to extend the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2029. Therefore, the applicable percent of up to 15 percent would apply for CYs 2027 through 2029. Section 6226 of the CAA, 2026 further provided that, notwithstanding any other provision of law, the Secretary may implement the amendments made by this section by program instruction or otherwise.

5. Conforming Regulatory Changes

In the CY 2027 PFS proposed rule (91 FR 43962—43963) we stated that in accordance with section 6226 of the CAA, 2026, we proposed to make certain conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we proposed to revise § 414.502 to

[177] *https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule/clfs-history.*

update the definitions of both the ''data collection period'' and ''data reporting period,'' specifying that the data collection period is the 6-month period from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period, and that the data reporting period for CDLTs that are not ADLTs is the 3-month period, May 1 through July 31, and for ADLTs is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period. We also proposed to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning May 1, 2026. In addition, we proposed to make conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 6226 of the CAA, 2026. Specifically, we proposed to revise § 414.507(d) to indicate that for CY 2026, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2025, and for CYs 2027 through 2029, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We noted in the proposed rule that the CYs 2018 through 2026 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016 through June 30, 2016. Under current law, the CLFS payment rates for those tests for CY 2027 through CY 2029 will be based on applicable information collected during the data collection period of January 1, 2025 through June 30, 2025, and reported to CMS during the data reporting period of May 1, 2026 through July 31, 2026.

We received public comments on our proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to make regulatory changes to conform to the statutory requirements pursuant to section 6226 of the CAA, 2026. Several commenters, however, expressed concerns about the private payor rate-based CLFS methodology and the potential effects of future payment reductions. Commenters stated that reported private payor rates may not fully reflect the costs or market value of laboratory services or adequately represent the range of laboratories furnishing services to Medicare beneficiaries, including physician-office, hospital outreach, rural, community-based, and oncology laboratories. Commenters cited inflationary pressures, labor and supply costs, limited negotiating leverage with commercial insurers, and increasing regulatory requirements, and expressed concern that additional payment reductions under the CLFS could affect laboratory sustainability, beneficiary access, diagnostic innovation, and practice consolidation. Similarly, another commenter expressed concern that upcoming CLFS rates could result in substantial payment reductions beginning in 2027 and continuing through 2029. The commenter stated that such reductions could make it difficult to invest in new or expanded laboratory services and could threaten access to care, particularly in rural areas.

Commenters urged CMS to monitor the completeness and representativeness of reported private payor data and the effects of resulting CLFS payment rates, limit or defer payment reductions where possible, and consider broader changes to CLFS data collection and rate setting. Another commenter recommended that CMS evaluate whether the applicable laboratory methodology and low-expenditure threshold result in sufficiently representative data and examine whether increasing Medicare Advantage penetration affects which laboratories satisfy the applicable laboratory criteria.

A commenter also urged Congress and CMS to further delay CLFS payment reductions while evaluating alternative approaches to data collection and rate setting and recommended that future payment updates rely on transparent and representative market data that account for laboratory services furnished across diverse provider settings.

Response: We appreciate the support of commenters for our proposed conforming regulatory changes and we appreciate their concerns regarding the completeness and representativeness of private-payor data, the composition of the reporting population, and the potential effects of CLFS payment changes. As the regulatory revisions proposed in this rulemaking are conforming changes intended to reflect statutory requirements, revisions to the statutory private payor rate-based methodology and timing of payment reductions are out of scope for purposes of this rulemaking. We note that the recommended changes to the statutory timing of payment reductions, the private payor rate-based methodology, or to other requirements established by section 1834A of the Act would require further Congressional action. We note that section 1834A(b)(3) of the Act limits the amount by which the payment amount for an existing test may be reduced, compared with the payment amount for the preceding year, as a result of implementing updated CLFS rates based on applicable information. Accordingly, the actual payment reduction for a particular test will depend on the applicable weighted median private payor rate and may be less than 15%, or may not result in a reduction, while the statutory phase-in provision prevents an annual payment reduction from exceeding 15 percent for CYs 2027 through 2029.

We will take the commenters' other recommendations, such as suggestions to review the regulatory low expenditure threshold, under advisement.

Comment: A commenter recommended that CMS publish comparisons between CLFS payment amounts and publicly available consumer cash prices as a transparency measure and continue to examine the definition of ''applicable laboratory'' to improve the representativeness of reported data.

Response: We appreciate the commenter's recommendation and agree with the importance of health care price transparency. Under current hospital price transparency requirements at 45 CFR part 180, the amount that a hospital negotiates with private payers for clinical laboratory services are required to be posted publicly in a hospital's machine-readable file (MRF) if the hospital furnishes the item or service and the lab is part of the licensed hospital. Hospitals are also required to include cash prices and gross charges in their MRFs if they have been established for that item or service. We believe that these price transparency requirements meet the criteria to facilitate the type of comparisons the commenter is requesting.

We also note that revisions to the definition of ''applicable laboratory'' are out of scope for purposes of this rulemaking.

Comment: A commenter recommended that CMS not publish code-level weighted median private-payor rates calculated under PAMA before applying the statutory phase-in of payment reductions when those amounts differ from the applicable Medicare payment rates. According to the commenter, when CMS disclosed these underlying calculations during the initial PAMA rate-setting cycle in 2018, laboratories reported that commercial payors used them as reimbursement benchmarks. The commenter urged

CMS to publish only the operative CLFS payment rate for each test code and present additional information concerning the reported data and rate-setting methodology in an appropriately aggregated form that cannot be used to establish code-specific commercial payment rates.

Response: In the CLFS final rule (81 FR 41071 through 41073) which implemented section 1834A of the Act, we stated that we intended to make available to the public a file that includes summary or aggregate-level private payor rate and volume data for each test code such as, the unweighted median private payor rate, the range of private payor rates, the total, median and mean volume, and the number of laboratories reporting. We stated that such information would also be released to the public before the final rates are published to better enable the public to comment on the general accuracy of the reported data. During the initial implementation of section 1834A of the Act, we published the raw data that contained reported private payor rate and volume information used in implementing the private payor rate-based CLFS; this included private payor data by HCPCS code, reported private payor payment rate, and associated volume of tests.[178] [179] To protect laboratory confidentiality, CMS removed laboratory National Provider Identifiers from the public-use file and excluded reported information for tests with volumes below 10. We also posted preliminary CLFS payment rates for CY 2018 to provide interested parties with an opportunity to review and comment on the information used in establishing the new payment rates and the final data. These files included private payor rates and volumes and preliminary and final weighted median-based payment rates. For the current data reporting period that ended on July 31, 2026, we similarly made information publicly available to permit interested parties to understand how the applicable CLFS payment rates were derived and to assess the general accuracy of the reported data.[180]

We recognize the commenter's concern that code-level information could be used by commercial payors for purposes other than the Medicare rate setting process, including as a benchmark in establishing commercial payment rates. Weighted median-based rates for test codes, however, are aggregate calculations derived from applicable information reported to CMS for the specific purpose of implementing the Medicare CLFS methodology under section 1834A of the Act. We continue to believe that publication of the code-level weighted medians serves an important transparency function by allowing interested parties to review and comment on revised CLFS payment rates before they are made effective. In addition, section 1834A(a)(10) of the Act and the implementing CLFS regulation at § 414.504(f) establish confidentiality requirements for applicable information reported to CMS under this payment system. In particular, CMS or its contractors will not disclose applicable information reported to CMS in a manner that would identify a specific payor or laboratory, or that reveals the prices charged or payments made to a specific laboratory, except to permit the Comptroller General, the Director of the Congressional Budget Office, and the Medicare Payment Advisory Commission, to review the information, or as CMS determines is necessary to implement CLFS requirements, such as disclosures to the HHS Office of Inspector General or the Department of Justice for oversight and enforcement activities. CMS will continue to comply with these protections when releasing CLFS information to the public.

Consistent with our established process, in the interests of transparency, we continue to believe that publishing the code-level weighted medians allows interested parties to understand and assess how the CLFS rates were calculated and implemented and is helpful to inform their comments on the general accuracy of the reported data.

6. Technical Correction (§ 414.523(a)(1))

a. Background

Section 1833(h)(3)(A) of the Act generally requires the Secretary to provide for and establish a nominal fee to cover the appropriate costs in collecting the sample on which a CDLT was performed and for which Medicare payment is made, in addition to the amounts provided under the Medicare CLFS. In addition, section 1834A(b)(5) of the Act requires that, when the sample is collected from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA), the otherwise applicable nominal specimen collection fee be increased by $2.00.

In the CY 2023 PFS final rule (87 FR 69744 through 69760), we finalized a policy to codify specimen collection fee provisions at § 414.523(a)(1), including updating the base specimen collection fee amount and establishing an annual CPI–U update. In that rulemaking, we also stated that the statutory $2.00 increase for specimens collected from a Medicare beneficiary in a SNF or by a laboratory on behalf of an HHA would continue to apply, consistent with section 1834A(b)(5) of the Act. However, due to a drafting or codification error, the operative regulatory text implementing this increase in the CY 2023 PFS final rule (87 FR 70225 through 70226) was not fully included in § 414.523(a)(1), and only a partial introductory clause remains in paragraph (a)(1)(v). Specifically, the introductory text to § 414.523(a)(1) states that payment is made ''[e]xcept as provided in paragraph (a)(1)(v),'' but § 414.523(a)(1)(v), as codified, consists only of the fragment: ''For a specimen collected from a Medicare beneficiary.'' This text is incomplete and does not contain operative language establishing an exception or alternative payment methodology. In addition, other provisions within § 414.523(a)(1), including paragraph (a)(1)(ii), already specify that the specimen must be collected from a Medicare beneficiary, creating an apparent internal inconsistency when read together with the introductory exception clause.

b. Technical Correction

In the CY 2027 PFS proposed rule (91 FR 43963), we explained that to resolve this internal inconsistency and accurately reflect the statutory provisions and longstanding policy, we proposed to revise § 414.523(a)(1) to restore the complete and operative language implementing the statutory $2.00 increase. That is, we proposed revising § 414.523(a)(1)(v) to state that for a specimen collected from a Medicare beneficiary in a skilled nursing facility or on behalf of a home health agency, the specimen collection fee otherwise paid under paragraph (a)(1) of this section is increased by $2.00.

We noted that we do not believe that this proposal reflects a substantive policy change. In the CY 2023 PFS proposed rule (87 FR 46043), we proposed to codify existing specimen collection fee policies and to

[178] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallabfeesched/downloads/cy2018-clfs-payment-rates.zip;https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinicallabfeesched/downloads/cy2018-clfs-payment-rates-analytics.zip*

[179] *https://data.cms.gov/provider-characteristics/hosptials-and-other-facilities/medicare-clinical-laboratory-fee-schedule-private-payer-rates-and-volumes;*

[180] *https://www.cms.gov/files/zip/clfs-raw-rates-volumes.zip*; *https://www.cms.gov/files/zip/cy-2027-preliminary-weighted-median-2027-clfs-rate-calculations-raw-vs-trimmed-rates.zip*

incorporate the statutory $2.00 increase for SNF and HHA collections into § 414.523(a)(1) as a discrete paragraph. Specifically, we proposed that, beginning April 1, 2014, for a specimen collected from a Medicare beneficiary in a SNF or on behalf of an HHA, the specimen collection fee otherwise paid under § 414.523(a)(1) would be increased by $2.00, consistent with section 1834A(b)(5) of the Act. In the CY 2023 PFS final rule (87 FR 69744 through 69760), we finalized policies consistent with this framework, including the continued application of the statutory $2.00 increase.

We noted in the CY 2027 PFS proposed rule that it has been, and continues to be, CMS' policy to pay the specimen collection fee only for qualifying specimens collected from Medicare beneficiaries, and to apply the additional $2.00 increase for specimens collected from a Medicare beneficiary in a SNF or by a laboratory on behalf of an HHA, as required by statute. We stated that we have consistently implemented this policy operationally through claims processing systems, subregulatory guidance, and annual payment updates.

We received public comments on our proposal. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed support for our proposal to revise § 414.523(a)(1)(v) to state that for a specimen collected from a Medicare beneficiary in a SNF or on behalf of an HHA, the specimen collection fee otherwise paid under paragraph (a)(1) of this section is increased by $2.00.

Response: We appreciate commenters' support for this proposal.

Comment: A commenter stated that, as CMS acknowledged that this existing regulation text is internally inconsistent, the current regulation is ambiguous and inoperative. The commenter therefore disagreed with CMS's characterization of the revision as a technical correction rather than a substantive policy change. The commenter requested that CMS clarify in the final rule that the revision to § 414.523(a)(1) applies only prospectively.

Response: We appreciate the commenter's concern. We disagree that the correction establishes a new substantive payment policy. As discussed in the proposed rule, section 1834A(b)(5) of the Act requires that the otherwise applicable specimen collection fee be increased by $2.00 for a specimen collected from a Medicare beneficiary when the sample is collected from an individual in a SNF or by a laboratory on behalf of an HHA. In the CY 2023 PFS final rule FR 87 (69744 through 69751), we finalized the implementation of this statutory increase and stated that it would continue to apply. We have also consistently implemented this policy through our claims-processing systems, payment rate files and subregulatory guidance.[181] The regulatory text at § 414.523(a)(1)(v) inadvertently omitted the remainder of the introductory clause but retained the operative language providing for payment of the specimen collection fee under the circumstances specified elsewhere in paragraph (a)(1). The correction therefore restores the complete introductory language and resolves the internal inconsistency without changing the policy as reflected in the statute. While the regulatory text modification is effective January 1, 2027, we continue to believe that this revision reflects current policy and we are finalizing it as proposed.

Comment: A commenter encouraged CMS to issue clear contractor instructions addressing specimen collection fees, travel allowances, collections from multiple residents during one trip, residents' Part A or Part B status, independent laboratory claims, and SNF consolidated billing.

Response: We will consider whether additional subregulatory guidance is needed to assist laboratories in billing in accordance with the specimen collection policies. We also appreciate concerns regarding access to laboratory services in rural and low-volume areas.

After consideration of public comments, we are finalizing as proposed the revisions to §§ 414.502, 414.504(a)(1), and 414.507(d) to update the CLFS data collection and reporting periods, the three-year data reporting cycle, and the phase-in of payment reductions consistent with section 6226 of the CAA, 2026, as well as the technical correction to § 414.523(a)(1) to restore language regarding the statutory $2.00 specimen collection fee increase for specimens collected from Medicare beneficiaries in SNFs or on behalf of HHAs.

D. Changes to the Ambulatory Specialty Model (ASM)

1. Executive Summary and Background

a. Executive Summary

(1) Purpose

We proposed to make changes to the Ambulatory Specialty Model (ASM or model) effective on the model start date of January 1, 2027 in the CY 2027 PFS proposed rule (91 FR 43963 through 43997). Based on the feedback we received after the publication of the CY 2026 PFS final rule and our own internal review, we determined that several technical refinements and adjustments to the model would facilitate implementation as well as improve the incentives initially intended in the model's design. This final rule will update and revise provisions related to ASM. This final rule also includes technical corrections to the regulatory text.

(2) Summary of Major Provisions

ASM is a mandatory alternative payment model tested by the CMS Center for Medicare and Medicaid Innovation (Innovation Center) under section 1115A of the Act. ASM will have 5 performance years that begin January 1, 2027 and end December 31, 2031, with performance-based payment adjustments occurring 2 calendar years (CYs) following the end of each ASM performance year.

We finalized ASM through notice-and-comment rulemaking in the Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program final rule (hereinafter ''CY 2026 PFS final rule'') (90 FR 49562 through 49720). As described in detail in section III.D.2 of the CY 2027 PFS proposed rule (91 FR 43963 through 43997), we proposed the following modifications:

- Revising select ASM definitions and adding new ASM definitions.
- Clarifying ASM participant exceptions from specified model requirements due to taxpayer identification number (TIN) changes before or during an ASM performance year.
- Excepting certain ASM heart failure participants from specified model requirements due to a redesignated specialty type.
- Incorporating an option to terminate ASM participants under certain circumstances.
- Incorporating an option for data submission for the improvement activities ASM performance category at either the individual or group level.
- Clarifying the scoring of multiple quality measure data submissions from ASM participants in small practices.
- Adding an administrative claims-based low back pain imaging quality measure and replacing the patient-reported outcome measure for low back

[181] *https://www.cms.gov/files/document/mm14345-travel-allowance-fees-specimen-collection-cy-2026-updates.pdf*

pain with a functional status outcome process measure.

- Adjusting benchmarking and scoring policies for quality measures.
- Adding a quality ASM performance category scoring incentive for the voluntary submission of patient-reported outcome (PRO) data to support the development of patient-reported outcome performance-based measures (PRO–PM) under ASM.
- Revising requirements of the Promoting Interoperability ASM performance category to align with proposed changes to the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category and adding a Promoting Interoperability measure suppression policy.
- Incorporating a rural scoring adjustment for ASM participants in rural areas.
- Revising the contents of the ASM performance report.
- Clarifying language on the application of ASM payment adjustments when an ASM participant reassigns billing rights to a new TIN during an ASM payment year.
- Clarifying the availability of the CMS-sponsored model arrangements and patient incentives safe harbor and applicability of programmatic waivers for ASM to reflect that such flexibilities are associated with active performance under ASM and would not be available or applicable during an ASM performance year in which an ASM participant is either ineligible for or excepted from, specified model requirements.
- Revising provisions establishing collaborative care arrangement (CCA) requirements to improve clarity and update the permissible parties, remuneration conditions, documentation requirements, and compliance terms.
- Clarifying and reorganizing select regulatory text to improve readability and flow.

The policies finalized in this final rule reflect our commitment to ensuring ASM's incentives help drive quality of care improvements for beneficiaries and reductions in Medicare expenditures.

b. Background

(1) Statutory Authority

Section 1115A of the Act authorizes the Secretary to test innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care furnished to beneficiaries. Under this authority, we may test models that modify payment methodologies, establish accountability for quality and cost outcomes, and incorporate financial risk arrangements. Under the authority of sections 1115A and 1871(a)(2) of the Act, through notice-and-comment rulemaking, we finalized ASM in the CY 2026 PFS final rule that published in the November 5, 2025, **Federal Register** (90 FR 49562 through 49720).

(2) Background

ASM will test whether holding physician specialists accountable for the quality and cost of care associated with the longitudinal management of specific chronic conditions, heart failure and low back pain, can reduce Medicare expenditures while preserving or enhancing quality of care for Medicare fee-for-service (FFS) beneficiaries. Clinical decisions made by specialists in ambulatory settings can meaningfully influence disease progression as well as downstream utilization and spending. ASM's design, in its goal to reduce Medicare expenditures while preserving or enhancing the quality of care, aims to: (1) improve the management of chronic disease and slow disease progression through more effective risk assessment; (2) increase active collaboration between specialists and primary care providers, and (3) reduce avoidable hospitalizations and low-value procedures (that is, procedures that provide little clinical benefit or the risk of harm outweighs its potential benefit).

In developing ASM, we considered specialist-managed conditions that often require ongoing outpatient management, diagnostic evaluation, medication management, coordination by specialists with other clinicians across different care settings, and, in some cases, procedural or surgical intervention (90 FR 49562 through 49564). Based on these factors, ASM selects individual specialists who manage one of two ASM targeted chronic conditions, heart failure or low back pain. As we designed ASM's participation criteria and performance evaluation framework to cover multiple conditions and associated specialists, we continue to explore whether including additional conditions and specialists would be appropriate.

Our goal with the model test is to select specialists who have a meaningful level of engagement in the care of Medicare FFS beneficiaries with ASM targeted chronic conditions as ASM participants. Under the provisions finalized in the CY 2026 PFS final rule (90 FR 49571 through 49596), we select ASM participants by a combination of a Taxpayer Identification Number (TIN) and a National Provider Identifier (NPI). ASM participants are clinicians who meet four ASM participant eligibility criteria: (1) bill claims under the Medicare Physician Fee Schedule, (2) have a selected physician specialty type relevant to an ASM targeted chronic condition, (3) meet a historical volume threshold of condition-specific episode-based cost measure (EBCM) episodes, and (4) have a service location in a selected mandatory geographic area (that is, selected Core-Based Statistical Areas (CBSAs) and metropolitan divisions). ASM heart failure participants include cardiologists, and ASM low back pain participants include physicians with specialty types of anesthesiology, interventional pain management, neurosurgery, orthopedic surgery, pain management, and physical medicine and rehabilitation.

ASM evaluates ASM participants across four ASM performance categories: quality, cost, improvement activities, and Promoting Interoperability. The evaluation of ASM participant performance leverages the MIPS Value Pathways (MVP) framework, which utilizes a cohesive set of measures and activities focused on performance in furnishing care for a particular specialty or clinical condition. ASM participants must meet each ASM performance category's requirements and report required data. We use data reported by ASM participants and other administrative data, such as inputs gathered from claims, to evaluate each ASM participant's performance on an annual basis. We determine a composite final score for each ASM participant based on performance across the four ASM performance categories and adjust final scores to account for beneficiary medical and social complexity as well as practice size.

Based on performance relative to other specialists treating the same ASM targeted chronic condition in an ASM cohort, ASM participants will receive a positive, neutral, or negative payment adjustment on all Medicare Part B claims for covered professional services during the CY 2 years following the applicable ASM performance year (for example, performance during the 2027 ASM performance year results in the application of ASM payment adjustments during the 2029 ASM payment year). Payment adjustments will range from negative 9 percent to positive 9 percent in the first 2 ASM payment years, gradually increasing to 12 percent in the final ASM payment year.

We refer readers to the CY 2026 PFS final rule (90 FR 49562 through 49720) and ASM's provisions at 42 CFR part 512, subpart G, for additional information on all provisions finalized prior to this final rule.

We received public comments about ASM. We note that some of these public comments were outside the scope of the CY 2027 PFS proposed rule. These out-of-scope public comments are not addressed with responses in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading.

The following is a summary of general comments related to ASM:

Comment: Several commenters supported ASM, specifically the focus on specialty care related to the longitudinal management of high-impact chronic conditions, such as heart failure and low back pain. A commenter stated that this shift to value-based care could reward specialists who have historically operated solely within a fee-for-service environment. Commenters noted ASM's potential to improve care quality and reduce costs for beneficiaries with low back pain and heart failure, both high-volume and high-cost conditions, through value-based care and payment.

Response: We thank commenters for their support of ASM.

Comment: Many commenters opposed launching ASM under the current timeline. Some commenters recommended that CMS establish a transition period, such as delaying ASM by 6 months to 1 year, using a pilot or reporting-only period of 1 year, or phasing in mandatory accountability after a testing period.

Response: We appreciate the commenters' concerns regarding the ASM implementation timeline and recommendations for a delayed start, pilot period, reporting-only period, or phased implementation of financial accountability. We do not agree that such a transition period is necessary. We finalized ASM in the CY 2026 PFS final rule, which was published in the **Federal Register** on November 5, 2025, more than one year before the model's January 1, 2027 start date. The CY 2026 PFS final rule identified the specialties included in the model and established the model's requirements. Following publication of the CY 2026 PFS final rule, we released the mandatory geographic areas in which ASM will be tested, issued preliminary and final ASM participant lists for the 2027 ASM performance year, and conducted targeted outreach to ASM participants regarding their participation status and model requirements. Taken together, we believe the advance notice provided through rulemaking and our implementation activities preceding the model's launch provide sufficient time to understand the requirements of and prepare for participation in the model. We also appreciate commenters' concerns regarding the application of financial accountability based on 2027 ASM performance. However, performance-based payment adjustments tied to measures of cost and quality are well established in Medicare and are not unique to ASM. In CY 2024, only 18.4 percent of Original Medicare payments were made on a fee-for-service basis without a link to quality or value,[182] reflecting the extent to which Original Medicare payments have incorporated quality and cost.

Comment: Many commenters stated concerns about the administrative and financial burden of ASM, citing costs associated with reporting, data management, care coordination, interoperability, and workflow redesign. Several commenters stated that workforce shortages, rising labor costs, increasing administrative requirements, and payment reductions elsewhere in the Medicare program may limit the ability of organizations to successfully participate in ASM. Comments emphasized CMS should design ASM to minimize unnecessary administrative burden and provide sufficient implementation time.

Response: We appreciate commenters' concern about the burden associated with ASM. We note that we have taken steps in this final rule to reduce burden, such as efforts to reduce ASM participant notifications and paperwork under the exceptions process and reduce reporting burden in the Promoting Interoperability ASM performance category for the 2027 ASM performance year. We believe these additional steps will help alleviate administrative and reporting burden for ASM participants. With respect to concerns about Medicare reimbursement and labor costs, we refer readers to the portions of this final rule discussing the underlying payment structure of the PFS.

Comment: A few commenters stated their viewpoints on the appropriateness of including additional conditions within ASM in the future. A commenter opposed expanding ASM to oncology, citing concerns that episode-based cost measures could be driven by oncology drug costs and differences in treatment regimens and case mix that may not reflect clinician efficiency or quality. Another commenter stated that amyotrophic lateral sclerosis (ALS)provides a compelling example of specialty-led care and that CMS should consider how insights from specialty-focused models could be applied to complex neurological diseases, such as ALS.

Response: We thank the commenters for their feedback on the pros and cons of potential conditions that we could consider for future inclusion in ASM. Should we propose the inclusion of a new ASM targeted chronic condition and new ASM cohort, we would do so through future notice-and-comment rulemaking.

Comment: A few commenters stated concerns that, if MVPs become the primary MIPS reporting option, ASM participants could report similar measures under the MVP framework while being subject to a different scoring methodology and greater financial risk and recommended that CMS end ASM if MVP reporting becomes mandatory. A commenter opposed the use of the MVP framework under ASM since they believe that MVPs reshuffled existing MIPS metrics and are focused on single specialties that do not align with the patient or care team. A few commenters recommended that CMS align policies and share insights across CMS as MIPS proposed to move towards full MVP adoption in CY 2029.

Response: We did not make any proposals in the CY 2027 PFS proposed rule related to the use of the MVP framework within ASM, and therefore, consider these comments out of scope. We refer readers to section IV.A.3 of this final rule for additional information about the MVP strategy in the Quality Payment Program.

Comment: A commenter recommended that CMS coordinate transitions between ASM and the Quality Payment Program to avoid duplicative reporting requirements or unintended payment penalties for clinicians moving between the programs.

Response: We note that we are sharing data on ASM participants across CMS to ensure that information displayed in Quality Payment Program eligibility information reflects mandatory ASM participation. We intend to make public information on these processes and the frequency at which such information will be updated through additional guidance posted on the ASM website or through direct electronic communication to ASM participants.

[182] 2025 Health Care Payment Learning & Action Network APM Measurement Effort Results; *https://hcp-lan.org/apm-measurement-effort-2/*.

2. Changes to Provisions of the Ambulatory Specialty Model (ASM)

a. Definitions

In the CY 2026 PFS final rule, we finalized certain terms for ASM. We described these finalized definitions in context throughout section III.C.2 of the CY 2026 PFS final rule and codified them at § 512.705 (90 FR 49569).

After internal review of ASM's provisions, we believed minor modifications to select definitions would improve the readability and overall clarity of ASM's provisions.

Accordingly, we proposed at § 512.705 to modify the definition of ''ASM beneficiary'' to clarify this term means a Medicare FFS beneficiary who is being treated by an ASM participant for an ASM targeted chronic condition. We believe this edit would improve the precision of the definition by using the finalized definition of ''ASM targeted chronic condition'' that is used throughout ASM's provisions, rather than just ''targeted chronic condition'' as the definition currently reads.

We also proposed to revise the definition of ''Dual eligible proportion'' at § 512.705 for clarity. Specifically, we proposed to clarify that the definition of ''Dual eligible proportion'' means ''the share of an ASM participant's beneficiaries who are dually eligible Medicare beneficiaries'' to more clearly refer to an ASM participant.

We refer readers to section III.D.2.f.(3) of this final rule for comments and responses on the proposed definition of ''Rural area'' as it is described in context of the rural scoring adjustment. We are also finalizing a revision to the definition of ''Small practice'' as described in context of the small practice reporting policy.

We sought comment on the proposed revisions to the ''ASM beneficiary'' and ''Dual eligible proportion'' definitions at § 512.705.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed revisions to the ASM beneficiary definition.

Response: We appreciate the commenters' support for the definition revision.

Comment: A few commenters supported the proposed revisions to the dual eligible proportion definition.

Response: We appreciate the commenter's support for the definition revision

After consideration of public comments, we are finalizing the revisions to the definitions of ''ASM beneficiary'' and ''dual eligible proportion'' as proposed at § 512.705.

b. Participation

(1) Background

As discussed in the CY 2026 PFS final rule (90 FR 49571 through 49596), we designed ASM with a focus on clinicians who commonly treat Medicare FFS beneficiaries in an ambulatory setting, develop longitudinal relationships with patients, and co-manage beneficiaries with primary care providers (PCP). In addition, we believe clinicians who treat ASM targeted chronic conditions are well-positioned to benefit from improved integration between specialty and primary care, creating greater opportunities to incentivize high-value care and tertiary prevention.

We determined the model would assess quality of care provided at the individual clinician level, as identified by a combination of TIN and NPI, rather than at the level of a group practice or facility, with limited exceptions, to align accountability with individual clinical decision-making and to better capture variation in individual clinical practice patterns among clinicians within the same organization (90 FR 49574). As a result, each ASM participant is individually responsible for meeting model requirements and is evaluated independently for the purposes of ASM performance category scoring, final scoring, and determining an ASM payment adjustment factor and corresponding ASM payment multiplier.

(2) Mandatory Participation

In the CY 2026 PFS final rule (90 FR 49571 through 49574), we finalized that once a clinician meets the ASM participant eligibility criteria and is selected as an ASM participant, they remain an ASM participant for the duration of the ASM test period. Once selected as an ASM participant, there may be circumstances where the ASM participant does not meet the ASM participant eligibility criteria for a specific ASM performance year. Accordingly, we developed a policy whereby an ASM participant is only subject to certain ASM requirements for the ASM performance year(s) in which they meet ASM participant eligibility criteria. We also finalized provisions that describe the effect of not meeting ASM participant eligibility criteria for an ASM performance year (90 FR 49571 through 49574). Specifically, under existing provisions, an ASM participant who does not meet ASM participant eligibility criteria for an ASM performance year is: (1) not subject to the requirements for performance assessment described at § 512.715, data submission described at § 512.720, and final scoring described at § 512.745; (2) not subject to payment adjustment described at § 512.750 for the corresponding ASM payment year; and (3) not eligible for Medicare program waivers described at § 512.775 provided under the model for the applicable ASM performance year.

To clarify and better incorporate policies related to exceptions of specific ASM performance requirements and ASM participant terminations, we proposed to revise our regulatory text describing mandatory ASM participation and the effects of not meeting ASM participant eligibility criteria for an ASM performance year.

Specifically, we proposed at § 512.710(a)(1) that a clinician who we select as an ASM participant for at least one ASM performance year is considered an ASM participant for the duration of the ASM test period unless we (1) terminate ASM in accordance with Standard Provisions for Mandatory Innovation Center Models described at § 512.165, or (2) terminate the ASM participant as described under § 512.710(h). We refer readers to section III.D.2.b.(5) of this final rule for further discussion on finalized provisions related to ASM participant terminations. We believe this revision is consistent with our original policy finalized in the CY 2026 PFS final rule describing that an ASM participant, once selected, remains an ASM participant for the ASM test period.

We also proposed to add a paragraph heading and revise § 512.710(a)(2) to clarify that this paragraph describes the effects of not meeting ASM participant eligibility criteria for an ASM performance year. We proposed to move select regulatory text at current § 512.710(a)(2)(i) to § 512.710(a)(2) to improve readability and to incorporate new proposals on the effects of not meeting ASM participant eligibility criteria for an ASM performance year.

First, we proposed to separate select regulatory text included in current § 512.710(a)(2)(i) into separate paragraphs by revising paragraph § 512.710(a)(2)(ii) and adding new paragraph § 512.710(a)(2)(iii). As we proposed, § 512.710(a)(2)(i) would describe the specified model requirements that an ASM participant would not be required to meet for the applicable ASM performance year, § 512.710(a)(2)(ii) would describe the specific model requirements not applicable for the corresponding ASM payment year, and § 512.710(a)(2)(iii)

would describe an ASM participant's ineligibility for waivers provided under the model for the applicable ASM performance year. These revisions do not introduce substantive changes to previously finalized provisions describing the effects of an ASM participant not meeting ASM participant eligibility criteria for an ASM performance year; rather, we believe such revisions help clarify that not meeting ASM participant eligibility criteria would not nullify the application of ASM payment adjustments on Medicare Part B claims for covered professional services during the corresponding ASM payment year based on performance in a prior ASM performance year. For example, a clinician may be selected for mandatory participation for the 2027 ASM performance year. If that ASM participant does not meet the ASM participant eligibility criteria for the 2029 ASM performance year, the revisions here help clarify that while the ASM participant would not be subject to the applicable performance assessment, data reporting, and scoring requirements during the 2029 ASM performance year (that is, CY 2029), but that ASM payment adjustments based on the ASM participant's performance from the 2027 ASM performance year would still be applied in CY 2029.

Second, we proposed at § 512.710(a)(2)(iv) that an ASM participant who does not meet ASM participant eligibility criteria for an ASM performance year would not be eligible for the CMS-sponsored model arrangements and patient incentives safe harbor described at § 512.765 for the applicable ASM performance year. We stated in the proposed rule that we believe this proposal is consistent with our intent to make this safe harbor available for ASM performance years where the ASM participant is actively performing in the model (90 FR 49709).

We sought comment on our proposed revisions to §§ 512.710(a)(1) and 512.710(a)(2).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that not allowing the safe harbors and Medicare program waiver to apply in ASM performance years when the ASM participant is not actively performing in the model could create operational and compliance challenges for ASM participants. A commenter believed that this proposal would create transition challenges due to providers inadvertently continuing arrangements or incentives originally structured under ASM waivers without realizing those protections no longer apply during an ASM performance year that the ASM participant was not required to meet the specified ASM requirements. A commenter recommended that ASM participants should continue to have access to the CMS-sponsored model arrangements and patient incentives safe harbor in every ASM performance year even if they do not meet the ASM participant eligibility criteria for that ASM performance year.

Response: We appreciate these comments and address comments pertaining to the CMS-sponsored model safe harbor at § 512.765 in section III.D.2.h of this final rule. With respect to waivers, we do not believe that it is appropriate to continue to make the waivers available under § 512.775 during a period in which an ASM participant is not eligible for specified requirements under the model.

We also received public comments on ASM's participation provisions that were out of scope to proposals in the CY 2027 PFS proposed rule. These out-of-scope public comments are not addressed with responses in this final rule.

After consideration of public comments described in this section of this final rule and described in section III.D.2.h of this final rule, we are finalizing the proposals at §§ 512.710(a)(1) and 512.710(a)(2) as proposed.

(3) Specialty Type

Participation in ASM is limited to clinicians who are within specialties and furnish covered professional services related to ASM targeted chronic conditions—heart failure or low back pain. As finalized in the CY 2026 PFS final rule, we determine specialty type based on the specialty code most frequently reported on a clinician's Medicare Part B claims (90 FR 49583 through 49585). Medicare Administrative Contractors (MACs) derive specialty codes on claims from clinician-reported specialty types provided during Medicare enrollment. Physicians report their specialty type as part of their Medicare enrollment application through the Provider Enrollment, Chain, and Ownership System (PECOS) or through submission of the CMS 855I paper application.[183] The Medicare enrollment form is also used for revalidations and ad hoc changes to certain information. We use data from the CY 2 years prior to each ASM performance year to determine whether a clinician meets the model's specialty type criteria. For example, we use CY 2025 data, including specialty type data, to select final ASM participants for the 2027 ASM performance year.

For the ASM heart failure cohort, we finalized inclusion of physicians with a specialty type of cardiology. Our rationale for including cardiologists as ASM heart failure participants, as explained in the CY 2026 PFS final rule, is that they commonly provide care to Medicare FFS beneficiaries with heart failure and are well-positioned to manage outcomes by ensuring patients are optimized on guideline-directed medical therapy to prevent exacerbation of their condition (90 FR 49576). We did not finalize the inclusion of other cardiac-related specialties (for example, cardiac electrophysiology, intensive cardiac rehabilitation, cardiac surgery, interventional cardiology, and advanced heart failure and transplant) as these clinicians are often proceduralists and not commonly involved in the longitudinal management of patients with heart failure (90 FR 49576). Because one of ASM's goals is to measure the performance of clinicians with similar patterns of heart failure care, we include cardiologists, but not other cardiac-related specialties, even though those cardiac-related specialists may be attributed patients with heart failure as measured through the heart failure EBCM (90 FR 49577).

For the ASM low back pain cohort, we finalized inclusion of physicians who have a specialty of anesthesiology, pain management, interventional pain management, neurosurgery, orthopedic surgery, or physical medicine and rehabilitation. In the CY 2026 PFS final rule (90 FR 49577 through 49580), we emphasized that specialty types for the ASM low back pain cohort include physicians who are most directly involved in the evaluation and management of low back pain and whose clinical decision-making is expected to meaningfully influence downstream utilization and spending. We explained that the included specialists commonly furnish services to Medicare FFS beneficiaries with low back pain and play a central role in determining the use of imaging, injections, procedures, and surgical interventions. We also noted that we did not include certain other specialties that may occasionally treat low back pain but are not typically responsible for its longitudinal management. By focusing on a defined set of specialties with similar roles in managing low back pain, we aim to support more meaningful comparisons of performance and to

[183] *https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms019477.*

align model incentives with opportunities to improve care coordination, reduce unnecessary procedures, and promote evidence-based treatment.

We did not propose any adjustments to the specialty types included in each ASM cohort as finalized at § 512.710(d) in the CY 2026 PFS final rule (90 FR 49576 through 49580). As part of the CY 2027 PFS proposed rule, we proposed to correct small typographical errors in the regulatory text at §§ 512.710(d)(1) and 512.710(d)(2) that did not introduce substantive changes to existing provisions.

We sought comment on the proposed correction of the typographical errors at §§ 512.710(d)(1) and 512.710(d)(2).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter appreciated and supported the corrections to the typographical errors in the proposed rule.

Response: We thank the commenter for their support.

We also received public comments more generally related to specialty type and ASM participant selection.

Comment: A commenter raised concerns about the accuracy of the preliminary ASM heart failure cohort ASM participant list, stating that they believed several preliminary ASM participants have a primary PECOS specialty type designations other than cardiology.

Response: We thank the commenter for their feedback. As we describe earlier in this section of this final rule, we identify a clinician's specialty based on the specialty code indicated on the plurality of a clinician's Medicare Part B claims for the purpose of selecting ASM participants. As we discussed in the CY 2026 PFS final rule (90 FR 49584), these claims-based specialty codes are derived from PECOS data; however, there may be some differences between a PECOS specialty type and the Medicare Part B claim-based specialty type because of how MACs process specialty type data from Medicare Part B claims. Therefore, we believe that it is possible for a clinician's PECOS specialty type designation and the specialty type derived from Medicare Part B claims used to select ASM participants to differ. We refer readers to section III.D.2.b.(4).(b) for further discussion on the rationale for using PECOS specialty type designations for the purposes of ASM participant exceptions.

Comment: A commenter stated that they do not agree with the use of Medicare Part B claims to determine specialty type for the purposes of ASM participant selection because CMS is modifying how specialty status is determined for groups reporting MVPs under the Quality Payment Program.

Response: We thank the commenter for their feedback but note that we did not propose any modifications to source of specialty type data that we will use to select ASM participants. Therefore, we believe this comment is out of scope. We refer readers to the CY 2026 PFS final rule (90 FR 49583) for further discussion on the use of Medicare Part B claims to determine specialty type for the purposes of selecting ASM participants. We also refer readers to the CY 2026 PFS final rule for further discussion on the finalized self-attestation process during MVP registration for identifying group specialty composition (90 FR 49843). We believe that the specialty type identification for the purposes of selecting ASM participants differs from the policy intent of self-attestation for identifying group specialty composition for the purposes of reporting an MVP under the Quality Payment Program and therefore believe that exact alignment is not necessary at this time.

We also received public comments related to the specialty types included in the ASM low back cohort that were distinct from comments related to an alternative we considered for excepting ASM low back pain participants from specified ASM requirements due to specialty type redesignations. We summarize these comments and respond to them here but also refer readers to section III.D.2.b.(4).(b) of this final rule for additional comments and responses related to the alternative we considered.

Comment: A few commenters recommended that we remove the specialty types of neurosurgery and orthopedic surgery from the specialty types in the ASM low back pain cohort. A commenter recommended that we exclude ASM participants who are total joint/hip-treating orthopedic providers, who could be identified from EBCM episodes where the diagnosis migrates from a low back pain code to a hip-specific code within a defined window. Another commenter recommended removal of neurosurgeons as ASM participants since they were not one of the most common specialty types attributed the low back pain EBCM episodes during that measure's field testing and because none of the quality measures for the ASM low back pain cohort are included in the MIPS Neurosurgery Specialty Set. A commenter stated that they believe that neurosurgery and orthopedic spine surgery specialists should be excepted from the model since their clinical decision-making, patient populations, treatment pathways, and outcomes differ substantially from those of clinicians whose practices focus primarily on the non-surgical management of low back pain

Response: We thank the commenters for their feedback. We did not make any proposals related to the specialty types that we include in the ASM low back pain cohort in the CY 2027 PFS proposed rule; therefore, we believe these comments are out of scope. We refer readers to the CY 2026 PFS final rule (90 FR 49577) for additional discussion on the justification of including neurosurgeons and orthopedic surgeons in the ASM low back pain cohort.

Comment: A commenter opposed the inclusion of the anesthesiology specialty type in the ASM low back pain cohort.

Response: We note that this comment is outside the scope of the proposed rule as we did not make any proposals related to the inclusion or exclusion of specific specialty types in the ASM participant eligibility criteria for the ASM low back pain cohort. We refer readers to the CY 2026 PFS final rule (90 FR 49577) for additional discussion on the justification of including anesthesiologists in the ASM low back pain cohort.

Comment: A commenter recommended that Certified Registered Nurse Anesthetists (CRNA) should be considered a low back pain specialty type for inclusion in the ASM low back pain cohort.

Response: We appreciate this commenter's recommendation. We note that this comment is outside the scope of the proposed rule as we did not make any proposals related to the inclusion or exclusion of specific specialty types in the ASM participant eligibility criteria for the ASM low back pain cohort. We refer readers to our discussion of why we did not include nonphysician practitioners, such as CRNAs, in ASM in the CY 2026 PFS final rule (90 FR 49575). Should we consider inclusion of these specialty types in the ASM low back pain cohort in the future, we would do so through notice-and-comment rulemaking.

Comment: A commenter stated that we should reconsider the exclusion of neuromusculoskeletal medicine and osteopathic manipulative medicine specialists from ASM since these specialists have the strongest conservative-care comparator.

Response: We thank the commenter for their feedback. We note that this

comment is outside the scope of the proposed rule as we did not make any proposals related to the inclusion or exclusion of specific specialty types in the ASM participant eligibility criteria for the ASM low back pain cohort. Should we consider inclusion of these specialty types in the ASM low back pain cohort in the future, we would do so through notice-and-comment rulemaking.

Comment: A few commenters discussed inclusion of specialties outside those currently included in ASM. A commenter recommended psychologists be able to participate in ASM as this would strengthen the model's ability to address the medical, behavioral, and psychosocial factors that influence health outcomes and advance CMS' goals of high-quality, person-centered care. A commenter recommended using measure attribution to identify physical therapist involvement in a low back pain episode as CMS does for ASM's administrative claims-based measures and commit to a pathway for physical therapist participation or formal care partnership as the model matures. A commenter encouraged CMS to provide explicit opportunities for pharmacist participation in ASM, noting their important role as part of an interdisciplinary team contributing to chronic disease management, medication optimization, care coordination, and quality improvement.

Response: We acknowledge the important role physical therapists, psychologists, pharmacists, and other clinicians play in whole-person care. ASM is designed around cohorts of clinicians who furnish comparable services and have a similar ability to influence the care and outcomes for which they are held accountable. This approach supports meaningful peer comparisons and consistent performance assessment within the model. We did not propose expanding ASM participation to additional clinician types at this time.

After consideration of public comments, we are finalizing the proposed correction of the typographical errors at §§ 512.710(d)(1) and 512.710(d)(2) describing specialty types as proposed.

(4) ASM Participant Exceptions

We recognize that there may be limited circumstances in which an ASM participant selected for participation for an ASM performance year should be excepted from certain ASM requirements for that ASM performance year and consequently excepted from the application of an ASM payment multiplier to the ASM participant's Medicare Part B payments for covered professional services during the corresponding ASM payment year. Accordingly, we finalized a narrow set of ASM participant ''exclusions,'' or situations in which an ASM participant is excepted from specified ASM requirements in the CY 2026 PFS final rule to balance operational feasibility with the need for robust evaluation and generalizable findings (90 FR 49582 through 49583). As finalized at § 512.710(c), an ASM participant who stops reassigning billing rights to the TIN we used to select the ASM participant and begins reassigning billing rights to a new TIN during an ASM performance year is not subject to certain ASM requirements—specifically the requirements for performance assessment described at § 512.715, data submission described at § 512.720, final scoring described at § 512.745, and payment adjustment described at § 512.750—and is no longer eligible for Medicare program waivers provided under the model described at § 512.775 for the applicable ASM performance year. An exception from specified ASM requirements for one ASM performance year does not apply for the entire ASM test period because we consider clinicians who meet ASM participant eligibility criteria for at least one ASM performance year to be an ASM participant for the remainder of the ASM test period. This means that an ASM participant will receive payment adjustments during a corresponding ASM payment year based on performance from an ASM performance year for which they were required to meet these specified ASM requirements (90 FR 49571 through 49574). In other words, if an ASM participant meets the ASM participant eligibility criteria for the 2027 and 2028 ASM performance years, but not the 2029 and 2030 ASM performance years, by continuing to remain an ASM participant, the ASM payment multipliers calculated based on the ASM participant's performance during the 2027 and 2028 ASM performance years would be applied to the ASM participant's Medicare Part B payments for covered professional services during the corresponding ASM payment years (that is, CY 2029 and CY 2030 respectively).

After internal review, we believed it would be more precise to refer to the situations in which an ASM participant is not required to meet specified ASM requirements for applicable ASM performance year(s) as ''exceptions'' to ASM requirements rather than ASM participant ''exclusions.'' We believed this revision to the terminology would better capture the intended policy to not require an ASM participant to meet certain ASM requirements for an ASM performance year under certain circumstances. Accordingly, we proposed revisions to existing regulatory text to clarify the current circumstances under which an ASM participant may be excepted from certain ASM requirements and proposed new provisions to include additional circumstances under which an exception would apply.

In the CY 2027 PFS proposed rule (91 FR 43968), we proposed, in addition to the current exception due to a change in the reassignment of billing rights (that is, change in TIN), to recognize a new exception. Specifically, we proposed that ASM heart failure participants who meet certain specialty type redesignation requirements may be excepted from specified model requirements. For each exception, we discussed proposals around the requirements and process for notifying us of a change that may warrant an exception. Finally, in accordance with the revisions to § 512.710(a)(2) discussed earlier in this section of this final rule, we made proposals at § 512.710(c) to describe the effect and duration of an exception due to a change in TIN or redesignation of primary specialty type.

(a) Exceptions Due to TIN Changes

In the CY 2026 PFS final rule (90 FR 49582 through 49583), we finalized that an ASM participant who stops reassigning billing rights to the TIN used to select the ASM participant and begins reassignment to a new TIN during the same ASM performance year would no longer be subject to specified ASM requirements for that ASM performance year under either TIN if the ASM participant notifies us of the reassignment change within 30 days. We explained that a TIN change during an ASM performance year may limit our ability to determine continued ASM participant eligibility and assess performance under the model using consistent claims history and EBCM data.

Since the finalization of the CY 2026 PFS final rule, interested parties have shared examples with us of additional circumstances, beyond changes in reassignment, that impact a clinician's affiliation with a particular TIN (for example, retirement from practice) and inquired whether those circumstances would qualify an ASM participant for an exception from specific ASM requirements. Our previously finalized provisions also did not account for

situations when an ASM participant reassigned their billing rights to a new TIN before the start of an ASM performance year. After internal review, we believed that it would be appropriate to address such circumstances in ASM's provisions.

Accordingly, we made multiple proposals in the CY 2027 PFS proposed rule (91 FR 43968) to simplify the exception from specified model requirements based on TIN changes including to recognize additional TIN change scenarios for possible exception from specified ASM requirements.

First, we proposed to redesignate the provisions at current § 512.710(c)(1), which describes the notification process for TIN changes that occur during an ASM performance year, as new § 512.710(c)(1)(i)(B). We proposed to revise § 512.710(c)(1) to describe how we may determine an exception applies. Specifically, we proposed that an ASM participant who demonstrates the circumstances described by an exception apply (that is, change in TIN or approved primary specialty type redesignation) would be excepted from specified ASM requirements, subject to CMS determination for the duration specified for each exception. For each of these exception situations, we discussed the proposed requirements that an ASM participant would be required to meet and, later in this section of this proposed rule, the duration of the exception.

Second, we proposed at new § 512.710(c)(1)(i) that an ASM participant who (1) stops reassigning billing rights to the TIN we used to select them as ASM participant for an applicable ASM performance year and (2) satisfies the TIN change notification requirements at proposed § 512.710(c)(1)(i)(A) or § 512.710(c)(1)(i)(B), as applicable, may be excepted from specified ASM requirements. We believed this provision provided additional clarity on how the notification processes proposed at §§ 512.710(c)(1)(i)(A) and 512.710(c)(1)(i)(B) could lead to an exception.

Third, we proposed new provisions related to ASM participant TIN changes that occur before the start of an ASM performance year. At § 512.710(c)(1)(i)(A), we proposed that an ASM participant who stops reassigning billing rights to the TIN that we used to select them as an ASM participant before the applicable ASM performance year must notify us in writing no later than 60 days after the start of the applicable ASM performance year; after receiving such notice, we may determine an exception to specified ASM requirements applies for the ASM performance year. We recognized that ASM participants may change organizational affiliations between the time we select ASM participants and the start of an ASM performance year. Based on our previously finalized provisions related to the TIN change exception in the CY 2026 PFS final rule, we believed that the same challenge of having consistent claims history and EBCM data to evaluate ASM participant eligibility criteria under the new TIN would apply in this circumstance and thus an exception would be appropriate. We believe that requiring the ASM participant to notify us in writing no later than 60 days after the start of the ASM performance year would provide an adequate window to provide us with notice of such change after we release the list of ASM participants for a given ASM performance year.

Finally, we proposed at § 512.710(c)(1)(i)(B) that an ASM participant who stops reassigning their billing rights to the TIN we used to select them for participation in ASM during an ASM performance year would not be required to reassign billing rights to a new TIN during the same ASM performance year to be potentially eligible for an exception from specified ASM requirements. We believed the proposed modification would capture additional organizational affiliation changes, such as retirements, that merit an exception from specified ASM requirements. We further believed this proposal was consistent with the original intent of the TIN change exception policy we finalized in the CY 2026 PFS final rule. We also proposed that an ASM participant who changes their TIN during an ASM performance year would need to provide written notice of the change in a form and manner determined by us within 30 days of stopping reassignment to that TIN. We believe that adding this additional detail on the form of the notification and required timing would clarify the notification process for ASM participants.

We sought comment on our proposal at § 512.710(c)(1) describing the notice and determination process for an exception from specified model requirements. We also sought comment on our proposal at § 512.710(c)(1)(i) to describe the requirements for an exception from specified model requirements for an ASM participant who stops reassigning billing rights to the TIN we used to select them as an ASM participant. We also sought comment on: (1) our proposed notification process for TIN changes that occur before the start of an ASM performance year described at § 512.710(c)(1)(i)(A); (2) our proposal to remove the requirement that an ASM participant who no longer reassigns their billing rights to the TIN we used to select them as an ASM participant during an ASM performance year must begin reassigning billing rights to a new TIN to be eligible for exception as described at § 512.710(c)(1)(i)(B); and (3) our proposal that an ASM participant must provide written notice of the change in TIN within 30 days of stopping reassignment of billing rights to the ASM participant's TIN as described at § 512.710(c)(1)(i)(B).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported providing exceptions when an ASM participant changes TIN affiliation.

Response: We appreciate the commenters for their support of these proposals.

Comment: Several commenters recommended changes or clarifications to the proposed process for ASM participant exceptions. A few commenters recommended simplifying the notification process, extending the notification timeframes (for example, to 60 or more days), providing more flexibility in the notification timeframe, or using information already available to CMS through its enrollment systems to identify TIN changes that may lead to an ASM participant exception.

Response: We thank commenters for their feedback on the proposed notification process for ASM participant exceptions related to TIN changes. While we had proposed to require that ASM participants notify us of a TIN change to align with the finalized notification process in the CY 2026 PFS final rule (90 FR 49582), we recognize that this process could increase administrative burden on ASM participants. We also acknowledge that we could identify and validate TIN changes through CMS enrollment systems. For these reasons, we believe that we would be able to identify changes in the TIN affiliations of ASM participants through our administrative data and could therefore except an ASM participant without requiring an ASM participant to notify us of such change. By removing the notification requirement, we also believe that it would be appropriate for CMS to notify an ASM participant that we determined an exception applies to ensure that the ASM participant is aware of the exception. We will directly notify ASM participants who receive an exception.

ASM participants may voluntarily provide written to us if they believe they meet the conditions for an exception; however, we emphasize that such notification is not required. We intend to publish guidance describing how ASM participants may submit these voluntary notifications.

Comment: A commenter recommended that CMS establish a streamlined process to notify organizations when newly affiliated clinicians have been identified as ASM participants and may qualify for an exception, and to allow an adequate review and correction period for the notifications.

Response: We thank the commenter for their feedback. As discussed earlier in this section of this final rule, we publicly release the list of ASM participants annually and notify ASM participants using emails available through our administrative systems. Our original proposals for the TIN change-based exception provided for a notification process initiated by the ASM participant depending on whether the TIN change occurred before the applicable ASM performance year or occurs during an ASM performance year. Based on the feedback we received from commenters, we believe that removing the requirement that ASM participants notify us of such enrollment change for purposes of ASM would reduce administrative burden on ASM participants because we can identify changes in organizational affiliations through our administrative data, provided ASM participants keep their Medicare enrollment files up-to-date.

After consideration of public comments, we are finalizing these proposals with modification at § 512.710(c)(1). We are removing the proposed requirements for an ASM participant to notify CMS of a TIN change for our determination that an exception applies. Instead, we will evaluate administrative data to determine if TIN changes occur and would result in an ASM participant exception. ASM participants must continue to keep their Medicare enrollment information up to date, but do not need to separately notify CMS of such enrollment change for purposes of ASM. We also are adding clarifying language at § 512.710(c) that we will notify an ASM participant in a form and manner determined by CMS if we determine that they qualify for an ASM participant exception. As described later in this section of this final rule, the effective date of the exception will be the date specified in the notice we provide. The notification will also specify the ASM performance year(s) and corresponding ASM payment years(s) for which the exception applies. We are retaining regulatory text providing that an ASM participant who believes they meet the requirements for an exception under §§ 512.710(c)(1)(i) or (c)(1)(ii) may voluntarily provide written notice of the change to CMS in a form and manner determined by CMS but emphasize ASM participant notification to CMS is not required for an exception determination.

We refer readers to section III.D.2.b(4)(c) for additional information on finalized provisions related to the effect and duration of exceptions related to TIN changes.

(b) Exceptions Due to Heart Failure-Related Specialty Type Redesignations

In the CY 2026 PFS final rule, we did not propose or consider an exception based on redesignations of specialty type made through Medicare enrollment before or during an ASM performance year.

Since publication of the CY 2026 PFS final rule, we received interested parties' feedback that we should consider adjustments to ASM participant eligibility determinations based on more recent Medicare enrollment information related to specialty type, which is used to derive the Medicare Part B claims-based specialty type that we use to evaluate ASM participant eligibility criteria.

We believe that using historical data to evaluate ASM participant eligibility criteria for each ASM performance year is still appropriate. In the CY 2026 PFS final rule (90 FR 49583 through 49585), we explained that determining a clinician's specialty type based on historical data from 2 CYs before an ASM performance year provides an objective and consistent approach because it allows us to use historical claims data to evaluate clinician specialty type, as well as the EBCM episode threshold, as part of the ASM participant eligibility criteria. This approach also supports operational feasibility because it enables us to provide advance notification for ASM participants to prepare for the start of an ASM performance year.

However, we recognize that clinicians may not have had sufficient time to formally update an out-of-date specialty type before the end of CY 2025 because ASM was not finalized until November 2025. For example, specialty type redesignations made in CY 2026 would not be reflected in the CY 2025 data used to select final ASM participants for the 2027 ASM performance year. Setting an appropriate scope of ASM participant exceptions is important in a mandatory model such as ASM to preserve the integrity of the model design and evaluation, and to ensure a representative ASM participant population. While allowing unrestricted ASM participant exceptions due to specialty type redesignations could introduce selection bias and undermine the model test, we believe that certain limited and clinically appropriate redesignations may warrant consideration based on the timing of ASM's announcement and selection of ASM participants.

Accordingly, we proposed in the CY 2027 PFS proposed rule (91 FR 43968) that ASM heart failure participants who officially redesignate their primary specialty type through an approved Medicare enrollment application (either PECOS or CMS–855 form paper application) to a limited set of specialty types and demonstrate proof of board certification would be excepted from specified ASM requirements and ineligible for Medicare program waivers and the safe harbor provisions available in the model for the applicable ASM performance year and for all remaining ASM performance years in the ASM test period.

Specifically, we proposed at § 512.710(c)(1)(ii) that we may approve an exception from specified model requirements for an ASM heart failure participant upon receipt of written notification of updated Medicare enrollment to the following redesignated primary specialty types described at § 512.710(c)(1)(ii)(A): cardiac electrophysiology, cardiac surgery, interventional cardiology, advanced heart failure and transplant cardiology, and adult congenital heart disease. We proposed at § 512.710(c)(1)(ii)(B) that an ASM heart failure participant who redesignated their primary specialty type through an approved Medicare enrollment application (either PECOS or CMS–855 form paper application) would need to provide us written notification of the approved redesignation, along with verification of board certification in the newly designated primary specialty type described under § 512.710(c)(1)(ii)(A) within 30 days of the effective date of the approved redesignation.

We believed that recognizing an exception for ASM heart failure participants who redesignate their specialty type to one of the proposed specialty types would be appropriate because these specialty types reflect highly specialized or procedure-focused practice areas that are distinct from the broader management of cardiovascular disease and heart failure captured under

the cardiology specialty. Excepting cardiac electrophysiology, cardiac surgery, and interventional cardiology would be appropriate because these specialties are predominantly procedure—focused and are generally organized around the performance of invasive or technical interventions rather than the longitudinal medical management of cardiovascular disease. Cardiac electrophysiology primarily involves the diagnosis and treatment of cardiac arrhythmias through procedures such as ablation and device implantation; interventional cardiology centers on catheter—based interventions (for example, percutaneous coronary intervention). Cardiac surgery involves operative treatment for cardiac conditions. Advanced heart failure and transplant cardiology specialists primarily manage patients with end-stage heart failure, mechanical circulatory support, or transplant-related care, while adult congenital heart disease specialists treat individuals with complex congenital conditions that persist into adulthood. Because the specialty types proposed for exception represent narrower scopes of practice than general heart failure management, their exception from specified requirements would help ensure that ASM remains focused on specialists who manage heart failure in a comprehensive and ongoing manner, thereby improving the specificity and consistency of the ASM heart failure cohort.

To be excepted from the specified ASM requirements under this proposal, we proposed that the ASM participant must (1) officially redesignate their primary specialty type to one of the specialty types described earlier through an approved Medicare enrollment application and (2) provide evidence of board certification in the redesignated specialty to ensure that an exception to specified ASM requirements is valid and appropriate. While Medicare enrollment requirements stipulate a clinician must supply documentation supporting eligibility for Medicare enrollment under § 424.510(d), these enrollment regulations do not specify a mechanism for substantiating specialty type. Initial enrollment, revalidation, and any interim changes to an existing enrollment require a physician to select a primary specialty and attest that they meet all State or Federal requirements for their selected primary specialty. Physicians must meet the same requirements for any secondary specialty selected. They must also provide information on the active certification relating to their selected primary specialty type, specifically certification number, effective date, certifying entity, and State where issued. If no certification is associated with the selected primary specialty, then the physician must report the certification relevant to the secondary specialty.[184] MACs have operational authority to validate reported information, including requesting supporting documentation, if needed. In addition to requiring the redesignation through a Medicare enrollment application, we believed that requiring an ASM participant to report additional proof of board certification in one of the proposed specialty types eligible for exception would promote a more accurate approach to the exception process while avoiding unrestricted or unverified exceptions that could introduce selection bias into the model test. Further, all of the proposed specialty types for exception have a certifying entity that provides evidence of board certification. The American Board of Internal Medicine (ABIM) provides board certification for cardiac electrophysiology, interventional cardiology, advanced heart failure and transplant cardiology, and adult congenital heart disease specialty types. The American Board of Thoracic Surgery provides board certification for the cardiac surgery specialty type. Therefore, we believed that an ASM heart failure participant seeking an exception would be able to produce evidence of board certification for all specialty types proposed for exception.

We considered an alternative proposal whereby we would only recognize specific specialty type redesignation-based exceptions that occur during 2027 and 2028 ASM performance years to limit the number of ASM participants potentially excepted. Based on the announcement of ASM in the CY 2026 PFS final rule in November 2025, we believed that potential ASM participants may not have had adequate time to officially redesignate their primary specialty type such that it is reflected in the Medicare Part B claims used to select ASM participants for these ASM performance years. For example, a 2027 ASM participant who redesignated their primary specialty type in CY 2026 would not have that change reflected in the CY 2025 claims data used to evaluate their eligibility. A similar timing challenge could occur for the 2028 ASM performance year because we will use CY 2026 data to select ASM participants for the 2028 ASM performance year. We believe that finalization of ASM in the CY 2026 PFS final rule provided potential ASM participants advanced notice to redesignate their specialty type, if appropriate, for CY 2027, which is the year of data that we will use to select ASM participants for the 2029 ASM performance year. However, we recognized that appropriate specialty type redesignations could occur after the 2028 ASM performance year and that allowing the potential for an exception based on specific specialty type redesignations for a longer period would retain consistency in the application of the proposed exception for specified ASM requirements.

We considered but did not propose exceptions based on specialty type redesignations for ASM low back pain participants. Unlike cardiac specialties, the specialty types included in the ASM low back pain cohort typically do not have Medicare specialty types that reflect further specialization that would be appropriate for excepting ASM low back pain participants. We also believed that the larger number of specialty types in the ASM low back pain cohort would naturally capture common changes in specialty type by ASM low back pain participants over time. For example, we would capture an anesthesiologist ASM low back pain participant who redesignates their primary specialty type to pain management or interventional pain management over the course of the ASM test period through our existing use of historical Medicare Part B claims to identify specialty type. Our rationale for recognizing exceptions based on specialty type redesignation was to ensure each ASM cohort represents specialists who can be appropriately held accountable for longitudinal management of heart failure or low back pain. Accordingly, we believed that the existing ASM low back pain participant specialty type criteria, together with the minimum episode attribution volume for the low back pain EBCM, accomplishes this objective and allowing unrestricted exceptions based on specialty type redesignations in the ASM low back pain cohort could introduce selection bias into the model test.

We sought comment on the proposed timeline and documentation requirements for notifying us of an ASM heart failure participant specialty type redesignation for the purpose of determining an exception proposed under § 512.710(c)(1)(ii). We also sought comment on the proposed specialty types—cardiac electrophysiology, cardiac surgery, interventional cardiology, advanced heart failure and

[184] *https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms019477.*

transplant cardiology, and adult congenital heart disease—to which an ASM heart failure participant may redesignate their primary specialty type through an approved Medicare enrollment application to be considered for an exception from specified ASM requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported establishing an exception process for ASM heart failure participants whose specialty designation changes or whose clinical practice does not align with the broader longitudinal management of heart failure targeted by the ASM.

Response: We thank the commenters for their support of these proposals.

Comment: A few commenters recommended that the CMS use information already available through Medicare enrollment systems to identify qualifying specialty type redesignations or eliminate duplicative ASM participant notification requirements. A commenter recommended that the exceptions should occur automatically without requiring notification or submission of additional documentation.

Response: We appreciate the commenters' recommendations on potential efficiencies in the proposed notification requirements for exceptions. After further consideration, we recognize that this process could increase administrative burden on ASM participants. We also acknowledge that we could identify and validate qualifying specialty type redesignations through PECOS. Since we can identify such redesignations through our administrative enrollment data, we believe we can remove the requirement for an ASM heart failure participant to notify us of such change within a specified time period. We also believe that it would be appropriate for us to notify an ASM heart failure participant that an exception applies to ensure that the ASM heart failure participant is aware of the effect and duration of the exception.

Comment: A few comments opposed the exception based on ABIM board certification since it may be unnecessarily burdensome and exclude certain physicians without that specific board certification. A commenter provided an example of an electrophysiologist who has ABIM certification and may later choose to stop maintaining the ABIM certification and begin maintaining their certification through the National Board of Physicians and Surgeons, which many hospitals accept for credentialing. Another commenter suggested that if CMS finalizes the board certification requirement to qualify for an exception, then CMS should also exclude physicians from ASM if they are not board certified in any of the specialty types included in ASM.

Response: We thank commenters for their feedback on the proposal to require an ASM heart failure participant to notify us of a qualifying specialty type redesignation and provide evidence of board certification in that specialty type. We would like to clarify that we did not propose a specific board certification (for example, ABIM) that would be required for each specialty type; we had provided illustrative examples of the types of certifying bodies for the proposed specialty type redesignations in the CY 2027 PFS proposed rule (91 FR 43969). This proposal was intended to provide us with additional evidence by which to validate a newly redesignated specialty type. However, upon further review and in response to interested parties' comments, we acknowledge that requiring the submission of additional documentation may increase administrative burden on ASM heart failure participants to receive an exception due to an approved specialty type redesignation. We believe that continuing to require the ASM heart failure participant to formally redesignate their specialty type in PECOS would be sufficient for the purposes of excepting the ASM heart failure participant from specified ASM requirements. We do not agree that requiring evidence of board certification for the purposes of an exception means that we should except all selected ASM participants who lack evidence of board certification. As discussed earlier in this section of this final rule, a clinician must attest that they meet all State or Federal requirements and report their active certification information for their selected primary as part of their Medicare enrollment. Therefore, we did not consider requiring board certification within a selected ASM selected specialty as an additional requirement in the ASM eligibility criteria for selecting ASM participants in the CY 2026 PFS proposed rule.

Comment: A commenter recommended that CMS should develop a standardized online tool that allows ASM heart failure participants and designated staff to submit specialty type redesignation-based exception requests along with supporting documentation and forms if applicable.

Response: We thank the commenter for this suggestion. As discussed earlier in this section of this final rule, we believe that the proposed notification and documentation requirements for the proposed specialty type redesignation-based exceptions may unnecessarily increase administrative burden on ASM heart failure participants and are therefore not finalizing them. We will determine exceptions based on enrollment data, so we encourage ASM participants to maintain updated enrollment data through the applicable enrollment application (PECOS or through submission of the CMS 855I paper application). We will directly notify ASM participants who receive an exception. We also intend to update publicly available ASM participant data periodically during the calendar year to indicate whether an ASM participant has received an exception.

ASM participants may voluntarily notify us if they believe they meet the conditions for an exception but emphasize that such notification is not required.

Comment: A commenter suggested that ASM should except ASM heart failure participants who are certificated specialists in hypertension since it would be in the same spirit as excluding ASM heart failure participants with a specialty type of advanced heart failure.

Response: We thank the commenter for the recommendation. We note that a clinician cannot select a specialty type of a certified specialist in hypertension as part of their Medicare enrollment at this time, so we would not be able to consider that specialty type for ASM heart failure participant exceptions at this time.

Comment: In the context of the proposed ASM heart failure participant specialty type redesignation-based exception, a commenter recommended that there should be a correction window after the posting of a final ASM participant list to allow for validation of the list against board certification, taxonomy and claims before the ASM performance year begins.

Response: As a mandatory model, ASM uses the ASM participant eligibility criteria to select ASM participants. We publicly release the list of ASM participants annually and notify ASM participants using emails available through our administrative systems. Accordingly, we did not believe that a general correction window related to ASM participant selection was needed except in the situations we had considered for ASM participant exceptions as described in the CY 2026 PFS proposed rule. Our original proposals for the ASM heart failure participant specialty type-based exceptions allowed a window for

qualifying ASM heart failure participant to notify us of such changes that may qualify them for an exception. Based on the feedback we received from commenters, we believe that removing the notification requirement would reduce administrative burden on ASM participants because we can identify these specialty type redesignations through our administrative data and notify ASM heart failure participants of a CMS-determined exception. As described earlier in this section of this final rule, we will notify ASM participants who are excepted. We also intend to release updated public-facing data on ASM participant status on a periodic basis, such as quarterly. While we will rely on administrative enrollment data to determine all ASM exceptions, ASM participant may voluntarily notify us if they believe they meet the requirements for an exception in a form and manner specified by us.

We also sought comment on our alternative to only consider exceptions for specific specialty type redesignations based on notifications that occur during the 2027 and 2028 ASM performance years. We did not receive any comments on this alternative.

Finally, we sought comment on whether we should consider ASM low back pain participant exceptions based on primary specialty type redesignations, including rationale on specific specialty type redesignations that we could consider for ASM low back pain participants.

We received public comments on this alternative. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that CMS better align participation in the ASM low back pain cohort with clinicians' specialty and actual scope of practice. A few commenters recommended that similar specialty type redesignation-based exceptions should be available to ASM low back pain participants based on their scope of practice. A few commenters recommended establishing a specialty redesignation or clinical-scope exception for ASM participants whose practices are highly specialized, procedure-focused, or do not involve longitudinal management of low back pain.

Response: We appreciate the commenters' feedback. We disagree with the commenters' suggestion that an additional exception should be included based solely on scope of practice. As discussed in the CY 2026 PFS final rule (90 FR 49577), we believe that attribution of low back pain EBCM episodes to a clinician, when considered in combination with a clinician's specialty type, provides sufficient evidence that a clinician furnishes longitudinal management related to low back pain care and is appropriate to select as an ASM low back pain participant. We sought comments on specific specialty type redesignations that may be appropriate for excepting ASM low back pain participants from specified ASM requirements because we believe that exceptions should relate to the ASM participant eligibility criteria used to select ASM participants. We believe that incorporating an additional criterion related to scope of practice beyond the EBCM episode volume and specialty type criteria would be unnecessary at this time. Should we wish to propose additional criteria, and consider it for the purposes of exceptions, we would do so through future notice-and-comment rulemaking.

Comment: A commenter stated that reliance on specialty codes alone may inadvertently include clinicians whose current clinical practice no longer aligns with the intended ASM population. A commenter suggested that ASM should recognize subspecialty differences within the ASM low back pain cohort for possible exceptions, providing an example of a spine surgeon who is predominantly focused on deformity, complex revision surgery, or other specialized spine conditions and who may not function as a longitudinal manager of routine low back pain.

Response: As discussed in the CY 2026 PFS final rule (90 FR 49577), we believe that a clinician's specialty type, when considered in combination with the low back pain EBCM episode threshold of 20 historical episodes, provides sufficient evidence that a clinician furnishes longitudinal management related to low back pain care and is appropriate to include in the ASM low back pain cohort. We appreciate the commenter's feedback on recognizing subspecialty differences within the ASM low back pain cohort and acknowledge that there are limited physician specialty types available as part of Medicare enrollment that indicate further sub-specialization within the treatment of low back pain that could be used for excepting ASM low back pain participants from specified ASM requirements. We continue to believe that the specialty types finalized for the ASM low back pain cohort are the most appropriate physician specialty types to include in the ASM low back pain cohort for the reasons described in the CY 2026 PFS final rule (90 FR 49577). The low back pain EBCM triggering and confirming claim structure, which is limited to a specific set of service and diagnosis codes, focuses on identifying episodes of care that are related to low back pain. While it includes diagnosis codes for a range of conditions that we determine to be relevant to the clinical management of low back pain, we also note that the low back pain EBCM methodology has exclusions for specific diagnoses or conditions to strengthen the specificity of the low back pain EBCM; these exclusions currently include cauda equina syndrome, myelopathy, osteoporotic compression fracture, spinal infection, spinal neoplasm, and trauma.[185] Therefore, we continue to believe that use of the low back pain ECBM and a minimum episode threshold in the ASM participant eligibility criteria is appropriate for selecting ASM low back pain participants.

Comment: A commenter recommended that ASM participants should be able to request an exception if beneficiaries with low back pain represent only a small proportion of an ASM participant's total patient panel.

Response: We do not agree that we should except ASM low back pain participants if management of low back pain only represents a small proportion of their patient panel. As discussed in the CY 2026 PFS final rule (90 FR 49585), we believe that the use of a 20-episode threshold for the low back pain EBCM is appropriate for selecting ASM low back pain participants who provide a higher volume of services related to low back pain and are involved in its longitudinal management, and therefore, could be held accountable for quality and cost related to low back pain care. Further, our final scoring provisions require that an ASM participant must receive a score in the cost ASM performance category to receive a final score for an ASM performance year; that is, if an ASM low back pain participant is not attributed at least 20 low back pain EBCM episodes during the applicable ASM performance year, then they will not receive a final score and will automatically receive an ASM payment adjustment factor that results in a neutral payment adjustment during the corresponding ASM payment year. We believe these final scoring provisions account for situations where a change in clinical practice (for example, furnishing fewer services related to the management of low back pain) and make it inappropriate to hold

[185] *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3568/2026-cost-measure-codes-lists.zip.*

an ASM participant accountable for quality and cost outcomes under the model. We refer readers to the CY 2026 PFS final rule (90 FR 49668) and § 512.745(a)(2) for additional information on the requirements to receive a final score under ASM.

Comment: A commenter recommended that CMS establish a consistent mechanism across episode-based payment models that allow clinicians whose scope of practice, patient population, subspecialty designation, or care patterns do not align with model assumptions to request redesignations or targeted exceptions.

Response: We appreciate the commenter's suggestion to establish a consistent exception process across episode-based payment models implemented by the Innovation Center. At this time, we believe that it is appropriate for each model to define their own participation policies and, if appropriate, exception policies that are tailored to model goals, participant profiles, and operational designs.

We also refer readers to section III.D.2.b.(3) of this final rule for additional comment summaries and responses more generally related to specialty types selected for participation in ASM.

After consideration of public comments, we are finalizing the proposals related to specialty type redesignation exceptions for ASM heart failure participants with modifications. We are finalizing the description of the exception based on ASM heart failure participant specialty type redesignation, while removing from the final regulatory text the proposed reference to ASM participant-initiated notification requirements at § 512.710(c)(1)(ii) and § 512.710(c)(1)(ii)(B).

We are finalizing the proposed specialty type redesignations for ASM heart failure participants as proposed at § 512.710(c)(1)(ii)(A). We are adding language in the regulatory text at § 512.710(c)(1) to state that CMS will provide notice to an ASM participant of a CMS-determined exception, including as described under § 512.710(c)(1)(ii). We are also including language at § 512.710(c)(1) that an ASM participant may voluntarily provide written notice to CMS that they believe an exception applies in a form and manner specified by us.

(c) Effect and Duration of Exceptions to Specific ASM Performance Requirements

We proposed at § 512.710(c)(2) to define the effect of an approved exception for an ASM participant. Specifically, we proposed that an ASM participant with an approved exception would: (1) not be subject to performance assessment described at § 512.715, data submission described at § 512.720, and final scoring described at § 512.745 for the applicable ASM performance year; (2) not be subject to payment adjustments described at § 512.750 for the corresponding ASM payment year; (3) not be eligible for Medicare program waivers available under the model described at § 512.775 for the applicable ASM performance year, and (4) not be eligible for the CMS-sponsored model arrangements and patient incentives safe harbor described at § 512.765 for the period for which we determine an exception applies. We believed that the proposed effect of an exception retains the intent of the finalized provisions related to ASM participant exclusions due to TIN changes in the CY 2026 PFS final rule while adding new elements that strengthen program integrity. This proposal was also similar to the effect of an ASM participant not meeting the ASM participant eligibility criteria for an ASM performance year discussed in more detail in the CY 2027 PFS proposed rule (91 FR 43965).

We proposed at § 512.710(c)(3)(i) that an exception related to a TIN change would be effective on the CMS-determined date and would only apply for the applicable ASM performance year. We believed that limiting an exception to a single ASM performance year would allow us to select the ASM participant with the exception (that is, the same TIN/NPI combination) for a future ASM performance year should the NPI again reassign billing rights to that same original TIN and meet ASM participant eligibility criteria under that original TIN.

We considered whether to extend an exception related to a TIN change for the remainder of the ASM test period. However, we believed that this approach could lead to unnecessary exceptions for later ASM performance years, particularly in the case that an excepted ASM participant begins reassigning billing rights to the same original TIN under which we previously selected them as an ASM participant, and excepted them, for a previous ASM performance year.

We proposed at § 512.710(c)(3)(ii) that an exception related to specialty type redesignation would be effective on the CMS-determined date and would apply for the applicable ASM performance year and remain effective for all ASM performance years in the remainder of the ASM test period. We believed that excepting ASM participants for specified specialty type redesignations for the remainder of the ASM test period would be appropriate since these ASM participants do not represent the target specialty type of an ASM cohort, and would, therefore, improve the specificity and consistency of the ASM cohort for the purposes of performance comparison.

We considered effectuating the exception related to specialty type redesignation type on the CMS-determined date and only having it apply for the applicable ASM performance year. However, we believed that effectuating the exception for the remainder of the ASM test period would be preferrable since we believe an ASM participant would be unlikely to revert to their previous primary specialty type redesignation during the remainder of the ASM test period.

We sought comment on the proposed effect of an exception from specified ASM requirements at § 512.710(c)(2). We did not receive specific comments on the proposed effect of an exception as proposed at § 512.710(c)(2).

We also sought comment on the proposed duration of an exception related to TIN changes as proposed at § 512.710(c)(3)(i), as well as the alternative we considered of setting the duration of a TIN change-related exception as the remainder of the ASM test period. We also sought comment on the proposal at § 512.710(c)(3)(ii) that an exception related to specialty type redesignation would apply for the ASM performance year for which we provide notice that the exception applies and for the remainder of the ASM test period. Finally, we sought comment on the alternative we considered to effectuate an exception related to specialty type redesignation for the applicable ASM performance year only.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters requested clarification regarding the duration of exceptions related to TIN changes or recommended avoiding repeated notification requirements when the circumstances supporting an exception have not changed. A commenter highlighted that under the duration-relation proposal, an ASM participant would need to notify CMS of the same organizational change every ASM performance year to continue the exception. A few commenters recommended that the exception should continue in each subsequent ASM performance year unless the NPI reassigns billing rights to the same TIN under which they were selected as an ASM participant later in the ASM test period.

Response: We appreciate the commenters' feedback on the duration of an exception related to a TIN change. Based on our use of historical information to select ASM participants and determine for which ASM performance years ASM participants must meet specified requirements, we acknowledge that the duration of a TIN change-based exception, as proposed, could require repeated notifications from an ASM participant. Consider an ASM participant who must meet the 2027 ASM performance year requirements but stops reassigning billing rights to TIN A (that is, the original TIN) and begins reassigning billing rights to TIN B during the 2027 ASM performance year. Given our use of historical data to select ASM participants and determine which ASM performance years they must meet specified requirements, we may still identify EBCM episodes attributed to the ASM participant under TIN A during CY 2026 and CY 2027. Accordingly, this ASM participant could be required to meet specified ASM requirements under TIN A for the 2028 and 2029 ASM performance years. Under the proposed notification requirement and duration of the TIN change-based exception, this example ASM participant would be required to notify us multiple times of this TIN change for the 2028 and 2029 ASM performance years. As discussed earlier in this section of this final rule, we are not finalizing the ASM participant notification requirements. Accordingly, we acknowledge that proposed duration of the TIN change-based exception would be potentially confusing to ASM participants if not effectuated for the ASM test period for which they remain unaffiliated with the TIN under which we originally selected them as an ASM participant. We intentionally designed ASM's participation provisions to account for movements across organizations and to select new ASM participants across the ASM test period, meaning that the same NPI under a different TIN could be selected as an ASM participant if they meet all ASM participant eligibility criteria later in the ASM test period. Accordingly, should an ASM participant decide to again reassign billing rights to their original TIN under which we selected them as an ASM participant (for example, TIN A in the earlier scenario) after an exception applies, but later in the ASM test period, we would not want to prevent that ASM participant from actively participating in ASM under this original TIN again. Therefore, we believe it would be appropriate to modify the duration of a TIN change-based exception to begin in the CMS-specified ASM performance year and last for the remainder of the ASM test period unless the ASM participant begins reassigning billing rights to that original TIN under which we selected the NPI as an ASM participant when they otherwise meet the ASM participant eligibility criteria under that original TIN for a future ASM performance year. Because we select an ASM participant using a unique TIN and NPI combination, we note that an NPI who we excepted under their original TIN could be selected as an ASM participant under a new TIN for a future ASM performance year should they meet the ASM participant eligibility criteria under that new TIN.

Comment: A commenter recommended that an exception related to a TIN change should take effect automatically and be retroactive to the beginning of the ASM performance year in which the change occurs.

Response: We thank the commenter for their feedback. We would like to clarify that we proposed that a TIN change-based exception would apply for a specific ASM performance year and would be effective as of the CMS-specified date in the notice we provide to the ASM participant.

Comment: Several commenters supported the proposal that an exception related to a specialty type redesignation would apply for the remainder of the ASM test period.

Response: We thank the commenters for their support of this proposal.

Comment: A commenter suggested that CMS should clarify the effect on exceptions resulting from moving away from an ASM mandatory geographic area, retirement, and death.

Response: We thank the commenter for their recommendations. We believe that an ASM participant no longer furnishing services in one of ASM's mandatory geographic areas would be covered by exceptions related to TIN changes. Additionally, as we discussed earlier in this final rule, we believe that the revisions to the exceptions based on TIN changes (that is, no longer reassigning billing rights to a TIN) will also capture retirements. Under the finalized ASM participant termination provisions discussed later in this section of this final rule, we will terminate a deceased ASM participant from participation in the model.

After consideration of public comments, including specific recommendations from commenters to remove notification requirements related to ASM participant exceptions, we are finalizing the proposed effect of an exception from specified ASM requirements at § 512.710(c)(2) with a modification. Specifically, to further clarify our intent in the proposed rule, we are finalizing that an exception is effective as of the date we specify in the notice to an ASM participant that the exception applies. We finalize this change to conform with the removal of the proposed requirement that an ASM participant provide notice to us regarding exceptions. We have also finalized regulatory text at § 512.710(c)(2)(i) through (iv) to add clarifications regarding effective dates. As noted throughout this section of this final rule, an ASM participant may voluntarily notify us if they believe they meet the criteria for an exception in a form and manner specified by CMS, but emphasize that such notice is not required to receive an exception.

We are finalizing the duration of exceptions described at § 512.710(c)(3) with modifications. For the duration of an exception related to TIN changes described at § 512.710(c)(3)(i), we are finalizing that a TIN-based exception will continue for the remainder of the ASM test period unless the ASM participant: (1) begins reassigning billing rights to the TIN under which they receive an exception later in the ASM test period and (2) meets ASM participant eligibility criteria under that TIN for a future ASM performance year. We are finalizing the proposed duration of an exception related to a specialty type redesignation at § 512.710(c)(3)(ii) as proposed but with modifications to clarify and align the regulatory text.

We provide several illustrative examples of how an exception related to a TIN change will work in practice, including the effect of such exceptions on the application of payment adjustments under ASM. In our first example, ASM participant Dr. A (TIN A/NPI A) receives a final score and an ASM payment multiplier for their performance at TIN A in the 2027 ASM performance year. Dr. A receives an exception applicable for the 2028 ASM performance year based on termination of billing rights to TIN A and reassignment of billing rights to TIN B. Under TIN B, Dr. A remains located in the same mandatory geographic area as they were located under TIN A. Dr. A is not required to meet the specified ASM requirements under TIN A or TIN B for the 2028 ASM performance year and for the rest of the ASM test period unless they begin reassigning billing rights to TIN A or TIN B and meet the ASM participant eligibility under either TIN for a future ASM performance year. However, because Dr. A began reassigning billing rights to TIN B after

the end of the 2027 ASM performance year but before the end of the 2029 ASM payment year, we will apply the ASM payment multiplier determined for the 2027 ASM performance year to payments for Medicare Part B covered professional service claims submitted by Dr. A under TIN B during the 2029 ASM payment year. We refer readers to section III.D.2.g. of this final rule and § 512.750(f) for additional information on payment adjustment provisions related to TIN changes that occur after an ASM performance year but before the end of the corresponding ASM payment year. We also note that Dr. A in this example could be selected as an ASM participant under TIN B for the 2030 ASM performance year if they meet ASM participant eligibility criteria under TIN B based on CY 2028 data. In this situation, Dr. A would be included in the list of ASM participants for the 2030 ASM performance year.

We also provide an example of how an exception due to TIN changes will work for an NPI who is selected as an ASM participant under multiple TIN/NPI combinations. As discussed in the CY 2026 PFS final rule, we believe that it would be rare, but possible, for the same NPI to be selected as an ASM participant under multiple TINs for the same ASM performance year (90 FR 49602). An exception based on a TIN change for one TIN/NPI combination does not affect the ASM participant's obligation to meet specified ASM requirements under any other TIN/NPI combination for which we selected the NPI as an ASM participant. For example, Dr. B (NPI B) is selected as an ASM participant under TIN C and TIN D for the 2028 ASM performance year. If Dr. B stops reassigning billing rights to TIN C during the 2028 ASM performance year and receives an exception applicable for the 2028 ASM performance year and the remainder of the ASM test period, then Dr. B is excepted from the specified ASM requirements under TIN C but must continue to meet ASM's requirements under TIN D for the 2028 ASM performance year and any future ASM performance years for which Dr. B meets the ASM participant eligibility criteria under TIN D.

We also provide several illustrative examples of how the exception related to specialty type redesignations will work in practice, including the effect of such exception on the application of payment adjustments under ASM. For example, consider ASM heart failure participant Dr. C (TIN E/NPI C) who receives a final score and an ASM payment multiplier for their performance under TIN E for the 2027 ASM performance year. Dr. C is notified of an exception during the 2028 ASM performance year because they redesignated their primary specialty type to cardiac electrophysiology as part of their Medicare enrollment. Dr. C will be excepted from the specified ASM requirements for the 2028 ASM performance year and the remainder of the ASM test period under TIN E. However, they will continue to receive payment adjustments on their Medicare Part B covered professional service claims submitted under TIN E during the 2029 ASM payment year based on the ASM payment multiplier determined for their performance during the 2027 ASM performance year. As we emphasized in the CY 2026 PFS final rule (90 FR 49696 through 49699), our goal is to maintain accountability for an ASM participant's performance for a given ASM performance year through performance-based payment adjustments during the corresponding ASM payment year.

A specialty type redesignation-based exception will apply to all TIN/NPI combinations for which we select the NPI as an ASM participant. For example, Dr. D (NPI D) is considered an ASM heart failure participant under TIN F and TIN G for the 2028 ASM performance year. Dr. D redesignates their primary specialty type to interventional cardiology as part of their Medicare enrollment during the 2028 ASM performance year. After our identification of the specialty type redesignation and providing notification, Dr. D will be excepted from specified ASM requirements for the 2028 ASM performance year and the remainder of the ASM test period under both TIN F and TIN G.

(5) ASM Participant Terminations

In the 2026 PFS final rule, we finalized application of the Standard Provisions for Mandatory Innovation Center Models (42 CFR part 512, subpart A) to ASM (90 FR 49720). These provisions describe actions that we may take to remediate actions associated with risks to program integrity.

As discussed in the proposed rule, these standard provisions are not intended to encompass all terms and conditions that apply to each Innovation Center model, because each model has unique design features and implementation plans that may require additional, more tailored provisions (91 FR 43971).

We proposed to include an additional remedial action for purposes of ASM starting in 2027 whereby we could terminate an ASM participant from participation in the model upon our determination that one or more grounds for remedial action described in § 512.160(a) has taken place. In addition, we proposed that we could terminate an ASM participant if we determine that continued participation would be inconsistent with the purposes of ASM or applicable law (91 FR 43971). Under this proposal, any termination of an ASM participant's participation would occur only upon a determination by CMS. For the avoidance of doubt, our proposal did not establish a right for an ASM participant to terminate their own participation.

We proposed to codify this provision at § 512.710(h) and to include a corresponding reference to termination in § 512.710(a)(1), which addresses the duration of participation under ASM.

We sought comment on this proposal at § 512.710(h).

In this section of this final rule, we summarize and respond to the public comments we received on these proposals.

Comment: A commenter expressed concern that termination of an ASM participant from the model could have significant consequences for ongoing remuneration and for model-related safe harbor and waiver protections, including potential retroactive liability for conduct undertaken in reliance on those protections.

Response: We appreciate concerns raised by commenters and provide clarifications as to our intent. We proposed § 512.710(h) to allow us to terminate an ASM participant only if we determine that (1) one or more grounds for remedial action described at § 512.160(a) have occurred, or (2) the ASM participant's continued participation would be inconsistent with the purposes of ASM, ASM's regulations, or applicable law. As discussed in the proposed rule, the grounds for remedial action at § 512.160(a) include failure to comply with Innovation Center model or Medicare program requirements, actions that threaten patient health or safety, submission of false data or representations, and changes in control that present a program integrity risk. The proposed regulatory text connects termination to these existing grounds for remedial action, adding termination as a supplemental action that we could take when appropriate. We believe the grounds for remedial action are sufficiently specified at § 512.160(a).

With respect to our proposal at § 512.710(h)(1)(ii) addressing termination when continued participation would be inconsistent with the purposes of ASM, the

requirements of ASM under its regulations, or applicable law, we do not intend for this provision to establish an open-ended basis for termination. Instead, our intent is to provide the ability for CMS to address situations where continued participation no longer makes sense due to changes in circumstances concerning the ASM participant in consideration of the model's structure and purpose. Examples of termination under this provision that we envision may include but are not limited to when an ASM participant is deceased.

We also appreciate the commenter's request for clarification on how termination affects the availability of the CMS-sponsored model arrangements and patient incentives safe harbor. We refer readers to section III.D.2.h of this final rule for discussion of safe harbor policies.

Comment: A commenter stated concern with the termination proposal, noting that it is unbounded by any specified notice requirement from CMS.

Response: We appreciate this commenter's remarks and agree that our regulations should describe a notice requirement in the event we terminate an ASM participant from the model. Accordingly, we are finalizing a modification to § 512.710(h) to add new paragraph § 512.710(h)(2) stipulating that, if we terminate an ASM participant from the model, we will provide notification to that ASM participant and specify the effective date of such termination in that notice. This approach preserves our ability to respond to circumstances arising during the model test period while informing an ASM participant of the basis for the termination.

Comment: A commenter expressed concern that CMS' proposal would terminate Medicare billing rights without adequate process. The commenter recommended that CMS establish a formal notice-and-cure process that includes written notice of the specific grounds for termination, at least a 30-day cure period for remediable violations, and an administrative appeal before an independent decision-maker prior to termination.

Response: We disagree that termination under proposed § 512.710(h) would affect a clinician's Medicare billing rights. The termination authority at § 512.710(h) applies only to a clinician's participation in ASM; it does not terminate, suspend, revoke, or otherwise directly affect a clinician's Medicare enrollment or billing privileges. These matters are outside the scope of ASM, its regulations, and this rulemaking. Termination, as the term is used under § 512.710(h), refers solely to termination from ASM.

As stated above, we nevertheless recognize that termination from ASM has consequences for model-related obligations and protections and are modifying our final policy to address concerns around notification of termination.

As described, we are finalizing § 512.710(h)(2) to state that we will provide notice of termination to an ASM participant identifying the grounds for termination and the effective date of a termination. We refer the commenter to the standard provisions at part 512, subpart A for information regarding administrative appeals processes.

We believe the modification we are finalizing to provide notice to ASM participants of termination, together with the existing framework under part 512, subpart A, appropriately balances transparency with our ability to respond to circumstances where termination is warranted.

After consideration of public comments, we are finalizing with modification our proposal at § 512.710(h) to terminate an ASM participant on grounds of remedial action or when participation is inconsistent with the model, its regulations, or applicable law. We are finalizing paragraphs §§ 512.710(h)(1), 512.710(h)(1)(i), and 512.710(h)(1)(ii) as proposed. We are finalizing the addition of new paragraph § 512.710(h)(2) to specify that, in the event an ASM participant is terminated from ASM, we will provide notice to the ASM participant specifying the grounds for termination and the effective date of such termination. We believe these modifications made in final regulation address commenters' requests for clarification and concerns.

c. Data Submission

(1) Background

We finalized in the CY 2026 PFS final rule that an ASM participant must meet established data submission requirements across the quality, improvement activities, and Promoting Interoperability ASM performance categories, consistent with §§ 512.725, 512.735, and 512.740, respectively (90 FR 49596 through 49605). We did not establish data submission requirements for the cost ASM performance category or for administrative claims-based quality measures as we will calculate performance on these measures using administrative claims data.

For the quality ASM performance category, we require the submission of numerator and denominator data for at least one required quality measure that satisfies the data completeness criteria (that is, data is submitted on at least 75 percent of the ASM participant's patients that meet a quality measure's denominator criteria). ASM participants in small practices (that is, a TIN with 15 or fewer clinicians) may submit quality data at the group (that is, TIN) level, while ASM participants in non-small practices must submit quality measure data at the individual (that is, TIN/NPI) level. Data submission for the improvement activities ASM performance category requires an ASM participant to attest at the group (that is, TIN) level. Finally, ASM participants must report the Promoting Interoperability ASM performance category at the group (that is, TIN) level. Regardless of the data submission level for each ASM performance category, each ASM participant receives an individual-level final score and corresponding ASM payment adjustment factor and ASM payment multiplier, which is used to adjust payments for each ASM participant's Medicare Part B covered professional service claims.

(2) Quality ASM Performance Category Data Submission for ASM Participants in Small Practices

In the CY 2026 PFS final rule, we finalized policies at § 512.720(a) describing data submission for the quality ASM performance category, including the requirement that quality measure data be submitted at the individual (that is, TIN/NPI) level. We also finalized at § 512.720(f) that ASM participants in small practices may report quality ASM performance category data at the group (that is, TIN) level.

In the CY 2027 PFS proposed rule (91 FR 43971), we proposed to reorganize § 512.720(a)(1)(i) and make technical, clarifying edits to the organization and text of our regulations to bring greater clarity to our provisions and better reflect our policy intent. We proposed to relocate where we describe small practice quality measure reporting from § 512.720(f) to new § 512.720(a)(1)(i)(C). Section 512.720(a)(1)(i)(C) would provide that an ASM participant in a small practice has the option to submit ASM quality measure data at either the group (that is, TIN) level or the individual (that is, TIN/NPI) level, consistent with our policy intent to provide ASM participants in small practices with flexibility in reporting ASM quality measure data.

We also proposed to make technical modifications at § 512.720(a)(1)(i)(A) to

correct a minor typographical error and at § 512.720(a)(1)(i)(B) to cross-reference new § 512.720(a)(1)(i)(C).

We solicited public comment on these proposals. The following is a summary of the public comments we received and our responses.

Comment: A few commenters supported CMS addressing typographical errors and the proposal to consolidate and clarify the regulatory text regarding quality data submissions, noting reorganized text improves readability and clarity.

Response: We appreciate the commenters' support and agree that the reorganized text improves readability.

Comment: Several commenters broadly supported allowing ASM participants in small practices to submit quality measure data at either the group level or the individual level and appreciated clarifications included in the proposed rule. Commenters stated that this flexibility recognizes the operational realities and varying administrative capacities of small practices while preserving meaningful quality measurement and accountability.

Response: We appreciate commenters' support for our proposed clarification regarding small practice quality ASM performance category data submissions.

After consideration of public comments, we are finalizing our proposals at § 512.720(a)(1)(i)(A) to correct a minor typographical error, clarify the small practice reporting flexibility for the quality ASM performance category at § 512.720(a)(1)(i)(C), and update at § 512.720(a)(1)(i)(B) to cross-reference new § 512.720(a)(1)(i)(C).

(3) Improvement Activities ASM Performance Category Data Submission

In the CY 2026 PFS final rule, we finalized that ASM participants submit improvement activity ASM performance category data by attesting to the completion of required improvement activities at the group (that is, TIN) level (90 FR 49599 through 49602). We believed that group-level data submission would be appropriately reflective of the team-based care and coordination envisioned by the improvement activities (90 FR 49601). We also believed that group-level data submission for the improvement activities ASM performance category would reduce administrative burden (90 FR 49601).

Since the publication of the CY 2026 PFS final rule, we received feedback from interested parties that group-level data submission for improvement activities may have unintentional consequences for certain ASM participants. In response to this feedback, we proposed at § 512.720(a)(1)(ii)(B) to allow an ASM participant to submit data for the improvement activities ASM performance category at either the group (that is, TIN) level or the individual (that is, TIN/NPI) level (91 FR 43972). We noted in the proposed rule that such policy would not affect how an ASM participant or its affiliated TIN may choose to structure a CCA required under improvement activity (IA)–2.

We sought comment on our proposal at § 512.720(a)(1)(ii)(B) to allow ASM participants to attest to completing ASM's improvement activities at either the group (that is, TIN) level or the individual (that is, TIN/NPI) level.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposal to allow ASM participants to submit improvement activity ASM performance category data at either the individual (that is, TIN/NPI) level or the group (that is, TIN) level. A commenter described how this policy would reduce the risk of subjecting ASM participants within a TIN to scoring penalties if certain ASM participants within the same TIN do not perform the required activities. Several commenters stated such flexibility reduces administrative burden for physicians practicing within larger organizations, including integrated delivery systems. A commenter that supported individual-level reporting noted this better aligns individual accountability frameworks with individual clinical decision-making, consistent with ASM's stated design principles.

Response: We appreciate commenters' support for our policy. We agree that this flexibility can reduce the risk of unintended scoring consequences while allowing practices to use group-level reporting where it aligns with their existing workflows. We appreciate the comment that individual level reporting supports the model's broader individual accountability framework.

Comment: Several commenters recommended further flexibilities beyond those proposed, including that CMS recognize subgroups for purposes of ASM improvement activity data submissions. A commenter stated that the proposed approach to allow for group or individual level reporting would increase the burden on a subgroup of physicians who meet the requirements for ASM improvement activities.

Response: We appreciate commenters' recommendations. However, we are not adopting additional reporting levels, such as subgroups. Introducing subgroup or other reporting configurations would add complexity to data submission, validation, and scoring and could make the reporting framework more difficult for ASM participants to understand and implement. We believe permitting reporting at either the individual or group level provides meaningful flexibility while maintaining a clear and administratively workable reporting structure. Further, we disagree that our proposal would create additional burden for subgroups of ASM participants. A TIN that includes multiple ASM participants may attest to completing the improvement activities ASM performance category data at the TIN level if all ASM participants within that TIN perform the required activities. If that group also includes non-ASM participants, that group could still attest ''yes'' to ASM improvement activities so long as all ASM participants in the group met the activity's requirements. If only some ASM participants within that group perform the required improvement activities, then individual level reporting would be available for those ASM participants who performed the required activities, and those ASM participants that did not perform required activities would not be able to submit an affirmative attestation. Thus, we do not agree there would be added benefit from subgroup reporting that would overcome the complexity it would introduce.

We also received comments on the improvement activities ASM performance category that were out of scope from the proposed rule, which are not addressed in this rule. However, we thank commenters for providing input on these matters.

After consideration of public comments, we are finalizing our proposal at § 512.720(a)(1)(ii)(B) to allow ASM participants to attest to completing ASM improvement activities at either the group (that is, TIN) level or the individual (that is, TIN/NPI) level.

(4) Treatment of Multiple Data Submissions for the Quality, Improvement Activities, and Promoting Interoperability ASM Performance Categories

In the CY 2026 PFS final rule, we finalized policies addressing the treatment of multiple data submissions for the quality, improvement activities, and Promoting Interoperability ASM performance categories at § 512.720(e) (90 FR 49604 through 49606). For the

quality and improvement activities ASM performance categories, when we receive multiple data submissions for an individual ASM participant from multiple organizations (for example, a qualified registry, practice administrator, or an electronic health record (EHR) vendor), we calculate and score each submission and assign the highest score to the ASM participant. When we receive multiple data submissions for an individual ASM participant from the same organization, we score the most recent submission. For the Promoting Interoperability ASM performance category, we calculate each submission and assign the highest score.

In the CY 2027 PFS proposed rule, we proposed technical modifications to regulatory text describing multiple data submissions to bring greater clarity to our regulatory structure by addressing each ASM performance category under a separate regulatory paragraph. Except for the proposed new policy for small practices at proposed § 512.720(e)(1)(iii), discussed later in this section of this final rule, the remaining revisions to § 512.720(e)(1) would not constitute substantive changes from the policies finalized in the CY 2026 PFS final rule. Specifically, we proposed to:

- Address the multiple data submissions policy for the quality ASM performance category at § 512.720(e)(1), the improvement activities ASM performance category at § 512.720(e)(2), and the Promoting Interoperability ASM performance category at § 512.720(e)(3). To accomplish this, we would:

++ Add the informative heading ''Quality ASM performance category'' to § 512.720(e)(1).

++ Revise §§ 512.720(e)(1)(i) and 512.720(e)(1)(ii) to reflect our policy for scoring multiple data submissions for the quality ASM performance category and make technical revisions to the text.

++ Redesignate existing § 512.720(e)(2) describing our multiple data submission policy for the Promoting Interoperability ASM performance category as new paragraph § 512.720(e)(3)(i).

++ Redesignate the portions of §§ 512.720(e)(1)(i) and 512.720(e)(1)(ii) that address our multiple data submission policy for the improvement activities ASM performance category to §§ 512.720(e)(2)(i) and 512.720(e)(2)(ii).

++ Add the informative heading ''Improvement activities ASM performance category'' at § 512.720(e)(2).

++ Revise newly redesignated §§ 512.720(e)(2)(i) and 512.720(e)(2)(ii) to make technical clarifications for the treatment of multiple data submissions for the improvement activities ASM performance category.

++ Add the informative heading ''Promoting Interoperability ASM performance category'' to new paragraph § 512.720(e)(3).

We invited public comment on this proposed reorganization of § 512.720(e).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported CMS' reorganization of the multiple data submission provisions of regulations. A commenter stated that such revisions bring greater clarity to the treatment of multiple submissions and scoring methodologies and help to reduce administrative complexity while supporting consistent and transparent performance assessment.

Response: We appreciate the commenters' support and agree that the revisions will bring greater clarity to our policies on multiple data submissions and the effect on performance assessment.

After consideration of public comments, we are finalizing the proposed policies at §§ 512.720(e)(1) through (3) describing treatment of multiple data submissions for the quality, improvement activities, and Promoting Interoperability ASM performance categories as proposed.

(a) Multiple Data Submissions for the Quality ASM Performance Category for ASM Participants in Small Practices

In the CY 2026 PFS final rule, we finalized that ASM participants in small practices may report quality measures in the quality ASM performance category at the group (that is, TIN) level (90 FR 49602). We finalized this policy because we recognize that reporting quality measures at the individual (that is, TIN/NPI) level may be particularly burdensome for ASM participants in small practices who may have limited capacity for data aggregation and reporting. We believe that EHR customization for individual-level reporting, and the costs associated with updating reporting mechanisms, may pose a more significant burden on ASM participants in small practices compared to ASM participants in larger practices because small practices may not have the requisite support, such as infrastructure or staffing, to facilitate individual-level reporting. Importantly, this reporting flexibility does not change ASM's intention to measure individual ASM participant performance; rather, this flexibility is limited to the reporting and scoring of ASM non-administrative claims-based quality measures. All other reporting and scoring requirements for the cost and quality ASM performance categories remain at the individual ASM participant level regardless of practice size. ASM participants in small practices will retain the option to report quality measure data at the individual level if they choose.

After internal review of the provisions finalized in the CY 2026 PFS final rule, we believe that permitting multiple submissions at different reporting levels within a small practice could create unintended incentives and scoring effects. If multiple reporting levels are permitted within the same small practice, an ASM participant's quality ASM performance category score could depend in part on the reporting level used, rather than on a consistent approach to reporting and evaluating quality performance. For example, a small practice could submit individual-level data for higher-performing ASM participants and group-level data for lower performing ASM participants. This variability could reduce comparability across ASM participants and create inconsistent scoring outcomes among ASM participants in similar practice arrangements. We believe ASM participants in small practice should report quality data at the reporting level that best meets their needs and capabilities.

We proposed at § 512.720(e)(1)(iii) that if we receive any quality ASM performance category data at the group (that is, TIN) level from an ASM participant in a small practice, we would score the group-level submission and assign that score to all individual ASM participants in the small practice. This proposal would mean that any individual (that is, TIN/NPI) level submission received for any ASM participants in that small practice would not be scored if any group-level quality data submission is received.

We believe this proposal maintains the desired reporting flexibility to decrease the administrative burden for ASM participants in small practices while preserving the integrity of the ASM scoring framework. Specifically, ASM participants in small practices would continue to have the option to report non-administrative claims-based ASM quality measures at either the group or individual level. Our proposed policy would mitigate the opportunity for ASM participants in small practices to submit data at multiples levels most opportune to achieve a higher score and establish a consistent scoring framework so that ASM participants in small practices are encouraged to submit required data based on needs and capabilities, rather than strategic

performance considerations. Table B–D1 in this section of this final rule summarizes existing finalized policies and new proposals relating to our treatment of multiple data submissions for the quality ASM performance category.

TABLE B-D1: TREATMENT OF MULTIPLE DATA SUBMISSIONS FOR THE QUALITY ASM PERFORMANCE CATEGORY

ASM Participant in a Small Practice	Multiple Quality Data Submissions Received	Source of Multiple Quality Data Submissions	Group-level Quality Data Submission Received	Quality Data Submission Scored
No	No	N/A	Not Permitted	Individual-level (TIN/NPI)
	Yes	Multiple Organizations	Not Permitted	Highest Individual-level (TIN/NPI)
		Single Organization	Not Permitted	Most Recent Individual-level (TIN/NPI)
Yes	No	N/A	Yes	Group-level (TIN)
			No	Individual-level (TIN/NPI)
	Yes	Multiple Organizations	Yes	Highest Group-level (TIN)
			No	Highest Individual-level (TIN/NPI)
		Single Organization	Yes	Most Recent Group-level (TIN)
			No	Most Recent Individual-level (TIN/NPI)

We sought comment on our proposal at § 512.720(e)(1)(iii) to score any group-level quality data submission received from small practices and assign that score to all ASM participants in the small practice regardless of any individual-level quality data submission received for individual ASM participants in that same small practice.

We received public comments on our proposal. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the policy whereby CMS would score all ASM participants in a small practice using group-level (TIN) data when a group-level data submission is received, rather than allow ASM participants in small practices to submit quality data at multiple levels and receive the best score. The commenter noted that selective submission of quality data undermines the comparability and integrity of ASM's quality scoring, invites gaming, and would be difficult for CMS to audit or validate at scale.

Response: We appreciate support for our proposal and agree this would help promote integrity in quality ASM performance category scoring and mitigate selective data submissions that could undermine that integrity.

Comment: Several commenters did not support CMS' proposal. A commenter stated that, due to the disadvantaged position small practices experience in MIPS, CMS should take the higher score if multiple ASM quality submissions are received from a small practice at different levels. Another commenter posited that CMS' policy would prevent a practice from submitting individual level data for the subset of ASM participants in the practice who can individually meet the minimum case requirements for a measure, while submitting TIN level data for those ASM participants without enough patients to be scored individually on the measure. According to the commenter, this could result in differences in the numbers of measures that ASM participants can report, which the commenter believed would be contrary to CMS' goal of accurately comparing performance across ASM participants.

Response: We note that ASM is distinct from MIPS. ASM incorporates flexibilities designed to support small practices, including the ability to report quality data at either the individual level or the group level. The treatment of multiple data submission policy does not eliminate that flexibility; rather, it establishes how we will score submissions when we receive both individual level and group level quality data for ASM participants within the same small practice. We have also established a 10-point final score adjustment for ASM participants in small practices to account for the additional administrative and reporting burdens they may experience.

At this time, we do not believe it is necessary or appropriate to select the higher score when both group-level and individual-level quality data are submitted by ASM participants in a small practice. Doing so could create an incentive to submit quality data at multiple reporting levels based on which submission is expected to produce the more favorable score and could result in inconsistent scoring among similarly situated ASM participants. Assigning the group-level score to all ASM participants in the small practice when CMS receives a group-level submission establishes a clear and consistent approach to scoring, preserves comparability across ASM participants, and reduces the potential for reporting-level selection to influence scoring outcomes.

After consideration of public comments, we are finalizing as proposed our policy at § 512.720(e)(1)(iii). This provision describes that, if we receive a TIN-level data submission in the quality ASM performance category for an ASM participant in a small practice, we score the TIN-level submission and assign that score to all individual ASM participants in the small practice, regardless of any TIN/NPI-level submission(s) received for one or more of those ASM participants.

d. Quality ASM Performance Category

(1) Background

As discussed in the CY 2026 PFS final rule, the quality ASM performance category supports the broader goals of the model by incentivizing improvements in the quality of care and reductions in unnecessary or low—value services for patients with heart failure and low back pain. To accomplish these objectives, we finalized in the CY 2026 PFS final rule the use of ASM cohort-specific quality measure sets at § 512.725(b) (heart failure) and § 512.725(c) (low back pain). ASM participants must report all measures applicable to their ASM cohort, with administrative claims-based measures calculated by us. This structure is similar to other CMS programs, such as MIPS Value Pathways (MVPs), that entail reporting on a clinically relevant subset of measures tailored to an eligible clinician's specialty and patient population. It also minimizes reporting burden, promotes consistency in measurement over the duration of the ASM test period, and supports rigorous evaluation by maintaining a stable set of quality indicators.

In finalizing these policies, we sought to ensure that each ASM cohort-specific quality measure set reflects agency goals to advance value-based care by linking payment to meaningful improvements in clinical outcomes and beneficiary experience. The measures selected for ASM represent a mix of utilization-focused measures, evidence-based care measures, and patient—reported outcome or experience measures. This structure supports nationwide measurement efforts focused on outcomes, safety, and patient experience.

We intended for the quality measure sets applicable to each ASM cohort to remain stable throughout the ASM test period; however, we may propose additions or removals through notice-and-comment rulemaking if refinements to the measure sets are warranted. Such updates may be considered in response to interested parties' feedback, changes in clinical guidelines, updates to measures used in ASM or other CMS programs, or the development of new quality measures. This framework keeps the quality ASM performance category aligned with current clinical practice while providing predictability that may reduce administrative burden over time.

(2) Low Back Pain Quality Measure Set

(a) Low Back Pain Imaging Measure for the ASM Low Back Pain Cohort

In the CY 2026 PFS proposed rule, we proposed inclusion of the ''Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain, Respecified to Be Relevant to ASM Participants Treating Low Back Pain'' measure in the ASM low back pain quality measure set (90 FR 32593 through 32597), but did not finalize its inclusion based on interested parties' feedback (90 FR 49616 through 49618). We indicated in the CY 2026 PFS final rule that we intended to revisit the inclusion of this measure in future notice-and-comment rulemaking (90 FR 49617). We intended to revisit this policy because the ASM low back pain cohort had only four quality measures, and none were focused on excess utilization or efficiency. As our goal is to have a well-rounded measure set for each ASM cohort that includes this focus area, we sought to include a measure that would complete the ASM low back pain quality measure set.

In the CY 2027 PFS proposed rule, we proposed at § 512.725(c)(5) to include the ''Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM)'' measure in the ASM low back pain quality measure set. We stated that this proposal would meet the goals of the ASM low back pain cohort's quality measure set of including an excess utilization focused measure. This measure is modified from the ''Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain'' measure that was specified for use in hospital outpatient departments at the facility level and previously included in the Hospital Outpatient Quality Reporting Program (HOQRP) as OP–8 (73 FR 68766).[186] While we removed the measure from the HOQRP in 2017 due to limited reliability from low average facility-level volumes, we have since re-evaluated the measure for use in ASM. In reassessing this measure, we considered interested parties' feedback, technical expert input, and measure reevaluation activities.

Commenters and experts indicated that, while the clinical concept remains important for assessing low-value imaging, the prior specification presented challenges related to attribution at the facility level, small sample sizes, and limited applicability to certain care delivery contexts. Interested parties also recommended exploring refinements to improve measure reliability and alignment with clinician decision-making in ambulatory specialty settings.

In response, we have made targeted specification modifications to improve the measure's applicability and statistical reliability in the ASM context. We believe these modifications address the previously identified limitations while preserving the measure's clinical intent of reducing unnecessary imaging for low back pain.

We believe the proposed administrative claims-based quality measure would effectively evaluate overuse and incentivize reductions in inappropriate MRI imaging for low back pain. Routine imaging (such as MRI) is not recommended for patients with non-specific low back pain in the absence of certain clinical indicators and concerning features.[187] However, analyses have shown that a significant proportion of patients with low back pain undergo imaging, often within the first few weeks of symptom onset, despite the lack of clear indication.[188] Overuse of imaging for low back pain can lead to unnecessary health care costs and potential patient harm from the cascade effect, where MRI findings, many incidental, may prompt further unnecessary testing or procedures.[189] [190] By including this measure in the ASM low back pain quality measure set, ASM would aim to incentivize adherence to evidence-based guidelines and a

[186] Hospital Outpatient Quality Reporting | Partnership for Quality Measurement. P4qm.org. Published 2025. Accessed April 23, 2025. *https://p4qm.org/taxonomy/term/216.*

[187] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020. *https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf.*

[188] Medicare Payment Advisory Commission. Health Care Spending and the Medicare Program: A Data Book. Medicare Payment Advisory Commission; July 2021. Accessed July 7, 2026. *https://www.medpac.gov/wp-content/uploads/2021/10/July2021_MedPAC_DataBook_Sec7_SEC.pdf.*

[189] Litkowski PE, Smetana GW, Zeidel ML, Blanchard MS. Curbing the Urge to Image. *The American Journal of Medicine.* 2016;129(10):1131–1135. doi: *https://doi.org/10.1016/j.amjmed.2016.06.020.*

[190] Chou R. Diagnostic Imaging for Low Back Pain: Advice for High-Value Health Care From the American College of Physicians. *Annals of Internal Medicine.* 2011;154(3):181. doi: *https://doi.org/10.7326/0003-4819-154-3-201102010-00008.*

reduction of unnecessary MRIs for patients with uncomplicated low back pain, where an MRI is not clinically indicated, particularly in the initial stages of evaluation and management. We believe this could also improve patient experience to the extent it reduces time spent at medical appointments and out—of—pocket health care costs. Furthermore, as an administrative claims-based quality measure, ASM low back pain participants would not assume new reporting requirements for this measure. We would provide detailed measure information for the MRI Lumbar Spine for Low Back Pain (modified for ASM) on the ASM website before the start of the 2027 ASM performance year, if finalized, to educate ASM participants on how they would be measured.

Our modifications seek to improve clinical validity and reliability for the purposes of ASM. Two of our modifications were related to denominator exclusions and the measure's performance period. We also made modifications to provider attribution, minimum case count, and the lookback period for antecedent care, for which we offer alternative options that seek comment on. We believe the modifications we proposed as part of the ''Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM)'' measure to be appropriately tailored to measure performance related to potentially unnecessary MRI utilization for patients with low back pain.

We sought comment on the inclusion of MRI Lumbar Spine for Low Back Pain (modified for ASM) measure in the ASM low back pain quality measure set at § 512.725(c)(5).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS' proposal to include the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure in the ASM low back pain quality measure set. Commenters appreciated CMS' efforts to improve the measure's applicability and statistical reliability and noted that use of an administrative claims-based measure could reduce reporting burden. Another commenter recommended that CMS publicly release the measure specifications, testing results, and supporting documentation before finalizing the measure.

Response: We appreciate commenters' support for the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure. We agree that since this is an administrative claims-based measure calculated by CMS, we expect its inclusion to limit additional reporting burden on ASM participants. We also intend to release additional resources, including detailed measure specifications, in advance of the start of the model to support ASM participant understanding and implementation.

Comment: Several commenters opposed finalizing the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure or recommended postponing its implementation. Commenters questioned whether the modified measure had been sufficiently tested and validated for use at the individual clinician level, noting that the measure on which it was based had previously been removed from the Hospital Outpatient Quality Reporting Program in part because of reliability concerns. Commenters recommended that CMS publicly release the complete measure specifications, reliability and validity testing results, feasibility analyses, and other supporting documentation before using the measure for performance assessment and payment. Some commenters also questioned whether the modified measure had undergone sufficient independent or consensus-based review.

Response: We appreciate commenters' feedback regarding the testing, reliability, and transparency of the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure. In CY 2026 PFS rulemaking, we proposed a version of this measure but did not finalize its inclusion in ASM in response to interested parties' feedback (90 FR 49616 through 49618). At that time, we indicated that we intended to revisit the measure in future rulemaking. This provided additional time to reevaluate the measure, conduct further testing, obtain technical expert and interested parties' input, and refine the measure specifications and methodology.

Based on this additional analysis, we determined that the modified measure achieves sufficient reliability for assessing performance at the individual ASM participant level. As discussed in the CY 2027 PFS proposed rule, we made several modifications intended to improve the measure's clinical validity and reliability, including refinements to the denominator exclusions and use of a 24-month performance period and a 20-case minimum. Our testing showed that these changes increased case volume and improved the stability and reliability of ASM participant-level performance estimates.

We recognize commenters' interest in reviewing additional technical information. CMS intends to release detailed measure specifications and other implementation resources in advance of the first ASM performance year. Because the measure will be calculated using administrative claims data and will not require ASM participants to submit additional measure data, we believe this approach provides ASM participants adequate notice and information to understand how their performance will be assessed without creating additional quality data reporting burden. Accordingly, we do not believe it is necessary to further delay implementation of the measure.

Comment: Several commenters expressed concern that an administrative claims-based measure may not adequately distinguish clinically appropriate from potentially unnecessary lumbar spine MRIs. Commenters stated that claims may not capture the complete clinical history, symptoms, or other factors that inform an imaging decision, particularly for patients with complex spinal conditions. Commenters were concerned that the measure could therefore characterize clinically appropriate imaging as overutilization and create incentives to delay or avoid medically necessary imaging. A commenter also stated that the measure does not assess potential underutilization of MRI and therefore may not provide a balanced assessment of quality.

Response: We appreciate commenters' concerns regarding whether this measure can appropriately distinguish potentially unnecessary imaging from clinically indicated MRI use. We carefully reevaluated the measure for use in ASM, including through clinical review, interested parties' feedback, and measure testing, and made targeted specification changes intended to improve its clinical validity and applicability to ASM participants.

We do not intend to discourage MRI use when imaging is clinically appropriate. Rather, the measure is designed to identify potentially unnecessary imaging for patients with low back pain in circumstances where immediate imaging may provide limited clinical benefit. As part of our clinical review, we retained denominator exclusions for conditions and ''red flag'' signs and symptoms for which more immediate imaging may be warranted, including relevant malignant neoplasms and autoimmune conditions. We also aligned the exclusion logic with the

HEDIS Use of Imaging Studies for Low Back Pain measure where supported by clinical review. These exclusions are intended to avoid assessing imaging as potentially unnecessary when the available claims information indicates a clinical circumstance warranting more immediate imaging.

More broadly, the measure is not intended to reduce MRI utilization indiscriminately or to establish that lower MRI utilization is always better. Its clinical focus is on avoiding imaging before it is indicated, including circumstances in which conservative or antecedent care would generally be appropriate before proceeding to MRI.

We also recognize that this measure is focused specifically on excess utilization and is not designed to assess every dimension of imaging quality, including underutilization. The measure is one component of a broader ASM low back pain quality measure set intended to assess multiple aspects of care. For these reasons, we believe the measure provides a meaningful and appropriately targeted assessment of potentially unnecessary MRI utilization while preserving appropriate imaging for beneficiaries with clinical indications.

Comment: A few commenters questioned the need for a separate MRI utilization measure because the low back pain episode-based cost measure already captures imaging and other utilization. These commenters stated that an additional MRI-focused quality measure could create duplicative accountability and potentially overemphasize reductions in a single service.

Response: We appreciate commenters' concerns regarding potential overlap between the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure and the low back pain episode-based cost measure. We do not consider the measures duplicative because they assess different aspects of performance. The episode-based cost measure evaluates resource use and spending across the broader low back pain episode, while the MRI quality measure is specifically designed to assess whether lumbar spine imaging occurs in circumstances where appropriate antecedent care would generally be expected before imaging.

Accordingly, the MRI measure is not intended simply to reward lower MRI utilization. Rather, it provides a more targeted assessment of potentially unnecessary imaging by considering whether imaging occurred after appropriate antecedent care and by excluding clinical circumstances in which more immediate imaging may be warranted. An MRI may contribute to overall episode spending regardless of whether it was clinically appropriate; the quality measure provides additional information about the appropriateness and timing of that utilization that is not captured by an aggregate episode-based cost measure. We therefore believe the measures are complementary and together provide a more complete assessment of value in low back pain care.

Comment: A commenter also requested clarification regarding how the proposed rolling 24-month performance period would operate.

Response: We appreciate the commenter's request for clarification. By a rolling 24-month performance period, we mean that the measure will include all eligible lumbar spine MRI studies occurring during the applicable two-year performance period used to calculate an ASM participant's measure score. The 2-year window will move forward with each successive ASM performance year rather than operate as a single fixed 24-month period that permanently resets the measure.

We selected a 2-year performance period because testing showed that expanding the performance period from 1 year, as used in the original OP–8 measure, to 2 years approximately doubled denominator volume. The additional case volume improves measure stability and supports more reliable performance assessment, particularly for ASM participants with lower annual imaging volumes.

Comment: Other commenters recommended that CMS provide ASM participants with sufficient advance notice of the final measure specifications and timely performance data before holding ASM participants financially accountable.

Response: We appreciate commenters' recommendations regarding advance notice and access to performance information. We intend to make detailed measure specifications and other implementation resources available in advance of the start of the model. We believe this timing provides sufficient notice because the measure will be calculated by CMS using administrative claims data and will not require ASM participants to establish new EHR functionality, reporting infrastructure, or other systems to submit measure data.

We also note that CMS has signaled its continued interest in an MRI utilization measure for the ASM low back pain cohort across successive rulemaking cycles, including in the CY 2026 PFS rulemaking, when we did not finalize the measure but stated our intent to revisit it in future rulemaking. We recognize the value of timely performance information in helping ASM participants understand their performance and identify opportunities for improvement and, as we further develop ASM's data sharing strategy, we will consider opportunities to provide relevant measure information and performance data to support transparency and ongoing improvement.

We discussed modifications to the measure's specifications in the proposed rule, as well as sought comment on potential alternatives to the proposed modifications related to provider attribution, minimum case count, and the lookback period for antecedent care.

(i) Denominator Exclusions

We conducted an evaluation of the measure's denominator exclusions to ensure that they reflect current clinical guidelines and appropriately identify cases where early lumbar spine imaging is clinically justified. This evaluation focused on exclusions that previously removed a large number of cases under the OP–8 specifications and involved reviewing each diagnosis code individually. Removing a large number of cases in OP–8 presented risks to the applicability and reliability of the measure.

We identified three clinical areas that had a large number of exclusions: cancer diagnoses, neurological impairment, and autoimmune or inflammatory conditions. Physicians assessed each code under these categories for appropriateness to include in the measure denominator. Most conditions, such as ''red flag'' signs and symptoms and for malignant neoplasms and autoimmune disorders where imaging would be warranted (regardless of completion of conservative therapy), were maintained as denominator exclusions. Conditions, such as benign neoplasm of the colon and hemangioma of skin and subcutaneous tissue, were removed as denominator exclusions since their presence would not warrant an immediate MRI for a patient with low back pain; the condition alone would not preclude a patient with low back pain from attempting conservative therapy prior to receiving a lumbar MRI. To improve clinical validity and acceptability, conditions and diagnoses were not removed as denominator exclusions if they were present in the list of denominator exclusions in the Healthcare Effectiveness Data and Information Set (HEDIS) Use of Imaging

Studies for Low Back Pain measure.[191] Under this approach, we ultimately aligned with the same exclusion logic used in the HEDIS Use of Imaging Studies for Low Back Pain measure and only diagnosis codes present in that measure and supported by clinical review remained as denominator exclusions in our ASM measure. As a result of these refinements, the ASM measure's exclusion criteria differ from the prior OP8 specification in these three clinical areas with the goal of more closely aligning to evidence—based practice guidelines.

In our analysis, these changes result in the inclusion of a significant number of imaging studies that would previously have been excluded, representing 52 percent of the cases that would have been removed under the earlier specification. Retaining these cases strengthens this measure by increasing denominator volume and improving our ability to identify potentially unnecessary imaging. We believe these refinements enhance the measure's clinical validity by ensuring that exclusions are limited to diagnoses that represent appropriate indications for more immediate imaging that do not warrant a prior trial of conservative therapy.

We received public comments on the denominator exclusions. The following is a summary of the comments we received and our responses.

Comment: A few commenters raised concerns about the revised denominator exclusions for the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure. Commenters acknowledged CMS's efforts to better account for circumstances in which early imaging may be clinically appropriate but stated that claims-based exclusions may not capture all clinical circumstances that warrant an MRI. Commenters expressed concern that the measure could therefore penalize clinically appropriate imaging or create incentives to delay medically necessary diagnostic evaluation.

Response: We appreciate commenters' concerns that claims-based exclusions may not capture every clinical circumstance in which an MRI is appropriate. In developing the modified measure, we conducted a detailed clinical review of the denominator exclusions, including review of individual diagnosis codes, to identify circumstances in which early imaging is clinically warranted. We retained exclusions for relevant ''red flag'' signs and symptoms and other conditions for which more immediate imaging may be appropriate regardless of antecedent conservative care.

The measure is intended to assess patterns of potentially unnecessary imaging across an ASM participant's eligible cases, rather than determine that every individual MRI included in the measure was clinically inappropriate. The 20-case minimum and 24-month performance period are intended to produce a more stable assessment and reduce the influence of isolated or atypical events. Accordingly, a single clinically appropriate MRI that is not captured by an exclusion is less likely to disproportionately affect an ASM participant's overall measure performance.

Comment: Other commenters recommended additional transparency regarding the revised denominator exclusions, including more information on the affected diagnosis codes and the clinical review supporting the changes. Commenters also questioned whether alignment with the HEDIS Use of Imaging Studies for Low Back Pain measure is sufficient for evaluating individual physician performance.

Response: We appreciate commenters' recommendations regarding transparency. As summarized in the CY 2027 PFS proposed rule, we conducted a diagnosis code-level clinical review of the denominator exclusions and intend to release additional measure specifications in advance of the 2027 ASM performance year. The historical OP–8 specifications are publicly available, and we used the HEDIS Use of Imaging Studies for Low Back Pain measure as an additional clinical cross-check, not as the sole basis for determining the measure's appropriateness for individual ASM participant-level assessment. That determination also reflected clinical review, technical input, and measure testing.

After consideration of public comments, we are finalizing as proposed the denominator exclusions for the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure.

(ii) Performance Period

We evaluated the performance period for the measure to ensure that ASM participant-level scores are reliable and suitable for use in the model's quality assessment framework. The original HOQRP version of the measure used a single-year performance period, which limited the number of eligible MRI studies available for scoring and contributed to concerns about measure reliability.[192] To address these issues, we tested an expanded performance period that included all eligible lumbar spine MRI studies occurring within a rolling 24—month window. Under this approach, each MRI meeting denominator criteria during the 2—year period was included in measure calculation, thereby significantly increasing the number of cases available for analysis. Testing showed that the expanded 2—year performance period resulted in approximately a 100 percent increase in denominator volume relative to a 1—year period. This increase in case volume improved the precision of ASM participant-level estimates and reduced small—sample volatility, particularly for clinicians with lower annual MRI volumes. We believe that a 2—year performance period enhances measure stability and supports more dependable performance assessment across all ASM low back pain participants and overcomes limitations and concerns that existed when the measure existed in the HOQRP. This is especially important for utilization measures, where annual case counts can vary substantially among specialties and practice types. Based on these findings, we believe that a rolling 24—month period provides the most robust and actionable representation of clinician imaging practices.

We received public comments on the performance period. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposed expansion of the performance period for the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure.

Response: We appreciate the commenter's support and note that this change improves the precision and stability of ASM participant-level estimates and reduces small-sample volatility. We believe this approach supports more reliable performance assessment, particularly for ASM participants with lower annual MRI volumes.

Comment: A commenter raised concerns about the proposed rolling 24-month performance period, including that it differs from the one-year periods used for other ASM quality measures, may include imaging furnished before

[191] National Committee for Quality Assurance. *Use of Imaging Studies for Low Back Pain (LBP).* NCQA, *https://www.ncqa.org/report-cards/health-plans/state-of-health-care-quality-report/use-of-imaging-studies-for-low-back-pain-lbp/.* Accessed 6 Apr. 2026.

[192] Hospital Outpatient Specifications Manuals, Hospital Outpatient Quality Reporting. CMS.gov. Accessed March 27, 2026. *https://qualitynet.cms.gov/outpatient/specifications-manuals.*

ASM begins, and may allow the same imaging event to affect performance in consecutive years. The commenter also questioned whether the longer period could delay the effect of practice changes and is primarily intended to increase case volume.

Response: We appreciate the commenter's concerns. We selected a 24-month performance period based on testing showing that it approximately doubled denominator volume compared with a one-year period, improving the precision and stability of ASM participant-level estimates and reducing small-sample volatility. The longer period is intended to support more reliable performance assessment, particularly for ASM participants with lower annual MRI volumes, rather than simply increase the number of ASM participants measured. Although some imaging events may contribute to consecutive annual measurement windows, the measure assesses aggregate performance across all eligible cases rather than assigning a separate penalty to an individual MRI. We believe this approach provides a more stable representation of imaging practices while allowing performance to change as newer cases enter the rolling window.

After consideration of public comments, we are finalizing as proposed the 24-month performance period for the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure.

(iii) Provider Attribution

The management of low back pain often involves several specialists over an extended period, and diagnostic and treatment decisions typically develop through multiple clinical encounters rather than a single visit. In modifying the original HOQRP measure for use in ASM, we had to address how to transition the measure from its original hospital outpatient department attribution method, which assigned imaging only to the facility that billed the MRI claim, to an approach that reflects physician—level accountability. This work included evaluating a single—participant attribution method that assigns each MRI to the physician with the highest number of qualifying encounters during the lookback period and a multiple—participant attribution method that assigns the MRI to all physicians who provided qualifying services to the patient. Testing showed that the multiple—participant method increased the number of attributed MRI studies by roughly 26 percent after exclusions, which strengthened measure stability and improved representation of the various physicians involved in that beneficiary's care. Multiple attribution better reflects real—world care patterns, particularly in increasingly common cases where beneficiaries receive longitudinal care by different team members over time. This approach also supports ASM's goals by recognizing the shared nature of clinical responsibility for decisions that influence downstream utilization and patient outcomes. Also, including all clinicians who contributed meaningfully to the beneficiary's care ensures that performance assessment captures the full set of ASM low back pain participants who may influence imaging decisions. We believe this attribution method provides a more complete and accurate understanding of imaging practices within the ASM low back pain cohort. For these reasons, we proposed multiple—participant attribution.

We also considered an alternative approach that would attribute each MRI to a single physician. Under this option, an MRI would be assigned to the ASM participant who furnished the highest number of qualifying encounters during the attribution window, which reflects a single point of clinical responsibility for many beneficiaries. This approach would provide a more streamlined assignment method and could reduce attribution complexity for the measure, but may not be reflective of real-world practice patterns and results in fewer attributed beneficiaries per ASM participant and thus slightly lower measure reliability.

We sought comment on the proposed use of a multiple-participant attribution method for this quality measure. We also sought comment on the alternate proposal of an attribution method involving a single ASM participant.

We received public comments on the provider attribution. The following is a summary of the comments we received and our responses.

Comment: Several commenters raised concerns regarding attribution of MRI utilization to ASM participants who may not have ordered the imaging or meaningfully influenced the imaging decision. Commenters stated that participation in a beneficiary's longitudinal low back pain care does not necessarily indicate responsibility for a particular MRI and expressed particular concern with attributing the same MRI to multiple ASM participants. Commenters recommended that CMS more closely align attribution with the clinician responsible for, or able to influence, the imaging decision and avoid attributing imaging ordered before the specialist became involved in the beneficiary's care or imaging required under applicable coverage policies.

Response: We appreciate commenters' feedback regarding attribution of MRI utilization. In response to these concerns, we are finalizing the alternative single-participant attribution methodology described in the proposed rule, under which each MRI will be attributed to the ASM participant with the highest number of qualifying encounters during the applicable lookback period. This approach avoids attributing the same MRI to multiple ASM participants and is intended to tie accountability more directly to the ASM participant with the strongest demonstrated treatment relationship during the relevant period. Although this approach results in fewer attributed beneficiaries and slightly lower reliability than multiple-participant attribution, we believe it more appropriately balances measure reliability with commenters' concerns regarding accountability.

Comment: A commenter supported the alternative single-participant attribution methodology, under which each MRI would be attributed to the ASM participant with the highest number of qualifying encounters during the lookback period.

Response: We appreciate the commenter's support. As discussed, after consideration of public comments, we are finalizing the alternative single-participant attribution methodology.

Comment: Other commenters stated that the alternative single-participant attribution methodology may still attribute an MRI to a clinician who did not order or influence the imaging decision. These commenters recommended that accountability be more directly tied to the clinician responsible for the MRI decision and expressed concern that specialists who become involved later in a beneficiary's care could otherwise be held accountable for earlier imaging decisions.

Response: We appreciate commenters' concerns. Although single-participant attribution may not identify the ordering clinician in every instance, attributing each MRI to the ASM participant with the highest number of qualifying encounters provides a consistent claims-based approach that more closely aligns accountability with the ASM participant who had the strongest treatment relationship during the lookback period. We believe this approach is preferable to multiple attribution because it avoids holding several ASM participants accountable for the same imaging event while preserving a practicable methodology for the measure.

Comment: A commenter recommended using episode-based cost measures triggered by discrete clinical events, such as surgery, injection, or initiation of specialist care, rather than the proposed MRI measure. The commenter believed this approach would better align ASM participant accountability with services and costs within the clinician's control.

Response: We appreciate the commenter's suggestion. ASM already assesses broader resource use through the low back pain episode-based cost measure, while the MRI quality measure serves a distinct purpose by assessing potentially unnecessary imaging and whether appropriate antecedent care occurred before MRI. We therefore believe the MRI measure provides complementary information and are not adopting the suggested alternative.

After consideration of public comments, we are finalizing the alternative proposal to use a single-participant attribution methodology, under which each MRI will be attributed to the ASM participant with the highest number of qualifying encounters during the applicable lookback period.

(iv) Minimum Case Count

We evaluated the appropriate minimum case count threshold for the MRI Lumbar Spine for Low Back Pain (modified for ASM) measure to ensure that clinician—level performance scores are reliable for use in the model's quality assessment framework. Low case volumes may produce substantial variation in provider scores and a wider distribution of results, which could reduce the measure's ability to distinguish true performance differences. At lower thresholds, such as one or 10 cases, our analysis found that many ASM low back pain participants would have insufficient volume to support stable estimates, and reliability decreased accordingly. At a threshold of 20 cases, the measure showed stronger reliability and a narrower distribution of scores across ASM participants, indicating that estimates were more consistent and reflective of meaningful patterns of imaging use. The threshold of 20 cases aligns with the ASM participant eligibility criteria that, in part, requires an ASM low back pain participant to have historically been attributed at least 20 low back pain EBCM episodes. The threshold of 20 cases also aligns with the case minimums for the other quality measures in the ASM low back pain quality measure set. This alignment ensures that the case count threshold is both operationally feasible and representative of the expected care volume for ASM participants. In addition, maintaining a minimum of 20 cases reduces the influence of isolated or atypical events that may disproportionately affect results when volumes are low. The analysis further showed that a substantial proportion of ASM low back pain participants would continue to meet eligibility for scoring at this case threshold, preserving the ability to assess quality performance across a broad ASM participant population. We believe that maintaining a minimum of 20 cases appropriately balances inclusiveness and methodological rigor. For these reasons, we proposed a threshold of 20 cases for the MRI Lumbar Spine for Low Back Pain (modified for ASM) measure.

We also considered an alternative minimum case count of 10 for the MRI Lumbar Spine for Low Back Pain (modified for ASM) measure. A threshold of 10 would allow a greater number of ASM low back pain participants to be scored on the measure, particularly those with smaller patient panels or lower annual imaging volume. Although reliability is lower at this threshold relative to a minimum of 20 cases, a 10—case minimum would offer meaningful insight into specialist practice patterns while expanding the proportion of ASM low back pain participants scored on the measure.

We sought comment on the proposed minimum case count of 20. We also sought comment on the alternate proposal of a minimum case count of 10.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed 20-case minimum, stating that it appropriately aligns with other ASM case minimums and provides greater reliability than the alternative 10-case threshold.

Response: We appreciate commenters' support. As discussed later in this section of this final rule, we believe the 20-case minimum appropriately balances measure reliability with the number of ASM participants eligible to be scored on the measure.

Comment: A few commenters expressed concern that a 20-case minimum may be too low to support sufficiently reliable ASM participant-level results, noting that individual cases could have a meaningful effect on performance rates and that the prior OP–8 measure used higher minimum case counts at the hospital level. Commenters also opposed the alternative 10-case minimum because lower volumes could increase score volatility.

Response: We appreciate commenters' concerns regarding reliability at lower case volumes. Our testing of the modified measure at the ASM participant level found that a 20-case minimum produced stronger reliability and more stable estimates than lower thresholds, while also aligning with ASM low back pain eligibility criteria and the case minimums used for other ASM low back pain quality measures. The OP–8 hospital thresholds are not directly comparable because that measure assessed performance at the facility level under different specifications. For ASM, we specifically tested the modified measure at the individual ASM participant level and use a 24-month performance period to increase case volume and stability. We therefore believe the 20-case minimum appropriately balances reliability with the number of ASM participants eligible to be scored on the measure and are not adopting the 10-case alternative.

After consideration of public comments, we are finalizing as proposed the 20-case minimum for the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure.

(v) Lookback Period

We evaluated the attribution lookback period to determine the timeframe during which clinician services should be considered for assigning each lumbar spine MRI to ASM low back pain participants. The measure needs a lookback period long enough to capture clinical encounters that inform decisions about imaging, while still maintaining a clear and comprehensive lookback approach. Chronic low back pain is managed over extended periods, and patients frequently receive evaluation and treatment, and require care coordination from multiple clinicians during this time. Based on these care patterns, we examined whether a longer window would more accurately identify the set of clinicians who meaningfully influence imaging decisions. Testing demonstrated that a 365-day lookback period compared to a shorter window like 90-days substantially increased the number of attributed MRI studies by approximately 27 percent. We believe a 365-day period better reflects the longitudinal nature of chronic low back pain management and ensures that attribution captures the full course of care that precedes a patient's imaging event. A full-year window also aligns with the model's annual ASM performance year and improves consistency across the various quality

measures included in the model. We believe that adopting a 365-day lookback window strengthens the completeness of performance assessment by ensuring that clinicians who contribute meaningfully to care are appropriately included. For these reasons, we proposed to use a 365-day lookback period for attribution of MRI studies within the measure.

We also considered an alternative 120-day lookback period. This approach would limit attribution to ASM low back pain participants who furnished lower back pain-related services in closer proximity to the imaging event and, therefore, would provide a more focused reflection of recent clinical decision-making. However, it would also result in fewer cases per ASM participant, which could create a narrower view of the ASM participant's trends related to MRI referral and low back pain.

We sought comment on the proposed 365-day lookback period and the alternative of a 120-day lookback period.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Other commenters supported a longer lookback period for the MRI measure, with a commenter noting that a 365-day period would be acceptable if the attribution methodology accurately identifies the accountable ASM participant.

Response: We appreciate commenters' support. We believe the 365-day lookback appropriately reflects the longitudinal nature of low back pain care, and our decision to finalize single-participant attribution further narrows accountability to one ASM participant.

Comment: A few commenters raised concerns that the proposed 365-day lookback period could attribute an MRI to an ASM participant whose involvement in the beneficiary's care occurred well before the imaging decision. Some commenters supported the 120-day alternative or another shorter period that would more closely reflect recent clinical decision-making, while others stated that even 120 days may be too long. Commenters also questioned whether the additional cases captured by the 365-day period sufficiently reflect care that ASM participants could meaningfully influence.

Response: We appreciate commenters' concerns. We continue to believe a 365-day lookback period appropriately reflects the longitudinal nature of chronic low back pain management and captures antecedent care that may occur over an extended period before imaging. Our testing showed that the 365-day period increased attributed MRI studies by approximately 27 percent compared with a 90-day period, supporting a more complete and reliable assessment of imaging patterns. The lookback period is not intended to establish that every prior encounter directly caused the imaging decision, but rather to identify the relevant course of low back pain care preceding the MRI. In addition, our decision to finalize single-participant attribution will narrow accountability relative to the proposed multiple-participant approach by attributing each MRI to only one ASM participant.

After consideration of public comments, we are finalizing the proposed 365-day lookback period.

After consideration of public comments, we are finalizing the inclusion of the Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM) measure in the ASM low back pain quality measure set at § 512.725(c)(5), with the measure specifications described earlier in this section of this final rule, including a modification to use the alternative single-participant attribution methodology rather than the proposed multiple-participant attribution methodology.

(b) Removing Functional Status Change for Patients With Low Back Impairments (MIPS Q220) and Adding Functional Outcome Assessment (MIPS Q182)

In the CY 2026 PFS final rule (90 FR 49620 through 49622), we finalized inclusion of Functional Status Change for Patients with Low Back Impairments (MIPS Q220) in the ASM low back pain quality measure set because it captures functional outcomes that are directly relevant to patients' experience of low back pain and their ability to perform daily activities. We noted that the measure aligns with the model's emphasis on patient-centered outcomes and longitudinal management and complements the broader set of prevention and utilization—focused measures included in the ASM low back pain quality measure set.

Since publication of the CY 2026 PFS final rule, the measure steward has indicated that they no longer intend to maintain Functional Status Change for Patients with Low Back Impairments (MIPS Q220), including key operational components such as the survey's online portal. Consistent with this change, we are removing this measure from the MIPS measure inventory.

Accordingly, we proposed at § 512.725(c)(4) to remove the Functional Status Change for Patients with Low Back Impairments (MIPS Q220) from the ASM low back pain quality measure set and replace it with Functional Outcome Assessment (MIPS Q182). This proposal would address the absence of the MIPS 220 measure by replacing one measure of functional status with another.

We believe that Functional Outcome Assessment (MIPS Q182) represents an appropriate replacement as it meets similar goals as MIPS Q220 and may be familiar to many ASM low back pain participants. However, we noted that we intended to pursue the potential future adoption of a more robust patient-reported outcome-based performance measure (PRO–PM) to further emphasize the importance of functional status improvement within ASM. Such a change to the ASM low back pain quality measure set would be proposed via future notice—and—comment rulemaking.

Functional Outcome Assessment (MIPS Q182) promotes the routine assessment of functional status and requires clinicians to document a care plan when functional outcome deficiencies are identified. As such, the measure supports a more patient—centered approach to care by encouraging ASM participants to incorporate patients' reported experiences and functional status assessments and limitations into clinical decision—making. The measure leverages patient—reported outcome tools and surveys to facilitate meaningful communication between clinicians and their patients regarding symptoms, daily functioning, and treatment goals; as a result, identified concerns can be addressed as part of the evaluation and management of the patient.

We believe that systematic measurement and improvement of functional status can increase patient self—efficacy, improve overall well—being, and potentially reduce downstream healthcare utilization and costs. Additionally, the use of validated and standardized assessment tools may enhance the reliability and sensitivity of detecting functional impairments and monitoring changes over time, particularly among older adults with low back pain.[193]

Although Functional Outcome Assessment (MIPS Q182) does not require the use of a specific instrument, examples of appropriate, validated tools relevant to the ASM low back pain cohort include the Modified Oswestry

[193] Wong AY, Karppinen J, Samartzis D. Low back pain in older adults: risk factors, management options and future directions. *Scoliosis and Spinal Disorders.* 2017;12(1):1–23. doi: *https://doi.org/10.1186/s13013-017-0121-3.*

Disability Index and the Patient—Reported Outcomes Measurement Information System (PROMIS). The use of such tools is supported by clinical guidelines and professional organizations. For example, the American Academy of Orthopedic Surgeons recommends the Modified Oswestry Disability Index as a preferred instrument for assessing functional outcomes in spine care.[194] [195] These functional status instruments may also capture information related to modifiable risk factors, such as physical activity levels and social isolation, which can inform clinical discussions and interventions aimed at preventing the progression of low back pain and associated comorbid conditions.

This proposal also responded to interested parties' feedback regarding operational concerns with Functional Status Change for Patients with Low Back Impairments (MIPS Q220). In addition, Functional Outcome Assessment (MIPS Q182) aligns with the Quality Payment Program's Rehabilitative Support for Musculoskeletal Care MIPS Value Pathway (MVP), further supporting its inclusion in the ASM. We also note that Functional Outcome Assessment (MIPS Q182) has a MIPS CQM collection type, the same collection type as the Functional Status Change for Patients with Low Back Impairments (MIPS Q220).

By embedding accountability for assessing and addressing functional status into the ASM quality measure set for ASM participants who treat low back pain, this measure supports a comprehensive, longitudinal approach to low back pain management, including appropriate evaluation, treatment planning, and ongoing monitoring of patient outcomes.

We sought comment on our proposal at § 512.725(c)(4) to remove the Functional Status Change for Patients with Low Back Impairments (MIPS Q220) from the ASM low back pain quality measure set and replace it with Functional Outcome Assessment (MIPS Q182).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

[194] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020.

[195] Performance Measures by Orthopaedic Subspecialty. Aaos.org. Published 2025. Accessed April 23, 2025. *https://www.aaos.org/quality/research-resources/patient-reported-outcome-measures/performance-measures-by-orthopaedic-subspecialty*.

Comment: Several commenters supported CMS' proposal to replace Functional Status Change for Patients with Low Back Impairments (MIPS Q220) with Functional Outcome Assessment (MIPS Q182). Commenters supported maintaining a functional status measure in the low back pain quality measure set and noted the flexibility to use different validated assessment instruments.

Response: We appreciate commenters' support. We agree that Functional Outcome Assessment (MIPS Q182) provides an appropriate way to maintain a focus on functional status while allowing flexibility in the assessment instrument used.

Comment: A few commenters supported CMS' proposal to remove Functional Status Change for Patients with Low Back Impairments (MIPS Q220), recognizing that the measure steward no longer intends to maintain the measure.

Response: We appreciate commenters' support. As discussed in the proposed rule, the measure steward no longer intends to maintain Functional Status Change for Patients with Low Back Impairments (MIPS Q220), including key operational components needed to support continued use of the measure. We therefore believe removal of the measure from the ASM low back pain quality measure set is appropriate.

Comment: Other commenters supported removal of Functional Status Change for Patients with Low Back Impairments (MIPS Q220) but opposed replacing it with Functional Outcome Assessment (MIPS Q182).

Response: We appreciate commenters' support for removing MIPS Q220 and recognize their concerns regarding the proposed replacement. Given the measure steward's decision to discontinue MIPS Q220, we believe it is important to maintain a functional status component within the ASM low back pain quality measure set rather than leave this aspect of care unmeasured. Functional Outcome Assessment (MIPS Q182) is currently the most appropriate available replacement because it supports routine assessment of functional status and development of a care plan when deficiencies are identified. While we may pursue more robust outcome-based measurement in the future, we believe MIPS Q182 provides an appropriate step toward maintaining a focus on functional status in ASM.

Comment: Several commenters raised concerns that Functional Outcome Assessment (MIPS Q182) is available only as a MIPS CQM and not as an eCQM, which could require some practices to establish new registry, vendor, or reporting workflows.

Response: We recognize commenters' concerns regarding the MIPS CQM collection type. Functional Status Change for Patients with Low Back Impairments (MIPS Q220), which was previously finalized for ASM, was also available as a MIPS CQM, so ASM participants have had notice that reporting a functional status measure in the ASM low back pain cohort may require MIPS CQM reporting capabilities. We recognize that replacing the measure may still require updates to existing workflows and systems, and we expect ASM participants and their reporting partners will use the implementation period before reporting is due to make necessary adjustments. We also intend to provide additional implementation information to support that transition in advance of model start.

Comment: Several commenters questioned the clinical value of Functional Outcome Assessment (MIPS Q182), noting that it is a broadly applicable process measure rather than a low back pain-specific outcome measure. Commenters also raised concerns regarding high MIPS performance rates, documentation burden, frequency of assessment, and potential patient survey fatigue.

Response: We recognize these concerns but believe Functional Outcome Assessment (MIPS Q182) is the most appropriate currently available option for maintaining functional status measurement within the ASM low back pain quality measure set. The measure advances ASM participants toward greater consideration of functional status by encouraging clinicians to assess functional limitations and incorporate identified deficiencies into the patient's care plan, while allowing flexibility in the standardized assessment instrument used. Although the measure has demonstrated high performance in MIPS, we do not expect MIPS performance distributions to necessarily translate directly to ASM because ASM requires ASM participants to report all applicable ASM cohort measures rather than allowing clinicians to select among measures. We also recognize concerns regarding physician and patient burden; however, we believe routine discussion of functional status and incorporation of identified needs into treatment planning are important components of high-quality low back pain care and can support a more patient-centered care plan.

Comment: A few commenters recommended using a more condition-specific functional improvement measure or PRO–PM instead of

Functional Outcome Assessment (MIPS Q182), or delaying replacement of MIPS Q220 until such a measure is available.

Response: We appreciate commenters' recommendations and agree that more robust condition-specific outcome measurement could further advance the goals of ASM. However, the currently available options suitable for immediate inclusion in ASM are limited, and we do not believe leaving functional status unmeasured while a future measure is developed is preferable. Functional Outcome Assessment (MIPS Q182) provides a flexible interim approach because it does not prescribe a single assessment instrument and allows ASM participants to select an appropriate validated tool for their practice and patient population. We believe this flexibility facilitates implementation while moving ASM toward greater emphasis on functional outcomes, and we intend to continue exploring more robust PRO–PMs for future rulemaking.

Comment: A commenter requested additional guidance regarding acceptable functional assessment instruments, timing and documentation requirements, care-plan expectations, and use of existing PRO collection platforms.

Response: We appreciate the commenter's request for additional implementation guidance. The measure specifications for Functional Outcome Assessment (MIPS Q182) describe the applicable assessment and care-plan requirements and allow use of multiple validated functional assessment instruments, rather than prescribing a single survey or tool. This flexibility is intended to allow practices to use approaches that fit their existing workflows, practice goals, and minimize unnecessary burden. We intend to provide additional measure guidance in advance of the start of the model to support ASM participant implementation. After consideration of public comments, we are finalizing as proposed our policy at § 512.725(c)(4) to remove Functional Status Change for Patients with Low Back Impairments (MIPS Q220) from the ASM low back pain quality measure set and finalizing as proposed to replace it with Functional Outcome Assessment (MIPS Q182).

(3) Data Completeness Requirement for the Quality ASM Performance Category

As discussed in the CY 2026 PFS final rule (90 FR 49631), we finalized policies to establish a data completeness requirement for applicable quality measures in the quality ASM performance category. Under this requirement, ASM participants reporting MIPS clinical quality measures (MIPS CQMs) or eCQMs would be required to submit data for at least 75 percent of patients who meet the denominator criteria for each measure, regardless of payer.

The regulatory text at § 512.725(f)(3) describing the data completeness requirement includes a non-substantive typographical error of a misplaced possessive ''s'' on ''ASM''.

We proposed at § 512.725(f)(3) to correct this typographical error so that it would read: ''CMS excludes from an ASM participant's total measure achievement points and total available measure achievement points any measure required under paragraph (b) or (c) of this section that meets the respective measure's data completeness requirement but does not have a benchmark.'' We believe this correction clarifies the regulatory text without substantively changing the policy under existing provisions.

We sought comment on our proposal to modify § 512.725(f)(3) to correct this typographical error.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

(4) Scoring and Benchmarks for Quality Measures

As discussed in the CY 2026 PFS final rule (90 FR 49634 through 49635), we finalized policies to benchmark and score ASM quality measures. We will use measure—specific benchmarks where separate benchmarks are calculated for each measure and collection type to reflect meaningful performance differences among ASM participants. Quality measure benchmarks will be derived from ASM participant data from the current or prior ASM performance years, or another CMS—determined period. We determined that separate benchmarks by collection type (for example, MIPS CQM and eCQM) are more appropriate than a single benchmark for each measure aggregated across collection types due to established scoring variation across collection types. Benchmarks will be decile—based percentile distributions, which enable consistent scoring and translate measure performance values uniformly. To score reported data against the benchmarks, ASM participants' performance on each measure will be mapped to decile ranges, with one to 10 achievement points assigned according to the decile in which the measure's reported rate falls.

In the CY 2026 PFS final rule, we explained that administrative claims—based quality measures do not require data submission (90 FR 49616) and finalized corresponding administrative claims—based quality measure scoring policies (90 FR 49630). However, we did not specify whether we would score such measures at the group (that is, TIN) or individual (that is, TIN/NPI) level.

We proposed to specify the level at which we would calculate administrative claims—based quality measures. Specifically, we proposed at § 512.725(e)(3)(i) to score all administrative claims—based quality measures at the individual (that is, TIN/NPI) level to ensure that performance assessment reflects individual ASM participant performance regardless of eligibility to report quality measures at the group (that is, TIN) level. Administrative claims—based quality measures do not require ASM participants to submit data, thereby reducing reporting burden for all ASM participants, including those that may be from a small group practice and otherwise receive flexibilities for ASM quality measures that require reporting. Scoring administrative claims-based quality measures at the individual (that is, TIN/NPI) level preserves the model's intended focus on individual specialist accountability without increasing burden.

We also proposed modifications to §§ 512.725(h)(1) and 512.725(h)(2) to clarify quality ASM performance category scoring policies applicable to quality measures reported by an ASM participant, compared to administrative claims—based quality measures calculated by us. These proposals aim to align regulatory text with the nature of quality measure collection types, distinguishing quality measures for which ASM participants actively submit data from administrative claims—based quality measures that we calculate and therefore do not require data submission.

Accordingly, we proposed to reorganize and revise regulatory text at § 512.725(h)(1)(i) to clarify the different requirements that administrative claims-based quality measures and non-administrative claims-based quality measures must meet to be scored. Specifically, we proposed to remove the phrase ''on which data is submitted'' from § 512.725(h)(1)(i), which describes how ASM participants are awarded achievement points for quality measures that meet the specified criteria, to conform with the proposed reorganization of this section of regulatory text.

We also proposed to describe all scoring requirements for non-administrative claims-based quality measures at § 512.725(h)(1)(i)(A).

Specifically, we proposed to redesignate former regulatory text § 512.725(h)(1)(i)(A) through (h)(1)(i)(C) as § 512.725(h)(1)(i)(A)(*1)* through (h)(1)(i)(A)(*3*), respectively. We then proposed to revise § 512.725(h)(1)(i)(A) to describe that quality measures other than administrative claims-based quality measures must meet the requirements described at § 512.725(h)(1)(i)(A)(*1)* through (h)(1)(i)(A)(*3*) to be scored. We also proposed to redesignate regulatory text formerly at § 512.725(h)(1)(i)(D) to § 512.725(h)(1)(i)(B) and to revise text to clarify the scoring requirements for administrative claims-based quality measures. We noted in the proposed rule that these proposed revisions do not make substantive changes to existing scoring requirements but would provide greater clarity to ASM participants on the specific requirements for quality measures to be scored.

We also proposed to clarify our provisions related to the determination of quality measure benchmarks. Specifically, we proposed to remove § 512.725(h)(2)(iii), which describes the periods we may use to calculate administrative claims-based quality measure benchmarks. We believe this paragraph is unnecessary in light of § 512.725(h)(2)(i), which sufficiently describes the periods we may use to calculate any quality benchmark, whether administrative claims-based or otherwise. To conform with this proposal, we also proposed to remove cross-references to § 512.725(h)(2)(iii) from §§ 512.725(h)(1)(i)(D) and 512.725(h)(2)(i), as well as redesignate former § 512.725(h)(2)(iv) as new § 512.725(h)(2)(iii). These proposals would allow more flexibility in determining appropriate and fair benchmarks and ensure that benchmark time periods align with the performance periods of the administrative claims-based quality measures.

We also proposed to clarify quality measure scoring when we are unable to determine a benchmark. Specifically, we proposed at § 512.725(h)(2)(iv) that we would exclude any required quality measure for which we cannot calculate a benchmark in the determination of an ASM participant's quality ASM performance category score. We would do so by removing the total measure achievement points (that is, the points calculated for the numerator of the quality ASM performance category score) and the total available measure achievement points (that is, the points calculated for the denominator of the quality ASM performance category score) from the quality ASM performance category score calculation for any quality measure that lacks a benchmark. While we state that a quality measure must have a benchmark to be scored under proposed § 512.725(h)(1)(i), we believe that this proposal clarifies the effect of a quality measure lacking a benchmark on the overall quality ASM performance category score.

We sought comment on our proposal at § 512.725(e)(3)(i) to score all administrative claims—based quality measures at the TIN/NPI level. We also sought comment on our proposed reorganization of regulatory text at § 512.725(h)(1)(i) to separately describe the scoring requirements for non-administrative claims-based quality measures and administrative claims-based quality measures. We sought comment on our proposals at § 512.725(h)(2) to clarify provisions related to the determination of quality measure benchmarks. Finally, we sought comment on our proposal at § 512.725(h)(2)(iv) describing how we would account for quality measures without benchmarks in the quality ASM performance category score calculation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported CMS' proposal to score administrative claims-based quality measures at the individual TIN/NPI level and to separately describe scoring requirements for administrative claims-based and other quality measures.

Response: We appreciate the commenter's support. We believe these policies appropriately preserve individual specialist accountability while clarifying the scoring requirements applicable to different quality measure types.

Comment: A few commenters opposed scoring all administrative claims-based quality measures at the individual TIN/NPI level. Commenters stated that individual-level scoring may not adequately reflect team-based care, particularly for ASM participants in small practices that report other quality measures at the TIN level. Commenters recommended allowing administrative claims-based measures to be calculated at the TIN level in those circumstances.

Response: We appreciate commenters' concerns regarding team-based care. We continue to believe that scoring administrative claims-based quality measures at the individual TIN/NPI level appropriately preserves ASM's focus on individual specialist accountability, including for ASM participants that report other quality measures at the TIN level. At the same time, care furnished by the broader care team may still influence the beneficiary outcomes and utilization reflected in an individual ASM participant's administrative claims-based measure performance, and group-level reporting of other applicable quality measures can further reflect team-based performance. Because these measures are calculated by CMS using claims data, individual-level scoring also does not create additional data submission burden for ASM participants.

Comment: A few commenters supported CMS' proposal to exclude a required quality measure from scoring when CMS cannot establish an applicable benchmark. Commenters stated that ASM participants should not be disadvantaged by measures that cannot be validly benchmarked and emphasized the importance of accurate performance assessment.

Response: We appreciate commenters' support. We agree that ASM participants should not be scored on a required quality measure when an applicable benchmark cannot be established. Excluding such a measure from both total achievement points and total available measure achievement points helps ensure that the quality ASM performance category score reflects only measures that can be meaningfully benchmarked.

Comment: A few commenters recommended that quality measure benchmarks be based on prior-year performance rather than current-year ASM performance. Commenters expressed concern that current-year benchmarks would prevent ASM participants from knowing performance expectations in advance and could result in lower scores despite improvements in performance. A commenter specifically recommended using prior-year MIPS performance to establish benchmarks during the initial ASM performance year.

Response: We appreciate commenters' concerns regarding benchmark predictability. We continue to believe it is important to retain flexibility to establish benchmarks. Current-year ASM data may provide the most representative comparison because they reflect the actual ASM participant population, applicable measure specifications, and collection types, whereas prior-year MIPS data may reflect different reporting populations and reporting choices. This flexibility is particularly important in the early years of ASM and for new or modified measures where comparable prior-year data may be limited. Accordingly, we are not limiting quality measure

benchmarks solely to prior-year performance data.

After consideration of public comments, we are finalizing as proposed our policies at § 512.725(e)(3)(i) to score all administrative claims-based quality measures at the individual TIN/NPI level. We are also finalizing as proposed the revisions at § 512.725(h)(1)(i) to clarify the scoring requirements applicable to administrative claims-based and non-administrative claims-based quality measures, and the revisions at § 512.725(h)(2) related to the determination of quality measure benchmarks. Finally, we are finalizing as proposed § 512.725(h)(2)(iv), under which a required quality measure for which we cannot calculate a benchmark will be excluded from both total measure achievement points and total available measure achievement points in calculating the quality ASM performance category score.

(5) Voluntary Data Submission for the Development of Patient-Reported Outcome-Based Performance Measures (PRO–PMs)

As discussed in the CY 2026 PFS final rule (90 FR 49612), we are considering future adoption of one or more patient-reported outcome-based performance measures (PRO–PMs) in ASM that would evaluate changes in patient-reported health status, physical function, symptoms, aggregate patient-reported health status, or other related outcomes over time. Unlike a functional status process measure that assesses whether a functional status assessment or other patient-reported assessment was completed, a PRO–PM would collect information directly from patients to assess whether the care furnished by an ASM participant is associated with improvement in, or slowing of decline in, ASM beneficiary-reported outcomes. We believe such measures could better capture outcomes that matter to ASM beneficiaries and support more patient-centered specialty care. Standardized assessment of patient-reported health status using a validated questionnaire can be useful for providing incremental information related to patient functional status and prognosis. It is also an independent predictor of hospitalization and mortality.[196] PRO–PMs may also encourage ASM participants to incorporate the patient voice and lived experience into clinical decision-making, treatment planning, longitudinal monitoring, and shared decision-making. At this time, we are considering the development of PRO–PMs specific to each ASM targeted chronic condition.

We are interested in using the Patient-Reported Outcomes Measurement Information System (PROMIS) as the basis for a PRO–PM as it is a set of standardized, validated patient-reported outcome instruments that can be used to assess domains such as physical function, symptoms, pain interference, mental health, social health, and quality of life.[197] We believe PROMIS would allow for a standardized measurement framework across ASM participants, ASM targeted chronic conditions, and care settings. Unlike other patient-reported outcome (PRO) instruments that exclusively focus on a particular clinical population, PROMIS includes domains relevant across chronic conditions and can be administered through flexible formats, including short forms and computer adaptive tests. It also has condition-specific profiles, like PROMIS+HF, that is relevant to ASM.[198] Finally, other Innovation Center models either use or plan to use PROMIS, such as the Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model.[199] We also note that PROMIS is already a permitted standardized tool to satisfy the Functional Status Assessments for Heart Failure measure (MIPS Q377) in the ASM heart failure cohort quality measure set and the Functional Outcome Assessment measure (MIPS Q182) in the ASM low back pain cohort quality measure set.

We recognize that some ASM participants may currently use different patient-reported assessment instruments. To the extent scientifically appropriate, existing crosswalks or linking methods may help inform transitions from other instruments to PROMIS. For example, PROsetta Stone provides methods for linking PROMIS scores with other patient-reported outcome measures (PROMs) that assess similar concepts, which may support comparability across instruments.[200] This could provide flexibility for ASM participants using other instruments while preserving the standardized measurement framework that would be important for PRO–PM development.

While we were prioritizing PROMIS data collection, we were also interested in collecting data from other PRO instruments where appropriate to support evaluation and validation of PROM-to-PROM crosswalks that may facilitate future PRO–PM implementation.

We believed providing an opportunity for voluntary data submission would be an important step toward developing meaningful, patient-centered outcome measures for ASM. Incentivizing early submission of PROMIS and, potentially, other PRO data would help us determine whether future PRO–PMs are feasible and appropriate to be proposed for inclusion in the model through notice-and-comment rulemaking. This voluntary data submission approach would have also provide ASM participants an opportunity to build PRO data collection infrastructure before any future PRO–PM would be proposed as a quality measure used in evaluating performance under ASM.

(a) Quality ASM Performance Category Scoring Incentive for Voluntary Patient-Reported Outcome (PRO) Data

To support the development of PRO–PMs under ASM, we proposed to establish a voluntary data submission opportunity and scoring incentive for ASM participants to report PRO data, including data collected using PROMIS instruments and, as applicable, other CMS-specified PRO instruments. The goal of this data submission was to support the development, testing, and potential future inclusion of PRO–PMs in ASM's quality measure sets. Since ASM currently does not require ASM participants to submit PROMIS or other PRO data for measure development purposes, we recognize that there may be insufficient incentives for ASM participants to voluntarily collect and submit such data. We believed establishing an appropriate incentive for voluntary data submission by ASM participants would support efforts to collect the data needed to inform PRO–PM development and whether any developed PRO–PM would be feasible for inclusion in an ASM cohort's quality measure set during the ASM test period. We believed this proposal is consistent with the Innovation Center's authority under section 1115A of the Act to test

[196] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18). doi:*https://doi.org/10.1161/cir.0000000000001063.*

[197] ''Patient-Reported Outcomes Measurement Information System (PROMIS).'' *NIH Common Fund,* National Institutes of Health, *https://commonfund.nih.gov/promis.*

[198] Ahmad, Fatima S., et al. ''Validation of PROMIS+HF Profile Instruments in Heart Failure Patients.'' ESC Heart Failure, vol. 9, no. 5, 2022, pp. 3380–3392. PubMed Central, *https://pmc.ncbi.nlm.nih.gov/articles/PMC9715763/.*

[199] ''ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model.'' *Centers for Medicare & Medicaid Services,* U.S. Department of Health and Human Services, *https://www.cms.gov/priorities/innovation/innovation-models/access.*

[200] ''PROsetta Stone.'' *PROsetta Stone, https://www.prosettastone.org.*

innovative payment and service delivery models that improve the quality and coordination of care, including approaches that support development and assessment of patient-centered quality measurement and beneficiary-reported outcomes.

Specifically, we proposed at § 512.725(i) to create a quality ASM performance category scoring incentive by adding 5 points to an ASM participant's quality ASM performance category score for an applicable ASM performance year if the ASM participant submits beneficiary-level PRO data that meets criteria established by CMS, provided such additional points would not cause the ASM participant's score to exceed the maximum quality ASM performance category score otherwise available under the model. We refer readers to section III.D.2.f.(4) of the proposed rule where we proposed to notify an ASM participant if they meet the data submission requirements to receive the quality ASM performance category scoring incentive through their annual ASM performance report.

We believed that this scoring incentive approach would recognize the additional effort required to collect and submit PRO data and would avoid disadvantaging ASM participants not yet prepared to voluntarily collect and submit PRO data. The proposed 5-point scoring incentive added to the quality ASM performance category score represents half of the maximum quality measure achievement points for a single quality measure. We believed this amount appropriately incentivizes voluntary data submission by offering an increase to the quality ASM performance category score without equaling the maximum achievement points that can be earned through performance on quality measures. We believed such an approach would preserve the integrity and importance of the existing quality measure set required of each ASM participant. We further believed that structuring the scoring incentive so that an ASM participant's total quality ASM performance category score cannot exceed the category's maximum score would preserve the integrity and fairness of performance comparisons while encouraging voluntary data submission.

Eligibility for the scoring incentive for voluntary data submission would have been limited to the ASM cohorts for the ASM performance years in which we are actively developing a PRO–PM. For example, if we had establish a voluntary heart failure PRO data submission opportunity in the 2027 ASM performance year, only ASM heart failure participants would have been eligible to receive the 5-point scoring incentive for the 2027 ASM performance year and ASM low back pain participants would not have been eligible for the scoring incentive for that year.

We clarify that we did not propose at this time to (1) adopt a new PRO–PM in the quality measure for either ASM cohort, (2) evaluate ASM participants on PROMIS performance, or (3) require ASM participants to collect or submit PROMIS or other PRO data. Rather, this proposal was intended to support voluntary data collection to support our evaluation of the feasibility, reliability, validity, and appropriateness of one or more future PROMIS-based or other PRO-based PRO–PMs before any such measure would be proposed for inclusion in an ASM cohort's quality measure set, which we proposed through future notice-and-comment rulemaking.

We considered an alternative approach under which ASM participants could receive a higher number of additional points as this could provide greater incentive to voluntarily submit sufficient data for measure development purposes. We did not propose a higher number of additional points because it could reduce the distinction between the measure achievement points available for existing performance-based quality measures and the voluntary submission of PRO data for measure development purposes. Conversely, we did not propose a lower number of additional points to the quality ASM performance category score because we believed this may not provide a sufficient incentive to encourage meaningful participation in voluntary data submission.

We also considered an alternative approach to award 10 points, the maximum quality measure achievement score, for the existing PROM-related process measure for ASM participants who successfully: (1) submit a required PROM-related process measure included in the quality ASM performance category measure set and (2) voluntarily submit the CMS-specified PRO data for an applicable ASM performance year. For example, under this alternative, an ASM heart failure participant who successfully reports the Functional Status Assessments for Heart Failure measure (MIPS Q377) and voluntarily submits the CMS-specified PRO data would have automatically received 10 measure achievement points for the Functional Status Assessments for Heart Failure measure regardless of actual performance as assessed against the applicable benchmark. For the same reasons noted earlier in this section of this final rule regarding our intent to draw distinction between performance-based quality measurement and data submission, we did not propose this alternative. Additionally, we believed this approach would not provide meaningful incremental incentives for some ASM participants because those ASM participants who successfully collect and voluntarily submit the required PRO data may already be likely to perform well on the associated PROM-related process measure.

We also considered establishing a tiered incentive structure under which the number of additional points awarded to the quality ASM performance category score would have been scaled based on the quantity, completeness, representativeness, or other related characteristics of the voluntarily submitted PRO data. For example, ASM participants that submit data for a larger number of ASM beneficiaries, achieve higher response or follow-up completion rates, or submit additional data elements that could support measure development and testing would have received a larger scoring incentive than ASM participants that meet the minimum data submission requirements. We did not propose this alternative because our goal was that all voluntarily submitted data intended for measure development should meet the minimum requirements necessary to support reliable and scientifically sound measure development and testing. We were concerned that a tiered approach could create an incentive that prioritizes submission volume over data quality or could imply that data meeting the minimum submission requirements is less valuable for measure development purposes. Therefore, we believed a single incentive tied to successful completion of all required data submission requirements was a more appropriate approach.

We also considered whether to encourage voluntary PRO data submission through non-scoring mechanisms, such as providing ASM participants with enhanced feedback reports, analytic tools, educational resources, or other related support. We recognized that such resources could be of operational value to ASM participants while supporting our development of PRO-based quality measures. However, we did not propose a non-scoring-based incentive as we did not believed this would, by itself, provide sufficient incentive to encourage broad voluntary participation in PRO data collection and submission activities. While we may consider providing operational support or

resources in the future, we believed a direct scoring incentive is more likely to generate the quantity and quality of data necessary to support timely PRO–PM development and testing.

We further considered another alternative whereby the maximum quality ASM performance category score would not be capped, allowing an ASM participant's quality ASM performance category score to exceed the maximum points otherwise available for the quality ASM performance category for the limited purpose of encouraging voluntary PRO data submission. For example, under this alternative, an ASM participant who earns a quality ASM performance category score of 46 points and voluntarily submits PRO data for the applicable ASM performance year would receive 51 points out of 50 points available for the final quality ASM performance category. We did not propose this alternative because it would be inconsistent with the existing quality ASM performance category scoring methodology. The quality and cost ASM performance categories were intentionally designed to have equal weight in the calculation of a final score. Allowing the quality ASM performance category score to exceed its current maximum could disrupt that balance and place disproportionate emphasis on quality scoring relative to cost performance. We believed maintaining the current maximum quality ASM performance category score preserves comparability across ASM participants and the integrity of the quality scoring framework.

Finally, we considered another alternative incentive whereby we would add additional points to the final score of an ASM participant who successfully reports the CMS-specified PRO data for the applicable ASM performance year. Under this approach, the additional points would have been added to the final score after calculation of any applicable ASM performance category scores to directly increase the ASM participant's final score. We did not propose this alternative because it would disconnect the incentive from the quality ASM performance category, where the benefits of collecting and reporting PRO data are most appropriately reflected. In addition, applying additional points directly to an ASM participant's final score could have broader effects on overall model performance and payment adjustment outcomes than intended and would be less consistent with the targeted objective of encouraging voluntary data submission to support future PRO–PM development.

We sought comment on our proposal at § 512.725(i) to provide 5 additional points to the quality ASM performance category score of an ASM participant who voluntarily submits CMS-specified PRO data and meets all data submission requirements for an applicable ASM performance year. We sought comment on all alternatives that we considered. We also invited comment on whether the proposal and alternatives would support voluntary data submission to achieve the goal of developing PRO–PMs applicable to ASM. Comments and responses regarding these topics are summarized below following the requirements for successful voluntary PRO data submission.

(b) Requirements for Successful Voluntary PRO Data Submission

Development of a valid, reliable, and feasible PRO–PM requires sufficient beneficiary-level PRO data prior to implementation and scoring of the measure. In particular, data is needed to: (1) analyze measure reliability and validity, (2) evaluate feasibility of data collection and submission, (3) measure response rates and missingness, (4) examine potential nonresponse bias, (5) identify appropriate risk adjustment variables, and (6) determine whether a measure can meaningfully and fairly distinguish performance across ASM participants within a given ASM cohort. For potential PRO–PMs, development may require that data be collected over an extended episode or longitudinal assessment period, including baseline and follow-up PRO assessments. Accordingly, early collection and submission of PRO data by ASM participants is important to support timely development and testing of PRO–PMs such that we could propose measures for future inclusion in ASM's respective quality measure sets through future notice-and-comment rulemaking.

To support PRO–PM development, we would specify the applicable PRO instrument(s), the required data that an ASM participant would need to voluntarily submit, and applicable data collection periods. Accordingly, we proposed to define the data submission requirements that an ASM participant would need to meet to ensure we receive sufficient and reliable data to develop and test PRO–PMs applicable to ASM.

Specifically, at § 512.725(i)(1), we proposed to define all data submission requirements an ASM participant would need to meet to receive the proposed scoring incentive in the quality ASM performance category for an applicable ASM performance year.

First, at § 512.725(i)(1)(i), we proposed that an ASM participant would need to submit CMS-specified baseline assessment data for at least 20 ASM beneficiaries during the first data collection period specified by us. By baseline data, we mean the initial CMS-specified PRO assessment data collected for an ASM beneficiary during the applicable data collection period that occurs before the collection of any corresponding follow-up assessment data for the beneficiary. After baseline data is collected, an ASM participant would submit CMS-specified follow-up assessment data for at least 20 ASM beneficiaries for whom they previously submitted a baseline assessment during the preceding data collection period specified by us.

Our goal in establishing minimum baseline and follow-up assessment requirements is to ensure we receive sufficient longitudinal PRO data to support development and testing of future PRO–PMs. We believed that collecting baseline assessment data initially then collecting corresponding follow-up assessment data during a subsequent data collection period would allow us to evaluate changes in beneficiary-reported outcomes over time while reducing operational burden during the initial year of data collection. The specific amount of time between a baseline and follow-up assessment would depend on the selected PRO instrument(s) and ASM targeted chronic condition, however, we anticipate that a collection period of at least 6 months between a beneficiary's baseline and follow-up assessments may be necessary to allow sufficient time to observe meaningful changes in patient-reported outcomes. We would provide specifications regarding the timing of baseline and follow-up assessments and specific data collection periods through sub-regulatory technical guidance.

Second, at § 512.725(i)(1)(ii), we proposed that an ASM participant would need to report all required data elements for the applicable PRO instrument as specified by us for the applicable data collection period. We anticipate that required data elements would include at least: (i) the PRO instrument name and version, (ii) ASM participant identification information, (iii) ASM beneficiary identification information and linkage information, (iv) assessment date, (v) baseline or follow-up assessment indicator, (vi) mode of administration, (vii) item-level responses, (viii) nonresponse and missingness indicators, (ix) raw and standardized scores, (x) score calculation method, and (xi) other data elements needed to support measure

testing and risk adjustment model testing. If testing would require use of a crosswalk, such as PROsetta, we anticipate that we would also require reporting of data elements specific to the crosswalk. The required data elements and format in which an ASM participant would need to submit the data would be specific to the selected PRO instrument(s) and would be specified by us in sub-regulatory technical guidance.

Third, at § 512.725(i)(1)(iii), we proposed that an ASM participant would need to submit data on a minimum set of risk variables for each ASM beneficiary from whom they collect PRO data. Risk adjustment is necessary to ensure that performance results under a PRO–PM reflect quality of care rather than patient complexity to avoid penalizing clinicians who may serve higher-risk beneficiary populations. Reporting a minimum set of risk variables for each ASM beneficiary receiving a PRO assessment would allow us to develop a scientifically acceptable, robust, and reliable risk model for any developed PRO–PM. The reported risk variable data would be used to conduct assessments of association between risk variables and the measured PRO to inform risk variable selection and ensure the risk model captures the most clinically and statistically relevant risk variables. Example risk variables could include but are not limited to age, race, ethnicity, socioeconomic status, clinical comorbidities, baseline clinical severity, physiological measures (for example, body mass index or blood pressure), pain history, surgical history, disease classification, medication usage, behavioral factors, functional and disability status, and other condition-specific characteristics. We believed that the risk variables would be different for each ASM targeted chronic condition for which we would develop a PRO–PM. We intend to provide the minimum risk variables applicable for the selected PRO instrument(s), including each risk variable's technical specifications, through sub-regulatory technical guidance.

Fourth, at § 512.725(i)(1)(iv), we proposed that an ASM participant must submit the PRO data for any applicable data collection period by the generally applicable data submission deadline for the applicable ASM performance year, which is March 31st, or later in the calendar year, as specified by us, following the close of the applicable ASM performance year. We recognize that, depending on the applicable PRO instrument, measure concept, and assessment interval, baseline and follow-up assessments for an ASM beneficiary may need to occur across ASM performance years to allow a sufficient interval between the initial and follow-up PRO assessments. In such cases, we would specify through technical guidance how ASM participants would submit baseline and follow-up data for data collection periods that span ASM performance years and how this would impact the availability of the scoring incentive for a given ASM performance year. We believed that aligning the voluntary PRO data submission deadline with the generally applicable data submission deadline for ASM performance category data would streamline and simplify the data submission and would provide us adequate time to confirm if the submitted PRO data meets the requirements to receive the proposed scoring incentive for the quality ASM performance category. We anticipate that the PRO data submission would occur through one or more mechanisms, such as a CMS-specified file format, registry submission, qualified clinical data registry or other intermediary, Health Level Seven Fast Healthcare Interoperability Resources (HL7 FHIR)-based submission, or another electronic submission mechanism specified by CMS. We would provide additional operational details through technical guidance, including applicable submission deadlines, data formats, validation processes, and any minimum data completeness or case minimum requirements. We also seek to preserve flexibility to align submission requirements with existing ASM participant workflows and health information technology capabilities to the extent feasible.

We recognize that in some instances ASM participants may need to correct their voluntary data submission. Accordingly, we proposed at § 512.725(i)(2) that ASM participants could correct and resubmit any PRO data corresponding with voluntary data submission by the proposed data submission deadline of March 31st in accordance with the generally applicable data submission deadline for the applicable ASM performance year, or a later date specified by CMS. Because the proposed scoring incentive would affect the quality ASM performance category score, we proposed to only accept timely submissions, corrections, or resubmissions and reject those received after the data submission deadline. We believed this approach is necessary to preserve the integrity and finality of the scoring process and payment adjustment methodology and to align voluntary PRO data submission with other ASM performance category data submission requirements. We would consider providing submission error reports or other technical feedback identifying errors, missing data elements, beneficiary linkage issues, data completeness concerns, or other issues before the applicable data submission deadline to support ASM participants.

Relatedly, we proposed at § 512.725(i)(3) that an ASM participant may seek review under ASM's timely error notice process for technical errors related to CMS' determination of whether the ASM participant met the voluntary PRO data submission requirements or correctly received the quality ASM performance category scoring incentive for the applicable ASM performance year as provided in the ASM participant's annual ASM performance report. To align with ASM's timely error notice requirements and process described at § 512.755, the ASM participant may submit a written timely error notice if they believe an error occurred in calculations due to data quality, misapplication of methodology, or other related issues that would relate to whether the ASM participant qualified for the proposed quality ASM performance category scoring incentive for the applicable ASM performance year. Examples of such errors include beneficiary linkage errors, failure to account for data timely submitted by the ASM participant, or other technical errors in our evaluation of the voluntary PRO data submission against data requirements.

We considered requiring that an ASM participant submit PRO data on more than 20 ASM beneficiaries or fewer than 20 ASM beneficiaries during each CMS-specified data collection period specified. We also considered requiring that an ASM participant submit PRO data on a minimum percentage of their ASM beneficiaries (for example, 25 to 100 percent) during the applicable data collection period. However, we believed an adequate number of ASM participants collecting and reporting PRO data on a minimum of 20 ASM beneficiaries each would provide an adequate sample size for PRO–PM development and align with the 20-case minimum for quality measures under ASM.

We also considered requiring an ASM participant to submit PRO data more frequently during an ASM performance year (for example, quarterly or biannually). Multiple data submission time points, such as quarterly or on a rolling basis rather than a single annual

submission, may offer several advantages. It would enable the selected submission mechanism (for example, data submission portal) to provide ASM participants who voluntarily submit data with timely, actionable feedback on the quality of the data submitted, flagging inaccuracies and offering opportunities for correction and resubmission before the applicable data collection period and ASM performance year ends. Iterative data collection and feedback could support a continuous improvement process, helping ASM participants identify and resolve data quality issues early. This would be particularly helpful for avoiding the scenario where a provider submits data once annually, only for that data to be found unusable at the point of determining eligibility for the quality ASM performance category scoring incentive. More frequent data submissions would likely improve the quality of data for measure development and testing. While more frequent data submission would offer several advantages, we believed that aligning the voluntary data submission deadline with the overall data submission deadline for ASM performance category data would be administratively simpler for ASM participants.

We also considered requiring ASM participants to submit both baseline and follow-up assessment data for the same ASM beneficiaries during a single ASM performance year. Under this alternative, an ASM participant would be required to collect and submit both the initial and follow-up PRO assessments within the same ASM performance year to receive the voluntary PRO data submission scoring incentive. We recognize that this approach could accelerate collection of matched assessment data and potentially expedite certain measure development and testing activities. However, we did not propose this alternative because the appropriate interval between baseline and follow-up assessments may vary depending on the selected PRO instrument, the targeted chronic condition, and the future PRO–PM concept under development. We are also concerned that requiring both assessments within a single ASM performance year could limit flexibility, increase operational burden on ASM participants, and reduce the amount of time available to observe meaningful changes in ASM beneficiary-reported outcomes.

For any data collection period following a baseline data collection period, we considered that an ASM participant would need to submit baseline assessment data for additional ASM beneficiaries that were either newly eligible for a selected instrument or had not previously been assessed using a selected instrument. This new baseline data would be in addition to the follow-up assessment data that we proposed to require. We believed that this structure could increase the amount of data available to develop a PRO–PM over time. However, we would require additional information to determine the minimum number of new baseline assessments that would be appropriate to require the ASM participant to collect during a subsequent data collection period.

We also considered whether to require additional criteria for successful voluntary PRO data submission, including submission of a denominator file of eligible ASM beneficiaries; use of a CMS-specified sampling methodology, such as consecutive, all-eligible, all-payer, or random sampling; minimum response or completion rates; minimum baseline and follow-up completion thresholds; and documentation of exclusions, where applicable, for identified ASM beneficiaries. We did not propose these additional requirements at this time because the appropriate denominator, sampling approach, response-rate threshold, completion threshold, and exclusion documentation requirements may vary based on the selected PRO instrument, ASM targeted chronic condition, data submission mechanism, and measure concept under consideration for development.

We sought comment on the proposed requirements for voluntary PRO data submission at § 512.725(i)(1) that an ASM participant would need to meet to receive the proposed quality ASM performance category scoring incentive. We also sought comment on all alternatives considered and other data submission requirements we should consider supporting PRO–PM development under ASM. Additionally, we sought comment on the appropriate timing of data submission and the scope of data elements that should be required for successful voluntary data submission, particularly data elements necessary to evaluate a PRO–PM's feasibility, reliability, and validity. We also invited comment on the specific risk variables applicable for each ASM targeted chronic condition that we should require ASM participants to report. We were particularly interested in comments on the earliest feasible timeframe for ASM participants to begin collecting and submitting PROMIS or other CMS-specified PRO data, the operational challenges ASM participants may face, and the types of technical assistance or guidance that would facilitate voluntary data submission. Finally, we sought comment on data submission mechanisms that would simplify the voluntary reporting of PRO data to support PRO–PM development under ASM.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed voluntary PRO data submission opportunity and associated quality scoring incentive, stating that the approach could encourage PRO data collection and support development of future PRO–PMs.

Response: We appreciate commenters' support for voluntary PRO data collection and the proposed scoring incentive. As discussed later in this section of this final rule, although we are not finalizing the proposal at this time, we remain interested in advancing PRO–PM development for ASM.

Comment: Several commenters supported the goal of advancing voluntary patient-reported outcome (PRO) data collection and developing PRO-based measures for ASM but recommended continued testing and validation before PRO measures are used for performance accountability. Commenters generally supported maintaining a voluntary approach while additional experience with PRO collection is developed.

Response: We appreciate commenters' support for advancing patient-reported outcome measurement. Interested parties' feedback raised important considerations regarding the readiness, feasibility, and implementation of the proposed approach and gave us reason to take additional time before establishing this policy. We believe additional development will help support broad ASM participant adoption and the collection of sufficiently complete and useful data for development of a future PRO–PM. Accordingly, we are not finalizing the proposed voluntary PRO data submission opportunity or associated scoring incentive at this time. We remain interested in advancing PRO–PM development for ASM and will continue to explore opportunities to obtain information and data needed to support measure development and testing.

Comment: Several commenters raised concerns regarding the proposed 5-point scoring incentive, including whether it could disadvantage ASM participants that are unable to submit PRO data,

particularly smaller practices with fewer resources. A commenter recommended considering a direct financial incentive rather than incorporating the incentive into ASM quality scoring.

Response: We appreciate commenters' feedback regarding the proposed scoring incentive and differences in ASM participants' ability to collect and submit PRO data. These comments highlighted the importance of designing an approach that encourages broad participation without creating unintended barriers for practices with fewer resources and contributed to our decision not to finalize the proposal at this time. If we explore a similar approach in the future, we will consider commenters' recommendations regarding incentive design, practice burden, and opportunities for broad participation.

Comment: Several commenters identified operational and administrative considerations associated with voluntary PRO data collection, including EHR integration, vendor and licensing costs, submission mechanisms, baseline and follow-up assessments, and the burden of meeting minimum data submission requirements. Commenters recommended flexible reporting approaches and sufficient advance notice of technical requirements.

Response: We appreciate commenters' feedback regarding the operational requirements associated with PRO data collection. These considerations contributed to our decision to take additional time before implementing such an approach. We believe further development could help minimize implementation burden, support broader adoption, and improve the completeness and usefulness of data collected for PRO–PM development. We will consider commenters' recommendations regarding reporting flexibility, technical specifications, implementation timelines, and advance guidance as we continue this work.

Comment: Other commenters recommended that future PRO data collection support digital quality measurement, provide clarity and flexibility regarding acceptable instruments, address accessibility and survey burden, and provide timely and actionable information to clinicians and patients.

Response: We appreciate these recommendations. We agree that instrument selection, accessibility, interoperability, ASM participant and patient burden, and the usefulness of collected information are important considerations in developing an effective PRO data collection approach. We will consider this feedback as we continue to explore opportunities to support PRO–PM development for ASM.

After consideration of public comments, we are not finalizing our proposals at § 512.725(i) to establish a voluntary PRO data submission opportunity and associated quality ASM performance category scoring incentive, including the proposed requirements for successful voluntary PRO data submission. We remain interested in advancing PRO–PM development for ASM and will continue to explore opportunities to obtain information and data needed to support measure development and testing. These efforts may inform a future proposal to include a PRO–PM in an ASM quality measure set through notice-and-comment rulemaking.

e. Promoting Interoperability ASM Performance Category

(1) Background

In the CY 2026 PFS final rule, we finalized at § 512.740(b)(2) that an ASM participant must report on Promoting Interoperability objectives and measures, as specified in MIPS technical documents (90 FR 49658 through 49661). Specifically, under §§ 512.740(b)(2)(i) through (iv), we finalized inclusion of the following objectives under the Promoting Interoperability ASM performance category:

- Electronic Prescribing;
- Health Information Exchange (HIE);
- Provider to Patient Exchange; and
- Public Health and Clinical Data Exchange (90 FR 49658).

We also finalized inclusion of attestations under §§ 512.740(b)(3) and 512.740(b)(4).

In the CY 2027 PFS proposed rule, we proposed a number of changes to the Promoting Interoperability ASM performance category requirements. For the 2027 ASM performance year, we proposed to include the Electronic Prior Authorization measure as an optional and unscored measure; remove the Security Risk Analysis measure attestation requirement; remove ONC-related attestations; establish measure-level exclusions for the measures under the Public Health and Clinical Data Exchange objective; and adopt a Promoting Interoperability measure suppression policy. For the 2028 ASM performance year, we proposed that the Electronic Prior Authorization measure and the new Electronic Prior Authorization for Prescription Drugs measure would both be required under the HIE objective.

Comment: Many commenters raised concerns about the administrative burden associated with the Promoting Interoperability ASM performance category. A few commenters questioned whether the category is necessary, stating that ASM participants already have incentives to use EHRs and other health IT functionalities when such tools improve care, facilitate coordination, or reduce costs. Several commenters recommended an exemption or automatic Promoting Interoperability ASM performance category credit for any ASM participant who is listed as a provider or supplier in an MSSP ACO that qualifies as an advanced APM or who participates in a voluntary advanced APM, since such models or programs require use of certified health information technology as a condition of participation.

A commenter expressed concern that Promoting Interoperability measures and attestations in ASM would add administrative burden and expose ASM participants to payment reductions without a corresponding benefit to patients. Commenters stated that compliance would require substantial investments of time, administrative effort, and financial resources for ASM participants, particularly in small practices, including hiring consultants with specialized expertise in ASM reporting and EHR implementation.

Many commenters requested that CMS recognize special-status circumstances in ASM that would exempt certain ASM participants from Promoting Interoperability ASM performance category requirements, including for ASM participants who are in small practices, rural areas, or non-rural areas upon demonstration that a hardship exists due to the conditions of the community in which they practice. Commenters are also recommended exemptions for ASM participants who are hospital-based, ASC-based, or non-patient-facing.

Commenters generally supported the proposed first-year flexibility proposed for the Electronic Prior Authorization measure, noting support for optional, unscored treatment in 2027. Some commenters also recommended a similar phased approach to the Electronic Prior Authorization for Prescription Drugs measure, including an initial optional or bonus period before mandatory reporting.

Separately, several commenters recommended a reporting-only or penalty-free transition year of ASM requirements and financial accountability more broadly. A commenter specifically recommended designating 2027 as a reporting-only

transition year without negative payment adjustments. Commenters stated that additional preparation time would allow participants and their vendors to develop reporting infrastructure, become familiar with model requirements, and adjust IT systems, EHR templates, and clinical workflows. A commenter recommended a structured ramp-up similar to the approach taken at the inception of MIPS.

Response: We acknowledge commenters' concerns about the administrative burden of the Promoting Interoperability ASM performance category, especially in the first ASM performance year and appreciate recommendations for a phased-in approach. We continue to believe that interoperable health information supports the care coordination and patient access goals of ASM, and that interoperability remains a critical part of effective upstream chronic condition management. For these reasons, we are retaining the Promoting Interoperability ASM performance category and decline to eliminate the category at this time or adopt special-status or categorical exemptions, consistent with the rationale stated in the CY 2026 PFS final rule (90 FR 49663 through 49664).

After consideration of the comments, however, we are revising our approach to the Promoting Interoperability ASM performance category during the initial year of ASM implementation to reduce reporting burden. As detailed below, we are finalizing a transition policy for the 2027 ASM performance year where all Promoting Interoperability ASM performance category measures and attestations described in § 512.740(b) will be treated as voluntary and unscored. In the 2027 ASM performance year only, we will provide full credit for the Promoting Interoperability ASM performance category for an ASM participant who uses CEHRT as defined in § 414.1305 for a minimum of a continuous 180-day period in 2027 and reports the CEHRT ID and performance period to CMS, as specified in §§ 512.720(a)(1)(iii)(A)(*3*) and (*4*). Use of CEHRT is required under our current regulations and we would retain this requirement for the 2027 ASM performance year under this transition policy.

We believe this final policy is responsive to commenters' concerns regarding initial year administrative burden and expands upon our proposal to establish a transition policy for the Electronic Prior Authorization measure to treat this measure as optional and not scored. Under our 2027 transition policy, all measures described under § 512.740(b) will be optional and unscored for the 2027 ASM performance year.

(a) Final 2027 Performance Year ASM Transition Policy

For the 2027 ASM performance year only, we are establishing a transition year policy for the Promoting Interoperability ASM performance category that expands upon proposals to reduce reporting burden. The policy we are finalizing provides broader first-year flexibility to reporting and scoring across the Promoting Interoperability ASM performance category. We believe a uniform transition gives all ASM participants a clear set of first-year reporting requirements while they develop the capabilities needed for full reporting beginning with the 2028 ASM performance year.

Specifically, to receive a 100-point score for the Promoting Interoperability ASM performance category for the 2027 ASM performance year, ASM participants must use CEHRT A as defined at § 414.1305 for any continuous 180-day period in 2027 and submit the following information to CMS:

- The CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL) for the CEHRT used in accordance with § 512.720(a)(1)(iii)(A)(*3*); and
- The start and end dates of the applicable performance period as described in § 512.740(a); that is, any continuous 180-day period within calendar year 2027 in accordance with § 512.720(a)(1)(iii)(A)(*4*).

As finalized through CY 2026 rulemaking, Promoting Interoperability ASM performance category data must be submitted at the TIN level in accordance with § 512.720(a)(1)(iii)(B)

We will assign a 100-percent Promoting Interoperability ASM performance category score if an ASM participant fulfills these requirements, which were finalized in the CY 2026 PFS final rule (90 FR 49654) starting in the 2027 ASM performance year. We will assign a zero-percent category score for an ASM participant who does not submit this information. Under § 512.745(a)(1)(iv), a 100-percent category score produces no negative Promoting Interoperability adjustment to the final score; a zero-percent category score produces the maximum 10-point negative adjustment when a final score is calculated.

For the 2027 ASM performance year, an ASM participant is not required to submit numerator and denominator data, yes/no measure responses, measure exclusions, or attestations for performance measures described in § 512.740(b. This includes the e-Prescribing and Query of Prescription Drug Monitoring Program measures; Health Information Exchange reporting options; the Provider to Patient Exchange measure; the Immunization Registry Reporting and Electronic Case Reporting measures; and the Electronic Prior Authorization measure. The SAFER attestation will not be required in 2027. The Security Risk Analysis and ONC direct review and ONC–ACB surveillance attestations are also not required as we are finalizing removal of these attestations as detailed below.

These measures will be treated as voluntary and unscored. This means that an ASM participant may elect to submit measure performance data or yes/no attestation statements to us on Promoting Interoperability measures, but we will not score that data and it will not contribute to the category performance score. Because no measure is scored in 2027, measure exclusions, redistribution of points, and measure suppression policies will not affect the category score.

We emphasize that, for the 2027 ASM performance year, ASM participants must do the following to receive a 100-percent Promoting Interoperability ASM performance category score:

- Must use CEHRT as defined at § 414.1305 for the ASM performance year.
- Must report to CMS the CMS EHR Certification ID (CEHRT ID) from the Certified Health IT Product List (CHPL) and the start date and end date for the applicable performance period as set forth in § 512.740(a).
- Must submit this information at the TIN level, as required under § 512.720(a)(1)(iii)(B).

Under § 512.745(a)(1)(iv), a 100-percent category score produces no negative Promoting Interoperability adjustment to the final score; a zero-percent category score produces the maximum 10-point negative adjustment when a final score is calculated.

This transition policy is limited to the 2027 ASM performance year, as it impacts the 2029 ASM payment year payment adjustment. Beginning with the 2028 ASM performance year, the Promoting Interoperability ASM performance category requirements described in § 512.740(b) and 512.740(c) will apply.

We are adopting this transition policy in response to comments concerning the burden and operational feasibility of implementing the Promoting Interoperability requirements during the first year of ASM. Rather than establish categorical exemptions or special-status

policies that would apply only to particular ASM participants, we believe that a uniform, one-year transition policy provides a clearer and more administrable approach and affords all ASM participants the same flexibility to develop reporting capabilities. At the same time, retaining the requirement to use CEHRT and report the CMS EHR Certification ID and the applicable performance period maintains the model's emphasis on the use of CEHRT and supports ASM participants' preparation for full Promoting Interoperability reporting beginning with the 2028 ASM performance year.

We continue to believe that interoperability and the use of CEHRT are important to ASM's goals of improving care coordination, patient access to health information, and effective management of chronic conditions. The transition policy does not alter those underlying policy objectives. Rather, it modifies the reporting and scoring requirements applicable during the first ASM performance year to address implementation concerns raised by commenters while maintaining the infrastructure necessary for full implementation in subsequent years.

To implement our 2027 transition policy for the Promoting Interoperability ASM performance category, we are making the following changes to the regulatory text. At § 512.740(b), we are adding prefatory language specifying that, beginning with the 2028 ASM performance year, to earn a Promoting Interoperability ASM performance category score greater than zero, an ASM participant must be a meaningful EHR user and must meet the criteria that follow, which include reporting on Promoting Interoperability objectives and measures and fulfilling attestation requirements. Specifically, we would modify the paragraph header at § 512.740(b) to read ''Reporting for the Promoting Interoperability ASM performance category beginning in the 2028 ASM performance year.'' We are revising the header text at § 512.740(c) to specify that its scoring provisions apply beginning in the 2028 ASM performance period by modifying the text to read ''Scoring the Promoting Interoperability ASM performance category beginning in the 2028 ASM performance year.''

We are adding new § 512.740(d) to describe the transition policy for the Promoting Interoperability ASM performance category for the 2027 ASM performance year to convey the following:

- Notwithstanding paragraphs (b) and (c) of this section, for the 2027 ASM performance year, an ASM participant satisfies the reporting requirements for the Promoting Interoperability ASM performance category by using CEHRT as defined at § 414.1305 for the ASM performance year and submitting, in accordance with § 512.720(a)(1)(iii), both—

++ The CMS EHR Certification ID for the CEHRT used by the ASM participant; and

++ The start date and end date of the performance period used by the ASM participant, as described in paragraph (a) of this section, consisting of a continuous 180-day period within the calendar year.

- CMS assigns a Promoting Interoperability ASM performance category score of 100 percent to an ASM participant that satisfies paragraph (d)(1) of this section.
- Beginning with the 2028 ASM performance year, paragraphs (b) and (c) of this section apply without regard to the transition policy described in this paragraph (d).

Table B–D2 summarizes the final policy as it pertains to objectives and measures in the Promoting Interoperability ASM performance category for the 2027 ASM performance year. All listed measures are optional and unscored; measure exclusions and redistribution of points do not apply.

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TABLE B-D2: ASM PROMOTING INTEROPERABILITY OBJECTIVES AND MEASURES FOR THE 2027 ASM PERFORMANCE YEAR

Objectives	Measures		Available Points (based on performance)	Redistribution if exclusion is claimed
e-Prescribing	e-Prescribing		Optional, unscored	Not applicable
	Query of PDMP			
Health Information Exchange (HIE)	Select one of the following three reporting options:			
	Option 1	Support Electronic Referral Loops by Sending Health Information		
		Support Electronic Referral Loops by Receiving and Reconciling Health Information		
	Option 2	HIE Bi-Directional Exchange		
	Option 3	Enabling Exchange under TEFCA		
	Electronic Prior Authorization measure			
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information			
Public Health and Clinical Data Exchange	Report to the following public health or clinical data registries: 1. Immunization Registry Reporting 2. Electronic Case Reporting			
	Option to report one of the following public health agency or clinical data registry measures: • Public Health Registry Reporting, • Clinical Data Registry Reporting, or • Syndromic Surveillance Reporting			

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(2) Update to CEHRT Definition

Under § 512.705, we define CEHRT for the purposes of ASM as technology that meets the requirements set forth in MIPS regulations at § 414.1305. We did not propose to depart from this approach. Therefore, updates finalized to the definition of CEHRT under MIPS are incorporated for purposes of ASM under the existing definition at § 512.705. We refer readers to Section IV.A.4.f.(4) of this final rule for a discussion on the definition of CEHRT under MIPS as finalized under this rule.

(3) Electronic Prior Authorization Measures in the Health Information Exchange Objective

(A) Overview

In the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program'' final rule (89 FR 8758) (hereinafter referred to as the ''2024 CMS Interoperability and Prior Authorization final rule''), we finalized requirements for Medicare Advantage organizations, Medicaid managed care plans, State Medicaid agencies, CHIP agencies, CHIP managed care entities, and issuers of qualified health plans on the Federally-facilitated Exchanges (collectively, ''impacted payers'') to improve the electronic exchange of health care information and streamline prior authorization for medical items and services. Impacted payers must implement and maintain prior authorization application programming interface (API) technology to communicate information related to prior authorization requests (89 FR 8763). As we explained in the 2024 CMS Interoperability and Prior Authorization final rule, the efficiencies associated with payer implementation of these APIs will be more fully realized when requesting providers also use API-enabled processes to submit prior authorization requests. Accordingly, we finalized the addition of an Electronic Prior Authorization measure as a required measure for MIPS eligible clinicians under the MIPS Promoting Interoperability performance category HIE objective (89 FR 8910 through 8927).

(B) Electronic Prior Authorization Measure in the 2027 ASM Performance Year

We proposed to include the Electronic Prior Authorization measure (Measure ID # PI_HIE_7) in the Promoting Interoperability ASM performance category under the HIE objective, consistent with MIPS, starting in the 2027 ASM performance year as an optional, unscored ASM Promoting Interoperability measure, without any scoring penalty for non-reporting. We proposed to codify this measure for ASM at § 512.740(b)(2)(ii)(B) and to rely on the measure specifications used in MIPS for the Electronic Prior Authorization measure. We refer readers to section IV.A.4.f.(4) of this final rule for discussion of the technical specifications for the Electronic Prior Authorization measure under MIPS.

To report the Electronic Prior Authorization measure, an ASM participant would submit a ''yes'' response attesting they satisfactorily met the requirements of the measure. We did not propose to adopt any exclusions for this measure for the 2027 ASM performance year, since the measure was proposed as optional and attesting ''no'' or not attesting at all would not result in a scoring penalty. We also considered, but did not propose, awarding 5 bonus points to the Promoting Interoperability ASM performance category score for voluntarily attesting ''yes'' to this measure in 2027. We explained that optional reporting could encourage ASM participants to develop capabilities before required reporting begins, but that adding bonus points would introduce scoring complexity inconsistent with ASM's approach to other optional Promoting Interoperability measures. We sought comment on both the proposed optional, unscored approach and the 5-point bonus alternative (91 FR 43985 through 43986). We received comments on both approaches.

Comment: Several commenters supported including the Electronic Prior Authorization measure under the HIE objective as an optional, unscored measure for the 2027 ASM performance year. Commenters recommended CMS provide a 2027 ''grace period'' for this measure to allow ASM participants time to implement and develop the necessary workflows and infrastructure to support the measure requirements. A commenter supported voluntary reporting in 2027, but suggested CMS evaluate the measure's technical feasibility and administrative effects before requiring it in 2028.

Response: We appreciate commenters' support for providing implementation flexibility for the Electronic Prior Authorization measure during the 2027 ASM performance year.

Comment: A few commenters recommended that CMS make the Electronic Prior Authorization measure available as a bonus measure for the 2027 ASM performance year, while retaining a no penalty policy for non-reporting or failure to meet the measure. In contrast, a commenter opposed the alternative to create bonus points for reporting the Electronic Prior Authorization measure, adding it would not create an effective incentive.

Response: We appreciate comments on our alternative approach that considered creating bonus points associated with optional reporting in 2027, however we believe the addition of any bonus points would be unnecessary under the transition policy we are finalizing for the 2027 ASM performance year.

After considering public comments, we finalize our policy to adopt the Electronic Prior Authorization measure as an optional, unscored measure for the 2027 ASM performance year, with modification, at § 512.740(b)(2)(ii)(B)(1). We finalize our proposal to rely on MIPS specifications, as modified and described in Section IV.A.4.f.(4) of this final rule. We are modifying our proposed regulatory text to remove the prefatory text specifying this measure is optional and unscored in the 2027 ASM performance year, since our final policy is to treat all measures as optional and unscored in 2027 and it is not necessary to state this for the Electronic Prior Authorization measure. We are also modifying text at § 512.740(b)(2)(ii) to remove the language ''For each ASM performance year'' as this is not necessary

(C) Electronic Prior Authorization Measure Beginning With the 2028 ASM Performance Year

In the CY 2027 PFS proposed rule, we proposed several changes to the HIE objective of the Promoting Interoperability ASM performance category starting in the 2028 ASM performance year to incorporate the two measures supporting electronic prior authorization. Specifically, beginning with the 2028 ASM performance year, we proposed to require ASM participants report both the Electronic Prior Authorization measure (Measure ID # PI_HIE_7) and the Electronic Prior Authorization for Prescription Drugs measure (Measure ID # PI_HIE_8). We proposed to codify these requirements at § 512.740(b)(2)(ii)(C)(*1*) and (*2*), respectively.

For the Electronic Prior Authorization measure, which applies to medical items and services other than prescription drugs, we proposed that an ASM participant would satisfy the measure requirement by submitting a ''yes'' response or claiming an applicable exclusion. We proposed to recognize the same measure specifications and exclusions as adopted for MIPS. The measure would not contribute points to the Promoting Interoperability ASM performance category score; however, an ASM participant that submits a ''no'' response, fails to submit an attestation, or does not claim an applicable exclusion would receive a score of zero for the Promoting Interoperability ASM performance category.

Comment: A few commenters supported incorporating the Electronic Prior Authorization measure into the Promoting Interoperability ASM performance category beginning in 2028. Several commenters supported having this measure be optional and unscored before requiring it.

Response: We appreciate the commenters' support for transition policies for this measure as well as for including this measure in 2028.

Comment: Several commenters did not support making the measure an all-or-nothing Promoting Interoperability requirement upon full implementation in CY 2028.

Response: We appreciate this feedback however we continue to believe that the proposed scoring approach is appropriate as it is consistent with the scoring methodology for other required measures that require an affirmative attestation or claim of an applicable exclusion to avoid a score of zero for Promoting Interoperability. We intend to assess implementation experience, payer and health IT readiness, technological advancements, and the availability of ONC-certified health IT as the measure becomes required.

After consideration of public comments, we are finalizing our proposed policy with modification. This measure will be required starting in 2028 as proposed; however, we are relocating this provision in our regulatory text to § 512.740(b)(2)(ii)(B)(*1*) under this final rule.

(D) Electronic Prior Authorization for Prescription Drugs Measure

We proposed to require the Electronic Prior Authorization for Prescription Drugs measure beginning with the 2028

ASM performance year. The measure would apply to prescription drugs covered under a pharmacy benefit and dispensed at pharmacies. We proposed that an ASM participant would satisfy the measure by submitting a ''yes'' response attesting that the ASM participant requested electronic prior authorization using CEHRT for at least one prescription drug during the applicable performance period, or by claiming an applicable exclusion. We proposed to adopt the same measure specifications and exclusion criteria proposed for this measure under the MIPS Promoting Interoperability performance category. As with the Electronic Prior Authorization measure, the Electronic Prior Authorization for Prescription Drugs measure would not contribute points to the Promoting Interoperability ASM performance category score; however, submission of a ''no'' response, failure to submit an attestation, or failure to claim an applicable exclusion would result in a score of zero for the Promoting Interoperability ASM performance category.

ASM participants would continue to be required to satisfy one of the three existing HIE reporting options specified at § 512.740(b)(2)(ii), in addition to satisfying both electronic prior authorization measure performance requirements. We proposed an effective date starting in the 2028 ASM performance period to provide ASM participants additional time to prepare to report these measures successfully.

Comment: Several commenters opposed requiring the Electronic Prior Authorization for Prescription Drugs measure beginning in the 2028 ASM performance year, stating that additional time is needed for health technology infrastructure development, deployment, workflow integration, and payer readiness. A commenter recommended making the measure available for bonus credit in 2028 and delaying required reporting until 2029. A few commenters recommended CMS allow a year for optional, unscored reporting but without bonus points, before the measure becomes required. A commenter recommended a phased implementation approach with sufficient time for testing and evaluation before considering whether the measure should be mandatory, including consideration of whether electronic prior authorization reduces administrative burden, reduces approval times, and improves patient access.

Response: We appreciate the commenters' recommendations. We believe that delaying required reporting until the 2028 ASM performance year provides for a meaningful period of continued development, testing, and workflow integration while also supporting the aim to advance interoperable, standards-based electronic exchange. We further note that there are exclusions available, if applicable, for the Electronic Prior Authorization for Prescription Drugs measure. We therefore do not believe it is necessary to make the measure optional or available only for bonus credit in 2028.

Comment: A few commenters supported efforts to reduce administrative burden and delays in patient care associated with prescription drug prior authorization but opposed making the Electronic Prior Authorization for Prescription Drugs measure an ''all-or-nothing'' requirement for the Promoting Interoperability ASM performance category. Commenters stated that successful electronic prior authorization may depend on the capabilities of payers, pharmacy benefit managers, health IT developers, and other entities outside the ASM participant's control and expressed concern that ASM participants could receive a zero score because of those external dependencies.

Response: We appreciate commenters' concerns regarding dependencies on other entities. We recognize that successful electronic prior authorization implementation requires coordination across a continuum. We will evaluate readiness to report this measure as we progress toward the 2028 ASM performance year and make changes if necessary, in future rulemaking.

After consideration of public comments, we finalize our proposed policy with modification. Starting in the 2028 ASM performance year, an ASM participant must report on one of the three HIE options, as well as report the Electronic Prior Authorization measure, or claim an exclusion, and Electronic Prior Authorization for Prescription Drugs measure, or claim an exclusion. We are modifying the location of where we describe the final policy for the Electronic Prior Authorization for Prescription Drugs measure such that it is codified at § 512.740(b)(2)(ii)(B)(*2*).

(4) Exclusions to the Public Health and Clinical Data Exchange Objective in the Promoting Interoperability ASM Performance Category

We proposed to clarify that measure-level exclusions are available to ASM participants for the measures under the Immunization Reporting Registry and Electronic Case Reporting objective by amending our regulation at § 512.740(b)(2)(iv). Under our proposal, an ASM participant would receive full credit for the Public Health and Clinical Data Exchange objective by reporting both Public Health and Clinical Data Exchange measures (Immunization Registry Reporting and Electronic Case Reporting), reporting one measure and claiming one exclusion, or claiming two exclusions. We believe this proposal would simplify ASM participant reporting requirements by aligning exclusions available in MIPS and redistributing points for excluded measures in accordance with MIPS redistribution policies.

We proposed to adopt the same exclusions as MIPS includes for these measures for ASM. We sought comment on this proposal at § 512.740(b)(2)(iv).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported aligning exclusions for Immunization Registry Reporting and Electronic Case Reporting measures with MIPS, particularly when public health agency readiness or connectivity is outside a provider's control.

Response: We appreciate support for our proposal to recognize exclusions for the Immunization Registry Reporting and Electronic Case Reporting measures under the Public Health and Clinical Data Exchange objective.

After consideration of public comments, we are finalizing our policy to establish measure-level exclusions for this objective at § 512.740(b)(2)(iv) as proposed.

(5) Security Risk Analysis Measure

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), as implemented through the HIPAA Security Rule (45 CFR part 160 and subparts A and C of part 164), includes administrative safeguards required of covered entities and business associates, including a risk analysis component and a risk management component. The Security Risk Analysis measure was adopted to require that MIPS eligible clinicians attest to having conducted a security risk analysis and security risk management activities as required by the HIPAA Security Rule. In the CY 2026 PFS final rule (90 FR 49656), we incorporated this measure into the Promoting Interoperability ASM performance category by requiring that ASM participants complete the actions included in the MIPS Promoting Interoperability Security Risk Analysis measure. At the time, we believed it would help drive more secure, efficient, and meaningful use of CEHRT under ASM.

To reduce reporting burden, beginning with the 2027 ASM performance year, we proposed to remove the requirement at § 512.740(b)(3)(ii) that an ASM participant submit an affirmative attestation as to completing a security risk analysis within the calendar year. We consider the use of CEHRT to demonstrate security risk analysis and security risk management activities sufficient as it complies with requirements pertaining to the security of data created and maintained by CEHRT in accordance with the HIPAA Security Rule.

We proposed to redesignate current § 512.740(b)(3)(iii) as § 512.740(b)(3)(ii) to conform our regulations with the proposed removal of the Security Risk Analysis measure.

We received public comments on this proposal; the following is a summary of comments and our responses.

Comment: Several commenters supported removing the Security Risk Analysis attestation. A commenter noted this proposal removes duplicate processes, while emphasizing that providers continue to have broader security risk analysis and risk management obligations under the HIPAA Security Rule.

Response: We agree that removing this measure would help reduce reporting burden. After consideration of public comments, we are finalizing as proposed our policy to remove the Security Risk Analysis measure as a required attestation starting in the 2027 ASM performance year and to redesignate current § 512.740(b)(3)(iii) as § 512.740(b)(3)(ii).

(6) Supporting Providers With the Performance of CEHRT

In the CY 2026 PFS final rule (90 FR 49661), we finalized that an ASM participant must support the performance of CEHRT by submitting certain affirmative attestations to receive a Promoting Interoperability ASM performance category score greater than zero. Specifically, as finalized at §§ 512.740(b)(4)(i)(A)(1) and 512.740(b)(4)(i)(A)(2), an ASM participant must support the performance of CEHRT by:

- Providing acknowledgement of the requirement to cooperate in good faith with the Office of the National Coordinator for Health Information Technology (ONC) direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received; and
- If requested, cooperate in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the ASM participant in the field.

An ASM participant may optionally attest to the following:

- The ASM participant acknowledges the option to cooperate in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received.
- If requested, that the ASM participant cooperates in good faith with ONC–ACB surveillance of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the ASM participant in the field.

Consistent with the proposal to remove these attestations from the MIPS Promoting Interoperability performance category, we proposed to remove the ONC Direct Review attestation and ONC–ACB Surveillance attestation from the Promoting Interoperability ASM performance category starting in the 2027 ASM performance year.

This aligns with our goals of reducing administrative burden while focusing on high-value, outcome-oriented measures. Removing attestations from the Promoting Interoperability ASM performance category reduces the number of discrete manual steps and reporting fields required for successful adherence to reporting requirements without diminishing central goals of the Promoting Interoperability ASM performance category.

We sought comment on the proposal to remove the ONC Direct Review attestation and ONC–ACB Surveillance attestation.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported removing ONC Direct Review and ONC–ACB Surveillance attestations to reduce duplicative reporting burden while maintaining underlying health information technology and security obligations.

Response: We appreciate the commenters' support.

After consideration of public comments, we are finalizing our proposals to remove the measures described at §§ 512.740(b)(4)(i)(A)(*1*) and 512.740(b)(4)(i)(A)(*2*) as proposed.

(7) Adopting a Measure Suppression Policy for the Promoting Interoperability ASM Performance Category

We finalized a measure suppression policy under the MIPS Promoting Interoperability performance category beginning with the CY 2026 MIPS performance year (90 FR 49881 through 49887). Under this policy, when circumstances arise that impede effective measurement of a MIPS Promoting Interoperability measure, we may suppress the measure by excluding it from MIPS Promoting Interoperability performance category scoring or from the determination of whether a MIPS clinician is a meaningful EHR user for the applicable MIPS performance year (§ 414.1380(b)(4)(iii)).

A decision to suppress a measure does not eliminate the requirement that MIPS eligible clinicians report the measure. However, regardless of the data, attestation, or other information related to the suppressed measure that is submitted by the MIPS eligible clinician, the suppressed measure would not affect the objective's score or the determination of meaningful EHR user status (90 FR 49883).

We did not adopt a measure suppression policy for the Promoting Interoperability ASM performance category because ASM performance had not yet begun. We stated we would monitor developments as the first ASM performance year approaches, with the goal of maintaining alignment with the MIPS Promoting Interoperability performance category where possible and indicated we may propose changes in future rulemaking.

After further consideration, we proposed at § 512.740(c)(2) to adopt a Promoting Interoperability measure suppression policy within ASM starting in the 2027 ASM performance year. Specifically, we proposed that if certain circumstances occur that impact our assessment of ASM participant performance on a measure specified for the Promoting Interoperability ASM performance category under § 512.740(b), we may suppress the affected measure by: (1) excluding it from our calculation of the Promoting Interoperability ASM performance

category objective score under § 512.740(c); or (2) excluding it from the determination of meaningful EHR user status, if the affected measure is not scored. We proposed to redesignate current § 512.740(c)(2) describing the Promoting Interoperability ASM performance category scoring policy as § 512.740(c)(3), without making changes to that existing regulatory text, to describe the measure suppression policy at § 512.740(c)(2).

For an applicable ASM performance year, we proposed to determine whether circumstances warrant suppression of an ASM Promoting Interoperability measure based on consideration of the same factors we identified for MIPS (90 FR 49883):

- The nature, breadth, and duration of the circumstance's effect on ASM participants' ability to fulfill the measure requirement;
- The availability of certified health IT modules to fulfill the measure;
- Whether the circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, including with respect to performance or compliance;
- Out-of-date or conflicting technical standards;
- Technical or operational capacity of required partners; or
- Other factors as determined by CMS.

We further proposed that, if we determine that a measure must be suppressed, we would notify ASM participants through existing communication channels. To the extent technically feasible, we intended to notify ASM participants prior to the beginning of the applicable data submission period. We noted in the proposed rule that, like in MIPS, the duration of suppression for a measure in ASM would be for an entire ASM performance year. If prolonged issues persist regarding a given circumstance, we would assess the circumstance to determine if a measure would warrant suppression for a subsequent ASM performance year.

We believed this policy would ensure the integrity of the ASM scoring methodology while protecting ASM participants from being penalized for circumstances beyond their control.

We invited public comment on our proposal at § 512.740(c)(2) to adopt a measure suppression policy within ASM.

Comment: A few commenters supported adopting a measure suppression policy for the Promoting Interoperability ASM performance category. Commenters supported aligning the policy with the MIPS to allow measures to be suppressed or excluded from scoring when circumstances outside an ASM participant's control prevent performance or reporting.

Response: We agree with commenters that this policy would help avoid holding ASM participants responsible for circumstances beyond their control.

After consideration of the comments, we finalize the proposal to adopt a measure suppression policy at § 512.740(c)(2) as proposed.

f. Final Score

(1) Background

In the CY 2026 PFS final rule (90 FR 49664 through 49679), we adopted a scoring methodology to evaluate the annual performance of each ASM participant through a final score. The final score represents an ASM participant's aggregate performance on a scale of zero to 100 points based on applicable performance standards for measures and activities in each ASM performance category. This scoring framework promotes accountability for performance across ASM participants within each ASM cohort. We use the final score to determine the ASM payment adjustment factor applied to an ASM participant's Medicare Part B claims for covered professional services during the corresponding ASM payment year.

We calculate the final score based on performance in the quality, cost, improvement activities, and Promoting Interoperability ASM performance categories (90 FR 49677). We also established policies to award additional points to ASM participants who furnish care to complex patient populations and to ASM participants who are part of small practices or who are solo practitioners (90 FR 49670 through 49676).

(2) Requirements To Receive a Final Score

In the CY 2026 PFS final rule (90 FR 49668 through 49669), we finalized that an ASM participant must meet minimum data submission requirement to receive a final score for an ASM performance year. An ASM participant who does not meet these data submission requirements receives a final score of zero points for the applicable ASM performance year, which results in the maximum negative payment adjustment applicable for the corresponding ASM payment year. Conversely, an ASM participant who meets the minimum data submission requirements but cannot be evaluated on quality and cost performance does not receive a final score and instead receives a neutral payment adjustment for the applicable ASM payment year. We refer readers to Table B–D8 in the CY 2026 PFS final rule for a summary of ASM's final score policies and their impact on payment adjustments (90 FR 49670).

After internal review of ASM's final scoring provisions, we believe we could clarify regulatory text describing when we will not assign an ASM participant a final score. Specifically, we proposed to revise § 512.745(a)(2)(iii)(B) by striking the ''Do not receive'' language that starts §§ 512.745(a)(2)(iii)(B)(*1*) and 512.745(a)(2)(iii)(B)(*2*). We then proposed to revise § 512.745(a)(2)(iii)(B) to read ''Do not receive either:'', referring to the conditions described at §§ 512.745(a)(2)(iii)(B)(*1*) and 512.745(a)(2)(iii)(B)(*2*). These specific changes do not introduce substantive changes to current requirements.

We sought comment on the proposed changes to clarify the regulatory text at § 512.745(a)(2)(iii)(B).

We did not receive public comments on this provision, and therefore, we are finalizing the regulatory text at § 512.745(a)(2)(iii)(B) as proposed.

(3) Rural Scoring Adjustment

In the CY 2026 PFS proposed rule, we considered, but did not propose, including a rural scoring adjustment in the calculation of an ASM participant's final score (90 FR 32604), as our analysis of historic data did not reveal a systematic difference in expected performance between likely ASM participants in rural and non-rural areas. In response to our discussion considering the rural scoring adjustment in the CY 2026 PFS proposed rule, we received interested parties' feedback recommending that we award a rural scoring adjustment to ASM participants in rural areas because ASM participants in rural areas face unique demands (90 FR 49676). However, we finalized ASM's final score policy without including a rural scoring adjustment.

The CY 2026 PFS final rule did establish policies to award additional points on the final score to ASM participants who furnish care to complex patient populations (up to 10 points) and to ASM participants who are part of small practices (10 points for ASM participants in small practices, 15 points for solo practitioner ASM participants) (90 FR 49670 through 49676). In the CY 2026 PFS final rule, we noted that small practice and solo practitioner scoring adjustments better support ASM participants in small practices by compensating for increased administrative burden and additional

reporting requirements (90 FR 49676). We noted in the CY 2026 PFS final rule that we expected a high degree of overlap between ASM participants in rural areas and those in small practices based on historical MIPS performance data that we analyzed (90 FR 49677), indicating that ASM participants in rural areas would be eligible for the small practice scoring adjustment and be supported accordingly. We also noted that a rural scoring adjustment could weaken incentives for ASM participants in large rural systems to improve (90 FR 49676).

However, as supported by interested parties' comments on the CY 2026 PFS proposed rule, together with additional research and analysis, the unique circumstances facing ASM participants in rural areas may warrant adjustments to their final scores. We recognize that ASM participants in rural areas may face structural challenges that affect their ability to perform under ASM, including limited resources for technology modernization, workforce shortages that constrain reporting capacity, and barriers to system interoperability. A 2025 analysis of physician participants in the Quality Payment Program found significantly higher physician adoption of EHRs in urban areas (74 percent) compared to rural areas (64 percent).[201] Another recent study suggests that physicians in rural areas were less likely to report ideal interoperability experiences for medication notes.[202] A report from the HHS Office of the National Coordinator for Health IT (ONC) notes that urban hospitals were more likely to engage in routine interoperable exchange (47 percent were routinely interoperable) than their rural counterparts (36 percent were routinely interoperable).[203] These findings align with interested parties' feedback highlighting additional interoperability barriers faced by rural clinicians. Accordingly, as stated in the proposed rule we believe ASM's existing scoring methodology may not adequately address the complex factors that may affect rural ASM participant's performance particularly because ASM has a unique focus on incentivizing interoperability improvements to strengthen care coordination.

Additionally, our analysis of preliminary ASM participants for the 2027 ASM performance year provided an updated understanding of the practice size of ASM participants in rural areas. In previous notice-and-comment rulemaking, we noted that we expected ASM participants in rural areas were primarily practicing in small practices and, therefore, would qualify for ASM's small practice or solo practitioner scoring adjustments (90 FR 49677). An additional rural scoring adjustment, on top of small practice or solo practitioner adjustments, for these ASM participants could have been duplicative and result in a disproportionate scoring benefit. However, upon review of updated data on preliminary ASM participants for the 2027 ASM performance year, we found that ASM participants in rural areas are typically part of larger practices and would be less likely to receive the small practice scoring adjustment.

To address continued interested parties' feedback about ASM participants in rural areas and additional analysis of preliminary ASM participants for the 2027 ASM performance year, we proposed the inclusion of a rural scoring adjustment in the calculation of an ASM participant's final score. We stated that we believe adding a rural scoring adjustment would adequately increase final scores to account for the unique challenges faced by this group of ASM participants.

To determine if an ASM participant is in a rural area, we proposed at § 512.705 to adopt the same definition and determinations of a ''rural area'' as defined, interpreted, and updated at § 414.1305 under MIPS. We believe that aligning our rural area definition with MIPS will reduce confusion for ASM participants in rural areas who have previously participated in MIPS and received associated flexibilities with rural special status under MIPS.

To incorporate the rural scoring adjustment proposal into ASM's regulatory text, we first proposed to redesignate current § 512.745(a)(5) as new § 512.745(a)(6). We then proposed at new § 512.745(a)(5) to add 5 points to the final score of an ASM participant who (1) is in a rural area as proposed to be defined at § 512.705, and (2) meets the requirements to receive a final score greater than zero as described at § 512.745(a)(2)(i) for an applicable ASM performance year. We emphasize that ASM participants in rural areas remain eligible to receive ASM's small practice or solo practitioner scoring adjustment and the complex patient scoring adjustment if they meet such scoring adjustment's eligibility criteria described at § 512.745(a)(4) and § 512.745(a)(3), respectively.

We considered but did not propose an alternative rural scoring adjustment policy to add 5 points to the final score of each ASM participant who (1) is in a rural area as proposed to be defined at § 512.705, (2) meets the requirements to receive a final score greater than zero as described at § 512.745(a)(2)(i) for an applicable ASM performance year, and (3) does not receive a small practice scoring adjustment as described in § 512.745(a)(4). However, rural practices regardless of size often face thinner operating margins that limit their potential investment in the quality and technology infrastructure necessary to succeed in ASM.[204] Uneven access to affordable broadband may further burden ASM participants in rural areas by financially challenging their ability to leverage health information exchanges and data sharing.[205] We believe that a rural scoring adjustment for ASM participants in small and non-small rural practices alike most accurately accounts for the potential burdens faced by ASM participants in rural areas.

We also considered but did not propose an alternative policy waiving Improvement Activity 2 (IA–2), Establishing Communication and Collaboration Expectations with Primary Care using CCAs, for ASM participants in rural areas. Although ASM participants in rural areas may face challenges forming partnerships with primary care practices due to limited primary care availability,[206] we believe that a rural scoring adjustment more broadly accounts for challenges that could affect ASM participant performance across the four ASM performance categories compared to only waiving IA–2.

To account for the proposed addition of the rural scoring adjustment, we proposed corresponding adjustments to the final score formula at

[201] Anzalone AJ, Geary CR, Dai R, Watanabe-Galloway S, McClay JC, Campbell JR. Lower electronic health record adoption and interoperability in rural versus urban physician participants: a cross-sectional analysis from the CMS quality payment program. BMC Health Serv Res. 2025 Jan 23;25(1):128. doi: 10.1186/s12913–024–12168–5. PMID: 39849475; PMCID: PMC11755824.

[202] Everson J, Adler-Milstein J, Phillips RL, Bazemore AW, Patel V. EHR Interoperability Experiences Reported by Family Physicians. JAMA Netw Open. 2025;8(11):e2542460. doi:10.1001/jamanetworkopen.2025.42460.

[203] *https://healthit.gov/data/data-briefs/interoperable-exchange-patient-health-information-among-us-hospitals-2023/.*

[204] HRSA National Advisory Committee on Rural Health and Human Services. *Interoperability and Broadband: Challenges to Rural Information Exchange* (January 2016). *https://www.hrsa.gov/advisory-committees/rural-health/correspondence/20160101.*

[205] Pritzker, Penny, and Tom Vilsack. ''Broadband Opportunity Council Report and Recommendations.'' *USDA, US Department of Commerce,* 20 Aug. 2015, *obamawhitehouse.archives.gov/sites/default/files/broadband_opportunity_council_report_final.pdf.*

[206] *https://www.ers.usda.gov/data-products/charts-of-note/chart-detail?chartId=106208.*

§ 512.745(a)(6). We also proposed to revise § 512.745(a) to cross-reference the final score formula now described at § 512.745(a)(6).

We sought public comment on our proposed definition of rural area at § 512.705 and our proposal at § 512.745(a)(5) to add 5 points to the final score of an ASM participant who is in a rural area and meets the requirements to receive a final score greater than zero. We also sought comment on the alternative we considered to only add the rural scoring adjustment to the final scores of ASM participants in rural areas who are not eligible to receive a small practice scoring adjustment, as well as the alternative to waive IA–2 for ASM participants in rural areas. We sought comment on our corresponding proposal at § 512.745(a)(6) to incorporate the rural scoring adjustment into the final score formula.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed 5-point rural scoring adjustment, stating that it would recognize the unique infrastructure, technology, staffing, workforce, and access challenges faced by ASM participants serving rural communities. Commenters supported allowing eligible rural ASM participants to receive the rural scoring adjustment in addition to the small practice or solo practitioner and complex patient scoring adjustments. Commenters requested clarifications regarding how the rural adjustment would interact with the small practice and solo practitioner scoring adjustments and whether the adjustments would be cumulative.

Response: We appreciate the commenters' support of the rural scoring adjustment policy and application. We refer readers to the CY 2027 proposed rule (91 FR 43990), where we propose that ASM participants who are eligible for the rural scoring adjustment are also eligible for the complex patient scoring adjustment and/or small practice scoring adjustment provided that they meet the requirements as specified in sections § 512.745(a)(3) and § 512.745(a)(4) respectively.

Comment: Several commenters supported the proposed rural scoring adjustment but recommended modifications or additional safeguards. A commenter recommended limiting the rural adjustment to ASM participants who are not eligible for the small practice scoring adjustment, stating that receiving both adjustments could reduce incentives for performance improvement. Another commenter recommended an additional adjustment for physicians caring for disproportionately high numbers of low-income or socially complex beneficiaries.

Response: We appreciate the commenters' feedback and acknowledge the commenters' recommendation to limit awarding the rural scoring adjustment to ASM participants who are not eligible for the small practice scoring adjustment. However, we disagree and stress that each scoring adjustment targets the unique challenges faced in different practice types. The small practice scoring adjustment is focused on correcting issues such as CEHRT implementation, and staff training costs (90 FR 49674). While the rural adjustment addresses workforce shortages, and thinner operating margins (91 FR 43990). We believe that an ASM participant in a rural area and small practice may experience both sets of challenges; thereby necessitating the need for the scoring adjustments to be additive.

We also stress that as stated earlier in this section of the final rule, preliminary ASM participant data for the 2027 ASM performance year found that ASM participants in rural areas are typically part of larger practices. Awarding both the small and rural scoring adjustments to a smaller percentage of ASM participants who meet both scoring adjustment requirements recognizes the significant challenges these ASM participants may face while not substantially changing scoring and payment incentives.

Additionally, we do not believe that the 5-point rural adjustment significantly diminishes the incentive for ASM participants receiving this scoring adjustment to improve. Because ASM's payment methodology remains tied to an ASM participant's performance relative to their ASM cohort, and not a pre-set performance threshold, an ASM participant who might receive both adjustments would still have an incentive to improve their performance components that factors into the final score. If an ASM participant's performance improves more than others in their ASM cohort, the ASM scoring and payment framework rewards the ASM participant with an increase in their payment adjustment factor regardless of their small or rural scoring adjustments.

Lastly, we note that the CY 2026 final rule finalized at § 512.745(a)(3) the ASM complex patient scoring adjustment. The complex patient scoring adjustment accounts for the HCC risk scores and the proportion of dually eligible beneficiaries of an ASM participant. We refer readers to the CY 2026 final rule where we document the link between dual eligible status and income level (90 FR 49674).

Comment: A commenter recommended that CMS consider similar adjustments to the rural scoring adjustment be awarded to non-rural clinicians and practices facing comparable resource or operational constraints, including small independent specialty practices, hospital-based or ambulatory surgical center (ASC) clinicians, and non-patient-facing clinicians.

Response: We thank the commenter for their recommendation. We emphasize that the ASM complex patient scoring adjustment as finalized at § 512.745(a)(3) accounts for social and medical risk factors faced by ASM participants regardless of size or geography. We did not consider awarding an additional scoring adjustment to ASM participants in hospitals or ambulatory surgical centers because we believe that the complex patient scoring adjustment adequately accounts for the challenges ASM participants serving in those practices face. We also stress that to receive a final score, an ASM participant must be attributed 20 EBCM episodes for the ASM performance year. If ASM participants do not meet the minimum 20 case threshold they would receive an automatic neutral payment adjustment (90 FR 49669). Furthermore, as part of the EBCM methodology, to qualify as an ASM participant a specialist would need to have billed at least 30 percent of triggering or confirming codes on Part B Physician/Supplier claim lines related to the ASM condition for the beneficiary (90 FR 49579). We therefore disagree with the commenter that a positive adjustment should be made to the final scores of non-patient-facing ASM participants. We expect that the EBCM minimum threshold and billing requirements will award ASM final scores primarily to patient-facing clinicians.

Comment: A commenter recommended comparing an ASM participant's performance with their peers in similar practice environments, patient populations, shared resource constraints, and geographic characteristics rather than relying solely on additional scoring adjustments like the rural scoring adjustment.

Response: We thank the commenter for their creative approach to scoring; however, we disagree and believe that a rural scoring adjustment adequately supports ASM participants in rural

areas facing targeted challenges. As discussed in the CY 2026 final rule (90 FR 49684) we finalized our proposal to calculate incentive pools and payment adjustment factors separately for each ASM cohort. We believe that calculating payment adjustments separately by ASM cohort supports meaningful comparisons among ASM participants treating the same targeted chronic condition. Further stratifying ASM participants based on practice environment, patient population, resource constraints, or geographic characteristics would result in smaller comparison groups. Thereby creating a situation in which small differences in an ASM participant's final score could lead to vastly different payment adjustment factors, an outcome not aligned with the model's stated goal of creating meaningful payment incentives (90 FR 49684).

Comment: A commenter requested that to account for specialists practicing at multiple sites who predominantly serve rural communities, CMS determine rural status based on the plurality of ASM beneficiaries served during the ASM performance year rather than solely on the specialist's primary PECOS enrollment address.

Response: We thank the commenter for their proposal to determine rural status based on the location of the plurality of ASM beneficiaries served during the ASM performance year. As discussed earlier in this section of this final rule, we believe that calculating the ASM rural scoring adjustment using the same definition and determinations of a ''rural area'' as defined, interpreted, and updated at § 414.1305 under MIPS will significantly reduce confusion and burden. We will provide specifications regarding the identification of the ASM participant's ZIP Code for use in the rural scoring adjustment determination through sub-regulatory technical documentation.

Comment: A few commenters opposed the proposed rural scoring adjustment, while acknowledging that some rural practices face additional challenges. Commenters stated that rural status alone may not reliably identify ASM participants facing greater barriers to ASM performance because some non-rural practices may experience comparable or greater socioeconomic, access, infrastructure, or patient-population challenges, while some rural practices may not experience any such challenges. A few commenters recommended addressing differences in practice circumstances through attribution, risk adjustment, benchmarks, measure specifications, and other relevant factors rather than adding points to ASM participants' final scores. Commenters also expressed concern that, because ASM performance is scored relative to other ASM participants, increasing the final scores of ASM participants in rural areas would affect the relative standing and payment adjustments of ASM participants in non-rural areas.

Response: We acknowledge commenters' concerns that some ASM participants in non-rural areas may experience similar or comparable challenges. However, the rural scoring adjustment is not intended to address all differences in ASM participant or patient circumstances. ASM includes other methodological features that account for relevant differences in performance. For example, the cost ASM performance category incorporates risk adjustment, as described in the CY 2026 PFS final rule (90 FR 49638), and MIPS Q492 in the quality measure set for the ASM heart failure cohort includes a risk-adjustment model incorporating demographic, clinical, and social risk factors. We believe these methodologies, together with the rural scoring adjustment and other applicable ASM scoring adjustments, appropriately account for differences in ASM participant and patient circumstances.

We also acknowledge that the ASM payment adjustment factors are determined relative to the performance of other ASM participants in the ASM cohort. We do not believe however that this effect provides a basis for excluding circumstances associated with ASM participants in rural areas. As discussed earlier in this section of the final rule the ASM rural adjustment is meant to correct for unmeasured disadvantages, rather than simply giving an arbitrary advantage to ASM participants in rural areas.

Comment: A commenter stated that its analysis of historical MIPS performance among likely ASM participants showed similar average performance for rural and non-rural physicians, while showing larger differences between small and large practices. The commenter therefore recommended that CMS not establish a rural scoring adjustment and instead waive interoperability requirements for ASM participants in rural areas and for ASM participants in non-rural areas when community conditions create a hardship.

Response: We appreciate the commenter's analysis of historical MIPS performance data among likely ASM participants. However, we stress that ASM's requirements differ in important respects from MIPS, including the improvement activities ASM performance category. Consequently, we do not believe that historical MIPS performance data provides an appropriate basis for determining whether a rural scoring adjustment is warranted under ASM.

As finalized in the CY 2026 final rule at § 512.735(c)(2) IA–2 requires established communication and collaborations with primary care using a CCA. As discussed earlier in this section of this final rule, ASM participants in rural areas may face challenges forming partnerships with primary care practices due to limited primary care availability. Therefore, we believe that historical MIPS performance may not fully reflect the circumstances and challenges ASM participants in rural areas experience when they move from MIPS to ASM.

We also considered but ultimately did not propose waiving IA–2 for ASM participants in rural areas in the CY 2027 proposed rule (91 FR 43990). A central goal of the ASM is to incentivize ASM participants to ensure that their patients have a regular source of primary care (90 FR 49563). We therefore believe that removing IA–2 entirely for ASM participants in rural areas would not provide sufficient incentive for improved care coordination.

Comment: A commenter supported the proposed 5-point rural scoring adjustment but stated that it would be insufficient to address the structural and financial challenges facing rural specialists in Kentucky and Indiana. The commenter cited rural hospital closure risks, Medicaid payment shortfalls, low rural hospital operating margins, and physician shortages in both States and expressed concern that the potential negative ASM payment adjustment could further threaten the financial viability of rural specialty care. The commenter also stated that many rural ASM participants may not qualify for the small practice scoring adjustment because CMS's analysis indicated that rural ASM participants tend to be in larger practices. The commenter recommended that CMS exempt Kentucky and Indiana from mandatory ASM participation or establish differential penalty structures for ASM participants in rural areas until additional geographic adjustments, infrastructure supports, and rural-specific quality measures are in place.

Response: We appreciate the commenters' feedback and support. We do though believe that the rural scoring adjustment appropriately addresses the structural concerns the commenter highlighted facing practices in Kentucky and Indiana. We also note that the rural scoring adjustment does not operate in

isolation. Eligible ASM participants, including those in Kentucky and Indiana, may also receive the complex patient scoring adjustment as described in § 512.745(a)(3). Elsewhere in the ASM performance category scoring methodology, the cost ASM performance category incorporates risk adjustment into the EBCM used to calculate the cost ASM performance category score as described in the CY 2026 PFS final rule (90 FR 49638); and the Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure measure (MIPS Q492) incorporates risk adjustment on demographic, clinical, and social risk factors (90 FR 49607).

We acknowledge that the rural scoring adjustment does not eliminate ASM's peer-relative scoring or guarantee avoidance of a negative payment adjustment. However, we believe the adjustment appropriately recognizes rural circumstances while preserving ASM's underlying goal of comparing ASM participants to their peers within an ASM cohort. We do not believe a separate payment adjustment structure for ASM participants in rural areas is appropriate as that would decrease the size of the ASM cohort and thereby create an inappropriate payment approach as discussed earlier in this section of this final rule. We refer readers to the CY 2026 final rule for a complete discussion regarding mandatory participation and its importance in ensuring a valid and robust model evaluation (90 FR 49589).

Comment: A commenter stated that it lacked sufficient information and comparative data to assess the proposed rural scoring adjustment and recommended that CMS examine anticipated differences in ASM scores between ASM participants in rural areas and ASM participants in non-rural areas before implementing the adjustment.

Response: We appreciate the commenter's recommendation; however, we believe that we have sufficient information to implement this adjustment as proposed. As discussed earlier in this section of this final rule, ASM participants in rural areas face specific interoperability and primary care coordination challenges. We believe that these circumstances could make success difficult for ASM participants in rural areas and therefore a rural scoring adjustment is warranted. We will closely monitor the results of the ASM rural scoring adjustment, and any modification will be made in future notice-and-comment rulemaking.

After consideration of public comments, we are finalizing our proposed corresponding adjustments to the final score formula at § 512.745(a)(6), our proposal to revise § 512.745(a) to cross-reference the final score formula now described at § 512.745(a)(6), our proposed definition of rural area at § 512.705, our proposal at § 512.745(a)(5) to add 5 points to the final score of an ASM participant who is in a rural area and meets the requirements to receive a final score greater than zero, and our corresponding proposal at § 512.745(a)(6) to incorporate the rural scoring adjustment into the final score formula.

(4) ASM Performance Report

In the CY 2026 PFS final rule (90 FR 49678), we finalized that we will provide performance information to each ASM participant for each ASM performance year through an annual ASM performance report. The ASM performance report will include information on each ASM performance category score, scoring adjustments as applicable, the final score, the ASM payment adjustment factor, and the ASM payment multiplier.

To incorporate additional information on scoring incentives and scoring adjustments proposed in the proposed rule, we proposed to revise the structure of the regulatory text on the ASM performance report in § 512.745(b). These proposed structural revisions to the regulatory text's structure are intended to improve readability on the logical flow of components of the annual ASM performance report, starting with each ASM performance category score, scoring incentives, scoring adjustments, final score, and ending with the resulting payment adjustment information. These specific changes do not introduce substantive changes to current requirements.

We also proposed at revised § 512.745(b)(2) to provide ASM participants with information on whether they receive the quality ASM performance category scoring incentive for successful voluntary reporting of PRO data through the annual ASM performance report, as applicable. We refer readers to section III.D.2.d.(5) of the proposed rule for additional information on the proposed voluntary PRO data submission and associated quality ASM performance category scoring incentive.

We also proposed at revised § 512.745(b)(5) to provide ASM participants with information on their rural scoring adjustment, if applicable, in the annual ASM performance report.

We believe these proposals would help an ASM participant understand their performance and whether they qualified for new scoring incentives and scoring adjustments proposed in the proposed rule.

We sought comment on our proposed clarifying revisions to § 512.745(b). We also sought comment on our proposal at § 512.745(b)(2) to provide information on the quality ASM performance category incentive for voluntary reporting of patient-reported outcome data, as applicable, and our proposal at § 512.745(b)(5) to provide information on the rural scoring adjustment, as applicable, in the annual ASM performance report.

We received public comments on the proposals to include additional scoring information in the ASM performance report as well as general comments on the ASM performance report. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed revisions to the annual ASM performance report. Commenters recommended that CMS provide ASM participants with transparent, detailed, and actionable performance information to help ASM participants understand and improve their performance. Commenters requested that the report identify the specific measures contributing to performance results, explain the attribution methodology as applied to ASM participants' patient populations, provide measure-level results, and identify specific opportunities for remediation. Commenters also recommended enhanced data sharing for cost and administrative claims measures and stated that ASM participants need access to sufficiently detailed attributed beneficiary-level data to audit their results.

Response: We thank the commenters for their support of the revisions to the annual ASM performance report. We agree that the ASM performance report should provide ASM participants with sufficient information to understand their performance across the ASM performance categories. However, to allow all ASM participants access to their performance data, regardless of whether they followed the attestation and data sharing agreement process for CMS sharing of beneficiary-identifiable information, we stress that the ASM performance report will not contain beneficiary identifiable information. As discussed in the CY 2026 final rule, the ASM performance report is designed to complement the other proposed data sharing approaches discussed in § 512.760(d) which are also designed to help ASM participants improve their ASM performance category score performance.

Comment: A few commenters recommended that CMS provide performance and attribution information more frequently than through an annual ASM performance report. A few commenters recommended monthly and quarterly reports identifying beneficiaries attributed to each ASM participant to allow ASM participants to validate attribution, support care coordination, and better understand the populations contributing to their quality, cost, and overall ASM performance scores. Another commenter requested that CMS specify when performance data would be delivered during each ASM performance year and provide ASM participants with sufficiently timely information to identify improvement opportunities and implement targeted strategies before accountability begins.

Response: We thank commenters for their recommendation to relay frequent performance and attribution reporting. However, we stress that we made no proposed changes to the cadence of the ASM performance report and are not making changes to its cadence in this final rule. The ASM performance report serves as the final source of information on the ASM Participant's annual performance in each ASM performance category and their resulting ASM payment adjustment factor and multipliers. We note though that the annual ASM performance report is not the only mechanism where we deliver performance data to ASM participants. We refer commenters to § 512.760(d) where we detail data sharing policies that help ASM participants understand their progress towards improving upon the model's performance metrics. These include information on beneficiary attribution, measure-specific dashboards, and appropriate aggregate data.

Comment: A commenter recommended permitting designated health system and accountable care organization personnel to receive model communications and performance reports on behalf of participating specialists, stating that integrated organizations may have analytic capabilities needed to translate performance information into actionable changes.

Response: We thank the commenter for their feedback. However, we note that we did not propose any changes to the recipients of the ASM performance report and are not making changes to the report recipient policy in this final rule. We will take the commenter's recommendation into consideration and any changes to the recipients of the ASM performance report will be made in future notice-and-comment rulemaking.

After consideration of public comments, and as discussed in section III.D.2.d.(5) of this final rule, we are not finalizing our proposal to establish voluntary PRO data submission and the associated quality ASM performance category scoring incentive. Accordingly, we are not finalizing the proposed revision at § 512.745(b)(2) to include in the annual ASM performance report whether an ASM participant received the quality ASM performance category scoring incentive for successful voluntary reporting of PRO data.

We are finalizing our proposal to make revisions to regulatory text at § 512.745(b). We are also finalizing our proposal to provide information on the rural scoring adjustment, as applicable, in the annual ASM performance report at § 512.745(b)(4), with corrections to numbering.

g. Payment Approach

(1) Background

In the CY 2026 PFS final rule, we finalized the overall payment approach for ASM (90 FR 49679 through 49699). We will apply performance-based payment adjustments to all payments for Medicare Part B covered professional service claims from ASM participants during an ASM payment year based on their performance during the corresponding prior ASM performance year. We explained that this approach will create meaningful financial incentives tied to performance in the model, while maintaining administrative feasibility and transparency (90 FR 49679 through 49680). To determine these payment adjustments, we finalized a methodology to compare ASM participant performance within each ASM cohort using final scores, which reflect ASM participants' performance across the four ASM performance categories (90 FR 49681 through 49683). We also finalized a methodology to calculate ASM payment adjustment factors and ASM payment multipliers used to apply the payment adjustments from the distribution of final scores (90 FR 49685 through 49696). We also finalized the level of two-sided risk (that is, the maximum and minimum payment adjustment), including the gradual increase in the two-sided ASM risk level from 9 percent in the 2027 and 2028 ASM performance years to 12 percent in the 2031 ASM performance year. We explained that this methodology supports strong incentives for performance improvement while maintaining ASM risk levels similar to MIPS during early model years. We will apply the ASM payment multiplier to all payments for Medicare Part B for covered professional services, not only those services related to each ASM cohort's ASM targeted chronic condition, during an ASM payment year (90 FR 49696 through 49699).

(2) Application of ASM Payment Adjustments With Changes in TIN Affiliations

In the CY 2026 PFS final rule, we finalized that Medicare Part B professional service claims submitted by an NPI who is an ASM participant for an ASM performance year but under a TIN (1) that we did not select the NPI as an ASM participant for the applicable ASM performance year and (2) to which the NPI began assigning billing rights after the ASM performance year but before the end of the corresponding ASM payment year would be adjusted using the ASM payment multiplier calculated for the ASM participant. In the limited instances where a single NPI is selected as an ASM participant under multiple TINs for an ASM performance year, we finalized that we would apply the highest of any ASM payment multipliers to all Medicare Part B covered professional service claims submitted under a new TIN during the applicable ASM payment year (90 FR 49696). We refer readers to Table B–D10 in the CY 2026 PFS final rule for additional information on how ASM payment adjustments will be applied under multiple scenarios (90 FR 49697). The goal of these policies is to maintain accountability for the ASM participant's performance through the application of their performance-based payment adjustments. By doing so, we track accountability to the ASM participant regardless of their specific TIN affiliation at the time we make payment adjustments.

While we did not propose substantive changes to these policies in the proposed rule, we noted that there are inconsistencies in the regulatory text describing how we will adjust payment in situations where the ASM participant begins reassigning billing rights to a new TIN during an ASM payment year.

Accordingly, to maintain consistency with the regulatory text governing the application of ASM's payment adjustments as described at § 512.750(a), we proposed to revise the regulatory text at §§ 512.750(f)(1) and (f)(2) to replace the phrases ''adjusts payments'' and ''adjust claims'' with ''multiplies the amount otherwise paid under Medicare Part B for covered professional services''. We also proposed clarifying revisions to § 512.750(f)(1). We

proposed to remove unnecessary text at § 512.750(f)(1)(i) because we only calculate ASM payment multipliers for ASM participants with final scores as described at § 512.750(c)(1). To improve readability of the provision with the proposed removal of § 512.750(f)(1)(i), we proposed to revise § 512.750(f)(1) to incorporate the text previously described at § 512.750(f)(ii).

We also proposed revisions to clarify how we would adjust payments for NPIs selected as ASM participants under multiple TINs and who reassign billing rights to a new TIN after an ASM performance year. Accordingly, we proposed to remove unnecessary language in § 512.750(f)(2) and § 512.750(f)(2)(i) to more clearly describe how we would adjust payments using the highest ASM payment multiplier calculated for an NPI who we select as an ASM participant under multiple TINs. We also proposed at § 512.750(f)(2)(ii) to replace the phrase ''assigning billing rights'' with ''reassigning billing rights'' to improve the accuracy of the regulatory text. These proposals do not create substantive changes to the proposed policies but would ensure clarity and consistency in language used to describe the application of payment adjustments under ASM under § 512.750.

We sought comment on our proposals to revise the regulatory text at § 512.750(f)(1) and § 512.750(f)(2).

We received public comments about ASM's payment approach that were outside the scope of the CY 2027 PFS proposed rule. These out-of-scope public comments are not summarized nor addressed with responses in this final rule.

We did not receive specific comments related to the proposed revisions to regulatory text at § 512.750(f)(1) and § 512.750(f)(2), and therefore, are finalizing as proposed.

h. Applicability of CMS-Sponsored Model Safe Harbor at 42 CFR 1001.952(ii)

In the CY 2026 PFS final rule, we determined that the CMS-sponsored model arrangements and patient incentives safe harbor at § 1001.952(ii) is available to ASM participants that comply with applicable requirements (90 FR 49709). We codified the availability of the safe harbor for ASM at § 512.765 with respect to remuneration associated with beneficiary incentives and remuneration exchanged under CCAs.

Once a clinician is selected as an ASM participant for any ASM performance year during the ASM test period, that clinician remains an ASM participant for the duration of the ASM test period. However, in limited circumstances, an ASM participant may not be required to meet specified model requirements for an ASM performance year. Specifically, if we determine that an ASM participant does not satisfy the ASM participant eligibility criteria as specified under § 512.710(a)(2) or is determined to meet an exception under § 512.710(c), the ASM participant is not: (1) subject to ASM performance assessment under § 512.715, (2) required to submit data under § 512.720, (3) subject to final scoring under § 512.745, and (4) eligible for the waivers available under the model described at § 512.775 (90 FR 49572, 90 FR 49583).

When we finalized these policies in the CY 2026 PFS final rule, we did not address how a period of ineligibility or excepted status affects the availability of the CMS-sponsored model arrangements and patient incentive safe harbor (§ 1001.952(ii)), as made available for ASM under § 512.765.

We proposed that the CMS-sponsored model arrangements and patient incentives safe harbor would be available only for remuneration attributable to periods during which an ASM participant is performing under the model. Conversely, the CMS-sponsored model arrangements and patient incentives safe harbor would not be available for remuneration attributable to a period during which an ASM participant is not performing under the model due to not meeting ASM participant eligibility criteria as described at § 512.710(a)(2) or a determination that an exception applies under § 512.710(c)

We proposed to add § 512.765(c) to provide that the CMS-sponsored model arrangements and patient incentives safe harbor is available only with respect to remuneration attributable to a period during which the ASM participant is performing under the model. We further proposed to specify that the safe harbor is not available with respect to remuneration attributable to any period of the ASM test period during which the ASM participant does not meet the ASM participant eligibility criteria as specified in § 512.710(a)(2) or is excepted from specified ASM requirements under § 512.710(c).

We sought comment on this proposal.

Comment: Several commenters requested clarification regarding the applicability of the fraud and abuse safe harbors when ASM participants become ineligible for, are excepted from specified ASM requirements, or exit the model.

Response: We appreciate the commenters' requests for clarification. The CMS-sponsored model arrangements and patient incentives safe harbor, as applied to ASM under § 512.765, is available only with respect to remuneration attributable to a period during which an ASM participant is performing under the model.

Eligibility under § 512.710(a)(2) is determined on an annual ASM performance year basis. Therefore, if CMS determines that an ASM participant does not meet the eligibility criteria for a particular ASM performance year, the safe harbor would not be available to protect remuneration attributable to that ASM performance year.

An exception under § 512.710(c), by contrast, may become effective during an ASM performance year. Under § 512.710(c), we determine whether an exception applies, provide notice to the ASM participant, and specify the effective date of the exception in the notice. In response to requests for clarification, we are finalizing § 512.765(c) with modification to more precisely describe the period for which the safe harbor is unavailable and to align this provision with the exception provisions at § 512.710(c). Specifically, we are clarifying the safe harbor is unavailable for remuneration attributable to the period beginning on the date specified in the exception notice, which is described in § 512.710(c)(2)(iv). This modification retains our original intent that the safe harbor would not be available during the period an exception applies but provides greater certainty around when that period begins by tying that date to the date specified in an exception notice. An exception does not affect the availability of the safe harbor for remuneration attributable to a period before the date specified in an exception notice, provided all requirements for the safe harbor are met.

''Remuneration attributable to'' refers to the period in which the underlying model activities occurred, rather than the date on which remuneration is exchanged. As we explained in the CY 2027 PFS proposed rule (91 FR 43992), remuneration related to model performance in one period may be exchanged in a subsequent period. Any such exchange must still satisfy all applicable safe harbor conditions.

Comment: A few commenters recommended alternatives to our proposal regarding the periods during which the safe harbor would be available under ASM. For example, commenters recommended establishing a ''wind-down period'' or making the

safe harbor available for the duration of the ASM test period regardless of whether an ASM participant remains eligible for, or subject to the requirements of, the model. One commenter stated that conditioning safe harbor availability on an ASM participant's eligibility is inconsistent with ASM's goal of improving care for patients with chronic conditions and could adversely affect patients and physicians. Specifically, the commenter expressed concern that annual fluctuations in attributed patient counts around the 20-patient threshold could cause ASM participants to lose safe harbor protection and discontinue in-kind patient engagement incentives or arrangements supporting primary care practices, even when they continue treating the same patients. The commenter stated that an ASM participant who furnished an item or service to a beneficiary during an ASM performance year in which the ASM participant met the eligibility criteria could be required to withdraw the item or service in a later year if the ASM participant subsequently became ineligible.

Response: We appreciate the commenters' feedback. We disagree that the safe harbor should remain available for the duration of the ASM test period regardless of whether an ASM participant remains eligible for the model or is subject to an exception from specified ASM requirements. We continue to believe that limiting the safe harbor under § 512.765 to remuneration attributable to periods during which an ASM participant is performing under the model appropriately balances program integrity and beneficiary protections with the need to provide ASM participants flexibility to furnish or exchange remuneration that supports beneficiary and primary care engagement consistent with the purposes and requirements of the model.

We also disagree with the characterization that our proposal would require an ASM participant to retrieve an item or service already furnished to an ASM beneficiary as a patient incentive under § 512.770 solely because the ASM participant subsequently becomes ineligible for the model or is subject to an exception under § 512.710(c). Neither § 512.765 nor § 512.770 requires an ASM participant to retrieve an item or service that was furnished in accordance with § 512.770 solely because of a subsequent change in the ASM participant's eligibility or exception status.

Comment: A commenter expressed concern that termination of an ASM participant from the model could have significant consequences for ongoing remuneration and for model-related safe harbor and waiver protections, including potential retroactive liability for conduct undertaken in reliance on those protections.

Response: The CMS-sponsored model arrangements and patient incentives safe harbor would not be available to a clinician who is terminated from ASM because that clinician is no longer an ASM participant after they are terminated. Under § 512.765, the CMS-sponsored model arrangements and patient incentives safe harbor is available only for remuneration furnished in accordance with the collaborative care arrangements that meet all safe harbor requirements set forth in §§ 1001.952(ii) and 512.771 or in the form of ASM beneficiary engagement incentives that meet all safe harbor requirements set forth in §§ 1001.952(ii) and 512.770. Termination does not, by itself, retroactively remove safe harbor protection for remuneration exchanged or furnished before the effective date of termination that otherwise satisfies all applicable requirements.

We are finalizing our proposal at § 512.765(c) with modification. Under our final policy, the safe harbor at § 512.765 will not be available with respect to remuneration attributable to: (1) any ASM performance year for which we determine that the ASM participant does not meet the ASM participant eligibility criteria under § 512.710(a)(2); or (2) in the case of an exception under § 512.710(c)(1), to the period described in § 512.710(c)(2)(iv).

i. Collaborative Care Arrangements (CCAs)

(1) Background

The improvement activities ASM performance category is intended to advance core goals of ASM to drive better outcomes through improved care coordination, increased collaboration between specialists and primary care practices, and interventions that address upstream drivers of health.

We finalized two improvement activities for ASM in the CY 2026 PFS final rule at § 512.735 that we believe best support these aims:

- Improvement Activity 1 (IA–1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening; and
- Improvement Activity 2 (IA–2): Establishing Communication and Collaboration Expectations with Primary Care using CCAs (90 FR 49648 through 49655).

To receive the maximum score available for the improvement activities ASM performance category, an ASM participant must attest ''yes'' to both improvement activities.

IA–2 specifications require an ASM participant to enter into at least one collaborative care arrangement (CCA) with a primary care practice with which the ASM participant shares a patient who is an ASM beneficiary. IA–2 also requires that a CCA address at least three of the five elements specified at § 512.735(c)(2)(ii): data sharing, co-management, transitions in care planning, closed-loop communication, and care coordination integration.

In addition to IA–2 specifications at § 512.735(c)(2)(ii), we outline requirements for CCAs at § 512.771. The function of the CCA is to memorialize the coordination activities central to ASM and described in IA–2.

We proposed certain updates to the CCA provisions at § 512.771 to improve implementation by ASM participants and primary care practices and to more closely align CCA conditions with IA–2 by revising § 512.771(a) and adding new paragraph § 512.771(d). In summary, proposed changes to § 512.771 included:

- Permitting one or more ASM participants to enter into a CCA with the same primary care practice, provided each ASM participant reassigns billing rights through the same entity's TIN and are named as parties to the CCA;
- Clarifying the requirement that an ASM participant and a primary care practice share a patient who is an ASM beneficiary and how this requirement applies in the context of the limitation on considering the volume or value of referrals;
- Streamlining the provision containing an illustrative list of authorities with which parties to a CCA must comply to simplify it, improve clarity, and reduce ambiguity;
- Updating the provisions that currently reference any elective exchange of payments between CCA parties to instead refer to the elective exchange of remuneration, to reflect a broader scope of value that may be exchanged under a CCA;
- Reorganizing regulatory requirements under § 512.771(a) that are associated only with the exchange of any elective remuneration under a CCA such that they appear together under a new paragraph at § 512.771(d) to bring greater clarity and to distinguish between those requirements that apply to all CCAs and those that apply only to CCAs that electively include the exchange remuneration;

- Revising the payment limitation that caps the exchange of remuneration based on an ASM participant's performance adjustment such that it can be more readily calculated in a timely manner and requiring that parties that elect to exchange remuneration before the limitation can be calculated reconcile any amounts that exceed the limitation following reconciliation;
- Clarifying that current requirements relating to traceability will continue to apply to monetary remuneration;
- Updating the contemporaneous documentation requirements to reflect any remuneration exchanged and adding requirements to bring transparency into the methodologies used to determine the value of such remuneration; and
- Relocating the conditions associated with remuneration at current §§ 512.771(a)(7) and 512.771(a)(8) to new paragraphs §§ 512.771(d)(2) and 512.771(d)(3), respectively, in accordance with our proposal to address requirements associated with CCAs that include an exchange of remuneration together under one paragraph. To conform with this relocation, we would redesignate existing sections §§ 512.771(a)(9) through 512.771(a)(13) to §§ 512.771(a)(7) through 512.771(a)(11). We would revise newly redesignated § 512.771(a)(7) (former § 512.771(a)(9)) to reference ''[a]ll parties'' rather than ''[b]oth parties'' and revise newly redesignated § 512.771(a)(9) (former § 512.771(a)(11)) to update documentation requirements as described, but otherwise would not revise text at newly redesignated § 512.771(a)(8) (former § 512.771(a)(10)), § 512.771(a)(10) (former § 512.771(a)(12)), or § 512.771(a)(11) (former § 512.771(a)(13)).

(2) Parties to a CCA

In the CY 2026 PFS final rule, we finalized at § 512.771(a)(1) a requirement that a CCA be in writing, signed by both parties, and contain the effective date of the arrangement. We also finalized at § 512.771(a)(2) a requirement that a CCA be exclusively between an ASM participant and a primary care practice with which the ASM participant shares at least one established patient who is an ASM beneficiary. At that time, we considered, but declined to permit, multiple ASM participants reassigning billing rights through the same TIN to be parties to a single CCA with a primary care practice party, citing concerns around the ability of ASM participants to accurately track any remuneration exchanged under a multi-ASM participant arrangement (90 FR 49712).

Following publication of the CY 2026 PFS final rule, we received interested party feedback anticipating significant burden associated with establishing separate CCAs for each individual ASM participant when more than one ASM participant is in the same group practice and such ASM participants wish to collaborate with the same primary care practice. As an example, 20 ASM participants operate within a single health system and reassign their billing rights to that system's TIN. Even if such ASM participants coordinate care regularly with the same primary care practice and wish to establish a CCA with the same primary care practice, the current regulation would require negotiation, execution, documentation, and tracking of 20 separate CCAs.

We believe that requiring a separate CCA for each ASM participant could impose administrative burden without a corresponding programmatic benefit. We now believe that concerns related to tracking remuneration under CCAs involving multiple ASM participants could be addressed through more targeted safeguards that apply to CCAs that elect to include remuneration, rather than a broader restriction applicable to all CCAs, including those that do not involve any exchange of remuneration.

Accordingly, we proposed to amend §§ 512.771(a)(1) and 512.771(a)(2) to permit one or more ASM participants to be parties to the same CCA, provided that each ASM participant be named as a party to the CCA and all ASM participants reassign billing rights to the same TIN. We would maintain the existing requirements at § 512.771(a)(1) that the CCA be in writing and specify an effective date; we would also maintain the requirement that a CCA be signed by the parties but proposed to amend regulatory text to stipulate CCA execution would be required for ''all'' parties rather than ''both'' parties.

We believed restricting a multi-ASM participant CCA to ASM participants within the same TIN is appropriate as clinicians who practice under the same group practice are more likely to be supported by shared operations, such as shared EHR systems, clinical support staff, and standardized administrative workflows. Accordingly, we believe terms of a CCA could be standardized across ASM participants within the same organization (that is, TIN) without compromising the level of detail needed to support meaningful care coordination. In contrast, ASM participants from separate, unaffiliated TINs may have distinct infrastructure, care coordination needs, support structures, and operational workflows. It is therefore unclear how a single arrangement could establish cohesive terms regarding shared responsibilities with a primary care partner in a manner consistent with the intent of CCAs. We are concerned that attempting to encompass these different capabilities and variable workflows within a single agreement could result in vague, overly broad, or highly fragmented contractual terms, which could undermine the intent of the CCA.

Our proposal to permit one or more ASM participants billing under the same TIN to join the same CCA with a primary care practice does not alter ASM's fundamental accountability framework. As noted, we proposed to clarify that any ASM participant seeking to join and rely on one CCA be expressly named as a party to the arrangement. We believe such requirement maintains individual ASM participant accountability, while reducing administrative burden. We did not propose to permit a group practice or TIN to serve as a sole contracting party on behalf of unnamed ASM participants, as this could obfuscate individual ASM participant accountability and introduce operational complexity, particularly when an ASM participant departs a group practice during an ASM performance year. Requiring each ASM participant to be named as a party would mitigate such concerns while still reducing contracting burden.

We clarified in the proposed rule that we did not intend to establish and did not propose prescriptive requirements around the meaning of a ''primary care practice'' that must be a party to a CCA. Our intent is that a CCA reflects coordination between the ASM participant and their ASM beneficiary's source of primary care services. We refer readers to discussion in response to interested party questions in the CY 2026 PFS final rule for further information (90 FR 49653).

Our proposal intended to reduce burden for ASM participants who practice within the same group and coordinate care with the same primary care practice. It does not intend to discourage individual CCAs. ASM participants who belong to the same group may continue to enter into separate CCAs and should consider a separate arrangement when doing so better reflects individual clinical relationships, sources of primary care for their individual ASM beneficiary panel, and care coordination needs.

We sought comment on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposal to permit one or more ASM participants reassigning billing rights through the same TIN to be parties to the same CCA with a primary care practice. Commenters stated that requiring separate CCAs for each ASM participant would impose unnecessary administrative burden on both ASM participants and primary care practices. Commenters representing integrated health systems stated that a single CCA would better reflect practice operations where clinicians share EHR systems, clinical support staff, and administrative infrastructure. A commenter stated that requiring a primary care practice to sign multiple duplicative agreements could make such practices less willing to assent to further agreements.

Response: We appreciate commenters' support. We agree that permitting ASM participants who reassign billing rights through the same TIN to enter into a single CCA with the same primary care practice would help reduce duplicative negotiation, execution, documentation, and tracking and better reflect shared operations. At the same time, requiring each ASM participant to be expressly named as a party to the CCA preserves individual accountability for satisfying applicable ASM requirements. We believe this approach appropriately balances administrative flexibility with the accountability and oversight objectives of the CCA requirements.

Comment: A few commenters recommended that CMS not limit multi-participant CCAs to ASM participants under one TIN. A commenter stated that such limitation would prevent solo practitioners or small practices from entering into a common CCA with a primary care practice. A commenter described that a single agreement could facilitate collaboration and reduce contracting burden and noted that independent practices may already contract collectively through arrangements such as independent practice associations. A commenter stated that ASM participants may practice within the same health system but reassign billing rights through different affiliated TINs and recommended that CMS permit such ASM participants to enter into a common CCA where they can demonstrate shared EHR infrastructure, unified workflows, and consolidated data governance.

Response: We appreciate commenters' consideration of varying organizational structures, including solo practitioners and small practices and integrated systems with multiple TINs but shared systems. We continue to believe that the TIN establishes the most appropriate boundary for a multi-participant CCA.

As we stated in the proposed rule, ASM participants practicing under the same TIN are more likely to share operational infrastructure, including EHR systems, clinical support staff, and standardized administrative workflows, such that a common set of CCA terms can meaningfully apply to each ASM participant. We recognize that some integrated delivery systems operating across multiple TINs may have comparable levels of operational integration. However, the degree and nature of integration across such systems may vary, and the existence of shared clinical or administrative systems across TINs would not, by itself, provide a similarly clear and readily administrable basis for determining which ASM participants should be permitted to participate under a common CCA.

We also distinguish such integrated delivery systems from independent practice associations and other joint-contracting arrangements. The existence of a contractual mechanism through which otherwise independent practices negotiate or contract collectively does not necessarily demonstrate that ASM participants share the operational infrastructure, workflows, or care-coordination processes necessary to support a common CCA. Accordingly, we do not believe that participation in an independent practice association or other joint-contracting arrangement, by itself, provides a sufficient basis to extend the multi-participant CCA policy across TINs. We may address ways to alleviate burden associated with CCAs for solo practitioners or small practices as appropriate based on experiences under the model, such as through additional resources or in future rulemaking.

Comment: A few commenters observed that CMS proposed to permit multi-participant CCAs while enforcing strict remuneration limits and restricting safe harbor applicability during exception periods. A commenter recommended that CMS tailor safe harbors for integrated delivery networks to allow alignment between employed primary care, hospital facilities, and specialists.

Response: We note that, as revised, the limitation on remuneration under a CCA is structured to account for and scale with the number of ASM participants joining a CCA. We proposed such revision to account for the proposed change allowing multi-participant CCAs.

We clarify that the applicability of the CMS-sponsored model arrangements and patient incentives safe harbor to ASM as described at § 512.765 is tailored to ASM since it was made available for purposes of ASM, rather than specifically to an integrated delivery system.

Comment: Commenters suggested that ASM participants or primary care practices may already participate in accountable care models, such as accountable care organizations (ACOs) and that such existing collaborations or shared infrastructures should count toward meeting CCA requirements. A commenter noted that the requirement for a formal contractual arrangement between ASM participants and primary care providers may impose burden without clear evidence of care improvement. Another commenter noted that requiring a new written arrangement where effective collaboration is already documented and operating adds paperwork without a demonstrated clinical gain. The commenter further asked CMS to publish model arrangement templates and operational guidance well in advance of the model start date, so that participants have time to evaluate requirements, build the workflows, execute the arrangements and train staff before performance is measured.

Response: We continue to believe that CCAs will drive meaningful collaboration by facilitating conversation and agreement among primary care and specialists on responsibilities for managing shared patient's care. Organizations that have existing pathways between ASM participants and primary care practices that facilitate those activities envisioned by IA–2 and CCAs can leverage those existing structures when meeting ASM requirements.

We appreciate requests for resources to assist with preparations for ASM, including CCAs, and note that we have published resources on our website to assist ASM participants with preparing for improvement activity requirements, including CCAs. We will continue to engage with ASM participants to learn what additional resources and information is needed to support them.

Comment: A commenter recommended that authorized leadership within a practice be permitted to execute a CCA on behalf of the respective parties, for example, cardiology leadership and primary care leadership—rather than requiring each individual ASM participant's signature. The commenter stated this flexibility would be particularly beneficial for large practices and organizations with 100 or more participating providers.

Response: We appreciate the commenter's concern regarding the burden associated with executing a CCA that includes multiple ASM participants. The purpose of the signature and party requirements under § 512.771 is to ensure that each ASM participant relying on the CCA is expressly identified as a party, is bound by the arrangement, and remains accountable for the applicable requirements thereunder. We do not intend to prescribe the internal process by which a party determines who has authority to execute an agreement on its behalf, provided the CCA is executed in accordance with applicable law and each ASM participant relying on the CCA is expressly named as a party and bound by its terms.

Comment: Several commenters recommended that CMS eliminate ASM improvement activities, eliminate CCAs, or continue to substantially simplify CCAs to reduce compliance and documentation burden. Commenters expressed concern that requiring a formal contractual arrangement between ASM participants and primary care providers could discourage collaboration, particularly where care coordination structures are already in place. Several commenters recommended CMS minimize overlapping requirements, such as for practices that already participate in programs such as the Medicare Shared Savings Program, in an integrated health system, or in an advanced APM by excepting from IA–2 requirements any ASM participants who demonstrate that they have existing coordination structures with primary care. A commenter suggested it is impractical to have detailed formal arrangements with multiple practices when as few as one patient is shared between each practice. The commenter further expressed that there is no requirement on primary care practices to join a CCA and anticipated this would create difficulty for specialists to convince primary care partners to engage in a CCA, recommending that CMS eliminate the CCA requirement and allow specialists to determine the best way to engage with primary care practices in the communities they serve.

Response: We appreciate commenters' concerns and recognize that some ASM participants may already have established mechanisms to coordinate with primary care practices. Where an ASM participant and a primary care practice have established care coordination infrastructure, those efforts may support meeting the requirements of the CCA. However, the existence of an affiliation or an informal collaboration would not, by itself, satisfy ASM performance requirements. As specified in § 512.771, a CCA must meet certain conditions, including that it be in writing, identify the parties, involve at least one shared patient who is an ASM beneficiary, and address at least three of the five collaborative elements specified at § 512.735(c)(2)(ii). We do not believe it would be appropriate to except an ASM participant from IA–2 or the associated CCA requirement based solely on affiliation status or on participation in another program or model. We continue to believe that requiring a CCA provides an important opportunity for specialists and primary care practices to formalize expectations regarding co-management, care coordination, data sharing, transitions in care planning, and infrastructure support for shared patients.

We emphasize that, although we encourage ASM participants to enter into multiple CCAs where doing so would support care coordination for a broader population of ASM beneficiaries, IA–2 requires only one CCA. An ASM participant therefore is not required to establish a CCA with every primary care practice with which they share a patient. Accordingly, we do not agree with the commenter's characterization that IA–2 necessarily requires detailed formal arrangements with every such practice.

We also appreciate the concern that primary care practices are not independently required to enter into a CCA. ASM is designed to include specialists as ASM participants, not primary care practices. We believe that primary care practices will be interested in efforts to address gaps in care for their patients and in collaborating with specialists for this purpose.

Comment: A commenter recommended that CMS establish a 90-day grace period from January 1, 2027 through March 31, 2027, during which an ASM participant would not receive a reduction to the improvement activities ASM performance category score for not having a CCA in place. The commenter stated that such a period would provide additional time to establish a CCA with primary care, EHR workflows, and data-sharing infrastructure.

Response: We appreciate the commenter's consideration of the steps that may be necessary to operationalize a CCA. However, we do not believe a separate 90-day grace period is necessary. Under § 512.735(a), the performance period for the improvement activities ASM performance category is a minimum of 90 continuous days within the applicable calendar year. Thus, an ASM participant is not required to have a CCA in place by January 1, 2027, or even by March 31, 2027. Rather, the ASM participant may use time during CY 2027 to establish the necessary workflows, data-sharing processes, and written CCA and still complete the required continuous 90-day performance period for improvement activities for the 2027 ASM performance year.

Comment: Several commenters supported CMS' refinements to CCA regulations at § 512.771 ahead of the model launch, stating that expanded CCA flexibilities would help make the model more administrable.

Response: We appreciate the commenters' support and agree that revisions will improve operationalizing CCAs.

After consideration of the comments, we are finalizing our policy at § 512.771(a)(1) and § 512.771(a)(2) to permit more than one ASM participant billing under the same TIN to join a common CCA, provided each ASM participant is named as a party to the CCA, with minor modifications to the regulatory text. We make a textual modifications to § 512.771(a)(1) from the proposed regulatory text to specify that the CCA must be exclusively between an ASM participant, or one or more ASM participants who reassign billing rights through the same TIN, and a primary care practice. We are modifying the final regulatory text at § 512.771(a)(2) to state that a primary care practice party must share one or more patients who are ASM beneficiaries with at least one ASM participant party to the collaborative care arrangement. This retains the substance of the proposal while making clear a CCA may be with one ASM participant regardless of whether that clinician reassigns billing rights.

(3) Requirement That CCA Parties Share a Patient Who Is an ASM Beneficiary

Sections 512.735(c)(2)(i) and 512.771(a)(2) require that parties to a CCA share a patient who is an ASM beneficiary. In the proposed rule, we proposed to retain the requirement at § 512.771(a)(2) that an ASM participant party or parties and the primary care practice party share at least one patient who is an ASM beneficiary. Under the proposal, this requirement would be satisfied if at least one that an ASM participant party or ASM participant parties and the primary care practice share a patient who is an ASM beneficiary would be satisfied so long as at least one shared patient who is ASM

beneficiary exists between any one ASM participant party to the CCA and the primary care practice party, regardless of the total number of ASM participants who are parties to that CCA.

The purpose of requiring the parties to share ''one or more'' patients who are ASM beneficiaries is to ensure a clear nexus exists between the CCA and coordination activities undertaken on behalf of shared ASM beneficiaries. In the absence of any shared ASM beneficiaries, there would be no common patient population with respect to which the parties could coordinate care consistent with the purpose of the CCA.

We also proposed to remove the term ''established'' from § 512.771(a)(2). Current § 512.771(a)(2) provides that, for purposes of satisfying the shared ASM beneficiary requirement, the ASM beneficiary must be an ''established'' patient. By contrast, the IA–2 specifications at § 512.735(c)(2)(i) do not include an ''established'' patient requirement. Upon further review, we concluded that the ''established'' qualifier is unnecessary and creates an inconsistency between § 512.771(a)(2) and the IA–2 specifications. We therefore proposed to remove the term ''established'' from § 512.771(a)(2) to align the CCA requirement with § 512.735(c)(2)(i).

Comment: A commenter supported the proposal to require the ASM participant or ASM participants and the primary care practice who are parties to the CCA share at least one patient who is an ASM beneficiary, agreeing that shared patients encourage collaboration and should be an expectation of the CCA. The commenter also agreed with the proposal to remove the term ''established.''

Response: We appreciate the support and agree that a shared patient relationship is fundamental to the purpose of a CCA.

We are finalizing our proposal at § 512.771(a)(2) that the primary care practice party share at least one patient who is an ASM beneficiary with at least one ASM participant party to the CCA, and finalizing the removal of the term ''established'' from § 512.771(a)(2) to conform with the IA–2 specifications at § 512.735(c)(2)(i).

(4) Requirement To Comply With Applicable Laws

We finalized in the CY 2026 PFS final rule at § 512.771(a)(5) that both parties to a CCA must comply with all applicable statutes, regulations, and guidance, including without limitation: Federal criminal laws; the False Claims Act (31 U.S.C. 3729 *et seq.*); the anti-kickback statute (42 U.S.C 1320a-7b(b)); the civil monetary penalties law (42 U.S.C. 1320a-7a); and the physician self-referral law (42 U.S.C. 1395nn).

We proposed to remove the illustrative list of legal authorities from § 512.771(a)(5) while retaining the requirement that parties to a CCA comply with all applicable statutes, regulations, and guidance (91 FR 43994). We invited comment on this proposal.

We did not receive public comments on this provision and therefore are finalizing without modification our changes to § 512.771(a)(5), which remove the illustrative list of legal authorities while retaining the requirement that all parties comply with applicable statutes, regulations, and guidance, and replacing ''[b]oth'' with ''[a]ll'' parties, as proposed.

(5) Restriction on Conditioning Remuneration on Referrals

In the CY 2026 PFS final rule, we established that neither the opportunity to enter a CCA nor the amount of any payment under a CCA may be conditioned, directly or indirectly, on the volume or value of past or anticipated referrals or business generated by, between, or among the parties to the arrangement or any other person (90 FR 49711). Separately, § 512.771(a)(2) requires that an ASM participant and a primary care practice party to a CCA share at least one patient who is an ASM beneficiary.

After review of our regulations, we became concerned that the current language at § 512.771(a)(6), when read together with the shared-beneficiary requirement at § 512.771(a)(2), could be interpreted to unnecessarily constrain the formation of the CCAs. The existence of shared ASM beneficiaries may reflect existing care relationships between ASM participants and primary care practices. As a result, § 512.771(a)(6) could be read to preclude prospective CCA parties from considering the existence of the very beneficiary-sharing relationship required under § 512.771(a)(2). We did not intend for this prohibition on conditioning entry into a CCA on referrals or business generated to prevent parties from considering whether they satisfy the shared-beneficiary requirement that is itself a requirement to CCAs.

Accordingly, we proposed to revise § 512.771(a)(6) to clarify that an ASM participant may consider, as a criterion for entering into a CCA, whether the ASM participant and a primary care practice share at least one patient who is an ASM beneficiary, provided that consideration of the shared-beneficiary relationship is for purposes of furthering the care coordination objectives of the CCA. Under the proposed revision, consideration of the existence of such a shared-beneficiary relationship would not, by itself, constitute conditioning the opportunity to enter into a CCA on the volume or value of referrals or other business generated.

We sought comment on this proposal and targeted revision intending to permit parties to consider whether they share one or more ASM beneficiaries for purposes of satisfying the shared-beneficiary requirement at § 512.771(a)(2) and furthering the purpose of the CCA. We also invited comment on whether our proposed approach is sufficiently clear and appropriately accommodates the operational realities of how practices contemplate establishing CCAs.

We received public comment on this proposal. The following is a summary of comments received and our responses.

Comment: A commenter agreed with the proposal that potential remuneration under a CCA should not be dependent on referral patterns or the generation of business based on referrals.

Response: We appreciate the commenter's agreement with our proposal.

After consideration of public comment, we are finalizing our proposed changes to § 512.771(a)(6) as proposed, which permits prospective parties to consider whether they share at least one patient who is an ASM beneficiary for purposes of furthering the care-coordination objectives of the CCA, while preserving the prohibition on conditioning participation or remuneration on the volume or value of past or anticipated referrals or other business generated.

(6) CCAs That Include the Exchange of Remuneration

In the CY 2026 PFS final rule, we stated our intent to allow ASM participants and their primary care partners to negotiate arrangements that are best suited to their practices (90 FR 49712). We also recognized that parties to a CCA may wish to include model-related incentives under a CCA to support shared accountability for the outcomes of ASM beneficiaries and to support coordination activities that benefit shared patients (90 FR 49713). Accordingly, we made the CMS-sponsored model arrangements safe harbor at § 1001.952(ii)(1) available under ASM at § 512.765 to protect remuneration exchanged under a CCA, provided that all requirements of the safe harbor at § 1001.952(ii)(1) and CCA

regulations at § 512.771 are met (90 FR 49713).

As stated in the proposed rule, we believe that provisions of § 512.771 that refer to payments exchanged under a CCA should be revised to apply more broadly to remuneration exchanged under a CCA to the extent applicable. Applying these provisions to remuneration would better align § 512.771 with § 512.765 and the CMS-sponsored model arrangements safe harbor at § 1001.952(ii)(1), both of which address remuneration. It would also more accurately reflect the full range of value that parties may exchange under a CCA, including monetary payments and in-kind items or services that support care coordination and other model-related activities.

Accordingly, we proposed to revise § 512.771 such that applicable provisions referencing payment instead reflect and apply more broadly to remuneration exchanged under a CCA. We believed this proposed modification would clarify that safe harbor protections, as well as requirements, apply to both monetary and in-kind remuneration exchanged under a CCA. We emphasized in the proposed rule that remuneration is not a required element of a CCA. Rather, parties to a CCAs may elect to include monetary or in-kind incentives that promote improvement activities or the goals of the model, provided that all applicable requirements are met (90 FR 49654). In-kind remuneration, such as shared data analytics platforms, care managers, or technology infrastructure could support the type of care coordination envisioned by ASM.

We also proposed to add new paragraph § 512.771(d) to introduce the additional requirements that apply when parties to a CCA elect to exchange remuneration. We would relocate conditions applicable to CCAs that elect to include remuneration such that they appear together under new paragraph § 512.771(d). We believe this construction would more clearly distinguish the regulatory requirements that apply to all CCAs from the additional conditions that apply when remuneration is exchanged under a CCA.

We received public comments on these proposals.

Comment: A few commenters stated that CMS appeared to be expanding application of the requirements under § 512.771 to include the broader category of remuneration, rather than just payment and expressed concern specifically in regard to application of the limitation described at § 512.771(d)(2) to in-kind remuneration, rather than just payment.

Response: We appreciate these comments and address these concerns in the section discussing § 512.771(d)(2), given that the expressed concerns are more closely associated with that specific provision rather than with the proposed change to expand the scope of the protections under the safe harbor more broadly.

After consideration of public comment, we are finalizing without modification the proposed changes to § 512.771, which revise references from ''payment'' to instead apply to ''remuneration'' as applicable. We are also finalizing our proposal to reorganize § 512.771 such that provisions applying to all CCAs are addressed together, and provisions that apply only to remunerative CCAs are addressed under § 512.771(d).

(a) Requirement for Remuneration To Reasonably Relate To CCA Purpose

In the CY 2026 PFS final rule, we finalized at § 512.771(a)(3) that a CCA must be entered into for the purpose of either furthering the ASM participant's performance in the improvement activities ASM performance category or furthering the clinical goals of the model as described by § 512.771(b) (90 FR 49712 through 49714).

We proposed to require at new § 512.771(d)(1) that any remuneration exchanged by the parties to a CCA be reasonably related to the purpose of the CCA, as defined in § 512.771(a)(3). We believed that aligning the purpose of any exchange of remuneration with the purpose of the CCA would support bona fide care coordination incentives while protecting program integrity.

We sought comment on our proposal at § 512.771(d)(1) to require that any remuneration exchanged under a CCA be reasonably related to the purpose of the arrangement, consistent with § 512.771(a)(3).

We did not receive public comment on the proposal at § 512.771(d)(1) to require that any remuneration exchanged under a CCA be reasonably related to the purpose of the arrangement as defined in § 512.771(a)(3) and therefore are finalizing it as proposed.

(b) Limitation on Remuneration

In the CY 2026 PFS final rule (90 FR 49712 through 49714), we finalized a limitation to the amount of any payments exchanged under a CCA at § 512.771(a)(7). Specifically, we finalized a requirement that any payment exchanged under a CCA must not exceed the sum total of the payment adjustments made to an ASM participant's claims for a given ASM payment year, which would be calculated based on the of application of the ASM payment adjustment factor to the ASM participant's payments for Medicare Part B covered professional services during the corresponding ASM payment year.

Our intent was to ensure that any financial or in-kind exchanges between CCA parties remain appropriately tied to patient outcomes and ASM's clinical goals (90 FR 49712).

We stated in the proposed rule our belief that the methodology finalized in the CY 2026 PFS final rule may be difficult for parties to operationalize and warrants revision. ASM payment adjustments are applied 2 CYs after the applicable ASM performance year. As a result, the information needed to determine the maximum amount permitted to be exchanged may not be available until well after the close of the applicable ASM performance year. This could create operational difficulty for parties that wish to exchange remuneration during or near the ASM performance year when care coordination activities are occurring.

Accordingly, we proposed updates to modify the temporal period used to calculate this limitation and provide for a reconciliation and repayment process to support compliance with the limitation. Consistent with our organizational update to § 512.771, we proposed to include the revised limitation on remuneration in new § 512.771(d)(2).

We proposed to tie the limitation on remuneration to performance-based payment adjustments made to an ASM participant's payments for Medicare Part B covered professional services using the ASM participant's ASM payment adjustment factor for the applicable ASM performance year, multiplied by the amount otherwise paid to the ASM participant by CMS under Medicare Part B for covered professional services during that ASM performance year. Stated another way, the proposed revision would change the temporal period used to calculate the limitation amount from the ASM payment year to the ASM performance year. Under both the current and proposed methodologies, the operative component is the ASM payment adjustment factor based on performance for the ASM performance year; the proposed revision changes only the temporal period used to calculate the limitation amount.

In accordance with our proposal permitting more than one ASM participant to join the same CCA, we

proposed to clarify that the remuneration limitation under proposed § 512.771(d)(2) would be calculated separately for each ASM participant that is a party to a CCA.

We also proposed additional safeguards to support consistent implementation of this limitation. Specifically, under proposed § 512.771(d)(2)(i), the CCA would be required to specify a methodology for identifying and calculating the total value of remuneration exchanged under the arrangement for the ASM performance year and determine whether the total value exceeds the applicable limitation. To the extent that remuneration is in-kind, we proposed at § 512.771(d)(2)(ii) that the valuation of such remuneration would be based on the offeror's costs using any reasonable accounting methodology, or the fair market value of the in-kind item or service. We believed this would support ASM participants that elect to exchange in-kind remuneration in ensuring such exchange complies with our regulations. Under proposed § 512.771(d)(2)(iii), the arrangement would be required to provide for reconciliation, if applicable, after the limitation is determined. Under proposed § 512.771(d)(2)(iv), if the total value of remuneration exchanged under the arrangement for the ASM performance year exceeds the limitation, the party that received the excess amount would be required to repay that excess amount to the other party within a reasonable time. We believed these provisions would promote consistent administration, clarify compliance requirements, and facilitate CMS oversight. We anticipated that these revisions to the remuneration limitation would establish a more viable pathway for parties to exchange remuneration during or close to the applicable ASM performance year by offering greater regulatory certainty that, should those exchanges exceed the final limitation, there would be a defined mechanism to reconcile the difference later.

We also recognized the inherent complexity with a limitation based on a mathematical formula as described in proposed § 512.771(d)(2) in the context of in-kind remuneration. Valuing in-kind remuneration to ensure it does not exceed the calculated threshold, and 'repaying' excess in-kind value during the reconciliation process, may present operational difficulties that could impede good faith exchanges of in-kind items or services intended to support the purpose of the CCA. We considered but did not propose an alternative where the limitation in proposed § 512.771(d)(2) would apply only to monetary payments (or cash equivalents) exchanged under a CCA. Under such alternative, we would establish a separate limitation for in-kind remuneration, such as requiring that any in-kind items or services exchanged meet a fair market value and commercial reasonableness standard rather than a limitation based on a dollar amount. While a separate safeguard tailored to in-kind remuneration could ease operational burden for ASM participants and their primary care partners, we believe that having one mathematical formula for valuing any remuneration exchanged under a CCA would be simpler for parties to CCAs to implement and therefore did not propose this approach.

We sought comment on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed applying the existing payment limitation more broadly to all remuneration exchanged under a CCA. A commenter stated that extending the limitation to in-kind support could make arrangements involving resources such as care managers difficult to operationalize, particularly where an ASM participant receives a negative payment adjustment and could effectively require a primary care practice to compensate an ASM participant for the value of in-kind support, noting that it appeared CMS was expanding the scope of the limitation in the proposed rule. Furthermore, another commenter expressed concern that this limitation would require practices to value and document in-kind arrangements that may lack published market-pricing benchmarks, making valuation complex and potentially contentious. Lastly, commenters recommended that CMS issue sub-regulatory guidance describing acceptable methodologies for valuing in-kind CCA remuneration, eliminate the limitation all together, or establish a fixed dollar threshold

Response: We appreciate the commenters' concerns and questions regarding this proposal. We did not intend to create additional burden or limit bona fide in-kind remuneration exchanged to advance a clinical goal of ASM in a manner that makes the provision of in-kind support impractical. We did not propose to establish a fixed dollar threshold however we may consider this suggestion in the future.

We are finalizing § 512.771(d)(2) as proposed. This provision describes the upper limit of remuneration exchanged under a CCA and describes a reconciliation process if the amount exchanged exceeds the limitation once it can be calculated.

With experience implementing ASM, we may modify the limitation on remunerative CCAs described through future rulemaking if we determine codified limitations present unnecessary and unintended barriers.

(c) Other Requirements for Remuneration Exchanged Under a CCA

We finalized in the CY 2026 PFS final rule that any payment exchanged under a CCA must be solely between the parties and be made by check, electronic funds transfer, or another traceable cash transaction (§ 512.771(a)(8)) (90 FR 49712 through 49714). Consistent with our organizational update to § 512.771, we proposed to include this requirement, with revisions to address remuneration more broadly, in new § 512.771(d)(3).

Specifically, we would require that any remuneration exchanged under a CCA be solely between the parties and that, to the extent the exchange is a monetary payment, payment must be made by check, electronic funds transfer, or other traceable transaction at § 512.771(d)(3).

We sought comment on these proposals.

We did not receive public comments on the proposal to relocate and revise the traceability requirement at new § 512.771(d)(3) and therefore are finalizing changes as proposed.

(d) Documentation Requirements

We finalized a requirement that ASM participants maintain contemporaneous documentation regarding all CCAs, including the relevant agreement and date and amount of payment at § 512.771(a)(11).

We proposed to update documentation requirements to better support ASM participants and their primary care partners in their compliance with applicable regulations and to update references to conform with other changes proposed under § 512.771, including that we proposed to redesignate existing §§ 512.771(a)(11) to 512.771(a)(9).

Specifically, we proposed to revise the documentation requirement at proposed revised § 512.771(a)(9) such that an ASM participant would be required to maintain contemporaneous documentation, in accordance with § 512.135, regarding all CCAs entered into, records of all remuneration exchanged for each ASM participant under a CCA, a description of the

remuneration, the value of the remuneration, the methodology for determining the value of any in-kind remuneration, and the date on which the remuneration was exchanged.

We also proposed to require documentation of the identity of each ASM participant that would be a party to the CCA. We proposed this change to conform with our proposal that a CCA may include more than one ASM participant to promote appropriate recordkeeping regarding the identity of each ASM participant covered by a CCA.

Together, we believed these proposed changes would clarify the minimum documentation that must be maintained by an ASM participant, better support compliance, and reduce ambiguity regarding documentation when a CCA includes multiple ASM participants as parties. These proposed changes would be reflected in proposed revised § 512.771(a)(9), if finalized.

We considered requiring that ASM participants maintain documentation supporting that all ASM participants who join the same CCA reassign their billing rights through the same TIN as a safeguard supporting compliance with our proposal that, if more than one ASM participant joins as a party to a CCA, such ASM participants must all reassign billing rights to the same TIN. We did not propose this approach as we believe we would be able to verify this information based on data already available to us.

We sought comment on these proposed changes.

Comment: Several commenters recommended CMS keep documentation requirements as simple as possible, particularly for arrangements involving multiple ASM participants. One commenter encouraged CMS to recognize existing care-coordination infrastructure and to further simplify documentation and record-retention requirements so that ASM participants can focus resources on clinical collaboration rather than administrative activities of limited incremental value to beneficiaries.

Response: We appreciate commenters' interest in keeping documentation requirements simple. The requirements at revised § 512.771(a)(9) specify the minimum documentation an ASM participant must maintain—contemporaneous documentation of relevant written agreements. This is the primary documentation requirement unless the CCA elects to include remuneration. Where remuneration is exchanged, we proposed to require a record and description of the remuneration, its value, the methodology for valuing any in-kind remuneration, and the date exchanged. We believe these requirements reflect the minimum necessary to support compliance and oversight, particularly where multiple ASM participants are parties to a single CCA. We do not believe these provisions establish overly burdensome documentation requirements and that such records are necessary to support compliance.

Comment: A commenter requested that CMS craft regulations regarding remuneration and documentation requirements with technology-enabled coordination in mind, noting that much of the coordination these arrangements contemplate occurs asynchronously through shared care plans, event notifications, electronic consultation, and shared access to monitoring data. The commenter recommended that documentation expectations be satisfiable through the electronic record rather than through a parallel paper trail.

Response: We appreciate the suggestion and agree with the commenter on the importance of technology-enabled coordination. The documentation requirements at revised § 512.771(a)(9) require an ASM participant to maintain contemporaneous documentation of all CCAs, including the written agreement and specified information regarding remuneration, if included under a CCA. Our regulations do not prescribe the medium in which the documentation must be maintained. ASM participants may satisfy these requirements through appropriate electronic means, including existing electronic health record and data systems, rather than a separate paper record.

After consideration of public comments, we are finalizing our policies at § 512.771(a)(9) as proposed, which make updates to the documentation requirements for remunerative CCAs to include additional elements describing any remuneration, its value, the methodology for valuing any in-kind remuneration, and the date exchanged.

j. Medicare Program Waivers

In the CY 2026 PFS final rule, we finalized at § 512.775 a waiver of MIPS reporting obligations for an ASM participant in each ASM performance year in which the ASM participant meets ASM eligibility criteria at § 512.710(b), except as specified in § 512.710(a)(2). Section 512.710(a)(2) addresses circumstances in which an ASM participant does not meet eligibility requirements for mandatory participation for a given ASM performance year.

We proposed to update § 512.775 to reflect our policy that when an ASM participant is excepted from specified ASM requirements pursuant to § 512.710(c), the MIPS waiver would similarly not apply in ASM performance years in which an exception applies. Specifically, we proposed to update § 512.775(a) to replace the reference to ''§ 512.710(a)(2)'' with ''§ 512.710(a)(2) or § 512.710(c)''. We sought comment on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported CMS' efforts to align ASM regulations with CMS' stated policy. The commenter requested clarification how the MIPS waiver will apply as traditional MIPS sunsets and MVP reporting becomes required in CY 2029, including whether any ASM reporting waiver would extend to MVP reporting obligations.

Response: We appreciate this comment. We do not intend the transition to MIPS Value Pathways (MVPs) to impact the waiver of MIPS performance and associated payment adjustments for purposes of ASM under § 512.775. The transition to MVPs envisions moving MIPS eligible clinicians to MVPs, and thus we do not believe at this time that revisions to our regulatory text are necessary to account for this transition. However, we may revisit the regulatory text in the future if it would add clarification that the waiver's scope applies to MVP reporting, once the transition occurs.

After consideration of the comments, we are finalizing § 512.775 as proposed.

3. Technical Corrections to Provisions of ASM

a. Technical Corrections to ASM Risk Level

We are taking this opportunity to make a technical correction to § 512.750(c)(1)(i) to restore regulatory text at paragraphs (A) through (E) of § 512.750(c)(1)(i) that were erroneously removed from the Code of Federal Regulations (CFR).

On March 12, 2026, we published a correcting amendment in the **Federal Register** (91 FR 12071) titled ''Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; Correction'' (hereinafter, March 2026 Correcting Amendment).

The March 2026 Correcting Amendment was intended to correct typographical and technical errors in the CY 2026 PFS final rule. However, the March 2026 Correcting Amendment contained an erroneous amendatory instruction for § 512.750(c)(1)(i). The instruction was intended to revise only the introductory text of § 512.750(c)(1)(i) but instead inadvertently removed paragraphs (A) through (E) of § 512.750(c)(1)(i) from the CFR. This removal was not intended.

Accordingly, we are restoring § 512.750(c)(1)(i)(A) through (E) through this final rule.

(1) Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect, in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, this notice-and-comment procedure may be waived if the Secretary finds, for good cause, that notice and comment is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of that finding and the reasons therefor in the notice.

We find good cause to waive notice and comment under 5 U.S.C. 553(b)(B) and section 1871(b)(2)(C) of the Act to restore paragraphs (A) through (E) of § 512.750(c)(1)(i). Notice and comment is unnecessary because the regulatory text we are restoring was previously proposed, subject to public comment (90 FR 32609), and finalized in the CY 2026 PFS final rule (90 FR 49688). The March 2026 Correcting Amendment did not intend to remove or substantively modify § 512.750(c)(1)(i)(A) through (E), and such revision was not discussed nor described in the preamble of that document.

We also find good cause to waive the 30-day delay in effective date under 5 U.S.C. 553(d)(3) and section 1871(e)(1)(B)(ii) of the Act because application of a delay would be impracticable Delaying restoration of the regulatory text at § 512.750(c)(1)(i)(A) through (E) would unnecessarily prolong a discrepancy between the CFR and our policy previously finalized through notice-and-comment rulemaking under the CY 2026 PFS and could result in confusion among the public and affected parties.

Accordingly, this final rule restores paragraphs (A) through (E) of § 512.750(c)(1)(i) as finalized in the CY 2026 PFS final rule.

b. Technical Correction to Small Practice Definition

We are also making a correction to the definition of ''small practice'' at § 512.705 such that a small practice means ''a TIN consisting of 15 or fewer clinicians at the time CMS identifies ASM participants for an ASM performance year as described at § 512.710(g)''. The definition at § 512.705 finalized in the CY 2026 PFS states that a small practice is ''a practice consisting of 15 or fewer clinicians . . .''.

In the CY 2027 PFS proposed rule preamble, we described a small practice as ''a TIN with 15 or fewer clinicians'' (91 FR 43971). This statement reflects our policy intent and how we will operationalize ASM's policies that may involve a small practice. We did not propose to amend § 512.705 in the CY 2027 PFS proposed rule to expressly provide that the operative unit for defining a ''small practice'' is the TIN. However, using the TIN as the operative unit of a ''practice'' for purposes of identification is supported by the ASM regulatory scheme and by broader Medicare policies and is consistent with our policy intent.

We find good cause to waive notice-and-comment rulemaking for finalizing the change to the definition of ''small practice'' such that it is defined at the TIN-level as notice-and-comment is unnecessary. As explained earlier in this section of this final rule, this amendment makes clear that we will use the TIN as the unit for identifying a small practice and brings our regulatory text into alignment with our preamble statements (91 FR 43971, 91 FR 43972) and policy intent. This amendment does not adopt a different mechanism for counting clinicians, change the 15-clinician threshold, or modify the time at which practice size is determined. Nor does this amended definition change which practices qualify for small-practice treatment or alter the applicable scoring or reporting policies. An additional opportunity for public comment is unnecessary because the amendment simply aligns the regulatory definition with the policy intent as described in preamble statements rather than establishing or changing substantive criteria for small-practice treatment.

Accordingly, we are finalizing a correction to ''small practice'' at § 512.705 to better reflect our intent and policy such that the definition reflects that a small practice means a TIN consisting of 15 or fewer clinicians.

E. Limiting Medicare Coverage of Certain Individuals

1. Background

On July 4, 2025, Public Law 119–21, which we refer to as the ''Working Families Tax Cut'' (WFTC) legislation, was enacted. Section 71201 of the WFTC legislation amended title XVIII of the Social Security Act (the Act) to add a new section 1899C, which provides that, subject to subsection 1899C(b) of the Act, an individual may be entitled to, or enrolled for, Medicare benefits only if the individual is in one of the following four groups: (1) a citizen or national of the United States; (2) an alien who is lawfully admitted for permanent residence under the Immigration and Nationality Act (INA) (lawful permanent resident or LPR); (3) an alien who has been granted the status of Cuban and Haitian entrant (CHE);[207] or (4) an individual who lawfully resides in the United States[208] in accordance with a Compact of Free Association (COFA migrant).

Prior to enactment of the WFTC legislation, benefits payable under the Medicare program for noncitizens generally depended on whether the individual was ''lawfully present.'' Section 401 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) (Pub. L. 104–193, August 22, 1996), codified at 8 U.S.C. 1611, generally provides that, subject to certain exceptions, only ''qualified aliens'' are eligible for Federal public benefits. However, section 401(b)(3) of PRWORA provides that Medicare benefits under title XVIII of the Act are not limited solely to ''qualified aliens,'' but instead may be available to individuals who are lawfully present in the United States. Section 401(b)(2) of PRWORA similarly provides that noncitizens who are lawfully present in the United States may be eligible for benefits payable under title II, such as Social Security retirement or disability insurance benefits. Historically, before paying Medicare or title II benefits, the Social Security Administration (SSA) used a common process to verify an individual's lawful presence status by determining whether the applicant was a U.S. citizen or was otherwise lawfully present in the United States and whether the individual resided in the United States. The SSA maintains a large set of policy and operational guidance, called Program Operations

[207] As defined in section 501(e) of the Refugee Education Assistance Act of 1980 (Pub. L. 96–422).

[208] See section 402(b)(2)(G) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA).

Manual System (POMS), that CMS and the SSA update as needed. The SSA's procedures for verifying lawful presence before payment of title II and Medicare benefits are delineated in POMS. Prior to the statutory changes to Medicare eligibility made by the WFTC legislation, a noncitizen could qualify for payment of Medicare benefits if they met all other eligibility criteria and the individual was in an immigration status or category considered lawfully present under 8 CFR 1.3(a), which encompasses a broad range of immigration classifications. These ''lawfully present'' categories included, but were not limited to, the following:

- An alien who is an LPR.[209]
- An alien who is granted asylum.[210]
- An alien admitted to the United States as a refugee.[211]
- An alien who is paroled into the United States for a period of at least 1 year.[212]
- An alien who is a Cuban and Haitian entrant.[213]
- An individual who lawfully resides in the United States under a Compact of Free Association (COFA).[214]

The WFTC legislation did not modify the requirements for payment of title II benefits under sections 202(y) and 223 of the Act. As such, noncitizens who are lawfully present in the United States, as defined by 8 CFR 1.3(a), may remain eligible for payment of title II benefits. As a result, eligibility for payment of title II benefits is no longer coextensive with eligibility for payment of Medicare benefits under title XVIII of the Act for certain noncitizens. Because continued reliance on the lawful presence verification framework used to determine noncitizen eligibility for payment of title II benefits would conflict with section 1899C of the Act when applied to Medicare, we proposed to establish Medicare-specific definitions and related enrollment and termination criteria concerning citizenship, nationality, and immigration status.

2. Limiting Coverage Under Medicare Part A and Part B to Certain Individuals

a. Amending the Eligibility Criteria for Part A and Part B

Sections 226 and 226A of the Act establish the conditions under which individuals are entitled to Medicare Part A benefits based on attainment of age 65, disability, or end-stage renal disease (ESRD). Individuals entitled to Medicare Part A under these provisions are not required to pay premiums for such coverage (known herein as premium-free Medicare Part A) and may elect to enroll in Medicare Part B. In general, individuals entitled to title II retirement benefits prior to attaining age 65 or entitled to title II disability benefits, upon attainment of age 65 or after satisfying any applicable waiting period, respectively, are automatically enrolled in premium-free Medicare Part A and will be enrolled automatically in Medicare Part B unless they decline Medicare Part B enrollment.[215] There are no statutory requirements for citizenship, nationality, immigration status, or residency in sections 226 and 226A of the Act. Eligibility determinations, including citizenship and lawful presence verification, for premium-free Medicare Part A have historically been made through the title II lawful presence verification framework administered by the SSA.

Section 1818 of the Act establishes the conditions under which certain individuals who are not entitled to premium-free Medicare Part A may enroll in the hospital insurance program by paying a monthly premium (herein referred to as premium Medicare Part A). Under section 1818 of the Act, an individual who has attained age 65, enrolled in Medicare Part B, and is not otherwise entitled to premium-free Medicare Part A may enroll if the individual is a resident of the United States and is either a citizen of the United States or an alien lawfully admitted for permanent residence who has resided continuously in the United States for the 5 years immediately preceding the month in which the individual applies for enrollment.

Section 1836 of the Act establishes eligibility requirements for Medicare Part B (also known as supplementary medical insurance). Under section 1836 of the Act, an individual may enroll in Medicare Part B if the individual is entitled to Medicare Part A or, alternatively, has attained age 65, is a resident of the United States and is either a citizen of the United States or an alien lawfully admitted for permanent residence who has resided continuously in the United States for the 5 years immediately preceding the month in which the individual applies for enrollment. The WFTC legislation did not eliminate the 5-year continuous residency requirement for LPRs in sections 1818(a)(3) and 1836(a)(2) of the Act and, as a result, we did not propose to alter this requirement. In other words, LPRs who meet the 5-year continuous residency requirement and other applicable Medicare requirements would maintain their Medicare benefit.

Similar to premium-free Medicare Part A, enrollment in Medicare Part B under section 1836(a)(1) of the Act has historically been administered in coordination with the SSA's lawful presence verification framework for confirming citizenship, nationality, lawful presence, and residency status for payment of title II benefits. However, section 1899C of the Act establishes specific statutory categories of individuals who may be entitled to, or enrolled in, Medicare under title XVIII of the Act. As a result, title II's lawful presence requirements no longer fully align with the Medicare Part B eligibility framework established by section 1899C of the Act.

To align Medicare eligibility regulations with section 1899C of the Act, we proposed to add a new definition of ''eligible noncitizen'' at 42 CFR 400.200 that includes the categories of noncitizens eligible for Medicare under sections 1899C(a)(2) through (4) of the Act. Specifically, the proposed definition would state that an ''eligible noncitizen'' is an individual who is (1) an alien lawfully admitted for permanent residence under the INA; (2) an alien who has been granted the status of CHE, as defined in section 501(e) of the Refugee Education Assistance Act of 1980 (Pub. L. 96–422); or (3) an individual who lawfully resides in the United States in accordance with a COFA referred to in 8 U.S.C. 1612(b)(2)(G).

The proposed definition of ''eligible noncitizen'' was not intended to apply to noncitizen U.S. nationals who are expressly eligible for Medicare under section 1899C(a)(1) of the Act. The proposed definition of ''eligible noncitizen'' applicable to Medicare eligibility would be distinguishable from the immigration status or category criteria in 8 CFR 1.3 applicable to noncitizen eligibility for title II benefits, which continues to be based on the ''lawfully present'' framework in section 401(b)(2) of PRWORA.

Further, we proposed to amend regulations at 42 CFR part 406 (Medicare Part A) and 42 CFR part 407 (Medicare Part B) to incorporate the proposed definition of ''eligible noncitizen.'' We proposed to add that, effective July 4, 2025, an individual must be a citizen or national of the United States or an eligible noncitizen

[209] Under the Immigration and Nationality Act (INA) [8 U.S.C. 1101 *et seq.*].

[210] Under section 208 of INA [8 U.S.C. 1158].

[211] Under section 207 of INA [8 U.S.C. 1157].

[212] Under section 212(d)(5) of INA [8 U.S.C. 1182(d)(5)].

[213] As defined in section 501(e) of the Refugee Education Assistance Act of 1980 (Pub. L. 96–422).

[214] Public Law 99–239; Public Law 99–658; see also 8 U.S.C. 1612(b)(2)(G).

[215] Section 1837 of the Act and the enrollment process outlined in 42 CFR 407.17.

as a basis for entitlement. These changes were proposed to be added or included in the following sections:

• Premium-Free Medicare Part A:

++ New paragraph (a)(2) was proposed to be added to § 406.5 (Basis of eligibility and entitlement). This proposed new paragraph would add the requirement that, in addition to satisfying the applicable age, disability, or ESRD-based entitlement criteria, an individual must also be a citizen or national of the United States or an eligible noncitizen. This revision would align the eligibility and entitlement criteria for premium-free Medicare Part A with section 1899C(a) of the Act.

++ New paragraph (a)(2) was proposed to be added to § 406.10 (Individual age 65 or over who is entitled to Social Security or Railroad Retirement benefits, or who is eligible for Social Security benefits). This proposed new paragraph would clarify that individuals age 65 or over who otherwise qualify for premium-free Part A through Social Security or Railroad Retirement pathways must also satisfy the citizenship, nationality, or immigration status or category requirements established by section 1899C(a) of the Act. This would ensure that automatic or application-based entitlement under this section is limited to U.S. citizens, U.S. nationals, and eligible noncitizens.

++ Paragraph (b)(2) was proposed to be revised in § 406.11 (Individual age 65 or over who is not eligible as a Social Security or Railroad Retirement benefits beneficiary, or on the basis of government employment). This proposed revision would align the eligibility language in § 406.11 with section 1899C(a) of the Act and clarify that individuals qualifying under this pathway must also satisfy the citizenship, nationality, or immigration status or category standards in section 1899C(a) of the Act. This change would ensure that entitlement is not available under this section unless the individual is a U.S citizen, U.S. national, or eligible noncitizen.

++ New paragraph (a)(2) was proposed to be added to § 406.12 (Individual under age 65 who is entitled to Social Security or Railroad Retirement disability benefits). This proposed new paragraph would provide that individuals under age 65 who otherwise qualify for premium-free Part A on the basis of disability must also meet the citizenship, nationality, or immigration status or category requirements of section 1899C(a) of the Act. This would align the regulation implementing premium-free Part A entitlement based on disability with the requirements in section 1899C(a) of the Act.

++ New paragraph (c)(4) was proposed to be added to § 406.13 (Individual who has ESRD). This proposed new paragraph would clarify that individuals who otherwise qualify for premium-free Part A on the basis of ESRD must also be a citizen or national of the United States or an eligible noncitizen. This revision would align the regulation implementing premium-free Part A entitlement based on ESRD with the eligibility limitations in section 1899C(a) of the Act.

• Premium Medicare Part A:

++ In § 406.20 (Basic Requirements), paragraphs (b)(2)(i) and (b)(2)(ii) were proposed to be revised and new paragraphs (b)(2)(iii), (b)(2)(iv), and (c)(5) were proposed to be added. These proposed revisions would update the eligibility requirements for enrollment in premium Part A to incorporate the proposed definition of eligible noncitizen. These changes would align premium Part A eligibility with section 1899C(a) of the Act by clarifying that only U.S. citizens, U.S. nationals, and eligible noncitizens may enroll under this pathway.

• Medicare Part B:

++ New paragraphs (a)(2)(ii)(A) through (D) were proposed to be added in § 407.10 (Eligibility to Enroll). These proposed revisions would update the Part B enrollment regulation to incorporate the proposed definition of eligible noncitizen. These proposed changes would align the Part B eligibility regulation with section 1899C(a) of the Act and clarify that only U.S. citizens, U.S. nationals, and eligible noncitizens may enroll under this pathway.

We noted in the proposed rule that the WFTC legislation also has implications for the Medicare Part B Immunosuppressive Drug benefit (Part B–ID) under section 1836(b) of the Act. Part B–ID is a limited Part B benefit that provides coverage only for immunosuppressive drugs for certain individuals whose entitlement to Medicare based solely on end-stage renal disease (ESRD) ended 36 months after a successful kidney transplant and who do not have other disqualifying health coverage. Although eligibility for Part B–ID is governed by the specific criteria set forth in § 407.55, individuals seeking to enroll in, or remain enrolled in, Part B–ID must also satisfy the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act. Accordingly, we proposed to revise § 407.55 (Eligibility to Enroll) to add new paragraphs (a)(1) and (2) to clarify that eligibility for Part B–ID is also subject to the limitations established by section 1899C(a) of the Act.

We received a number of comments that were outside the scope of the policies discussed in the proposed rule (for example, general immigration policies, general opposition or support of the WFTC, effects on safety-net providers, eligibility requirements for other HHS programs, the broader health care system, and employers). We will not be addressing those comments in this rulemaking.

We also received a number of comments on the changes to the eligibility criteria as well as general comments on CMS and the SSA's implementation of these statutory changes. The following is a summary of the general comments we received and our responses.

Comment: Multiple commenters expressed general opposition to, or concern regarding, implementation of section 71201 of the WFTC legislation and the mandated changes to the eligibility criteria for all parts of the Medicare program. Some commenters, while noting CMS's obligation to implement the statute, urged CMS to use its available administrative authority to minimize harm with the implementation of these provisions and take into consideration the disproportionate impact on certain populations that have greater communication barriers, resources, and physical and mental health care needs and the potential harm to broader community health, such as preventable hospitalizations and communicable disease outbreaks.

Response: We acknowledge the commenters' feedback. The WFTC legislation established section 1899C of the Act, which requires that, in order to be enrolled or entitled to Medicare, an individual must be a U.S. citizen or national, a lawful permanent resident, an alien who is a CHE, or a COFA migrant, and these new eligibility requirements apply to all parts of Medicare. As noted by the commenters, CMS is obligated to implement the new Medicare eligibility requirements as established by section 1899C of the Act.

To help beneficiaries impacted by the statutory changes prepare for implementation of these changes, CMS, along with the SSA, plans to conduct an outreach effort for impacted individuals, caregivers, and relevant interested parties including healthcare providers, taking into account the needs of the impacted population, such as using existing resources to address language barriers. In addition, we are finalizing policies in this final rule to notify those

who will be terminated from coverage due to not meeting requirements in section 1899C of the Act and to provide information regarding how individuals can regain Medicare should they become eligible again. Finally, we appreciate commenters' concerns regarding potential broader community health effects, including preventable hospitalizations and communicable disease outbreaks. However, these potential downstream effects are beyond the scope of this rulemaking.

Comment: Multiple commenters noted that implementation of these new Medicare requirements are being implemented at the same time similar changes are occurring with Medicaid and eligibility for premium tax credits (PTCs) as enacted in sections 71109 and 71301 of the WFTC legislation, respectively. Commenters also expressed concern that the cumulative effect of these coverage changes could increase administrative burdens on healthcare providers and disproportionally impact dual-eligible populations. A commenter also suggested that CMS coordinate implementation and information provided regarding the Medicaid and Medicare eligibility changes to limit disruption on dual-eligible enrollees.

Response: We acknowledge the commenters' concerns. Implementation of changes to Medicaid and changes to eligibility for PTCs in the WFTC legislation and the potential impact due to loss of coverage from those two programs are outside of scope of this final rule. We note that the related statutory provisions have different applicability dates: section 71109 applies beginning October 1, 2026; section 71302 applies for taxable years beginning after December 31, 2025; and section 71301 applies for plan years beginning on or after January 1, 2027. These differing statutory timelines limit the extent to which implementation of the Medicare, Medicaid, and Marketplace changes can be aligned. We acknowledge that the cumulative changes could impact health care providers and dual-eligible enrollees disproportionately. CMS plans to conduct outreach to impacted individuals, caregivers, providers, plans, and other interested parties on the changes to Medicare eligibility. We plan to include states and those serving dual-eligible enrollees who are losing eligibility for both Medicare and Medicaid in our outreach efforts.

Comment: A commenter requested that CMS and HHS urge Congress to grandfather individuals who were already Medicare beneficiaries when the law was enacted and who had Medicare taxes withheld for many years. The commenter also requested clarification on the treatment of individuals pursuing lawful permanent residence status and if Medicare coverage could continue without interruption while status is pending. Another commenter requested clarification on whether individuals who were granted asylum and are currently enrolled in Medicare would be impacted.

Response: We appreciate the commenters' concerns. The new eligibility criteria in section 1899C of the Act does not provide the authority to grandfather individuals enrolled into Medicare prior to enactment. The commenter's request that CMS and HHS advocate for such a legislative change is outside the scope of this rulemaking, which implements section 1899C as enacted. Further, the new eligibility criteria require that an individual be either a U.S. citizen or national or an eligible non-citizen in order to be enrolled or entitled to Medicare, and once this rule goes into effect, coverage must be terminated in accordance with this final rule if an individual does not meet that requirement. Further, noncitizens who do not meet the new eligibility requirements set forth in section 1899C of the Act will no longer be eligible to be entitled to or enrolled in Medicare, including individuals granted asylum, unless the individual also has an immigration status or category that meets the requirements of section 1899C(a). Further, the fact that an individual has applied for an immigration status or category that, if approved, would meet the requirements of section 1899C(a) does not, in itself, confer eligibility. In other words, a pending application for a particular immigration status or category is not sufficient. An individual's application for an immigration status or category that meets the requirements of section 1899C(a) must have been granted.

Comment: A commenter expressed concern that the title and abstract of the proposed rule did not specifically identify the provisions addressing Medicare eligibility based on citizenship, nationality, or immigration status or category and that beneficiaries, immigrant rights organizations, and other interested parties primarily focused on Medicare eligibility could therefore have difficulty identifying or locating these provisions.

Response: We acknowledge the commenter's concern. Including this provision, ''Limiting Medicare Coverage of Certain Individuals,'' in the Physician Fee Schedule proposed rule provided CMS with the opportunity to reach a broad audience of interested parties and ensure timely implementation of the new statutory requirements, especially in regard to the grace period population outlined in Section 1899C(b)(2)(A) and (B). In addition to being included in the broader proposed rule, this provision was highlighted in fact sheets and outreach materials on the proposed rule. Based on the comprehensive feedback we received from a variety of stakeholders on the proposed rule, we are confident that interested parties were able to locate these provisions and provide thoughtful feedback.

Comment: Multiple commenters requested that CMS and the SSA conduct robust outreach and interested parties' engagement before implementing section 1899C of the Act. Commenters' recommendations include training, educational materials, frequently asked questions (FAQs), phone scripts, provider education, and other resources to organizations that will assist affected individuals, including State Health Insurance Assistance Programs (SHIPs), Aging and Disability Resource Centers (ADRCs), Area Agencies on Aging, legal services organizations, immigrant-serving organizations, disability and aging organizations, community health centers, religious organizations, Medicare providers, Medicare Advantage (MA) organizations, Part D sponsors, Medicaid managed care organizations, and Programs of All-Inclusive Care for the Elderly (PACE) organizations.

Response: We plan to conduct a robust outreach and education effort that is accessible, multimodal, and broad in reach. CMS and the SSA have been working to develop a comprehensive communications plan to support implementation of section 1899C of the Act and to provide timely and understandable information to affected individuals and the organizations that assist them. We also plan to use existing communication and education channels, including the Medicare Learning Network (MLN), to provide information and educational resources to Medicare providers and other interested parties. We have also notified the SHIPs of the changes in eligibility and are planning additional communications to the provider community. CMS will continue to coordinate with the SSA and other partners, as appropriate, to refine materials and outreach activities.

Comment: Several commenters noted the impact on providers needing to verify Medicare eligibility and to provide guidance to their patients who lose Medicare due to not meeting the requirements in section 1899C of the

Act. Commenters requested guidance for providers and other interested parties that includes information on the implementation timing, guidance on eligibility file updates, and on processes related to the new enrollment periods.

Response: We acknowledge the commenters' request for guidance. As mentioned above, CMS and the SSA plan to conduct a robust outreach and education effort that includes using MLN to share relevant information with providers regarding the implementation of the new eligibility criteria, including information on timing and enrollment periods. CMS will take the feedback provided by the commenters into account when developing future communications. Regarding eligibility verification, there are no changes proposed to the HIPAA Eligibility Transaction System (HETS) associated with the implementation of section 1899C of the Act and providers should continue to use this system to verify Medicare eligibility using existing procedures.

Comment: A commenter requested that CMS work with the SSA to establish new POMS processes and procedures for implementing section 1899C of the Act and protecting individuals affected by the new Medicare eligibility restrictions. The commenter also requested that the new POMS provisions be made available to the public for comment before implementation.

Response: CMS recognizes that implementation of section 1899C of the Act will require coordination with the SSA and clear operational instructions for the review, notice, termination, correction, and enrollment processes. CMS will coordinate with the SSA, as appropriate, regarding updates to operational guidance, including POMS instructions, needed to support implementation of section 1899C of the Act. As POMS represent internal agency guidance and technician instructions, POMS are not made available to the public prior to publication.

CMS will continue to coordinate with the SSA, as appropriate, to support accurate implementation of section 1899C of the Act and to provide information needed by affected individuals, the SSA staff, and other partners.

Comment: Multiple commenters recommended that CMS engage in ongoing data analysis and monitoring of the implementation of section 1899C of the Act. Commenters recommend tracking the number of notices sent, eligibility determinations corrected prior to termination and actual terminations due to ineligibility based on the criteria in section 1899C(a) of the Act. A commenter also recommended that CMS track related appeals, challenges, complaints, requests for language access, use of the newly established SEP, and track the dates between attaining qualifying eligibility status for Medicare and reinstating coverage, which should be considered a core implementation outcome. This commenter recommended that where legally permissible and statistically reliable, these outcomes should be examined by State, language, disability status, race and ethnicity, and other relevant characteristics.

Commenters also recommended monitoring impacts to individuals after Medicare coverage is terminated including tracking gaps in coverage, uncompensated care due to loss of Medicare, ability to acquire alternative health coverage, emergency health care use, and interruptions in care.

Multiple commenters suggested that CMS make the number of individuals who lose or regain Medicare eligibility due to the implementation of section 1899C of the Act publicly available. In addition, several commenters also recommended that CMS report on a variety of measures publicly, including terminations, corrections, reenrollment, coverage gaps, language assistance, complaints, and the impact of uncompensated care particularly on safety-net providers, and unnecessary use of acute care due to loss of Medicare. A commenter recommended using CY 2026 as a baseline for these measurements and reporting annually on these measures compared against the baseline year.

Response: We thank the commenters for their suggestions on monitoring and oversight of the implementation of section 1899C of the Act and the recommendation to report data and analysis publicly. CMS and the SSA track a number of internal measures to monitor enrollment and eligibility in Medicare and will utilize existing resources to monitor the number of individuals who receive notice of termination, if terminations become effective, and those who regain eligibility. CMS and the SSA also monitor enrollment periods used and will continue to monitor the use of all SEPs, including the newly established SEP. CMS does track the amount of uncompensated care reported to us by hospitals for purposes of Medicare Uncompensated Care Payments and we will monitor this data to help assess the impact of section 1899C to the extent that the changes are significant enough to fall outside the expected variability range. We will take the commenters' suggestions on additional measures to monitor implementation into consideration in our oversight and monitoring of the implementation of section 1899C of the Act. We do not track and analyze the healthcare experience of individuals who are no longer enrolled in Medicare.

Finally, we do not publicize granular data on Medicare terminations or enrollments. Currently, we publish enrollment reports that provide summarized information on total Medicare enrollees, Original Medicare enrollees, Medicare Advantage and other health plan enrollees, newly enrolled beneficiaries, deaths, Medicare-Medicaid enrollees, and Medicare Part D enrollees by yearly trend, demographic characteristics, and geography. We will take the recommendations for making additional data and analysis publicly available into consideration.

Comment: A commenter recommended that CMS establish a formal mechanism through which SHIPs, community health centers, civil-rights organizations, aging organizations, disability groups, legal-service providers, and other community-based organizations could report implementation issues for section 1899C of the Act.

Response: We appreciate the commenter's recommendation. We have regular communication with interested parties, including SHIPs, States, providers, and community-based organizations and appreciate feedback provided during those communications on our programs, especially newly implemented policies. We will take this recommendation into consideration on whether additional communication channels are warranted to monitor the implementation of section 1899C of the Act.

Comment: Several commenters opposed the proposed definition of ''eligible noncitizen'' and requested that CMS retain the prior, broader definition to allow a larger group of lawfully present noncitizens to remain eligible for Medicare. A commenter suggested that CMS provide clear and consistent definitions across Medicare programs.

Response: We thank commenters for their comments regarding the proposed definition of ''eligible noncitizen.'' As noted above, Section 1899C(a) of the Act establishes the categories of individuals who may be entitled to, or enrolled for, Medicare based on citizenship, nationality, or immigration status or category. Because these eligibility categories are established by statute, CMS does not have authority to retain the prior, broader lawful-presence

standard for Medicare eligibility. The defined term of ''eligible noncitizen'' provides a clear and consistent way to refer to the three categories of noncitizens who remain eligible under section 1899C(a), rather than repeating each category throughout the Medicare regulations. Using the term ''eligible noncitizen'' across the applicable Medicare regulations promotes consistency and readability while maintaining the eligibility requirements established by statute.

After consideration, we are finalizing the definition of ''eligible noncitizen'' at § 400.200, and the incorporation of that definition into the eligibility requirements in 42 CFR 406 (§§ 406.5, 406.10 through 406.13, 406.20) and 42 CFR 407 (§§ 407.10 and 407.55), as proposed.

b. Termination of Entitlement for Individuals Who Were Entitled to, or Enrolled for, Medicare as of July 4, 2025, in Accordance With Section 71201 of the WFTC Legislation (''Grace Period'' Population)

Due to the statutory changes to Medicare eligibility made by section 71201 of the WFTC legislation, individuals who are not U.S. citizens or U.S. nationals and who have an immigration status or category other than LPR, CHE, or COFA migrant, and who were entitled to, or enrolled for, Medicare as of July 4, 2025, will no longer be eligible for Medicare on the date that is 18 months after July 4, 2025. As shorthand, we are referring to this 18-month time period as the ''grace period'' and the applicable individuals identified and notified during the grace period as the ''grace period population.'' Section 1899C(b)(2)(A) of the Act directs the SSA to complete a review of all individuals entitled to, or enrolled for, Medicare as of July 4, 2025, and identify those beneficiaries entitled to, or enrolled for, Medicare as of July 4, 2025, who do not meet the requirements of section 1899C(a) of the Act. Section 1899C(b)(2)(A) of the Act provides the SSA with 1 year to complete this task for the grace period population. Section 1899C(b)(2)(B) of the Act directs the SSA to provide notice to such beneficiaries as soon as practicable after identifying such beneficiaries that their entitlement to, or enrollment in, Medicare will be terminated as of the date that is 18 months after July 4, 2025.

As stated in the proposed rule, the notice will inform them that the SSA records indicate that they do not meet one of the eligibility criteria in section 1899C(a) of the Act, and their Medicare entitlement and enrollment will be terminated if they cannot provide evidence proving eligibility. The proposed rule also stated that individuals would be instructed to contact the SSA if they believe the information is incorrect and to provide updated evidence of eligibility before their entitlement and enrollment is terminated. In addition, the proposed rule also stated that, if applicable, the notice would state that a formal initial determination of ineligibility will be sent prior to their termination date if the individual takes no action to update their records or if the individual confirms that they do not meet the eligibility criteria in section 1899C(a) of the Act. As proposed, the SSA would provide a termination notice towards the end of December 2026 to all identified individuals determined to be ineligible based on data available to the SSA. The termination notice would explain that the identified individuals do not satisfy the requirements in section 1899C(a) of the Act and therefore are not entitled to, and may not be enrolled for, Medicare. As explained in the proposed rule, the notice would state that termination of enrollment will be effective February 1, 2027. The notice would inform individuals of their appeal rights under existing appeals regulations for initial determinations delineated in 42 CFR, part 405, subpart I, specifically 42 CFR 405.900(b)(1), which establishes that appeals of initial determinations for entitlement to benefits under Part A or Part B of Medicare are administered in accordance with the SSA's regulations governing reconsiderations of these initial determinations at 20 CFR, part 404, subpart J.

We noted in the proposed rule that entitlement to premium-free Part A and enrollment in premium Part A and Part B are referenced in the Act as ''monthly insurance benefits'' or ''benefits for a month'' (see section 226(c)(1) and (2) of the Act) and entitlement to or enrollment in Medicare always begins on the first day of the month and always ends on the last day of the month (see section 1838(a) and (b) of the Act). Consequently, the termination in proposed §§ 406.14(d)(2), 406.28(g)(3)(ii), and 407.27(e)(3)(ii) would be at the end of the calendar month.

Accordingly, we proposed to amend the following regulations to implement termination procedures for individuals who were entitled to, or enrolled for, Medicare as of July 4, 2025, but do not meet or potentially do not meet the eligibility requirements of section 1899C(a) of the Act:

- Premium-Free Medicare Part A:

++ New § 406.14 (End of Entitlement Due to Change in Citizenship, Nationality, or Immigration Status or Category) was proposed to be added, in accordance with section 1899C(b)(1) of the Act, to establish the termination framework for individuals who were entitled to premium-free Part A as of July 4, 2025, but who either do not meet or potentially do not meet the eligibility requirements of section 1899C(a) of the Act. Specifically, new paragraph (b) would provide that individuals entitled or enrolled as of July 4, 2025, who either do not meet or potentially do not meet the requirements of § 406.5(a)(2) will be identified and notified by the SSA per section 1899C(b)(2) of the Act. Individuals not meeting § 406.5(a)(2) requirements will have their entitlement or enrollment terminated in accordance with paragraph (d).

++ New paragraph (b)(3) was proposed to be added to § 406.10 (Individual age 65 or over who is entitled to Social Security or Railroad Retirement benefits, or who is eligible for Social Security benefits) to add a cross reference to the termination provision in the new § 406.14.

++ New paragraph (d)(2)(v) was proposed to be added to § 406.12 (Individual under age 65 who is entitled to Social Security or Railroad Retirement disability benefits) to add a cross reference to the termination provision in the new § 406.14.

++ New paragraph (f)(3) was proposed to be added to § 406.13 (Individual who has end-stage renal disease) to add cross reference to the termination provision in the new § 406.14(b).

- Premium Medicare Part A:

++ New paragraph (g)(1) was proposed to be added to § 406.28 (End of Entitlement Due to Change in Citizenship, Nationality, or Immigration Status or Category) in accordance with section 1899C(b)(1) of the Act, to establish the termination framework for individuals who were entitled to, or enrolled for, premium Part A as of July 4, 2025, but who either do not meet or potentially do not meet the eligibility requirements of section 1899C(a) of the Act. Specifically, the new paragraph (g)(1) would provide that individuals entitled to or enrolled as of July 4, 2025, who either do not meet or potentially do not meet the requirements of § 406.20(b)(2) will be identified and notified by the SSA per section 1899C(b)(2) of the Act. Individuals not meeting § 406.20(b)(2) requirements will have their entitlement or enrollment terminated in accordance with paragraph (3).

- Medicare Part B:

++ New paragraph (e)(1) was proposed to be added to § 407.27 (Termination of entitlement: Individual), in accordance with section 1899C(b)(1) of the Act, to establish the termination framework for individuals who were enrolled in Part B as of July 4, 2025, but who either do not meet or potentially do not meet the eligibility requirements of section 1899C(a) of the Act. Specifically, the new paragraph (e)(1) would provide that individuals enrolled as of July 4, 2025, who either do not meet or potentially do not meet the requirements of § 407.10(a)(2) will be identified and notified by the SSA per section 1899C(b)(2) of the Act. Individuals not meeting § 407.10(a)(2) requirements will have their enrollment terminated in accordance with paragraph (3).

We address all comments related to the proposed termination processes in the next section.

c. Termination Process for Certain Noncitizens Entitled to, or Enrolled for, Medicare Who Were Not Identified and Notified by the SSA Per Section 1899C(b)(2) of the Act (Outside of the ''Grace Period'' Population)

We turn now to the proposed termination processes that would be used for all other individuals whose eligibility for Medicare, including both initial eligibility and continued eligibility, is impacted by the statutory changes to Medicare eligibility made by section 71201 of the WFTC legislation and whose entitlement and enrollment was not terminated by the SSA under the processes implementing section 1899C(b) of the Act. The proposed termination processes for this population provides the framework to terminate enrollment in Medicare if they are not eligible to be entitled or enrolled per section 1899C of the Act while ensuring all impacted individuals are notified of termination and retain their appeal rights. Under this proposal, all terminations made under section 1899C of the Act would be prospective.

We proposed that entitlement and enrollment for those not identified during the grace period and found not to meet the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act would end according to the termination processes in the following proposals: § 406.14(c) and (d) for those with premium-free Part A, § 406.28(g)(2) and (3) for those with premium Part A, and § 407.27(e)(2) and (3) for those with Part B benefits. The proposed termination processes in §§ 406.14(d), 406.28(g)(3) and 407.27(e)(3) included providing notice to such individuals that their entitlement and enrollment for Medicare will be terminated if they do not meet section 1899C(a) of the Act, and for terminating entitlement or enrollment where the SSA determines that the individual either does not or no longer meets the requirements of section 1899C(a) of the Act.

As stated, this proposed termination process would apply to anyone enrolled in Medicare whom the SSA determines does not meet eligibility requirements under section 1899C(a) of the Act and was not part of the grace period population per section 1899C(b)(2)(B) of the Act. The proposed rule acknowledged that there would be a period of time between enactment of the WFTC legislation on July 4, 2025, and the SSA starting to screen individuals for new Medicare enrollment under the criteria in section 1899C(a) of the Act, which we noted in the proposed rule is expected to begin in 2026. Individuals enrolled after enactment of the WFTC legislation but before screening procedures are implemented do not fall into the grace period population because they were not enrolled as of the date of enactment. Thus, the proposed rule noted that individuals enrolled during the previously discussed time period who do not meet the eligibility requirements in section 1899C(a) of the Act would be terminated according to proposed §§ 406.14(d), 406.28(g)(3) or 407.27(e)(3), as appropriate.

Additionally, the proposed termination process would apply to anyone enrolled in Medicare whom the SSA determines does not meet the eligibility requirements in section 1899C(a) of the Act and was not notified as part of the grace period population per section 1899C(b)(2)(B) of the Act. This would include individuals whose status changed prior to the finalization of this rule, such as an individual who was enrolled in Medicare in October 2024 and met the eligibility requirements under section 1899C(a) of the Act based on their conditional LPR status when the SSA identified and notified the grace period population. Therefore, they were not included in the grace period population per section 1899C(b)(2)(B) of the Act. However, if the SSA's records indicate that their conditional LPR status is scheduled to expire in December 2026, and the status is not extended and is terminated accordingly, this proposed termination process would apply upon termination of their conditional LPR status and would provide the framework for this individual's Medicare enrollment to be terminated as they would no longer satisfy the requirements of section 1899C(a) of the Act. We emphasized that the same process would also apply to individuals enrolled after this proposed rule is implemented, if finalized as proposed. As an example, consider the case of an individual enrolled in Medicare with conditional LPR status whose enrollment began in April 2028. In February 2030, the SSA records indicate that the individual's conditional LPR status expires in April 2030, and the status is not extended. Upon termination of the individual's status following expiration of their conditional LPR status in April 2030, the individual would no longer satisfy the requirements of section 1899C(a) of the Act, and the SSA would send notice to the individual that they no longer meet the requirements of section 1899C(a) of the Act. As a result, under the proposed process for termination of enrollment, the individual's Medicare enrollment would be terminated at the end of the month following the month in which the notice is dated.

There are several circumstances in which individuals are identified as no longer meeting the requirements of section 1899C(a) of the Act outside the grace period. We proposed the same termination process for individuals in these circumstances in proposed §§ 406.14(d), 406.28(g)(3) or 407.27(e)(3), as appropriate.

For these individuals outside the grace period, we proposed that a termination notice from the SSA would be sent to each individual identified as ineligible. We proposed the notice would explain that, per data available to the SSA, the individual does not satisfy the requirements of section 1899C(a) of the Act. Under the proposed termination process, an individual would not lose Medicare entitlement or enrollment during the month in which the SSA determines that the individual does not or no longer meets the requirements of section 1899C(a) of the Act. Rather, Medicare entitlement or enrollment would terminate at the end of the month following the month in which the notice is dated. For example, if the date of the termination notice is in March 2027, termination would be effective at the end of April 2027. This proposed termination timeline would be explained in the notice. We emphasized that the SSA will not terminate anyone's entitlement or enrollment prior to notification. Further, no termination of Medicare would occur for any individual entitled to, or enrolled for, Medicare for failure to meet the requirements of section 1899C(a) of the Act prior to the effective date of this rule, if finalized as proposed. We proposed an effective date of January 1, 2027.

We proposed that individuals whose Medicare entitlement and enrollment are terminated because they do not meet the requirements of section 1899C(a) of the Act would be provided appeal rights under our existing appeals regulations for initial determinations. Appeals of initial determinations for entitlement to benefits under Medicare Part A or Part B are administered in accordance with 20 CFR, part 404, subpart J (*see* 42 CFR 405.900(b)(1)). We proposed to include the information about appeal rights in the proposed termination notices.

We also proposed that termination notices would be sent to affected individuals on an ongoing basis, as applicable, when the SSA receives information that an individual enrolled in Medicare does not meet the requirements of section 1899C(a) of the Act.

In the proposed rule, we explained that these proposals are necessary to ensure implementation of section 1899C of the Act is consistent with the efficient administration of the Medicare program under section 1102(a) of the Act. Therefore, to implement the proposed termination framework, we proposed adding and revising the following sections:

- Premium-Free Medicare Part A:

++ New § 406.14 (End of entitlement due to change in citizenship, nationality, or immigration status or category) would be added. The proposed new § 406.14(c) would provide the termination framework for individuals entitled to premium-free Part A who were not identified and notified by the SSA per section 1899C(b)(2) of the Act and were subsequently determined by the SSA to not meet the requirements of § 406.5(a)(2). Proposed § 406.14(d) describes the proposed termination notice and appeal rights in accordance with existing regulations governing Medicare entitlement determinations, states the effective date of premium-free Part A entitlement termination, and states that the individual should contact the SSA if their citizenship, nationality, or immigration status or category changes such that they may be entitled to, or enrolled for, premium-free Part A benefits.

++ New paragraph (b)(3) would be added to § 406.10 (Individual age 65 or over who is entitled to Social Security or Railroad Retirement benefits, or who is eligible for Social Security benefits). This proposed new paragraph would add a cross-reference to § 406.14 so that individuals entitled to, or enrolled for, premium-free Part A through the age-65 pathway would be subject to the termination procedures in that section if they do not or no longer meet the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act.

++ New proposed paragraph (d)(2)(v) would be added to § 406.12 (Individual under age 65 who is entitled to Social Security or Railroad Retirement disability benefits). This proposed new paragraph would add cross-references to § 406.14(b) and (c) so that disability-based premium-free Part A entitlement would be subject to the proposed termination procedures for an individual who does not or no longer meets the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act.

++ New proposed paragraph (f)(3) would be added to § 406.13 (Individual who has ESRD). This proposed new paragraph would add a cross-reference to § 406.14 to specify that individuals entitled to, or enrolled for, premium-free Part A on the basis of ESRD would be subject to the proposed procedures for termination when an individual does not or no longer meets the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act.

- Premium Medicare Part A:

++ New proposed paragraph (g)(2) was proposed to be added to § 406.28 (End of entitlement) for individuals who were entitled to, or enrolled for, premium Part A, who were not identified and notified by the SSA per section 1899C(b)(2) of the Act and were subsequently determined by the SSA as not meeting the requirements of § 406.20(b)(2). Under proposed paragraph (g)(2), entitlement would end as provided under paragraph (g)(3) of this section.

++ New proposed paragraph (g)(3) was proposed to be added to § 406.28 (End of entitlement). It describes the proposed termination notice, which would specify the individual's appeal rights in accordance with existing regulations governing Medicare entitlement determinations, state the effective date of premium Part A enrollment termination, and state that the individual should contact the SSA if their citizenship, nationality, or immigration status or category changes such that they may be entitled to, or enrolled for, premium Part A benefits.

++ Paragraphs (a) and (b) of § 406.50 was proposed to be revised to change the word ''alien'' to ''eligible noncitizen.''

- Medicare Part B:

++ New proposed paragraph (e)(2) was proposed to be added to § 407.27 (Termination of entitlement: Individual enrollment). This new paragraph would specify that individuals who are enrolled in Part B, who were not identified and notified by the SSA per section 1899C(b)(2) of the Act and were subsequently determined by the SSA as not meeting the requirements of § 407.10(a)(2), would have their enrollment terminated under the new proposed paragraph (e)(3) of the section.

++ New proposed paragraph (e)(3) would be added to § 407.27 (Termination of entitlement: Individual enrollment). This new paragraph would describe the termination notice, which would specify the individual's appeal rights in accordance with existing regulations governing Medicare entitlement determinations, state the effective date of Part B enrollment termination, and state that the individual should contact the SSA if their citizenship, nationality, immigration status or category changes such that they may be enrolled for, Part B benefits.

We received public comments on the proposed termination process. The following is a summary of the comments we received and our responses.

Comment: Multiple commenters recommended that the preliminary notice be sent to the grace period population as early as possible and well in advance of their termination date. Commenters requested multiple notices, with several commenters specifying at least three notices and several recommending that preliminary notices be sent at least 90 days before termination. A commenter suggested color coded notices and another recommended patient navigators and providing notices through a variety of methods, such as phone calls, text messages, e-mails, and letters.

Response: We acknowledge the comments regarding the timing and frequency of notices to the grace period population. We stated in the proposed rule that, in accordance with section 1899C(b)(2)(B) of the Act, the SSA would send, as soon as practicable, notice to individuals identified as not meeting or potentially not meeting one of the eligibility criteria in section 1899C(a). Accordingly, the SSA plans to send to these individuals a preliminary notice in November 2026. As such, preliminary notices will be sent almost 90 days before a termination would take effect. The preliminary notice will instruct the individual to contact the SSA and provide updated evidence of eligibility and inform them that they could potentially lose entitlement to Part A and/or enrollment in Part B. Individuals who do not establish continued eligibility will subsequently

receive a formal termination notice in December 2026 before their Medicare entitlement and/or enrollment terminates.

Additionally, CMS plans to send a notice in December 2026 to those affected following the SSA's preliminary notice. CMS's notice will emphasize the importance of reviewing SSA's preliminary notice and encourage individuals to call 1–800–MEDICARE or reach out to the SSA for any needed assistance. CMS will include in the notice taglines in 14 different languages for those with limited English proficiency. CMS also plans to send emails to beneficiaries who have a *Medicare.gov* account and are receiving a disenrollment notice from the SSA. CMS's and the SSA's call centers are prepared for calls from beneficiaries. CMS has also notified the SHIPs of the changes in eligibility and is planning communications to the provider community.

At this point, color-coded notices are not feasible. We will take into consideration other mechanisms of communication, such as outbound telephone calls and text messages, as those avenues become available. We believe the SSA preliminary notice, the CMS notice, and the SSA termination notice, as well as emails to those with a *Medicare.gov* account, provide several opportunities for affected and potentially affected individuals to be informed in advance of proposed termination dates.

Comment: Multiple commenters recommended that notices explain the basis for the determination of ineligibility (including the specific immigration status of the individual), the effective date of termination, the information or records relied upon, the documentation the individual may submit to establish continued eligibility or correct the determination, applicable appeal or review rights, the availability of good-cause extensions of appeal deadlines, and where the individual may obtain free assistance. Another commenter suggested that CMS make notices to impacted individuals available for comment and review before distribution.

Response: CMS appreciates the commenters' recommendations regarding the content of notices. The preliminary notice will explain that based on the information that the SSA has, the individual does not or potentially does not meet the requirements of section 1899C(a) of the Act and will instruct the individual to contact the SSA and provide updated evidence if they believe the determination is incorrect. The notices will also explain how to obtain a copy of and correct their immigration record with the United States Citizenship and Immigration Services (USCIS). The preliminary notice will provide contact information for the SSA, including the website, customer service number, and a telephone number for contacting their local office.

If the individual fails to provide updated or sufficient evidence of eligibility and the SSA subsequently determines that the individual does not meet the requirements of section 1899C(a) of the Act, the termination notice will explain the determination, state the effective date of termination, and provide information regarding the individual's appeal rights. The termination notice will also inform the individual that an appeal filed after the deadline may be accepted if the individual shows good cause for the late filing. For assistance, the notice provides the SSA customer service number, website, and telephone number for contacting their local SSA office.

CMS and SSA have an existing process for developing notices and communications to Medicare enrollees and will follow the current process for issuance of these new notices consistent with applicable statutory and regulatory requirements and we will not be issuing these notices for public comment prior to release.

Creating individualized notices delineating the sources relied upon, the immigration status of each individual, and the specific documentation needed to maintain eligibility is not operationally feasible at this time. The notices are similar in content to what was previously used for individuals who were not lawfully present. However, the SSA will ensure that guidance for evidentiary requirements for Medicare entitlement and enrollment is clear for both employees and the public. Finally, CMS and the SSA will take these suggestions regarding including individualized information in the preliminary notice into consideration for future updates.

Comment: Multiple commenters requested that notices clearly explain that a determination under section 1899C of the Act concerns Medicare entitlement or enrollment and does not, by itself, terminate an individual's Social Security title II benefits.

Response: We thank commenters for the recommendation. The SSA will be issuing notices based on whether the individual is receiving Medicare only or both title II and Medicare benefits. That is, if the individual is only receiving Medicare coverage, the notice will only refer to Medicare benefits, whereas individuals that are entitled to title II benefits, but not entitled to Medicare, will receive a notice stating that they will continue to receive title II benefits and their Medicare entitlement and enrollment will be terminated.

Comment: A commenter requested that CMS require that notices sent out by the SSA and any other entity contain an explanation of the Cuban and Haitian Entrant (CHE) classification, how to prove the classification, and community resources to assist individuals in determining whether they qualify as a CHE.

Response: We thank the commenter for this recommendation. The preliminary and termination notices from the SSA will state the citizenship and immigration categories that qualify for Medicare entitlement and enrollment under section 1899C of the Act. In addition, the notices will direct individuals to the USCIS to get a copy of their immigration record to determine their status and how to correct the records, if necessary. The USCIS also provides information on the types of documentation that may be presented to demonstrate CHE status.[216] Finally, as noted above, CMS and the SSA plan outreach to community resources, such as organizations that assist affected individuals, including SHIPs and other community-based and immigrant-serving organizations, to help connect individuals with additional information and assistance regarding the new Medicare eligibility requirements.

Comment: Multiple commenters requested that notices comply with the language-access requirements of section 1557 of the Affordable Care Act and other Medicare language access requirements; be written in plain language and at an accessible reading level; be translated into commonly spoken languages; and be accessible to individuals with disabilities and limited English proficiency.

Response: We thank commenters for these recommendations. The SSA will develop and issue these notices consistent with current applicable Federal plain-language, language-access, and accessibility requirements.

The SSA has existing procedures for providing notices in accessible formats to certain individuals who are blind or visually impaired through its Special Notice Option program. Under these procedures, available notice options include Braille, large print, audio CD, a Microsoft Word file on CD, certified mail, or first-class mail accompanied by a follow-up telephone call, as

[216] *https://www.uscis.gov/save/resources/information-for-save-users-cuban-haitian-entrants.*

applicable. The SSA's POMS GN 00211.001, Section 504 of the Rehabilitation Act of 1973: Standard and Non-Standard Accommodations, also provides procedures for requests for other notice accommodations. These existing accessibility processes will continue to apply, as appropriate, to individuals receiving the SSA's communications.

The SSA also provides language assistance to individuals who prefer to conduct business in a language other than English. The SSA provides free interpreter services by telephone and in Social Security offices, where interpreters are available in more than 200 languages. The SSA translates most Social Security notices into Spanish; notices not available in Spanish include a Spanish-language cover letter offering translation assistance through a local Social Security office. The SSA also makes public information materials available in multiple languages through its Multilanguage Gateway.

Finally, CMS plans to send a courtesy notice to the grace period population and to those individuals outside the grace period following the SSA's notice. CMS's notice will include taglines in 14 different languages for those with limited English proficiency and contains a statement informing individuals that they can request accommodations.

Comment: A couple of commenters recommended that Medicare termination notices include information to help affected individuals maintain access to health care after their Medicare entitlement or enrollment ends. Commenters requested that CMS and the SSA provide information regarding continuity-of-care considerations and resources that may assist individuals in identifying other health coverage options for which they may be eligible. Some commenters also recommended that CMS and the SSA facilitate handoffs to alternate coverage options or providers to help individuals transition from Medicare coverage.

Response: We appreciate the commenters' concerns regarding continuity of care and access to other health coverage following termination of Medicare. As availability of other coverage options will be dependent on an individual's circumstances, it will not be feasible to include information on other health care options in individual notices or facilitate handoffs to alternative coverage options. CMS and the SSA plan to implement a robust outreach and education effort with the implementation of section 1899C of the Act and will include relevant information on other health coverage options available, whenever possible.

Comment: Multiple commenters requested that CMS and the SSA provide individuals outside the grace period population with earlier and more robust notice before terminating Medicare entitlement or enrollment under section 1899C of the Act. Commenters recommended that individuals outside the grace period population receive a preliminary notice at least 90 days before termination. Commenters also recommended that preliminary notices be provided on an ongoing basis for individuals identified after the initial implementation period.

Response: We thank commenters for their recommendations regarding advance notice for individuals outside the grace period population. The SSA plans to send a preliminary notice in November 2026 to all individuals it has identified as not meeting or potentially not meeting the requirements of section 1899C(a) of the Act, regardless of whether the individual is within the grace period population. As such, preliminary notices will be sent almost 90 days before a termination would take effect. The preliminary notice will inform individuals that the SSA's records indicate that they may not meet the requirements of section 1899C(a) of the Act, instruct them to contact the SSA and provide updated evidence of eligibility, and inform them that they could potentially lose entitlement to Part A and/or enrollment in Part B. Similar to the grace period population, individuals who receive the preliminary notice who do not establish continued eligibility will subsequently receive a formal termination notice in December 2026 before their Medicare entitlement and/or enrollment terminates. As discussed previously, termination for those individuals outside of or not notified as part of the grace period population will be effective at the end of the month following the month in which the termination notice is dated. Therefore, for these individuals, this final rule provides that, based on a December 2026 termination notice date, the earliest that Medicare entitlement/enrollment termination will occur is at the end of January 2027. In practical terms for Medicare beneficiaries, this means that they will not have Medicare coverage beginning February 1, 2027.

To note, the SSA and CMS currently plan to send preliminary notices only to Medicare enrolled individuals that the SSA is able to identify before November 2026 as not meeting or potentially not meeting the requirements of section 1899C(a) of the Act. The preliminary notice is an additional implementation measure intended to provide affected individuals with an opportunity to update their records during the initial transition to the new Medicare eligibility requirements established by section 1899C of the Act. Because this rule implements new statutory eligibility requirements and establishes a new termination framework, we believed that additional advance communication was appropriate during this transitional period. However, once the new requirements have been fully implemented, notices will be sent consistent with the process described in this final rule.

Comment: Multiple commenters requested that CMS explicitly hold harmless individuals who became entitled to, or enrolled in, Medicare after July 4, 2025, before the SSA implemented screening procedures for the new eligibility requirements under section 1899C of the Act, and who are subsequently determined not to meet the new eligibility requirements. A commenter requested that terminations not apply retroactively to physician payments and that guidance be provided regarding services rendered prior to an individual's termination date.

Response: We thank commenters for these recommendations. Individuals who were enrolled in Medicare after July 4, 2025, but before the SSA implemented screening for the requirements of section 1899C(a) of the Act, and who are subsequently determined not to meet those requirements, will have their Medicare entitlement or enrollment terminated prospectively under the termination process described previously. Their Medicare entitlement or enrollment will not be retroactively terminated for the months in which they were enrolled.

Accordingly, CMS will take no action to recover any Medicare payments for services rendered before the individual's prospective termination due to not meeting the requirements of section 1899C(a) of the Act. Claims for services rendered prior to a termination of entitlement and enrollment will be processed according to existing procedures. Because the termination framework does not retroactively terminate the individual's Medicare entitlement or enrollment for those months, a separate hold-harmless policy is not necessary.

Comment: Multiple commenters were concerned with the high likelihood of erroneous terminations and requested that CMS and the SSA delay implementation to establish stronger pre-termination review procedures and safeguards for all individuals whose

Medicare entitlement or enrollment may be terminated under section 1899C of the Act. A commenter also recommended that CMS extend the 18-month grace period, which would in effect delay implementation of terminations for individuals in the grace period population.

Response: We appreciate the commenters' recommendations. The SSA used and is using the most current information and verification tools available to it to make accurate determinations under section 1899C of the Act, including information or documentation provided by individuals. Individuals identified as potentially not meeting the requirements of section 1899C(a) of the Act, including those individuals in the 18-month grace period population, will receive a preliminary notice and have an opportunity to provide updated evidence to the SSA before a formal determination of ineligibility is made. We believe that sufficient safeguards have been established to identify ineligible individuals and to provide them with opportunities to furnish updated evidence of eligibility and appeal determinations that individuals believe are erroneous. Further, section 1899C(b)(1) of the Act specifies that individuals entitled to, or enrolled for Medicare benefits as of July 4, 2025, who no longer meet the requirements under section 1899C(a) of the Act, will have their Medicare entitlement and enrollment terminated beginning on the date that is 18 months after July 4, 2025. No provision in section 1899C of the Act permits extension of the grace period.

Comment: Multiple commenters stated that, regardless of when or how an individual is identified as potentially ineligible, the individual should have a meaningful opportunity to correct inaccurate, incomplete, outdated, or inconsistent citizenship, nationality, or immigration status or category information before coverage ends or to promptly restore coverage.

Response: We thank commenters for these recommendations. As noted previously, individuals identified as not meeting or potentially not meeting the requirements of section 1899C(a) of the Act prior to November 2026 will be sent preliminary notices from the SSA instructing them to contact the SSA and provide updated evidence if they believe they meet the requirements of section 1899C(a) before a formal notice of termination of entitlement and enrollment is sent. Further, any individual identified as not meeting the requirements of section 1899C(a) of the Act will receive a termination notice stating that their enrollment will be terminated at the end of the month following the month in which the notice is dated and will have the opportunity for successive levels of appeals, including a reconsideration, a hearing before an administrative law judge, a hearing before the Appeals Council, and filing a complaint with a Federal district court, subject to any applicable requirements for each level of appeal.

Comment: Multiple commenters also requested that CMS clarify what happens when an individual submits documentation before the scheduled termination date but agency review remains pending. Commenters urged CMS and the SSA to delay Medicare terminations when an individual has timely submitted documentation or other information to establish continued eligibility under section 1899C of the Act but agency review remains pending, and not to terminate coverage solely on the basis of an automated data match or incomplete administrative record..

Response: We appreciate the commenters' request for clarification and recommendation that Medicare termination be delayed while an eligibility review or correction request is pending. Except as provided in section 1899C(b)(1) of the Act, an individual may not remain entitled to, or enrolled for, Medicare unless the individual meets the requirements of section 1899C(a) of the Act. CMS therefore does not have authority to establish a continued-coverage exception based solely on the pending status of an eligibility review or correction request. In some cases, an individual may submit documentation before termination, but the SSA may not complete its review until after the termination has taken effect. If the SSA subsequently determines that the individual met the applicable Medicare eligibility requirements at the time of termination, existing procedures allow the prior determination to be corrected and Medicare entitlement or enrollment to be reinstated retroactively, as appropriate. For premium Part A or Part B, the individual may be responsible for applicable premiums for any retroactive period. Once entitlement or enrollment is restored retroactively, Medicare claims for covered services furnished during the restored period may be processed, consistent with applicable Medicare claims rules.

Individuals have the right to file an appeal, or a request for reconsideration, within 60 days of receiving notice of the SSA's determination. The 60-day timeframe for filing a request for reconsideration may be extended for good cause. Finally, in making a determination under section 1899C(a), the SSA will consider available information from its records and any updated information or documentation provided by the individual. As available to SSA and appropriate, SSA will also consider information available from records from other agencies.

Comment: Multiple commenters requested that termination notices clearly explain applicable reconsideration, appeal, and judicial review rights, including how to challenge an erroneous determination. Further, multiple commenters requested that Medicare coverage continue during a timely appeal process.

Response: We appreciate these comments and note that termination notices sent by the SSA to individuals that do not meet the requirements of section 1899C(a) of the Act will provide information regarding the individual's appeal rights and how to request the first level of appeal, which is a request for reconsideration. Appeals of Medicare Part A and Part B entitlement determinations are administered under 20 CFR part 404, subpart J. This process provides for reconsideration, a hearing before an administrative law judge, Appeals Council review, and judicial review, as applicable. However, section 1899C of the Act does not provide CMS with authority to extend Medicare coverage during an appeal.

Comment: Multiple commenters also requested that notices explain how individuals may request good-cause extensions of appeal deadlines when they need additional time to gather documentation, are receiving medical treatment, or otherwise cannot file within the standard timeframe.

Response: We appreciate the commenters' request. As noted previously, appeals of initial determinations, or a request for reconsideration, regarding Medicare Part A or Part B entitlement and enrollment are governed by existing SSA appeals procedures. Under those procedures, a request for reconsideration generally must be filed within 60 days after the individual receives notice of the initial determination. An individual who misses the filing deadline can request an extension based on good cause, including where the individual did not timely receive the notice. Termination notices will state that individuals can file beyond the 60-day reconsideration deadline if they have a good reason.

Comment: Several commenters requested expedited appeal or pre-termination review procedures for individuals who are terminated or denied enrollment in order to challenge

determinations that the individuals believe are erroneous. A commenter suggested that reconsideration decisions be issued within a set timeframe. Additionally, a commenter recommended that the appeal timeframe be changed to run from the time the person first became aware that they are not covered, for example, when they learn at a medical appointment that they no longer have Medicare, rather than from the notice date.

Response: We thank commenters for these recommendations. As noted previously, appeals of initial determinations regarding Medicare Part A or Part B entitlement are governed by existing SSA reconsideration procedures. Under the existing process, a request for reconsideration generally must be filed within 60 days after the individual receives notice of the initial determination, rather than 60 days from the date of the notice. This ensures that the time required for delivery of the notice does not reduce the individual's 60-day period to request reconsideration. SSA generally presumes that an individual receives the notice five days after it is mailed, unless the individual shows otherwise. If an individual does not timely receive the notice or otherwise has good cause for missing the filing deadline, the individual may request an extension for good cause under existing SSA procedures, which may include situations in which an individual demonstrates that they did not receive notices. If an individual timely requests reconsideration, and the SSA determines that the individual meets the requirements of section 1899C(a) and that their Medicare entitlement and enrollment should not have been terminated, the SSA will reinstate Medicare entitlement and enrollment, as appropriate. The SSA's existing appeals procedures have been used for decades to adjudicate questions of Medicare entitlement and enrollment, and we believe these procedures are well suited to address eligibility issues under section 1899C(a) of the Act. Therefore, we are not adopting a separate appeals process or timelines for individuals who are terminated for failure to meet the eligibility criteria under section 1899C(a) of the Act.

Comment: Multiple commenters expressed concern that individuals may be incorrectly identified as ineligible and therefore denied or terminated for Medicare under section 1899C of the Act because citizenship, nationality, or immigration-status information maintained across Federal systems may be incomplete, outdated, delayed, or inconsistent. Commenters stated that the SSA may need to coordinate with CMS, DHS, USCIS, and other Federal agencies to ensure that noncitizen status is accurately and timely established and that individuals who remain eligible are not swept into termination processes because of data-sharing delays, database mismatches, name or identifying-information discrepancies, pending document renewals, or other record errors.

Response: We thank commenters for their comments regarding the accuracy of citizenship, nationality, and immigration status or category information used to implement section 1899C of the Act. To reduce the risk of erroneous determinations resulting from incomplete, outdated, or inconsistent records, the SSA will only use data that has been determined appropriately accurate to assure fairness in its determinations. The SSA will also consider updated information or documentation provided by the individual. When available information indicates that an individual may not meet the requirements of section 1899C(a) of the Act, individuals will have an opportunity to contact the SSA and provide updated evidence if they believe the information is incorrect or has changed.

CMS will continue to coordinate with the SSA and other Federal agencies, as appropriate, regarding implementation of these verification processes and explore opportunities to enhance coordination and ensuring up-to-date information.

Comment: A commenter requested that CMS address potential confusion among mixed-status families, or families that have members with different Federal health insurance program enrollments when issuing immigration-related Medicare notices. The commenter stated that notices should clearly identify whose Medicare eligibility is changing, whose eligibility is not changing, and where families can obtain reliable assistance. The commenter also requested that CMS state plainly that a Medicare eligibility change affecting one household member does not, by itself, alter another eligible family member's Medicare, Medicaid, or other health-program eligibility. Another commenter stated that confusion about eligibility or administrative complexity may deter individuals and families from seeking needed healthcare services.

Response: We acknowledge the commenters' concerns regarding communications to mixed-status families. Eligibility determinations under section 1899C of the Act are made with respect to the individual whose Medicare entitlement or enrollment is being reviewed. A change in one individual's Medicare eligibility under section 1899C of the Act does not, by itself, change another family member's eligibility for Medicare, Medicaid, or another health program; eligibility for other household members continues to be determined under the requirements applicable to each program. CMS and the SSA will address these issues, as appropriate, through beneficiary notices, educational materials, and subregulatory guidance.

Comment: Several commenters expressed concern that the SSA may not have sufficient staffing, resources, systems, or call-center capacity to implement section 1899C of the Act accurately and timely and recommended that CMS and the SSA prepare the SSA field offices and call centers, develop standardized scripts and multilingual materials, and ensure staff are trained to respond to questions from affected individuals and organizations assisting them.

Response: We thank commenters for their comments regarding the SSA staffing and operational capacity. CMS and the SSA are coordinating to ensure a robust outreach effort, including call center scripts, updated educational and translated materials, and training of the SSA field office technicians. The SSA is working to ensure sufficient customer service in addressing interested parties' questions and the processing of documentation.

After consideration of public comments, we are finalizing, as proposed, the provisions pertaining to termination processes for certain noncitizens entitled to, or enrolled for, Medicare—both the grace period population, as well as those that fall outside of the grace period.

3. Enrollment Pathway for Individuals Who Gain or Regain Eligibility

Section 1899C of the Act limits eligibility for Medicare to specified categories of individuals based on citizenship, nationality, or immigration status or category. As a result, except as provided in section 1899C(b) of the Act, no individual may be entitled to, or enrolled for, Medicare if the individual does not meet the requirements of section 1899C(a) of the Act. Conversely, individuals may later become eligible if their citizenship, nationality, or immigration status or category changes, such that they satisfy section 1899C(a) of the Act, as well as applicable Medicare eligibility requirements.

To address circumstances in which individuals who initially did not meet the eligibility requirements of section

1899C(a) of the Act at the time they met all other Medicare eligibility requirements but, subsequently, do meet the section 1899C(a) of the Act requirements, we proposed to establish a special enrollment period (SEP) under §§ 406.27(f) and 407.23(f). The SEP would also apply to those individuals whose Medicare entitlement or enrollment is terminated because they do not or no longer meet the requirements in section 1899C(a) of the Act, but who subsequently experience a change such that they meet the requirements of section 1899C(a) of the Act. Establishing an SEP for these scenarios is within the Secretary's authority under sections 1837(m) and 1838(g) of the Act, which provide for the establishment of SEPs for exceptional conditions. In the proposed rule, we stated that we consider the enactment of the WFTC legislation and addition of section 1899C of the Act to constitute an exceptional condition because it created a new and narrower class of noncitizens who may be eligible for Medicare than are eligible for title II benefits, despite the close associations between title II entitlement and Medicare entitlement, as discussed in section III.F.1. of the proposed rule, and despite the fact that lawful presence has been the standard for noncitizen eligibility for both title II and Medicare benefits for decades. In addition, the statutory changes made by the WFTC legislation fundamentally altered the consequences of changes in immigration status. We noted in the proposed rule that prior to enactment of the WFTC legislation, noncitizens enrolled in Medicare who had a loss of lawful presence status would have remained enrolled in Medicare, but payment for benefits would have been suspended. Now, in accordance with section 1899C of the Act, an individual who no longer meets the requirements of section 1899C(a) of the Act must have their entitlement and enrollment terminated. If such an individual later meets the requirements of section 1899C(a) of the Act, it may be at a time that does not clearly fall within an established enrollment period. In addition, individuals who otherwise meet the eligibility requirements for Medicare but for the eligibility requirements of section 1899C(a) of the Act may gain eligibility at a time that does not clearly fall within an established enrollment period. For this proposed SEP, we also proposed that the general rule in §§ 406.27(a) and 407.23(a) that an individual must have missed an enrollment period due to the exceptional condition would not apply. We believe this is necessary because, for example, as explained below, the 7-month initial enrollment period under sections 1818(c)(1) and 1837(d) of the Act does not align well with the unpredictable nature as to when an individual may experience a change in citizenship, nationality, or immigration status or category, such that they would meet the requirements of section 1899C(a) of the Act. As another example, an individual may lose and subsequently regain eligibility under section 1899C(a) of the Act during a period that does not overlap with an otherwise available enrollment period, such that no enrollment period is actually missed. Accordingly, this SEP would be available to individuals who later meet, or again meet, the requirements of section 1899C(a) of the Act, regardless of whether an enrollment period was missed.

We proposed that the SEP would begin in the month in which the individual, upon contacting the SSA, provides sufficient documentation to establish eligibility, and the proposed SEP would end 6 months later. The duration of this proposed SEP would be the same time frame afforded to individuals granted an SEP for exceptional conditions under §§ 406.27 and 407.23. We proposed that entitlement and enrollment would be prospective for premium Part A and Part B, beginning with the first day of the month following the month of enrollment. We believed a prospective effective date is appropriate and consistent with the Secretary's authority under section 1818(c)(8) of the Act for premium Part A and section 1838(g) of the Act for Part B to establish the date on which coverage begins for individuals enrolling during an SEP, in a manner consistent, to the extent practicable, with protecting continuity of health benefit coverage. Although an individual may in some cases be able to demonstrate an earlier date on which the requirements of section 1899C(a) of the Act were met, we proposed a uniform prospective effective date for premium Part A and Part B because citizenship data in the SSA records is gathered and verified at a point in time and does not provide a reliable or administrable basis for consistently establishing earlier eligibility dates for enrollment purposes. In addition, a retroactive effective date for premium Part A and Part B could require the assessment of back-due premiums for months of coverage that the individual had not yet affirmatively elected, which would add operational complexity and could create unexpected financial obligations for beneficiaries. We believed a prospective-only approach is therefore the most practicable and administrable method for implementing this SEP for premium Part A and Part B.

We considered an alternative pathway which consisted of establishing an initial enrollment period for premium Part A and Part B for eligible noncitizens who would have been eligible for Medicare based on entitlement to benefits under title II of the Act and attainment of age 65 or completion of the 24-month waiting period for disability benefits, as applicable, but whose entitlement was never effectuated because they did not meet the citizenship, nationality, or immigration status or category requirements specified in section 1899C(a) of the Act. However, we note that the 7-month initial enrollment period articulated in sections 1818(c)(1) and 1837(d) of the Act is largely tied to the attainment of age 65 or completion of the 24-month waiting period for disability benefits and begins on the first day of the third month before the month in which an individual meets the eligibility requirements for premium Part A and Part B. Traditionally, this 3-month pre-eligibility period provides an opportunity for individuals to explore coverage options (for example, original Medicare or MA) and enroll in Part A and Part B. This 3-month period helps individuals avoid delays and gaps in coverage. As a practical matter, such an initial enrollment period could not be applied in an analogous manner to changes that would make an individual eligible for Medicare by virtue of meeting the requirements of section 1899C(a) of the Act because an individual may not be enrolled for Medicare benefits unless and until they meet the requirements of section 1899C(a) of the Act. As a result, establishing an initial enrollment period under sections 1818(c)(2) and 1837(d) of the Act or these individuals would effectively shorten the enrollment period by 3 months because such individuals could not be enrolled in Medicare until the section 1899C(a) of the Act requirements are met, which would conflict with the requirements of the Act. Instead, we opted for a proposed approach of establishing a SEP for individuals enrolling in Medicare for the first time, as well as individuals who lost and regained Medicare, due to changes in citizenship, nationality, or immigration status or category because it comports with the requirements of the Act.

For premium-free Medicare Part A, we proposed that entitlement may be retroactive for up to 6 months, but not

earlier than the first month in which the individual met all the eligibility requirements in proposed § 406.5(a). Under this proposal, if acceptable evidence establishes the month in which the individual first satisfied the citizenship, nationality, or immigration status or category requirements in § 406.5(a)(2), the SSA would use that month, subject to the applicable retroactivity limit. If the earliest month of eligibility cannot be established based on acceptable documentary evidence, entitlement would instead begin on the first day of the month in which the SSA verifies that the individual satisfies § 406.5(a)(2).

Accordingly, to implement the enrollment processes described earlier for individuals who establish or reestablish eligibility under section 1899C(a) of the Act, we proposed to amend the regulations at 42 CFR part 406 (Medicare Part A) and 42 CFR part 407 (Medicare Part B) to specify the availability, duration, and effective date rules for enrollment under these circumstances. We proposed to add and revise the following sections:

- Premium-Free Medicare Part A:

++ Paragraph (b) would be revised in § 406.6 (Application or enrollment for hospital insurance) to include the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act for individuals who need not file an application for hospital insurance.

++ New paragraph (f) would be added to § 406.6 (Application or enrollment for hospital insurance) to establish rules for individuals who would otherwise qualify for premium-free Part A based on entitlement to title II benefits, but who were not entitled because they did not meet the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act at the time they otherwise would have become eligible. It would also specify how such individuals may initiate entitlement upon later meeting those requirements and clarify the applicable entitlement effective date, including the circumstances under which premium-free Part A entitlement would begin consistent with current law. Paragraph (1) applies to those who meet the conditions of paragraph (b) of this section and, as such, need not file an application for hospital insurance. These individuals must contact the SSA to initiate entitlement to hospital insurance. Paragraph (2) applies to those who meet the conditions of paragraph (c) of this section and, as such, must file an application for hospital insurance. These individuals must contact the SSA to file such application.

- Premium Medicare Part A:

++ Paragraph (f) would be redesignated as paragraph (g) and new paragraph (f) would be added to § 406.27 (Special enrollment periods for exceptional conditions). This new paragraph would establish an SEP for individuals whose premium Part A enrollment was previously terminated because they lost the citizenship, nationality, or immigration status or category required under section 1899C(a) of the Act, but who later regain a qualifying status and again become eligible. The SEP would also apply to individuals who would otherwise meet the eligibility requirements for Medicare, except for those in section 1899C(a) of the Act, and later meet the eligibility requirements of section 1899C(a) of the Act. The new provision would specify the availability and duration of this SEP and clarify that enrollment under this pathway would be prospective, consistent with the Secretary's authority to establish SEPs for exceptional conditions. An individual does not need to miss an applicable enrollment period to be eligible for this SEP.

- Medicare Part B:

++ Paragraph (f) would be redesignated as paragraph (g) and new paragraph (f) would be added to § 407.23 (Special enrollment periods for exceptional conditions). This new paragraph would establish a SEP for individuals whose Part B enrollment was terminated because they no longer met the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act, but who subsequently regain a qualifying status and again become eligible to enroll. The SEP would also apply to individuals who otherwise met the eligibility requirements for Medicare, except for those in section 1899C(a) of the Act, and later meet the eligibility requirements of section 1899C(a) of the Act. It would specify the duration of the SEP and the prospective effective date of Part B coverage for individuals enrolling under this pathway. An individual does not need to miss an applicable enrollment period to be eligible for this SEP.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Multiple commenters expressed support for CMS's proposal of an SEP but urged CMS to extend the proposed 6-month SEP, with some recommending either an 8-month, 12-month, or an indefinite SEP, because affected individuals may need additional time to obtain immigration or citizenship documentation, secure appointments with the SSA, update Federal records, and complete verification.

Response: We appreciate commenters' suggestions and concur with extending the duration of the SEP. We recognize the unique challenges that individuals may face and the additional time that may be required to obtain documentation from their countries of origin, navigating through immigration processes, updating documentation, and providing pertinent documentation to the SSA. Therefore, we are modifying the proposed SEP from 6 months to 12 months to account for the additional time that may be required and to provide flexibility to individuals establishing Medicare eligibility. The SEP will begin on the first day of the month in which the individual contacts the SSA and provides sufficient information to establish that the applicable eligibility requirements are met, and ends the last day of the 12th month after the month in which the individual provides sufficient evidence of eligibility.

Comment: Multiple commenters also requested that individuals enrolling under the SEP be permitted to elect prospective or retroactive premium Part A and Part B coverage. Several commenters suggested allowing individuals to select the retroactive coverage start month.

Response: We concur with commenters' suggestions to allow the choice of prospective or retroactive coverage for premium Part A and Part B enrollment. The option to select retroactive coverage is intended to provide time for individuals who become eligible for Medicare following a change in citizenship, nationality, or immigration status or category to gather relevant paperwork and contact the SSA, while preventing extended gaps in coverage. As noted above, in the proposed rule, prospective-only entitlement and enrollment for premium Part A and Part B was proposed due to the fact that citizenship and immigration status data in the SSA records is gathered and verified at a point in time, which we were concerned would not provide a reliable or administrable basis for establishing earlier, retroactive eligibility dates for enrollment purposes. We were also concerned that retroactive eligibility for premium Part A and Part B could result in back-due premiums, which would add operational complexity and could create unexpected financial obligations for beneficiaries. However, upon

reviewing comments on the proposed rule and after further consideration, we are finalizing providing beneficiaries the option of prospective or retroactive coverage for premium Part A and Part B enrollment. We recognize that it is feasible to provide evidence of and to verify retroactive eligibility for Medicare, especially as verification procedures and informational databases improve in the future. Allowing for retroactive coverage will minimize gaps in coverage and provide flexibility for individuals to obtain documentation and make a choice that best fits their circumstances. The choice of retroactive coverage will also allow individuals to determine whether they can pay retroactive premiums. The limit of retroactive coverage to six months serves as a guardrail by limiting the amount of retroactive premiums owed and mitigating potential abuse of individuals delaying enrollment and using the SEP to avoid late enrollment penalties.

We are modifying the proposed effective date for premium Part A and Part B to state that the default will be for a prospective enrollment date, that is, the first day of the month following the month of enrollment, but individuals will have the option to elect retroactive coverage. When individuals use the SEP, they will be presented with the option of retroactive coverage through enrollment forms and prompts, which the SSA will then process. The individual will need to provide the SSA with sufficient evidence of retroactive eligibility. If an individual chooses retroactive coverage, the effective coverage date is 6 months before the month of enrollment, but not before the month in which the individual meets all of the Medicare eligibility requirements. The individual must provide sufficient documentation for which the SSA can verify their eligibility for any months of retroactive coverage. The individual would not be allowed the option to pick the number of retroactive months, which is consistent with other SEPs that allow retroactive enrollment. In addition, the individual would be required to pay all applicable premiums if they choose a retroactive enrollment date. To illustrate, if a 70-year old individual who was previously ineligible for Medicare goes to an SSA office in July of 2029, applies for and uses a Medicare special enrollment period, and presents evidence of becoming a lawful permanent resident three months earlier, that individual could select the option of retroactive coverage. The individual would be responsible for paying three months of retroactive premiums since only three months of retroactive Medicare eligibility has been established and verified. If the individual cannot pay retroactive premiums as a one-time payment, the individual could request an installment plan, per the SSA's existing procedures.[217] In the event of retroactive coverage, the individual would inform their providers of their retroactive entitlement/enrollment status and the provider could submit claims to the Medicare Administrative Contractor for payment and reimburse previously paid claim amounts to the individual or other payor.

We are adopting a 6-month retroactive coverage period, which aligns the treatment of premium Part A and Part B under this SEP with the retroactive coverage period applicable to premium-free Part A. This SEP is not intended to replace or limit the Secretary's authority under section 1837(h) of the Act and 42 C.F.R. §§ 406.38 and 407.32 to provide appropriate relief where the statutory requirements are satisfied.

Comment: Multiple commenters further urged CMS to ensure that individuals whose Medicare coverage is interrupted because they no longer meet the requirements of section 1899C(a) of the Act, and who later regain eligibility, are not subject to late enrollment penalties, or other disadvantages attributable solely to the statutory termination or processing delays. Commenters stated that these individuals should not be treated as having voluntarily declined or delayed Medicare enrollment and requested protections to facilitate prompt reenrollment and minimize gaps in coverage and care.

Response: We appreciate these comments regarding late enrollment penalties and other enrollment consequences. Individuals who enroll in premium Part A or Part B using the SEP will not be assessed a late enrollment penalty in connection with the enrollment, consistent with the treatment of SEPs for exceptional conditions under sections 1818(c) and 1839(b) of the Act. The SEP provides individuals with the opportunity to enroll once eligibility is established minimizing gaps in coverage and care and avoiding any late enrollment penalties.

Comment: A few commenters requested that CMS and the SSA maintain accessible nondigital pathways, such as telephone, mail, and in-person appointments, for individuals to correct citizenship, nationality, or immigration status information and to enroll or reenroll in Medicare after meeting the requirements of section 1899C(a) of the Act.

Response: We thank the commenters for their comments. The SSA has a national customer service number, as well as a telephone number and address for individuals to contact their local social security office, which often have in-person appointments available. In addition, individuals can create an individualized social security account on ssa.gov. CMS and the SSA will maintain the existing pathways and consider additional pathways as they become available to allow individuals to update their documentation and verify eligibility.

Comment: A couple commenters requested that CMS clarify how Medicare enrollment rules apply to individuals who first become eligible for Medicare because they newly meet the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act. The commenters stated that individuals who qualify for Medicare for the first time based on a change to an eligible immigration status or citizenship should be entitled to the same initial enrollment period as other new Medicare enrollees.

Response: We acknowledge the comments regarding initial enrollment periods (IEP) for individuals who first meet the citizenship, nationality, or immigration status or category requirements under section 1899C(a) of the Act. We considered establishing an IEP for individuals who would otherwise initially meet the age- or disability-based Medicare requirements, but whose Medicare entitlement or enrollment was not effectuated because they did not meet the requirements of section 1899C(a) of the Act. However, as discussed in the proposed rule, the IEPs in sections 1818(c) and 1837(d) of the Act are tied to an individual's attainment of age 65 or completion of the 24-month disability waiting period. Those IEPs include a period before the individual first becomes eligible for Medicare, which allows the individual to enroll before eligibility begins and avoid delays in coverage.

That predictable timeframe and structure does not apply in the context of when an individual may attain eligible non-citizen status for Medicare. In this circumstance, eligibility to enroll or be entitled to Medicare is predicated on a future change in citizenship, nationality, or immigration status or category, and the timing of any such change is likely unpredictable. Therefore, an IEP beginning three

[217] POMS HI 00805.180—Payment of Premium Arrearage.

months before the month in which the individual first meets section 1899C(a) of the Act proves infeasible. More pointedly, applying the IEP provisions in sections 1818(c) and 1837(d) of the Act in the cases of individuals who meet the requirements of section 1899C(a) later than when they meet, for example, the age or disability criteria for Medicare eligibility would be unfair to those individuals, as they would functionally lose out on several months of an enrollment period that they would have been eligible for during an IEP based on age or disability.

Sections 1818(c) and 1837(m) of the Act authorize the Secretary to, in his discretion, establish the SEP for individuals who first meet the requirements of section 1899C(a) of the Act, or who lose and later regain Medicare eligibility due to a change in citizenship, nationality, or immigration status or category. In exercising this discretion, the Secretary is establishing an enrollment period timeframe that provides an analogous enrollment opportunity that they would have during an initial IEP. Further, the extension of the SEP to 12 months, along with the option of up to 6 months of retroactive coverage provides a greater opportunity for enrollment and minimizes gaps in coverage.

Comment: A commenter also requested clarification on whether a protective filing date for an SEP would be established when a person contacts the SSA in person.

Response: The SSA's rules on protective filing dates for disability applications are not relevant for purposes of the timing or duration of the SEP. We are finalizing, as proposed, that the SEP begins on the first day of the month in which the individual contacts the SSA and provides the SSA with sufficient information to demonstrate that the Medicare eligibility requirements have been met. This policy will apply regardless of how the individual contacts the SSA or whether the individual provides the information (necessary to prove U.S. citizenship or nationality or eligible noncitizen status) in person, by mail, or electronically (such as through an individual's ssa.gov account), which will then require verification by the SSA. The individual will have 12 months from the month in which the individual contacts the SSA and provides the SSA with sufficient information to demonstrate that the Medicare eligibility requirements have been met to enroll prospectively using the SEP. As noted previously, an individual enrolling during the SEP may elect retroactive coverage of up to 6 months, but not before the month in which the individual first met all of the Medicare eligibility requirements. The requirements for retroactive coverage for premium Part A and Part B are at §§ 406.27(f)(3)(ii) and 407.23(f)(3)(ii).

The effective date rules in this SEP do not govern coverage established under a State buy-in agreement under sections 1843 and 1818(g) of the Act; the beginning of coverage under a buy-in agreement continues to be governed by §§ 406.26(b) and 407.47.

After consideration of public comments, we are finalizing the changes to §§ 406.27 and 407.23 as proposed, with the following modifications:

- Sections 406.27(f)(2) and 407.23(f)(2) would be revised to reflect that the SEP duration is 12 months; and
- In §§ 406.27 and 407.23, paragraph (f)(3) would be revised to reflect that individuals enrolling during the SEP will have prospective coverage (that is, the first day of the month following the month of enrollment) unless they elect retroactive coverage (up to 6 months).

4. Limiting Coverage Under Medicare Part C, Medicare Part D, and Cost Plans to Certain Individuals

Under section 1851(a)(3) of the Act, MA is available only to individuals who are entitled to Medicare Part A and are enrolled in Medicare Part B. Medicare Part D (the Medicare prescription drug benefit) is available to individuals who are entitled to Medicare Part A or are enrolled in Medicare Part B, as specified in section 1860D—1(a)(3) of the Act. Section 1876(a)(1)(A) of the Act outlines eligibility requirements to enroll in Medicare cost plans and provides that individuals may enroll in cost plans if they are entitled to Medicare Part A and are enrolled in Part B or are enrolled in Part B only. Eligibility for enrollment in an MA plan, Part D plan, or cost plan is therefore dependent on an individual's underlying entitlement to and/or enrollment in Medicare Part A and/or Part B, as applicable. Prior to the enactment of section 1899C of the Act, individuals who satisfied the statutory conditions for Medicare Part A entitlement and/or Medicare Part B enrollment, as applicable, were likewise eligible to enroll in MA plans, Part D plans, or cost plans, provided they met applicable enrollment requirements. The eligibility requirements in section 1899C of the Act apply to all parts of Medicare. Individuals who do not meet the eligibility requirements of section 1899C of the Act are not eligible for Medicare Part A or Part B and may not enroll or remain enrolled in MA plans, Part D plans, or cost plans.

Individuals enrolled in MA plans, Part D plans, or cost plans who do not meet the eligibility requirements of section 1899C of the Act must be disenrolled from those plans. Under 42 CFR 417.460(b)(2)(iii), 422.74(b)(2)(ii), and 423.44(b)(2)(ii), individuals who lose eligibility for enrollment are involuntarily disenrolled from the plan. Such disenrollments will be prospective and effective the first day of the calendar month following the month in which the plan receives a notice from CMS of the individual's loss of entitlement to Part A or Part B as specified under 42 CFR 417.460(h), 422.74(d)(5), and 423.44(d)(3).

Plans do not process these disenrollments. CMS processes these automatically through the MARx system when the SSA provides updated eligibility and entitlement records and CMS will notify the plan of the disenrollment due to loss of entitlement, through MARx transaction reply codes. Plans have the option, but are not required, to provide a notice of disenrollment due to loss of entitlement. Since the SSA provides a loss of entitlement notice for Part A and Part B, there is no need to require plans to provide additional notification.

Accordingly, we proposed to amend the regulations at 42 CFR part 417, part 422, and part 423 to incorporate the new eligibility limitations established by section 1899C of the Act. We proposed to revise the following sections to reflect the applicability of section 1899C of the Act:

- Paragraph (b) of § 417.2 (Basis and scope): We proposed to amend paragraph (b) of § 417.2 to add a reference to section 1899C of the Act, which establishes eligibility limitations applicable to cost plan enrollment.
- Paragraphs (a)(1)(xii) and (a)(2) of § 422.1 (Basis and scope): We proposed to amend § 422.1 to add paragraph (a)(1)(xii) to reference section 1899C of the Act, which establishes eligibility limitations applicable to MA enrollment. We further proposed to remove and reserve paragraph (a)(2) that references 8 U.S.C. 1611.
- Paragraphs (a)(1) and (3) of § 423.1 (Basis and scope): We proposed to amend paragraph (a)(1) of § 423.1 to add a reference to section 1899C of the Act, which established eligibility limitations applicable to Part D enrollment. We further proposed to remove and reserve paragraph (a)(3) of § 423.1 that references 8 U.S.C. 1611.

We also proposed to add that effective July 4, 2025, an individual must be a citizen or national of the United States or an eligible noncitizen as a basis for entitlement. We proposed to revise the following sections to add this language:

• Paragraph (h) of § 417.422 (Eligibility to enroll in an HMO or CMP).

• Paragraph (a)(7) of § 422.50 (Eligibility to elect an MA plan).

• Paragraph (a)(1)(iii) of § 423.30 (Eligibility and enrollment).

Additionally, we proposed to update the regulations at 42 CFR part 417, part 422 and part 423 to clarify the circumstances under which individuals must be disenrolled from MA plans, Part D plans, or cost plans due to failure to meet the eligibility requirements of section 1899C of the Act. Though failure to meet the eligibility requirements of section 1899C of the Act results in a loss of Part A and Part B eligibility, we proposed to create an involuntary disenrollment process for MA plans, Part D plans, and cost plans that is separate from the existing loss of entitlement to Part A or Part B disenrollment process. Administratively, separating failure to meet section 1899C of the Act eligibility requirements from all other reasons for loss of Part A or Part B entitlement allows CMS to better track the impact of this provision and create new technical processes with the SSA and internally. Specifically, we proposed to revise the following sections to add this language:

• Paragraphs (b)(2)(iv) and (j) of § 417.460 (Disenrollment of beneficiaries by an HMO or CMP): We proposed to amend paragraph (b)(2)(iv) of § 417.460 to state that a cost plan must disenroll an enrollee if they no longer meet the requirements of § 417.422(h). We proposed to amend paragraph (j) of § 417.460 related to the disenrollment effective date to apply to an enrollee who is not a U.S. citizen, U.S. national, or eligible noncitizen.

• Paragraphs (b)(2)(v) and (d)(9) of § 422.74 (Disenrollment by the MA organization): We proposed to amend paragraph (b)(2)(v) of § 422.74 to state that an MA plan must disenroll an enrollee if they no longer meet the requirements of § 422.50(a)(7). We proposed to amend paragraph (d)(9) of § 422.74 related to the disenrollment effective date to apply to an enrollee who loses U.S. citizenship or nationality, or eligible noncitizen status.

• Paragraphs (b)(2)(vi) and (d)(8) of § 423.44 (Involuntary disenrollment from Part D coverage): We proposed to amend paragraph (b)(2)(vi) of § 423.44 to state that a Part D plan must disenroll an enrollee if they no longer meet the requirements of § 423.30(a)(1)(iii). We proposed to amend the heading for paragraph (d)(8) of § 423.44 related to the disenrollment effective date to apply to an enrollee who loses U.S. citizenship or nationality, or eligible noncitizen status.

We also proposed to amend the regulations at 42 CFR part 422 and part 423 to replace the SEP that is currently applicable when an individual who is a non-U.S. citizen attains lawful presence status. Under this proposal, the SEP would apply when an individual verifies their eligible noncitizen/citizenship status with the SSA, after attaining the eligibility requirements of section 1899C(a) of the Act. The SEP would begin when the individual provides the SSA with sufficient information to demonstrate that the requirements of § 406.20(b)(2) and § 407.10(a)(2)(ii) have been met. Providing this information to the SSA and establishing eligibility would result in automatic entitlement for Part A, assuming that the individual was otherwise eligible for premium-free Part A. For Part B entitlement, the individual would also need to enroll in Part B under § 407.4(a)(2), after which the individual would become entitled to Part B.

We proposed to revise this language in the following sections:

• Paragraph (b)(16) of § 422.62 (Election of coverage under an MA plan).

• Paragraphs (c)(21)(i) and (ii) of § 423.38 (Enrollment periods).

Because eligibility to elect an MA plan requires an individual to be both entitled to Medicare Part A and enrolled in Medicare Part B, we proposed, that the SEP at § 422.62(b)(16) would last for 2 calendar months after the month in which the individual becomes entitled to Medicare Part A and enrolled in Medicare Part B. Similar to the way the MA Initial Coverage Election Period (ICEP) works under § 422.62(a)(1), we proposed that this SEP would be available as soon as the individual is entitled to Medicare Part A and enrolled in Medicare Part B. As a result, this SEP would be available to individuals who previously had and lost Part A and/or Part B because they did not have eligible noncitizen/citizenship status. For such individuals, they would not have access to the ICEP because their new entitlement to Medicare Part A and enrollment in Medicare Part B would not be their ''first'' entitlement, as required by the ICEP. We proposed this SEP as a way of ensuring that individuals gaining eligible noncitizen/citizenship status have the opportunity to enroll in MA upon becoming entitled to Medicare Part A and enrolling in Medicare Part B. Consequently, this SEP will replace the existing SEP for gaining ''lawful presence status,'' which is no longer a relevant eligibility criterion and needs to be removed. An enrollment using this SEP would be effective the first day of the calendar month following the month in which the election is made, as specified in § 422.68(d).

We proposed that the Part D SEP at § 423.38(c)(21)(i) and (ii) would last for 2 calendar months after either the individual's Part A or Part B entitlement or enrollment date, as applicable, since they can differ and individuals are eligible for Part D with either Part A or Part B. We also proposed that the SEP would end based on the earlier of the two dates. The Part D SEP needs a different timeline than its Part C equivalent since the eligibility criteria for the two programs differ. Importantly, we intended for this SEP to be used surrounding the period that an individual establishes their eligible noncitizen/citizenship status with the SSA, so we proposed that the SEP eligibility window begins upon the entitlement to Part A or enrollment in Part B, whichever is earlier. This timeline ensures that the SEP is based upon both the eligibility requirements for Part D and the intent to provide these individuals with an opportunity to enroll in Part D when initially eligible to make such an election after establishing eligible noncitizen/citizenship status. This SEP would also replace the existing SEP for gaining ''lawful presence status.'' An enrollment using this SEP would be effective the first day of the calendar month following the month in which the election is made, as specified in § 423.40(c).

We received public comments on the proposals related to limiting coverage under MA, Part D, and cost plans. The following is a summary of the comments we received and our responses.

Comment: Many commenters urged CMS to require MA, Part D, PACE, and cost plans to issue multiple notices to ensure impacted enrollees are fully informed of their loss of coverage as people may not connect the SSA termination notice with the health care they receive through these other programs. A commenter stated plans need to inform enrollees that the premiums they pay for their private health plans will stop being deducted from their SSA check, including what to do if premiums continue to be collected after their Medicare eligibility ceases.

Response: We thank the commenters for these recommendations. We do not believe multiple notices from MA, Part D, PACE, and cost plans should be a required condition of plan disenrollment. Disenrollment from MA, Part D, and cost plans following loss of

Part A or Part B entitlement is derivative of the underlying SSA Medicare entitlement determination. After the SSA updates entitlement records, CMS effectuates the plan disenrollment and notifies the plans. Plan premiums cease based on the disenrollment date. Our current regulations do not require plans to issue a disenrollment notice in this instance because the SSA provides notice of the loss of Medicare entitlement. The termination notices issued by the SSA will contain a statement that termination of entitlement and enrollment to Part A and Part B may impact any MA or Part D enrollment. We maintain our current regulations and continue to encourage plans to provide the enrollee with a notice of disenrollment using the model notice that includes language to contact the SSA as it pertains to Medicare entitlement.[218] CMS will continue to coordinate with the SSA and consider additional implementation guidance for plans.

Comment: Many commenters urged CMS to develop and require plans to use standard phone scripts and educational materials for their members explaining these changes in the law, and to refer their affected enrollees to resources in their local community (for example, SHIPs, ADRCs, Area Agencies on Aging, etc.). They also suggested that CMS provide training, educational materials, FAQs, scripts, and other resources to organizations that will assist affected individuals.

Response: CMS thanks the commenters for their suggestions. While our current regulations or policies finalized in this final rule do not require plans to use standard phone scripts and educational materials for their members explaining changes in the law and to refer their affected enrollees to resources in their local community, CMS intends to conduct a robust outreach and education effort that is accessible, multimodal, and broad in reach. CMS and the SSA have been working to develop a comprehensive communications plan to support implementation of section 1899C of the Act, including updated webpages and beneficiary materials and prepared scripts for 1–800–MEDICARE. CMS also plans to use existing communication and education channels, including the Medicare Learning Network (MLN), to provide information and educational resources to Medicare providers, SHIPs, and other interested parties. CMS will continue to coordinate with the SSA and other partners, as appropriate, to refine materials and outreach activities, including existing model disenrollment notices.

Comment: A few commenters suggested ongoing Medicare-related plan coverage pending a decision on a termination of enrollment appeal, including MA, Part D, cost, and PACE. Commenters suggested that MARx and other internal systems should reflect when an appeal is filed and a termination date communicated to plans should be suspended until the outcome of the appeal.

Response: We appreciate the commenters' suggestion. Disenrollment from MA, Part D, and cost plans following loss of Part A or Part B entitlement is derivative of the underlying Medicare entitlement determination. Continued Medicare coverage pending a decision on an appeal does not apply to terminations based on the eligibility requirements in section 1899C(a) of the Act. If an appeal results in a determination that the individual met the applicable Medicare eligibility requirements at the time of termination, including section 1899C(a) of the Act, the SSA will correct the prior determination and restore Medicare entitlement or enrollment retroactively, as appropriate, consistent with existing procedures. Related plan reinstatement would be addressed based on the corrected period of entitlement or enrollment, in line with current procedures.[219]

Comment: Several commenters expressed support for establishing SEPs for individuals who become eligible noncitizens. A commenter suggested extending the MA and Part D SEPs from two months to at least 6 months to enroll in a plan following restoration of Medicare eligibility and coverage, or align these enrollment opportunities with the longer Part A and Part B SEP. A commenter suggested that the SEP for enrollment into a plan start when an individual receives actual notice, rather than from the Part A and/or Part B entitlement date. Another commenter expressed that individuals should receive written notice of the SEP availability with clear start and end dates. A commenter questioned whether the SEP would require CMS approval and be restricted to the Medicare Online Enrollment Center and for guidance on interactions with other SEPs.

Response: We thank the commenters for their feedback. Our proposed SEP would have started when the individual was entitled to Part A and/or enrolled in Part B, as applicable; however, with the option to choose retroactive coverage in premium Part A and Part B, we are making a conforming modification to the MA and Part D SEPs at §§ 422.62(b)(16)(i) and 423.38(c)(21)(ii), respectively, to start the SEP for MA when the individual receives notice of Part A entitlement and Part B enrollment, and to start the SEP for Part D when the individual receives notice of either Part A entitlement or Part B enrollment. The MA SEP continues for an additional 2 calendar months after the month in which notice of Part A entitlement and Part B enrollment is received. For the Part D SEP, the SEP continues for an additional two calendar months after the month in which the individual received notice of the Part A entitlement or Part B enrollment, whichever is earlier. As discussed previously, the intent of the SEP is to provide individuals with an opportunity to enroll in a plan when initially eligible to make such an election after establishing eligible noncitizen status (or U.S. citizenship or nationality). We believe that the SEP start date and the two-month duration are appropriate and provide sufficient time for a beneficiary to select a plan, if desired, and is consistent with other SEPs for MA and Part D.

With respect to the question of whether utilization of this SEP would require CMS approval and be limited to CMS enrollment mechanisms, we are not requiring CMS approval. We will provide guidance, as appropriate, on the use of the SEP and possible considerations with other SEPs. CMS also intends to conduct a robust outreach and education effort and has been working with the SSA to develop a comprehensive communications plan to support implementation of section 1899C of the Act and to provide timely and understandable information, including SEP availability with clear start and end dates, to affected individuals and the organizations that assist them.

Comment: Several commenters recommended that CMS establish clear, coordinated, and timely implementation guidance and procedures for these eligibility changes, including specific operational guidance for MA organizations and Part D sponsors. A commenter suggested that CMS should clearly delineate the responsibilities of

[218] Model notices are available in the Medicare Advantage Enrollment and Disenrollment Guidance Appendices and Exhibits: MA Exhibit 14 (Model Notice of Disenrollment Due to Loss of Medicare Part A and/or Part B) and Part D Exhibit 14 (PDP Model Notice of Disenrollment Due to Loss of Part D Eligibility), available at: *cms.gov/files/document/cy-2027-ma-appendices-exhibits.pdf.*

[219] See Section 70.3.1 of the Medicare Advantage and Part D Enrollment and Disenrollment Guidance.

CMS, other Federal agencies, and MA and Part D plans.

Response: We agree with the commenters' recommendations and will issue operational guidance or other operational resources for plans, as needed.

Comment: A few commenters encouraged CMS to coordinate disenrollment and reenrollment across Medicare Part A, Part B, Part C, Part D, and cost plans to minimize gaps in coverage and disruptions in care. In addition, they urged CMS to facilitate advance and prompt data sharing of identified individuals who are losing Medicare entitlement to all plans.

Response: We acknowledge the commenters' concerns. CMS and the SSA data systems have regular data exchanges regarding enrollments and disenrollments and CMS promptly communicates enrollment and disenrollment information to plans. CMS and the SSA will continue to coordinate and consider additional implementation guidance for plans.

Comment: Another commenter stated that CMS explains in the proposed rule that it—and not the plans—processes plan disenrollments and that CMS will notify plans of disenrollment due to loss of entitlement. The commenter noted that CMS also clarified that plans may, but are not required, to separately notify their members of disenrollment, yet CMS proposes to codify this process at §§ 422.74(b) and 423.44(b) as a reason for which a plan must disenroll an individual. The commenter recommended a revision to the proposed regulations text to clarify that MA organizations are not independently responsible for effectuating disenrollments, consistent with CMS's stated intent in the proposed rule.

Response: While we acknowledge the commenter's recommendation, we respectfully decline to revise the proposed regulatory text. As discussed previously, CMS effectuates the plan disenrollment (after the SSA updates entitlement records) and notifies the plans. This is in accordance with §§ 422.74(d)(5) and 423.44(d)(3), which are unaffected by this rule. The proposed amendments to §§ 422.74(b) and 423.44(b) pertain to the implementation of section 1899C of the Act.

After consideration of public comments, we are finalizing the changes to 42 CFR 417, 42 CFR 422, and 42 CFR 423 as proposed with the following changes. We made conforming modifications to §§ 422.62(b)(16)(i) and 423.38(c)(21)(ii) to clarify that the MA and Part D SEPs start the month that the individual receives notice and continues for a subsequent 2 calendar months. We also made conforming modifications to §§ 417.460(j), 422.74(d)(9), and 423.44(d)(8) to clarify that disenrollment is effective the first day of the month following the month in which the plan receives notice from CMS that the individual is ineligible.

F. Medicare Prescription Drug Inflation Rebate Program

1. Background

a. Overview of the Medicare Prescription Drug Inflation Rebate Program

Sections 11101 and 11102 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117—169, enacted August 16, 2022) established requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain drugs payable under Part B and/or covered under Part D faster than the rate of inflation. Specifically, section 11101 of the IRA amended section 1847A of the Act by adding new subsection (i) which establishes a requirement for drug manufacturers to pay rebates into the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the specified amount, as determined under section 1847A(i)(3)(A)(ii) of the Act, exceeds the inflation—adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The IRA, under section 1847A(i)(5) of the Act, also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation—adjusted payment amount instead of the applicable payment amount. Section 1847A(i)(2) of the Act defines a ''Part B rebatable drug,'' as a single source drug or biological product (as defined in section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), but excluding a qualifying biosimilar biological product (as defined in section 1847A(b)(8)(B)(iii) of the Act) for which payment is made under Part B, except such term also does not include a drug or biological described in clause (i) and (ii) of such section 1847A(i)(2)(A) of the Act.

Section 11102 of the IRA added section 1860D–14B of the Act, which requires drug manufacturers to pay rebates into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for each 12-month applicable period, starting with the applicable period that began on October 1, 2022, for Part D rebatable drugs if the annual manufacturer price (AnMP) of such drug, which is calculated as set forth in section 1860D–14B(b)(2) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1860D–14B(b)(3) of the Act. Section 1860D–14B(g)(1)(A) of the Act defines a ''Part D rebatable drug,'' as a drug or biological described at section 1860D–14B(g)(1)(C) of the Act that is a ''covered Part D drug'' as that term is defined in section 1860D–2(e) of the Act, and excludes drugs and biologicals described in subparagraph (B) of such section 1860D–14B(g)(1) of the Act. The definition of a Part D rebatable drug includes drugs approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act, drugs approved under an abbreviated new drug application under section 505(j) of the FD&C Act that meet certain sole source criteria described at sections 1860D–14B(g)(1)(C)(ii)(I) through (IV) of the Act, and biologicals licensed under section 351 of the Public Health Service (PHS) Act, including biosimilars.

The IRA sets forth different parameters for determining rebates under the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program. In regard to the rebates owed, for each calendar quarter beginning on or after January 1, 2023, the manufacturer of a Part B rebatable drug is required, for such drug, not later than 30 days after the date of receipt of the Rebate Report from us, to pay a rebate into the Federal Supplementary Medical Insurance Trust Fund if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act exceeds the inflation-adjusted payment amount (calculated as set forth in section 1847A(i)(3)(C) of the Act) for an applicable calendar quarter. In contrast, for each 12-month applicable period beginning on or after October 1, 2022, the manufacturer of a Part D rebatable drug is required, for such drug, not later than 30 days after the date of receipt of the Rebate Report from us, to pay a rebate into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund if the amount of the AnMP (calculated as set forth in section 1860D–14B(b)(2) of the Act) exceeds the inflation-adjusted payment amount (calculated as set forth in section 1860D–14B(b)(3) of the Act). In regard to invoicing manufacturers for the rebate amount owed, under section 1847A(i)(1) of the Act, we must report

rebate amounts to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each calendar quarter, except that for calendar quarters beginning in 2023 and 2024, section 1847A(i)(1)(C) of the Act provides that we had until September 30, 2025, to invoice manufacturers for rebates. In contrast, under section 1860D–14B(a) of the Act, we must report rebate amounts to each manufacturer of a Part D rebatable drug no later than 9 months after the end of each applicable period, except that for the first two applicable periods (that is, October 1, 2022, to September 30, 2023, and October 1, 2023, to September 30, 2024), section 1860D–14B(a)(3) of the Act provides that we had until December 31, 2025, to invoice manufacturers for Part D inflation rebates. Additionally, there are statutory differences in the inputs (that is, data sources) used to calculate the rebate amounts for Part B and Part D.

In the CY 2025 PFS final rule (89 FR 98228 through 98313), to implement sections 11101 and 11102 of the IRA, we codified these requirements and established other policies at parts 427 and 428 under title 42, chapter IV of the Code of Federal Regulations for Part B and Part D, respectively.

b. Summary of Policies for the Medicare Prescription Drug Inflation Rebate Program

We proposed new policies for the Medicare Part B Drug Inflation Rebate Program as follows:

- Section 427.20 will clarify the definition of ''first marketed date'' to clarify the data sources we will use to identify the first marketed date when relevant Average Sales Price (ASP) data is not available.
- Section 427.101(b)(5) will modify the skin substitutes excluded product category for Part B rebatable drugs so that the exclusion applies only to certain skin substitute products.
- Section 427.302(e)(6) and (f)(1) will clarify what Consumer Price Index for All Urban Consumers (CPI–U) data will be used to determine the benchmark period CPI–U in place of the month for which CPI–U data are unavailable.

We also proposed new policies for the Medicare Part D Drug Inflation Rebate Program as follows:

- Section 428.20 will clarify the definition of ''applicable period CPI–U'' when the CPI–U data for the first month of the applicable period are not available.
- Section 428.202(e)(6) will clarify what CPI–U data would be used to determine the benchmark period CPI–U in place of the month for which CPI–U data are unavailable.
- Section 428.203(c) will require providers and suppliers that are covered entities as defined at § 10.3 to submit Part D 340B data to the 340B repository beginning with claims with a date of service on or after January 1, 2027.

We received public comments on the proposed provisions, comments on the Medicare Prescription Drug Inflation Rebate Program, and comments related to policies for which we did not make proposals. The following is a summary of the comments received on the Medicare Prescription Drug Inflation Rebate Program. We summarize comments on specific proposed provisions and provide responses in the relevant sections.

Comment: Some commenters wrote in support of the Medicare Prescription Drug Inflation Rebate Program, and some of these commenters also wrote that any savings realized through the Medicare Prescription Drug Inflation Rebate Program should be made available to people with Medicare.

Response: We appreciate the commenters' feedback. We note that Part B and Part D inflation rebates paid by drug manufacturers are deposited into the Federal Supplementary Medical Insurance Trust fund in accordance with sections 11101(a) and 11102(a) of the IRA. Additionally, under the Medicare Part B Drug Inflation Rebate Program, beneficiary coinsurance is 20 percent of the inflation-adjusted payment amount, which is less than what the beneficiary would pay in coinsurance otherwise.

Comment: A commenter suggested that CMS provide information on estimating savings realized through the Medicare Prescription Drug Inflation Rebate Program, including information on the collection of rebates, drugs subject to the Medicare Prescription Drug Inflation Rebate Program, and the impact on people with Medicare.

Response: For further information on how Part B rebatable drugs and Part D rebatable drugs are identified, please refer to §§ 427.101 and 428.101, respectively. We publish information, including annual aggregate rebate amounts by rebatable drug, on the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program on our website at *https://www.cms.gov/initiatives/medicare-prescription-drug-affordability/overview/medicare-inflation-rebate-program* under ''Medicare Part B Inflation Rebate Reports'' and ''Medicare Part D Inflation Rebate Reports.'' We note that people with Original Medicare and Medicare Advantage who use Part B rebatable drugs that have an adjusted coinsurance rate based on the inflation-adjusted payment amount may pay a reduced amount for their coinsurance during a specific quarter. Sections 11101 and 11102 of the IRA do not direct CMS to publish a report evaluating the Medicare Prescription Drug Inflation Rebate Program's impact on people with Medicare. CMS does publish related materials, such as Trustees Reports,[220] which discuss the Medicare Prescription Drug Inflation Rebate Program's financial effects.

Comment: A commenter stated that CMS should ensure that changes to the Medicare Prescription Drug Inflation Rebate Program do not unintentionally reduce access to essential drugs. This commenter did not reference specific proposed policies of concern.

Response: We generally monitor the Medicare Prescription Drug Inflation Rebate Program, including using CMS' formulary review process to assess any practices that may undermine beneficiary access to certain drugs and ensuring that Part D plan sponsors comply with existing statutory and regulatory restrictions on formulary design.

Comment: A couple of commenters opposed CMS' proposals for the Medicare Prescription Drug Inflation Rebate Program but did not provide more information.

Response: We thank the commenters for providing input.

2. Medicare Part B Drug Rebates for Single Source Drugs and Biological Products With Prices That Increase Faster Than the Rate of Inflation

a. Definitions (§ 427.20)

In the CY 2025 PFS final rule (89 FR 98579), we codified at § 427.20 the definition of ''first marketed date'' to mean the earliest date of first sale of any NDC–11 within a billing and payment code among all products and package sizes under the same FDA application. In that definition, we specify that the first marketed date will be identified using ASP data reported by NDC–11 to CMS by a manufacturer as required under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2) of the Act, if available. We noted in the proposed rule that we use ''date of first sale'' as reported in the ASP Data Collection System for the first marketed date as specified at § 427.20. There may be scenarios where a drug is being marketed but the first marketed date is not available in the ASP data such as when a manufacturer is not subject to sections 1927(b)(3)(A)(iii)(I) or

[220] See: *https://www.cms.gov/data-research/statistics-trends-and-reports/trustees-report-trust-funds.*

1847A(f)(2) of the Act and is not required to report ASP data. In this example, ASP units sold also would be unavailable in the ASP Data Collection System. Currently we generally use the NDC Directory to identify the first marketed date when it is not available in the ASP Data Collection System. In the proposed rule, to improve transparency of operations to address instances when first marketed date is missing from ASP data, we proposed to amend § 427.20 for the definition of the term ''first marketed date'' to clarify the data sources we would use to identify the first marketed date when ASP data are not available. Specifically, when the first marketed date is missing from ASP data for any NDC–11 associated with any FDA application number ever associated with the billing and payment code, we proposed to identify the first marketed date from an alternative public source, such as from the NDC Directory. For example, when the first marketed date is missing from ASP data for a given NDC, we would identify the first marketed date for the NDC–11 from the NDC Directory; and if the first marketed date also is missing from the NDC Directory for a given NDC, we would default to using the FDA approval date as listed in the Orange Book or Purple Book. We noted in the proposed rule that we believe data in the NDC Directory are accurate, reliable, and up to date. The Food and Drug Administration (FDA) updates the NDC Directory daily with information submitted to FDA by labelers. A labeler may be a manufacturer, including a repackager or relabeler, or the entity named on the product label that is required to list their products with FDA under 21 CFR part 207. The FDA also requires that labelers update their drug product listing data twice a year or certify that there were no changes to such data.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters recommended CMS use alternative data sources to the ones CMS proposed to use to identify ''first marketed date'' when the first marketed date is missing from ASP data for any NDC–11 associated with any FDA application number ever associated with the billing and payment code. A couple of commenters recommended CMS use the ''market date'' from the Medicaid Drug Rebate Program (MDRP); a commenter suggested using the ''market date'' from MDRP in place of the NDC Directory in instances when ''first marketed date'' is missing from the ASP Data Collection System and another commenter suggested using the ''market date'' from MDRP in place of the Orange Book and Purple Book in instances when ''first marketed date'' is missing from the NDC Directory. Both commenters noted that MDRP's ''market date'' is an established benchmark for determining rebate liability in Medicaid and that using this date would promote consistency across Federal drug pricing programs. Additionally, a commenter recommended that CMS rely on manufacturers to provide the ''first marketed date'' via an attestation of the date the drug was first made commercially available. This commenter expressed concern that CMS' described hierarchy of data sources to determine first marketed date may not always provide an accurate or sufficiently precise indication of when a drug or biological product was first marketed. In particular, the commenter raised that the Orange Book and Purple Book do not include the first marketed date and instead include the marketing status as ''Prescription'' or ''Discontinued,'' adding that a marketing status of ''Prescription'' does not necessarily indicate that commercial sales have occurred. The commenter also noted that the Orange Book and Purple Book are not comprehensive and are not updated daily. Lastly, the commenter stated that if CMS finalizes its definition as proposed, CMS should provide additional guidance regarding the specific data sources, documentation, and procedures that will govern first marketed date determinations, including any potential disputes that manufacturers may have with CMS' determinations, noting that doing so would promote transparency, consistency, and accuracy.

Response: We appreciate commenters recommending alternative data sources to the sources that CMS proposed. With regards to the Orange Book and Purple Book not being accurate or sufficiently precise and up to date, we note that as stated in the proposed rule we generally use the NDC Directory to identify the first marketed date when it is not available in the ASP Data Collection System and that we would use the FDA approval date as listed in the Orange Book or Purple Book only in instances when the first marketed date for a given NDC also is missing from the NDC Directory. Although such instances are infrequent, they do occur and so we proposed to use the FDA approval date in the Orange Book and Purple Book and not the marketing status field, which we do not believe is sufficiently precise, as the commenter noted. The monthly updates that occur for the Orange Book and the Purple Book provide up-to-date information for CMS to calculate quarterly rebate calculations for Part B rebatable drugs. We do not use MDRP data for any other variables in the Part B inflation rebate calculation. Using such data in the infrequent instances when first marketed date is not available in the ASP Data Collection System would be operationally inconsistent with how we have implemented section 1847A(i) of the Act. In contrast, we already use the listed FDA sources for these Part B inflation rebate calculations. Specifically, we use the first marketed date from the NDC Directory to determine whether a drug is sold or marketed during the applicable calendar quarter, and we use the Orange Book to determine if a Part B rebatable drug has become a multiple source drug by reviewing for therapeutic equivalence. Therefore, we decline to use ''market date'' from the MDRP for the calculation of Part B inflation rebates. Further, based on our analysis, the NDC Directory appears to be a more comprehensive resource, compared to MDRP, for determinations of first marketed date when such date is not available in the ASP Data Collection System, such as scenarios when a manufacturer is not subject to sections 1927(b)(3)(A)(iii)(I) or 1847A(f)(2) of the Act and is not required to report ASP data. In this circumstance, such drug or biological may not appear in the MDRP, and then we would need to rely on another source to identify the marketed date. In contrast, we are required by statute to use MDRP data for certain inputs in the Part D inflation rebate calculation. Additionally, establishing an operational process requiring manufacturers to provide and attest to their first marketed date would create administrative burden and demand additional resources for both CMS and manufacturers. Therefore, we decline to implement the commenter's suggestion at this time. Lastly, with regards to the suggestion that CMS provide additional guidance on the specific data sources, documentation, and procedures that will govern first marketed date determinations, we do not believe this is necessary because we will follow the process described in § 427.302(c). That is, we will use the earliest first marketed date (as defined at § 427.20) of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed.

Comment: A commenter supported CMS' efforts to clarify ''first marketed date'', and recommended CMS finalize a clear definition that prevents gaming while preserving predictable administration for manufacturers, providers, plans, and CMS. To help avoid ambiguity, prevent gaming, and promote consistent administration across drugs and biological products paid under Part B, the commenter also suggested that CMS include examples addressing acquisition of a previously marketed product, product withdrawal followed by product relaunch, reformulations or packaging changes, transitions from miscellaneous billing and payment codes to product-specific billing and payment codes, and products assigned to new billing and payment codes after an initial period of marketing.

Response: We appreciate the commenter's input. We believe the proposed policy provides a clear definition of ''first marketed date'' in scenarios where a drug is being marketed but the first marketed date is not available in the ASP data. That is, if ''first marketed date'' is unavailable in ASP data, we will identify it using an alternative public source, such as the NDC Directory. If the first marketed date also is missing from such alternative public sources for a given NDC, we will use the FDA approval date listed in the Orange Book or Purple Book. We decline to provide specific examples to address particular gaming scenarios because we will follow the process described in this final rule. With respect to the suggestion to provide examples regarding changes in ownership and market status, we note that when identifying the payment amount benchmark quarter, we will follow the process described in § 427.302(c), which is to use the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed.

Comment: A couple of commenters recommended CMS establish a process through which manufacturers can identify and correct errors with the first market date, and one of these commenters suggested this error process should occur before CMS uses the data to conduct rebate calculations.

Response: We thank commenters for this input and note that, as described in § 427.501(b)(1), CMS provides manufacturers with a Preliminary Rebate Report at least 1 month prior to the issuance of the Rebate Report. As described in § 427.503, a manufacturer may submit a Suggestion of Error about the information in their Preliminary Rebate Report to CMS, for its discretionary consideration, if the manufacturer believes that there is a mathematical error or errors to be corrected before the Rebate Report is finalized.

After consideration of public comments, we are finalizing the definition of ''first marketed date'' in § 427.20 as proposed with a non-substantive, technical modification. We are correcting a typographical error in the ''first marketed date'' definition in § 427.20, we revised ''If ASP date are'' to ''If an ASP first marketed date is''.

b. Treatment of Skin Substitutes as a Part B Rebatable Drug Excluded Product Category (§ 427.101(b)(5))

In the CY 2025 PFS final rule (89 FR 98580), we codified skin substitutes (that is, products included within the suite of cellular- and tissue-based products that aid wound healing) as an excluded product category at § 427.101(b)(5) and therefore they are not considered Part B rebatable drugs. We finalized this policy because we aimed to create a consistent coding and payment approach for skin substitute products. Since that policy was finalized, in the CY 2026 PFS final rule (90 FR 49496, 50009), we modified how skin substitutes are paid under Part B. In particular, we finalized our proposal to limit application of the ASP payment methodology under section 1847A of the Act to skin substitutes that are approved as a drug or biological product under section 351 of the PHS Act. Additionally, we modified payment for the provision of certain groups of skin substitutes as incident-to supplies.

To avoid an overly broad exclusion at § 427.101(b)(5), we proposed to clarify that skin substitutes licensed as a drug or biological product under section 351 of the PHS Act would not be excluded from the definition of a Part B rebatable drug, and, as such, would be subject to Part B inflation rebates and subject to the beneficiary coinsurance adjustment under § 427.201. We noted in the proposed rule that currently there are no skin substitute products licensed as a drug or biological product under section 351 of the PHS Act; however, our proposal would make clear that any future skin substitute products that are licensed as a drug or biological product under section 351 of the PHS Act could be rebatable. We proposed to amend § 427.101 by revising paragraph (b)(5), which describes skin substitutes as an excluded product category for Part B rebatable drugs, to state a skin substitute is ''[a] product included within the suite of cellular- and tissue-based products that aid wound healing, other than skin substitute products that are licensed as a drug or biological product under section 351 of the Public Health Service Act''. If finalized, this proposal would not impact Rebate Reports for the fourth quarter of 2026 or earlier.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that CMS' proposal to modify the skin substitutes excluded product category for Part B rebatable drugs has implications on tribally owned products because tribes use section 351 of the PHS Act as a regulatory pathway for such products. The commenter requested CMS consult tribal nations before finalizing this policy.

Response: We appreciate the commenter raising these concerns. CMS' Tribal Technical Advisory Group (TTAG), which provides advice and input to CMS on policy and program issues impacting American Indians and Alaska Natives served by CMS programs, as applicable, did not comment on either the proposed rule or the final rule. As part of our ongoing implementation of the Medicare Prescription Drug Inflation Rebate Program, we will engage with CMS' TTAG.

Comment: A commenter recommended that CMS monitor skin substitute utilization and pricing after any change in rebatable status.

Response: We confirm that we monitor utilization of all drugs and biologicals payable under Part B as well as changes in prices for such drugs and biologicals to assess inflation rebates on drug manufacturers.

After consideration of public comments, we are finalizing § 427.101(b)(5) as proposed.

c. Identification of the Benchmark Period CPI–U and Rebate Period CPI–U (§ 427.302)

Section 1847A(i)(3)(C) of the Act provides that, for each Part B rebatable drug by billing and payment code, CMS will calculate the inflation-adjusted payment amount for each quarter using the benchmark period CPI–U and the rebate period CPI–U, among other inputs, as described at § 427.302(g). For each Part B rebatable drug, we identify the applicable benchmark period CPI–U as described at §§ 427.302(e)(1) and (2), and subject to paragraphs (e)(3) through (5). Specifically, under section 1847A(i)(3)(E) of the Act and as described at § 427.302(e)(1), for a Part B rebatable drug first approved or licensed

by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, the benchmark period CPI–U is the CPI–U for January 2021. Additionally, under section 1847A(i)(4)(A) of the Act and as described at § 427.302(e)(2), for a Part B rebatable drug that is a subsequently approved drug, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after a drug's first marketed date. For the rebate period CPI–U, we will identify and use the greater of the benchmark period CPI–U index level or the CPI–U index level for the first month of the calendar quarter that is 2 calendar quarters before the applicable calendar quarter in which the Part B rebatable drug is furnished, under section 1847A(i)(3)(F) of the Act and as described at § 427.302(f).

As stated in the CY 2025 PFS final rule (89 FR 98247), we will retrieve CPI–U index level information from the Bureau of Labor Statistics (BLS). The BLS did not release CPI–U survey data for October 2025 due to a lapse in appropriations.[221] As a result of the October 2025 CPI–U data being unavailable, multiple interested parties, including drug companies and a pharmaceutical industry trade association, requested that we clarify in a timely manner how we would calculate inflation rebates that would otherwise use the October 2025 CPI–U data. To respond to these inquiries and to promote transparency with regard to the most immediate calculations for the Inflation Rebate Program, including particular Part B beneficiary coinsurance calculations for the second quarter of 2026, we released a Health Plan Management System (HPMS) memo on March 6, 2026,[222] affirming our intent to use November 2025 CPI–U data in place of the missing October 2025 CPI–U data for such calculations. As we explained in that memo, we used the November 2025 CPI–U data issued by the BLS in place of the missing October 2025 CPI–U data because November 2025 was the first month with available CPI–U data in the calendar quarter identified by statute and regulation.

We released this memo in accordance with section 1847A(c)(5)(C) of the Act, which permits CMS to implement, by program instruction or otherwise, any of the provisions of section 1847A of the Act. We also noted that, to complete such calculations, it would have been impracticable to engage in notice-and-comment rulemaking to affirm the policy stated in that memo because the timing of this final rule would be after our deadline to publish the April 2026 Medicare Part B Payment Limit files, including Part B rebatable drugs subject to a coinsurance adjustment. We further noted that the absence of October 2025 CPI–U data also would be relevant to calculating Part B and Part D inflation rebate amounts that will be reported to manufacturers in 2027 and later and stated our intent to address the broader need for a gap-filling methodology as part of future rulemaking through the Physician Fee Schedule.

Currently, our regulations do not address explicitly how the agency should identify the CPI–U, for the purposes discussed previously in this section of the preamble, when the otherwise relevant CPI–U index level information is unavailable from BLS, as occurred for the October 2025 CPI–U. Therefore, we proposed to amend § 427.302 by adding paragraph (e)(6) to ensure that in the event CPI–U data are unavailable, we would use the CPI–U data for the first month for which CPI–U data are available following the month for which CPI–U data are unavailable. This proposal also aligns with the policy and the rationale we provided in the HPMS memo released on March 6, 2026, to address the instance of unavailable CPI–U data for October 2025. Consistent with the reasons we set forth in such memo, this proposed approach most closely aligns with statute because it would result in use of CPI–U data from a month within, and in any event no earlier than the quarter specified by the statute. For the same reasons, we also proposed to amend § 427.302 by adding paragraph (f)(1) to state that when CPI–U data are unavailable, we would use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.

As an alternative to the proposal at § 427.302(f), we considered using the Department of the Treasury's (''Treasury'') index number according to the index contingency provisions for Treasury Inflation-Protected Securities, which is based on the last available 12-month change in the CPI.[223] This alternative approach does not align with statute, which directs us to use the CPI–U value from the first month of the relevant period and makes no reference to an alternate calculated value. Specifically, section 1847A(i)(3)(F) of the Act defines the rebate period CPI–U as, for the applicable calendar quarter, ''the greater of the benchmark period CPI–U and the consumer price index for all urban consumers (United States city average) for *the first month of the calendar quarter that is two calendar quarters prior* to such described calendar quarter'' (emphasis added). We also considered calculating our own inflation factor rather than using the BLS reported CPI–U data; however, it is impracticable for us to administer a CPI–U survey and calculate an alternate CPI–U index. Finally, we considered using the previous month for which CPI–U data are available, but this approach is less consistent with statute, which as noted previously specifies that we use the CPI–U value from the calendar quarter that is 2 calendar quarters prior to the relevant quarter. We did not propose these alternative options for the reasons described in the proposed rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We note that commenters provided comments and made recommendations for both the Medicare Part B and Part D Drug Inflation Rebate Programs. We have provided responses to these comments in both sections.

Comment: A few commenters stated CMS' proposed approach to use the CPI–U data for the first month for which CPI–U data are available following the month for which CPI–U data are unavailable does not recognize seasonal fluctuations in the U.S. economy. Specifically, the commenters stated that prolonged government shutdowns are more likely to occur in October because the Federal fiscal year ends on September 30, which would increase the likelihood that the October CPI–U may be unpublished. The commenters noted that the November CPI–U, which is the CPI–U that likely would be used in rebate calculations, is often lower than the October CPI–U due to seasonal fluctuations in inflation common in November (for example, holiday discounts and decreasing gasoline prices). A few commenters stated that our proposed approach could have adverse financial consequences for manufacturers by decreasing their ability to predict the financial impact of inflation rebates, impacting future rebate liability when BLS CPI–U data are not available, or systematically underestimating inflation.

[221] BLS, *https://www.bls.gov/cpi/additional-resources/2025-federal-government-shutdown-impact-cpi.htm#:%7E:text=Yes.,in%20appropriations%E2%80%9D%20will%20be%20included*.

[222] CMS, Medicare Prescription Drug Inflation Rebate Program: Impact of Missing October 2025 CPI–U Data on Medicare Part B Inflation Rebate Program in Second Quarter of 2026, *https://www.cms.gov/files/document/cpi-u-gap-filling-memo-final-508.pdf*.

[223] 31 CFR part 356, Appendix B. *https://www.ecfr.gov/current/title-31/subtitle-B/chapter-II/subchapter-A/part-356#ap31.2.356_135.b*.

Response: Section 1847A(i)(3)(F) of the Act specifies that with respect to a calendar quarter, the rebate period CPI–U is the greater of the benchmark period CPI–U and the CPI–U for the first month of the calendar quarter that is two calendar quarters prior to such described calendar quarter. Section 1847A(i)(3)(E) of the Act defines the benchmark period CPI–U as the CPI–U for January 2021. However, section 1847A(i)(4)(A) of the Act provides that for Part B rebatable drugs approved or licensed after December 1, 2020, the benchmark period CPI–U is defined as the CPI–U for the first month of the first full calendar quarter after the day on which the drug was first marketed. The statute does not specify other factors to consider when determining the rebate period or benchmark period CPI–U values to use in rebate calculations, including how such values are impacted by seasonality or how such value impacts rebate liability. Therefore, we believe it is consistent with statute to determine the rebate period and benchmark period CPI–U values using data from within the same calendar quarter as soon as there is CPI–U data available from a month within that specified calendar quarter.

Comment: A few commenters recommended that we consider the CPI–U values for the month prior to and the month following the month(s) with unavailable CPI–U data and then use the higher CPI–U value. Among these commenters, a few also stated that if CMS declines to adopt this recommendation, then CMS should use the average of the CPI–U values for the month prior to and the month following the month(s) with unavailable CPI–U data. A few commenters suggested that CMS adopt the contingency method used by Treasury instead of BLS' CPI–U values for the month following the month in which such data is unavailable. These commenters stated that while statute does not require CMS to use a specific source for determining the CPI–U, the statute does require CMS to apply the CPI–U in a specific month for Part B inflation rebate calculations. Additionally, a commenter stated that CMS did not meaningfully evaluate reasonable alternatives such as options to estimate the CPI–U for the month for which the CPI–U is needed to calculate a Part B inflation rebate, did not consider seasonality of inflation values, did not evaluate relative effects of the proposed approach on payment amounts, coinsurance, and rebate liability, and did not sufficiently explain why the proposed approach is more consistent with statute than using CPI–U from the month prior to the month in which CPI–U is missing. Another commenter stated that CMS' proposed approach raises concerns under the Administrative Procedure Act (APA) because CMS did not adequately address predictable seasonality, financial consequences, uncertainty, and alternative approaches. A few commenters stated that the proposed approach exceeds CMS' statutory authority because the statute requires CMS to use the CPI–U for a specific month but does not specify the source from which the CPI–U value must originate.

Response: As discussed in section III.F.2.c. of this final rule, we considered alternative approaches and why we believe those alternatives are not feasible or appropriate. As noted in that section, we considered an approach in which we would use the previous month for which CPI–U data are available but believe this approach is less consistent with statute than using CPI–U values that are within the same calendar quarter as the month for which CPI–U data is missing. Section 1847A(i) of the Act describes the identification of CPI–U values after a specified time period has elapsed, and using data from a month that is before that time period is inconsistent with statute. For this same reason, we do not believe alternatives to use the average of or the higher of the month prior and the month subsequent to the month for which CPI–U values are missing are supported by statute and we therefore decline to adopt these approaches. We also considered using Treasury's index number according to the index contingency provisions for Treasury Inflation-Protected Securities; however, as we stated, this alternative approach does not align with statute (specifically section 1847A(i)(3)(F) of the Act), which directs CMS to use the CPI–U value from the first month of the relevant period and makes no reference to an alternate calculated value. As such, we decline to adopt the suggestion to use Treasury's contingency method. Lastly, regarding the comment that CMS did not consider options to estimate the CPI–U for the month for which the CPI–U is missing, we considered calculating our own inflation factor rather than using the BLS reported CPI–U data; however, we determined that it is impracticable for us to administer a CPI–U survey and calculate an alternate CPI–U index. Similarly, we determined that was inconsistent with statute to estimate an alternate CPI–U value because statute directs CMS to use the CPI–U for a specific month.

After consideration of public comments, we are finalizing § 427.302(e)(6) and § 427.302(f) as proposed.

d. Clarification of Date of Receipt for Rebate Reports

As stated in the CY 2025 PFS final rule (89 FR 98264) which was effective on January 1, 2025 and appeared in the December 8, 2024 **Federal Register**, § 427.500 defines the date of receipt as the calendar day following the day on which a report of a rebate amount (as set forth in § 427.501(b) through (d) and § 427.502(b) and (c)) is made available to the manufacturer of a Part B rebatable drug by CMS. The ''date of receipt'' starts the clock for calculation of deadlines at multiple points in the rebate reporting process, including for manufacturer submission of a suggestion of error and for payment of rebate amounts owed. For example, as set forth in § 427.505(a), a rebate amount owed is due no later than ''the 30th calendar day after the date of receipt of information regarding the rebate amount[.]''

For clarity and transparency, in the CY 2027 PFS proposed rule (91 FR 44007 through 44008) we made technical corrections to the examples provided in the CY 2025 PFS final rule of the calculation of due dates based on the ''date of receipt''. In the CY 2025 PFS final rule (89 FR 98265), we provided examples of the ''date of receipt'', including: (1) ''if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, will be the date of receipt and, therefore, day 1 of the 10-calendar-day period to submit a Suggestion of Error. In this example, Suggestions of Error would be due by 11:59 p.m. PT on June 10, 2026[ ]''; and (2) ''if the Rebate Report is provided on June 30, 2026, then July 1, 2026, would be the date of receipt and therefore day 1 of the 30-calendar-day payment period; payment would be due no later than 11:59 p.m. PT on July 30, 2026.'' In the CY 2027 PFS proposed rule (91 FR 44007 through 44008), we corrected these examples to be consistent with the definition of ''date of receipt'' in § 427.500. Specifically, in each example provided, the ''date of receipt'' should be day zero of the relevant calendar period, not day one. Therefore, if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, will be the ''date of receipt'' and day zero of the 10-calendar-day period to submit a Suggestion of Error, such that Suggestions of Error would be due by 11:59 p.m. PT on June 11, 2026. Likewise, if a Rebate Report is provided

on June 30, 2026, then July 1, 2026, will be the ''date of receipt'' and day zero of the 30-calendar-day payment period, such that payment would be due no later than 11:59 p.m. PT on July 31, 2026.

We did not receive public comments on this clarification.

e. Enforcement of Manufacturer Payment of Rebate Amounts (§ 427.600)

In accordance with section 1847A(i)(1)(B) of the Act, the manufacturer of a Part B rebatable drug is required to provide a rebate equal to the rebate amount specified in section 1847A(i)(3) of the Act for the rebatable drug for the calendar quarter not later than 30 days after receipt of the rebate amount from CMS. Section 1847A(i)(7) of the Act gives us the authority to impose a civil money penalty (CMP) equal to at least 125 percent of the rebate amount for each drug for each applicable calendar quarter on a manufacturer that fails to pay the rebate amount for each rebatable Part B drug. Subpart G implements this section of the Act and establishes the procedures for determining and collecting a CMP.

In the CY 2027 PFS proposed rule (91 FR 44008), we clarified that the imposition of CMPs under section 1847A(i)(7) of the Act, in accordance with § 427.600, is not the exclusive remedy for a manufacturer's failure to comply with its rebate payment obligations described in § 427.505(a), nor the exclusive remedy for other conduct that may impact obligations, such as rebate amounts owed, under the Medicare Part B Drug Inflation Rebate Program. For example, whether imposing CMPs under section 1847A(i)(7) of the Act or not, when warranted, we may refer manufacturers to the Department of Justice, the Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation.

We did not receive public comments on this clarification.

3. Medicare Part D Drug Rebates for Certain Drugs and Biologicals With Prices That Increase Faster Than the Rate of Inflation

a. Definitions (§ 428.20)

As stated in the CY 2025 final rule (89 FR 98276), we codified the definition of ''applicable period CPI–U'' at § 428.20 as ''with respect to an applicable period, the CPI–U for the first month of such applicable period (that is, October)'' based on the definition set forth in section 1860D–14B(g)(5) of the Act. The BLS did not release CPI–U survey data for October 2025 due to a lapse in appropriations.[224] As a result of the October 2025 CPI–U data being unavailable, multiple interested parties, including drug companies and a pharmaceutical industry trade association, requested that we clarify in a timely manner how we would calculate inflation rebates that would otherwise use the October 2025 CPI–U data. We acknowledge that the missing October CPI–U data impacts Preliminary Rebate Reports and Rebate Reports for the applicable period that runs from October 2025–September 2026. The current in-effect regulation at § 428.20 does not address our inability to retrieve CPI–U index level information from BLS. To provide clarity on how to gap fill the missing October CPI–U data, we proposed to amend § 428.20 to include, ''in the case where the first month's CPI–U data is unavailable, we will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.'' As applied in the case of missing October 2025 CPI–U data, CMS would use November 2025 CPI–U data.

We received public comments on this proposal. Please refer to section III.F.3.b. of this final rule for a summary of comments and our responses.

After consideration of public comments, we are finalizing the definition of ''applicable period CPI–U'' in § 428.20 as proposed.

b. Identification of Benchmark Period CPI–U (§ 428.202(e))

Section 1860D–14B of the Act provides that for each Part D rebatable drug, CMS will identify the benchmark period CPI–U as described at § 428.202(e)(1) and (2) and subject to paragraphs (e)(3) through (5). Specifically, under section 1860D–14B(g)(4) of the Act and as discussed in § 428.202(e)(1), for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, the benchmark period CPI–U is the CPI–U for January 2021. Additionally, under section 1860D–14B(b)(5)(C) of the Act and as described at § 428.202(e)(2), for a subsequently approved drug, the benchmark period CPI–U is the CPI–U for January of the first calendar year beginning after a drug's first marketed date as stated under section 1860D–14B(b)(5)(A) of the Act. Under section 1860D–14B(b)(5)(C) of the Act and as described at § 428.202(e)(5) when a Part D rebatable drug is no longer considered to be a selected drug, the benchmark period CPI–U is the CPI–U for January of the last calendar year of such price applicability period. Due to the BLS not releasing CPI–U survey data for October 2025, we recognized a need to adopt a gap filling methodology in the event that any future CPI–U data are not released. As a result of the October 2025 CPI–U data being unavailable, multiple interested parties, including drug companies and a pharmaceutical industry trade association, requested that we clarify in a timely manner how we would calculate inflation rebates that would otherwise use the October 2025 CPI–U data. To respond to these inquiries and to promote transparency, as well as to align with the HPMS memo released on March 6, 2026,[225] we proposed to amend § 428.202 by adding paragraph (e)(6) to state, when CPI–U data are unavailable, CMS will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable. In using the first month of CPI–U data available, this proposed approach most closely aligns with section 1860D–14B(g)(5) of the Act.

As an alternative to the proposal at § 428.202(e)(6), we considered using Treasury's index number according to the index contingency provisions for Treasury Inflation-Protected Securities, which is based on the last available 12-month change in the CPI–U. This alternative approach does not align with statute, which directs CMS to use the CPI–U value from the first month of the relevant period. We also considered calculating our own inflation factor rather than using the BLS reported CPI–U; however, it is impracticable for us to administer a CPI–U survey and calculate an alternate CPI–U index. Finally, we considered using the previous month with available CPI–U data, but this approach is less consistent with statute, which directs CMS to use the CPI–U value from the first month of the relevant period. The previous month's CPI–U data would not fall within the relevant period. We did not propose these alternative options for the reasons described in the proposed rule.

We received public comments on these proposals. We note that commenters provided comments and made recommendations for both the Medicare Part B and Medicare Part D Drug Inflation Rebate Programs. We provided responses to these comments in both sections.

Comment: A few commenters stated CMS' proposed approach to use the CPI–U data for the first month for which

[224] BLS, *https://www.bls.gov/cpi/additional-resources/2025-federal-government-shutdown-impact-cpi.htm#:%7E:text=Yes.,in%20appropriations%E2%80%9D%20will%20be%20included.*

[225] *https://www.cms.gov/files/document/cpi-u-gap-filling-memo-final-508.pdf.*

CPI–U data are available following the month for which CPI–U data are unavailable, does not recognize seasonal fluctuations in the U.S. economy. Specifically, the commenters stated that prolonged government shutdowns are more likely to occur in October because the Federal fiscal year ends on September 30, which would increase the likelihood that the October CPI–U may be unpublished. The commenters noted that the November CPI–U, which is the CPI–U that likely would be used in rebate calculations, is often lower than the October CPI–U due to seasonal fluctuations in inflation common in November (for example, holiday discounts and decreasing gasoline prices). A few commenters stated that our proposed approach could have adverse financial consequences for manufacturers by decreasing their ability to predict the financial impact of inflation rebates, impacting future rebate liability when BLS CPI–U data are not available, or systematically underestimating inflation.

Response: Section 1860D–14B(g)(5) of the Act specifies that with respect to an applicable period, the applicable period CPI–U is the CPI–U for the first month of such applicable period. Section 1860D–14B(g)(7) of the Act defines the applicable period as a 12-month period beginning with October 1 of a year (beginning with October 1, 2022). Under section 1860D–14B(g)(4) of the Act, the benchmark period CPI–U is January 2021 for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021. For a subsequently approved drug, the benchmark period CPI–U is the CPI–U for January of the first calendar year beginning after a drug's first marketed date as stated under section 1860D–14B(b)(5)(A) of the Act. Under section 1860D–14B(b)(5)(C) of the Act, when a Part D rebatable drug is no longer considered to be a selected drug, the benchmark period CPI–U is the CPI–U for January of the last calendar year of such price applicability period. Statute does not specify other factors to consider when determining the applicable period CPI–U value to use in rebate calculations, including how such values are impacted by seasonality or how such values impact rebate liability. Therefore, we believe it is consistent with statute to determine the applicable period and the benchmark period CPI–U values using data from within the same applicable period as soon as there is CPI–U data available from a month within that specified applicable period.

Comment: A few commenters recommended that we consider the CPI–U values for the month prior to and the month following the month(s) with unavailable CPI–U data and then use the higher CPI–U value. Among these commenters, a few also stated that if CMS declines to adopt this recommendation, then CMS should use the average of the CPI–U values for the month prior to and the month following the month(s) with unavailable CPI–U data. A few commenters suggested that CMS adopt the contingency method used by Treasury instead of BLS' CPI–U values for the month following the month in which such data is unavailable. These commenters stated that while statute does not require CMS to use a specific source for determining the CPI–U, the statute does require CMS to apply the CPI–U in a specific month for Part D inflation rebate calculations. Additionally, a commenter stated that CMS did not meaningfully evaluate reasonable alternatives such as options to estimate the CPI–U for the month for which the CPI–U is needed to calculate a Part D inflation rebate, did not consider seasonality of inflation values, did not evaluate relative effects of the proposed approach on rebate liability, and did not sufficiently explain why the proposed approach is more consistent with statute than using CPI–U from the month prior to the month in which CPI–U is missing. Another commenter stated that CMS' proposed approach raises concerns under the APA because CMS did not adequately address predictable seasonality, financial consequences, uncertainty, and alternative approaches. A few commenters stated that the proposed approach exceeds CMS' statutory authority because the statute requires CMS to use the CPI–U for a specific month but does not specify the source from which the CPI–U value must originate.

Response: As discussed in section III.F.3.b. of this final rule, we considered alternative approaches and why we believe those alternatives are not feasible or appropriate. As noted in that section, we considered an approach in which we would use the previous month for which CPI–U data are available but believe this approach is less consistent with statute than using CPI–U values that are within the same applicable period as the month for which CPI–U data is missing. Section 1860D–14B of the Act describes the identification of CPI–U values after a specified time period has elapsed, and using data from a month that is before that time period is inconsistent with statute. For this same reason, we do not believe alternatives to use the average of or the higher of the month prior and the month subsequent to the month for which CPI–U values are missing are supported by statute and we therefore decline to adopt these approaches. We also considered using Treasury's index number according to the index contingency provisions for Treasury Inflation-Protected Securities; however, as we stated, this alternative approach does not align with statute (specifically sections 1860D–14B(b)(5)(C) and 1860D–14B(g)(4) of the Act), which direct CMS to use the CPI–U value from the first month of the relevant period. As such, we decline to adopt the suggestion to use Treasury's contingency method. Lastly, regarding the comment that CMS did not consider options to estimate the CPI–U for the month for which the CPI–U is missing, we considered calculating our own inflation factor rather than using the BLS reported CPI–U data; however, we determined that it is impracticable for us to administer a CPI–U survey and calculate an alternate CPI–U index. Similarly, we determined that was inconsistent with statute to estimate an alternate CPI–U value because statute directs CMS to use the CPI–U for a specific month.

After consideration of public comments, we are finalizing § 428.202(e)(6) as proposed.

c. Exclusion of 340B Acquired Units From Part D Rebatable Drugs (§ 428.203(b)(2) and (c))

Section 1860D–14B(b)(1)(B) of the Act requires that beginning with the plan year 2026, when calculating the total rebate amount to be paid by a manufacturer for a Part D rebatable drug, CMS shall exclude from the total number of units for a Part D rebatable drug, for an applicable period, those units for which a manufacturer provides a discount under the 340B Program. In the CY 2025 PFS final rule (89 FR 98278 through 98279), we finalized the proposal at § 428.201(a) to codify the total rebate amount calculation methodology described in section 40 of the revised Medicare Part D Drug Inflation Rebate Guidance,[226] which provides that the total Part D drug inflation rebate amount is equal to the per unit Part D drug inflation rebate amount, as determined under § 428.202(a), multiplied by the total number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors, as determined in accordance with § 428.203. In the CY 2025 PFS final rule (89 FR 98593), we also finalized the

[226] See: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf.*

proposal at § 428.203(b)(2)(i), to exclude from the total number of units determined under § 428.203(a), units for which a manufacturer provided a discount under the 340B Program (''340B units''). We also finalized the proposal at § 428.203(b)(2)(ii) to determine the total number of 340B units by using data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. As we stated in the CY 2025 PFS final rule (89 FR 98289) and CY 2026 PFS final rule (90 FR 49740), because this exclusion requirement starts after the first quarter of the applicable period that begins on October 1, 2025, the exclusion of 340B units will only apply for the last 3 quarters of such applicable period. That is, we are excluding 340B units from the total number of units for a Part D rebatable drug starting with claims with dates of service on or after January 1, 2026.

As we stated in the CY 2025 PFS final rule (89 FR 98289) and the CY 2026 PFS final rule (90 FR 49740), data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable from the data sources specified at section 1860D–14B(d) of the Act (that is, information submitted by manufacturers, States, and Part D plan sponsors), and we do not currently have access to this data through other means. We understand that the 340B status of a Part D drug is usually not known by the dispenser at the point-of-sale, and that 340B covered entities (hereinafter ''covered entities'') typically identify the 340B status of a Part D drug retrospectively. Because the covered entity and CMS do not exchange dispensed Part D drug information confirming the 340B status of a Part D rebatable drug, we are unable to precisely identify 340B units at the claim-level based solely on Part D claims submitted to us by the covered entity (or a contract pharmacy operating on behalf of the covered entity) at this time. For these reasons, in the CY 2026 PFS final rule (90 FR 49747), we adopted a claims-based methodology (described in the CY 2026 PFS final rule and hereinafter as ''Prescriber-Pharmacy Methodology'') that we leverage to exclude 340B units from the total number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during an applicable period, starting on January 1, 2026. Additionally, we adopted our proposal to establish a voluntary Medicare Part D Claims Data 340B Repository (''340B repository'') to collect data about 340B units voluntarily submitted by covered entities (90 FR 49750). The data submitted to the 340B repository will not be used to calculate inflation rebates unless and until we propose and finalize a policy to use such data to exclude 340B units from rebate calculations.

(1) Claims-Based Methodology To Remove 340B Units From Rebate Calculations

As finalized in the CY 2026 PFS final rule (90 FR 49741 through 49749), to implement the exclusion required by section 1860D–14B(b)(1)(B) of the Act and described in § 428.203(b)(2), under the Prescriber-Pharmacy Methodology, beginning on January 1, 2026, we remove 340B units from the Part D inflation rebate calculations by evaluating whether a Prescription Drug Event (PDE) record is potentially 340B-eligible based on (1) the affiliation of the National Provider Identifier (NPI) of the prescriber associated with that PDE record with a registered covered entity, and (2) the designation of the dispensing pharmacy associated with that PDE record as a 340B contract pharmacy. If the NPI of the prescriber associated with the PDE record is affiliated with a registered covered entity for a given month, and the dispensing pharmacy is a contract pharmacy associated with such covered entity for the same month, the PDE record is considered as potentially 340B-eligible, and the units associated with that PDE record are removed from Part D inflation rebate calculations. We refer readers to the CY 2026 PFS final rule for a more detailed explanation of the Prescriber-Pharmacy Methodology (90 FR 49741 through 49749).

In the CY 2026 PFS proposed rule (90 FR 32639 through 32641), we acknowledged that the 340B Office of Pharmacy Affairs Information System (OPAIS) database, which the Prescriber-Pharmacy Methodology relies on, may not list all pharmacies that dispense 340B-eligible drugs, including covered entities that have ''in-house'' pharmacies that are not registered in the 340B OPAIS database or 340B-eligible AIDS Drug Assistance Programs (ADAPs) [227] (also considered covered entities) that collect rebates to receive 340B discounts instead of receiving such discount at the time of purchase from a contract pharmacy registered in the 340B OPAIS database. We solicited comments on whether and how to account for this limitation. Similar to the acknowledgments we made in the proposed rule, we received comments stating that the Prescriber-Pharmacy Methodology may underrepresent 340B claims from Ryan White (RW) clinics and ADAPs. To address this, some commenters recommended that we use an alternative methodology to identify these claims. In the CY 2026 PFS final rule (90 FR 49747), we adopted modifications to the Prescriber-Pharmacy Methodology aimed at improving our ability to identify 340B claims associated with RW clinics, but we did not adopt modifications to the Prescriber-Pharmacy Methodology to address the limitations relating to ADAP claims. Our prior preliminary analyses suggested not modifying the Prescriber-Pharmacy Methodology to address the limitations relating to ADAP claims would have minimal impact. Specifically, the percentage of 340B units identified for drugs commonly covered by ADAPs, such as antiretrovirals, was comparable to the average percentage of 340B units identified overall across all drug classes, indicating no meaningful differential. In the CY 2026 PFS final rule (90 FR 49747), we stated that we may consider methodological refinements in the future to further address commenters' feedback on ADAPs.

Since publishing the CY 2026 PFS final rule, we have reviewed additional evidence relating to the need to adjust the Prescriber-Pharmacy Methodology to sufficiently identify units of drugs for which a manufacturer provided a discount under the 340B Program to account for ADAP clients. Consequently, we have become aware of evidence suggesting that, in contrast to our statement in the CY 2026 PFS final rule, the percentage of 340B units identified for drugs commonly covered by ADAPs, such as antiretrovirals, may be higher than the average percentage of 340B units identified overall. One study found that, using 2012 data from the Walgreens Co. 340B database, (1) antivirals were 10 times more likely to be dispensed through the 340B Program and specialty medications [228] were more

[227] ADAPs are State- and territory-operated Ryan White HIV/AIDS Program grantees that provide FDA-approved medications (including, in some States, medications beyond those used to treat HIV/AIDS) to low-income people living with HIV. Under section 340B(a)(4)(E) of the PHS Act, ADAPs are eligible to be enrolled with the 340B Program as covered entities, and HRSA has affirmed that any individual registered in an ADAP covered entity will be considered to meet the 340B patient definition. See: *https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf.*

[228] The authors of the study defined ''specialty drugs'' as those ''generally considered to be high

Continued

than 20 times more likely to be dispensed through the 340B Program compared to all drugs dispensed; and, (2) nearly 80 percent of all specialty medications dispensed under the 340B Program were antiretrovirals indicated for HIV.[229] This study hypothesized that these results can be at least partially explained by the types of covered entities participating in contract pharmacy arrangements with Walgreens in 2012, that is, covered entities that disproportionately treat people with HIV. Additionally, a Congressional Budget Office (CBO) study published September 2025 found that the majority of spending on anti-infective drugs (including HIV treatments) purchased through the 340B Program in 2021 occurred at Federal grantee sites, including ADAPs.[230] In addition to other evidence reviewed, these data points suggest that Federal grantee sites, including ADAPs, may significantly contribute to the percentage of 340B claims for antiretrovirals, that this percentage may be higher than for other drug classes, and that without methodological refinement to fully account for 340B claims dispensed to ADAP clients, the Prescriber-Pharmacy Methodology may under-identify 340B units for drug classes such as antiretrovirals to a greater extent than previously assumed during the CY 2026 rulemaking cycle. Based on this review, we proposed to make methodological refinements to the Prescriber-Pharmacy Methodology. We do not believe that adoption of the Prescriber-Pharmacy Methodology as described in the CY 2026 PFS final rule established significant reliance interests that would prevent us from modifying the Prescriber-Pharmacy Methodology. Given that Rebate Reports impacted by the Prescriber-Pharmacy Methodology (that is, Rebate Reports for applicable periods beginning October 1, 2025) have not yet been issued, CMS believes that any reliance interests that may relate to use of the Prescriber-Pharmacy Methodology would not be outweighed by the need to implement a more accurate methodology. Additionally, as we stated earlier, we provided notice to interested parties in the CY 2026 PFS final rule (90 FR 49747) that we may consider methodological refinements in the future to further address commenters' feedback relating to ADAPs.

As part of this reevaluation, we revisited comments we received on the CY 2026 PFS proposed rule. In particular, we revisited comments that explained the unique nature of ADAPs compared to other covered entity types, and the limitations in the Prescriber-Pharmacy Methodology's ability to identify PDE records for ADAP clients as 340B-eligible. As a commenter explained, the Prescriber-Pharmacy Methodology may under-identify 340B-eligible PDE records for ADAP clients for two reasons. First, PDE records for ADAP clients would typically not meet the first criterion of the Prescriber-Pharmacy Methodology (that is, that the prescriber with the NPI listed on the PDE record provides care at a covered entity). ADAPs are not providers or suppliers as defined under § 400.202, and a patient enrolled in an ADAP is typically prescribed medications by a provider not affiliated with the ADAP. Therefore, for a PDE record for an ADAP client, the prescriber NPI on the PDE record will not be affiliated with the covered entity that claimed the 340B price for such dispense (that is, the ADAP). Second, the majority of ADAPs access 340B pricing via a rebate model.[231] These ADAPs allow their clients to fill medications at a broad network of pharmacies that may not be registered in the OPAIS database as contract pharmacies. A PDE record for an ADAP client will thus not meet the second criterion of the Prescriber-Pharmacy Methodology (that is, that the pharmacy NPI on the PDE record is a contract pharmacy for the same covered entity that the prescriber NPI is affiliated with).

After further review of the additional evidence as discussed previously and revisiting comments we received on the CY 2026 PFS proposed rule, we conducted a more comprehensive analysis to assess whether the existing Prescriber-Pharmacy Methodology adequately identifies 340B-eligible drugs obtained through ADAPs for Medicare Part D enrollees. The analysis was conducted in two parts. The first reexamined the preliminary analyses described in the CY 2026 PFS final rule (90 FR 49747) assessing whether the Prescriber-Pharmacy Methodology systematically under-identifies drugs used in the treatment of HIV as 340B-eligible relative to all other drugs, and it built upon this analysis by examining whether the Prescriber-Pharmacy Methodology under-identifies drugs used in the treatment of HIV as 340B-eligible for ADAP clients specifically. We identified ADAP clients using the Coordination of Benefits (COB)-Other Health Insurance (OHI) file—specifically the COB–OHI Supplemental Record file—using a Supplemental Type Code that flags enrollees that have supplemental ADAP coverage.[232] This analysis reaffirmed our preliminary findings that the Prescriber-Pharmacy Methodology identifies drugs used in the treatment of HIV at a percentage close to the overall Part D average for all drug classes. However, when the analysis was isolated to ADAP clients only, we found that the Prescriber-Pharmacy Methodology identified drugs used in the treatment of HIV as 340B-eligible at a significantly lower percentage than was identified for Part D beneficiaries overall. This finding is contrary to expectations given that ADAPs are eligible to be enrolled with the 340B Program as covered entities, and that HRSA has affirmed that any individual registered in an ADAP will be considered to meet the 340B patient definition (as described earlier in this section). Further, this under-identification of 340B units for ADAP clients could impact the completeness and accuracy of data used for Part D inflation rebate calculations for certain drug classes such as antiretrovirals, if not sufficiently addressed.

The second part of the analysis examined how a modification to the Prescriber-Pharmacy Methodology would identify drugs used in the treatment of HIV as 340B-eligible compared to the existing Prescriber-Pharmacy Methodology. We analyzed the impact on the overall percentage of identified Part D 340B units for both antiretrovirals and all other drug classes if CMS were to consider all Part D units for ADAP clients as 340B-eligible. This analysis of the modification to the Prescriber-Pharmacy Methodology to treat all ADAP units as 340B-eligible determined that: (1) for certain drug

value; high-touch—for example, medications that require temperature control or other special handling, and medications that require ongoing management by a physician or pharmacists specialized in the relevant condition; or complex—for example, biotechnology products or orphan drugs; or some combination of the above.''

[229] Clark BL, Hou J, Chou CH, Huang ES, Conti R. The 340B discount program: outpatient prescription dispensing patterns through contract pharmacies in 2012. Health Aff (Millwood). 2014 Nov; 33(11):2012–7. doi: 10.1377/hlthaff.2014.0833. PMID: 25367997; PMCID: PMC4545491.

[230] CBO, Growth in the 340B Drug Pricing Program, September 9, 2025. *https://www.cbo.gov/publication/60661.*

[231] ''Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option.'' 63 FR 35239. See: *https://www.govinfo.gov/content/pkg/FR-1998-06-29/pdf/98-17142.pdf.*

[232] As explained in the Plan Communication User Guide for Medicare Advantage Prescription Drug Plans (February 27, 2026), the Supplemental Record file lists other health insurance that is supplemental to, that is, pays after, Part D. The Supplemental Type Code indicates the type of supplemental insurance contained in the record. *https://www.cms.gov/files/document/mapd-plan-communications-user-guide-v19-0-march-2026.pdf.*

classes, specifically antiretroviral medications used in the treatment of HIV, a modification to account for ADAP clients would result in a meaningful increase in the number of rebatable units identified as 340B-eligible, and (2) for all other drug classes, the modification would not have a substantial impact on the percentage of Part D units identified as 340B-eligible. Based on the additional evidence reviewed and subsequent analyses demonstrating the extent to which relevant PDE records for ADAP clients would be under-identified as 340B-eligible, we now concur with comments on the CY 2026 PFS proposed rule that we revisited. We agree with the commenters' assertion that a modification to the Prescriber-Pharmacy Methodology is needed to fully account for 340B-eligible units for ADAP clients. Where the ADAP acts as a payor of the Part D medication, we would consider all Part D units for ADAP clients as 340B-eligible. Such units would be removed from the total number of units and total rebate amount for a Part D rebatable drug as described in the Preliminary Rebate Report and Rebate Report detailed at § 428.401(b) and (c), respectively.

Specifically, we proposed the following modification to the Prescriber-Pharmacy Methodology: CMS would identify PDE records for beneficiaries who have ADAP supplemental coverage as listed in the COB–OHI Supplemental Record file using the Supplemental Type Code that flags enrollees that have supplemental ADAP coverage. CMS would then exclude all units associated with those PDE records from Part D inflation rebate calculations.

If a beneficiary included in the COB–OHI Supplemental Record file is identified as having supplemental insurance from an ADAP at the time a Part D drug was dispensed to such beneficiary during the applicable period, we would designate the units as 340B-eligible and remove the associated units from the inflation rebate calculation. Because State ADAP formularies can vary, and because we will not have State-specific insight regarding an ADAP's formulary coverage for a specific beneficiary's claims dispensed in a specific State, we would treat all PDE records dispensed for a beneficiary identified as having ADAP supplemental insurance on the COB–OHI file as 340B-eligible and remove the units associated with these PDE records. Since some of the ADAP clients identified in the proposed modification to the Prescriber-Pharmacy Methodology may already have Part D units identified as 340B-eligible using the existing Prescriber-Pharmacy Methodology, counting all ADAP clients' units identified under the proposed modification as 340B-eligible could potentially double-count 340B-eligible units. To avoid double-counting, we would identify units that were already flagged as 340B-eligible using the existing Prescriber-Pharmacy Methodology and exclude those from the count of ADAP 340B-eligible units identified under the proposed modification.

CMS acknowledges that this approach may result in an overestimation of 340B-eligible units for ADAP clients. Notwithstanding this limitation, CMS has determined that treating all Part D drugs dispensed to ADAP clients as 340B-eligible is appropriate for the following reasons: (1) the manner in which 340B discounts are realized for 340B-eligible ADAP units varies among State ADAP programs, and (2) variability in drug coverage across State-specific drug formularies presents significant challenges in developing a single, uniformly applicable methodology capable of accurately identifying 340B eligibility on a drug-by-drug or program-by-program basis. Further, in CMS' analysis of the proposed modification to the Prescriber-Pharmacy Methodology, and the corresponding treatment of all ADAP client units as 340B-eligible, CMS determined that: (1) for certain drug classes, specifically antiretroviral medications used in the treatment of HIV, the proposed modification would result in a meaningful increase in the percentage of Part D rebatable units identified as 340B-eligible, and (2) for all other drug classes, the proposed modification would not have a substantial impact on the percentage of units identified as 340B-eligible if all ADAP client units were treated as 340B-eligible. In other words, CMS' analysis indicates, for the majority of drug classes with exception of antiretroviral medications used in the treatment of HIV, treating all ADAP client units as 340B-eligible is expected to have minimal or no impact on the identification of 340B-eligible units from the Prescriber-Pharmacy Methodology. These findings demonstrate that the modification to the Prescriber-Pharmacy Methodology is narrowly and appropriately targeted towards antiretroviral medications used in the treatment of HIV, which aligns with the evidence described earlier in this section suggesting that the percentage of 340B units identified for antiretrovirals may be higher than the average percentage of 340B units identified overall. In light of these considerations, CMS has determined that a broad, programmatic approach to identifying 340B-eligible ADAP units is preferable to a more granular methodology that may yield inconsistent or inaccurate results. If adopted, the modification to the Prescriber-Pharmacy Methodology included in the proposed rule would be effective for Rebate Reports issued for the applicable period that begins October 1, 2025, and subsequent applicable periods.

We solicited comments on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposal to modify the Prescriber-Pharmacy Methodology to exclude Part D units dispensed to beneficiaries with ADAP supplemental coverage, as identified through the COB–OHI file, from Part D inflation rebate calculations.

Response: We appreciate the commenters' support.

Comment: A couple of commenters stated that the existing Prescriber-Pharmacy Methodology undercounts ADAP-associated 340B units because ADAPs function as payors rather than prescribers and often access 340B pricing through rebates from drug manufacturers rather than access the 340B discount upfront through registered contract pharmacies and stated that a beneficiary-level identification approach is more workable than a claim-level one because claim-level identification depends on linking a prescriber NPI to a covered entity and matching a dispensing pharmacy to that entity's registered OPAIS contract pharmacy, and it cannot capture ADAP-associated 340B units since ADAPs have neither element. A couple of commenters identified a specific mechanism, distinct from the general overestimation CMS acknowledged, that would further inflate estimates of rebatable claims: ADAP rebate model claims are triggered only when an actual cost-sharing payment occurs, and most ADAP clients reach the Part D out-of-pocket cap early in the plan year, but the proposed methodology would treat all ADAP-associated units as 340B-eligible. One of these commenters recommended that CMS acknowledge this dynamic explicitly in the final rule and also confirm that the COB–OHI file reliably and promptly reflects new ADAP enrollments and disenrollments. Another commenter separately stated

there are over- and under-counting risks in the Prescriber-Pharmacy Methodology generally, stating that in-house dispensing pharmacies and unreported Medicare Provider Numbers to the OPAIS database can cause 340B units to be missed. A commenter stated their concern that the proposed methodological enhancement to the Prescriber-Pharmacy Methodology could reduce 340B savings available to RW clinics and other safety-net providers, with downstream effects on wrap-around services, pharmacy participation, and continuity of HIV treatment. Another commenter recommended that CMS consider an all-payer rebate model as a longer-term solution, stating that following every State's ADAP formulary in real time to identify covered drugs is not feasible under the current Prescriber-Pharmacy Methodology, and that an all-payer model could improve the precision of CMS' Part D inflation rebate calculations without replacing the existing ADAP rebate model.

Response: We appreciate the feedback and suggestions for further improvement to the Prescriber-Pharmacy Methodology to mitigate potential for over- or under-counting ADAP units as 340B-eligible. We acknowledge the broader over- and under-counting risks commenters raised regarding in-house dispensing pharmacies and unreported Medicare Provider Numbers. As finalized in the CY 2026 PFS final rule, we addressed the unreported Medicare Provider Number concern through an augmented prescriber NPI mapping methodology, and we addressed the in-house pharmacy concern by incorporating covered entities' OPAIS-listed ''Shipping Addresses'' as additional dispensing locations. These enhancements do not, however, address the distinct circumstance of ADAP clients. The proposed modification is intended to close that remaining gap. We agree with commenters that the proposal may result in overestimation of 340B-eligible units for ADAP clients. We have determined that treating all Part D claims for ADAP clients as 340B-eligible is nonetheless appropriate for two reasons: (1) the manner in which 340B discounts are realized for ADAP-associated units varies among State ADAPs, and (2) variability across State-specific drug formularies presents significant challenges to developing a single, claim-level methodology capable of accurately identifying 340B eligibility on a drug-by-drug basis. Our analysis of the modification to the Prescriber-Pharmacy Methodology to treat all ADAP units as 340B-eligible determined that: (1) for certain drug classes, specifically antiretroviral medications used in the treatment of HIV, a modification to account for ADAP clients would result in a meaningful increase in the number of rebatable units identified as 340B-eligible, and (2) for all other drug classes, the modification would not have a substantial impact on the percentage of Part D units identified as 340B-eligible. Therefore, a broad, programmatic approach is preferable to a more granular methodology that could yield inconsistent results. Additionally, we are taking steps to minimize overestimation; for example, to avoid double counting 340B units, we will identify units already flagged as 340B-eligible under the existing Prescriber-Pharmacy Methodology and exclude those units from the count of ADAP-associated 340B-eligible units identified under this modification. We also confirm that the COB–OHI Supplemental Type Code is updated monthly to reflect new ADAP enrollments and disenrollments, and we will continue to monitor the reliability of this data source as we implement the methodology. In response to concern that the proposed modification to the Prescriber-Pharmacy Methodology could affect 340B savings available to RW clinics and other safety-net providers, we note that the methodology is designed to account for and exclude 340B units associated with ADAP clients from the Part D inflation rebate calculation and does not alter the underlying 340B Program discounts available to covered entities. Comments recommending that we adopt an all-payer rebate model are out of scope for this final rule. These comments address a broader payment methodology beyond the Medicare Part D Drug Inflation Rebate Program policies addressed in this rule.

After consideration of public comments, we are finalizing the policy as proposed to identify PDE records for beneficiaries who have ADAP supplemental coverage as listed in the COB–OHI Supplemental Record file. If a beneficiary included in the COB–OHI Supplemental Record file is identified as having supplemental insurance from an ADAP at the time a Part D drug was dispensed to such beneficiary during the applicable period, we will designate the units as 340B-eligible and remove the associated units from the inflation rebate calculation.

(2) Medicare Part D Claims Data 340B Repository

In the Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D–14B of Social Security Act, and Solicitation of Comment (''initial Medicare Part D Drug Inflation Rebate Guidance''),[233] CMS solicited comments on the best mechanism to identify 340B units dispensed under Part D to exclude units from Part D inflation rebate calculations. Interested parties recommended that CMS create a mechanism through which covered entities would retrospectively submit data to CMS identifying 340B-purchased drugs dispensed under Part D and urged that this mechanism allow covered entities to submit these data directly to CMS, rather than through claims that dispensers submit via Part D plan sponsors. In response to these recommendations, we solicited comments in the CY 2025 PFS proposed rule (89 FR 61971 through 61972) on a 340B repository. As highlighted in the CY 2025 final rule (89 FR 98292), interested parties provided different perspectives, including strong support for a 340B repository from many covered entities and drug manufacturers. In the CY 2026 PFS proposed rule (90 FR 32641 through 32644), we proposed to establish a 340B repository, and as described in the CY 2026 PFS final rule (90 FR 49749), many commenters supported this proposal to establish a 340B repository.

In the CY 2026 PFS final rule (90 FR 49750), we established a 340B repository to receive voluntary submissions from covered entities of certain data elements associated with Part D claims for which the covered entity dispensed (directly or indirectly, including via retrospective replenishment and contract pharmacy arrangements) units of a drug for which a manufacturer provides a discount under the 340B Program (''Part D 340B claims''). We established the 340B repository to allow for assessment of such data for potential use in identifying units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program in a future applicable period. We established that covered entities will be allowed to submit data on units of Part D 340B claims beginning in 2026 to begin testing the usability of the 340B repository. The 340B repository launched on October 1, 2026, and some covered entities have begun voluntarily

[233] See: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf.*

submitting Part D 340B data. Covered entities may now create an account and begin submitting Part D 340B data and can access the 340B repository and technical instructions for creating an account and submitting data via the CMS website.[234] We will use submitted data to begin testing the usability of data voluntarily submitted by covered entities, starting with claims with dates of service in 2026. Covered entities that voluntarily submit data to the 340B repository need to follow the processes and requirements that CMS has established for voluntary reporting starting in 2026 and the associated information collection currently approved under OMB control number 0938–1485.

In the CY 2026 PFS final rule (90 FR 49750), we strongly encouraged all covered entities to submit data elements to the 340B repository during the 2026 testing period, noting that this participation would allow for robust testing of data quality and completeness and provide an opportunity for covered entities to develop and test their data submission processes. We also noted that we would address the possibility of requiring covered entities to report data elements to the 340B repository in future years in future rulemaking and that we were actively considering proposing mandatory reporting to the 340B repository in the near future.

We proposed at § 428.203(c) to require providers and suppliers that are covered entities as defined under § 10.3 (hereinafter collectively ''340B providers'' unless otherwise noted) to submit Part D 340B data to the 340B repository beginning in 2027. Such reporting would fulfill a 340B provider's obligation to provide access to documentation relating to covered Part D drugs written or ordered by such 340B provider to maintain enrollment in Medicare, as we proposed at § 424.516(f)(4). We described these proposals in further detail in sections III.F.3.c.2.a. through III.F.3.c.2.c. of the proposed rule.

(a) Background: Requirement for Physicians, Other Suppliers, and Providers To Maintain and Provide Access to Documentation

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to implement enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P. They address, among other things, requirements that providers must meet to obtain and maintain Medicare billing privileges.

Section 6406(a) of the Patient Protection and Affordable Care Act (ACA) amended section 1842(h) of the Act by adding a new paragraph which establishes that the Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under Title XVIII of the Act, as specified by the Secretary.

In addition, section 6406(b)(3) of the ACA amended section 1866(a)(1) of the Act to require that providers maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider, as specified by the Secretary.

To implement section 6406 of the ACA, on May 5, 2010, CMS published an interim final rule titled ''Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements,'' (75 FR 24437) which amended § 424.516(f) to specify requirements for, among other things, documentation and access to documentation related to certain orders and referrals. We clarified in that rulemaking that the documentation includes both written and electronic documentation. CMS also amended § 424.535(a)(10) to establish that CMS may revoke enrollment, for a period of not more than one year for each act of noncompliance, for a provider or a supplier if such provider or supplier fails to meet the requirements of § 424.516(f). CMS finalized the interim final rule in an April 27, 2012 final rule titled ''Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements'' (77 FR 25284).

(b) Proposal To Require Providers and Suppliers That Are Covered Entities To Submit Documentation Relating to Part D 340B Claims (§§ 424.516(f)(4), 424.535(a)(10), and 428.203(c))

To inform policy development for this rulemaking, we reviewed and considered the comments received on the CY 2026 PFS proposed rule. In this feedback, many commenters suggested that we require covered entities and/or their contractors to report data to a 340B repository. We agree. To ensure robust data submissions in 2027 to determine if data submitted to the 340B repository could be used reliably in the future to remove 340B units from Part D inflation rebate calculations in accordance with section 1860D–14B(b)(1)(B) of the Act, we believe it necessary to transition from voluntary submission to requiring 340B provider participation in the 340B repository.

We therefore proposed at § 424.516(f)(4) that a provider or supplier that is a covered entity as defined at § 10.3 would be required to maintain and provide access to documentation as set forth at proposed § 428.203(c). We proposed this requirement in accordance with sections 1866(a)(1)(X) and 1842(h)(9) of the Act. As finalized, CMS would reserve the right to revoke, in accordance with existing § 424.535(a)(10), a currently enrolled provider or supplier's Medicare enrollment and any corresponding provider agreement or supplier agreement for failure to comply with the requirements for maintaining and providing access to documentation specified in proposed § 424.516(f)(4). Although we acknowledged that § 424.516(f) has historically set forth documentation requirements for providers and suppliers for their Part A and Part B services, the statutory authorities underlying that provision, sections 1842(h)(9) and 1866(a)(1)(X) of the Act, do not expressly limit documentation requirements to services furnished under Part A and Part B. Sections 1842(h)(9) and 1866(a)(1)(X) of the Act collectively set forth that providers and suppliers must maintain and provide access to documentation relating to ''items or services written or ordered by the provider *under this title,*

[234] See here to create an account with the 340B repository: *https://medicare340breporting.cms.gov/sec340b/login.* See here to access instructions and technical specifications on the 340B repository: *https://www.cms.gov/initiatives/medicare-prescription-drug-affordability/overview/medicare-inflation-rebate-program.*

as specified by the Secretary'' (emphasis added). Both sections 1842(h)(9) and 1866(a)(1)(X) of the Act fall under Title XVIII (that is, the Medicare statute), which inherently includes Part D. As such, requiring providers and suppliers to maintain and provide access to documentation related to covered Part D drugs written or ordered by a provider or supplier is consistent with sections 1866(a)(1)(X) and 1842(h)(9) of the Act. By transitioning from voluntary submission to mandatory participation in the 340B repository, CMS would be able to ensure more complete and reliable data submissions, thereby improving its ability to accurately assess potential future use of the 340B repository to exclude 340B units from Part D rebate calculations, consistent with its obligations under section 1860D–14B(b)(1)(B) of the Act.

At § 428.203(c), we proposed the documentation to which a 340B provider must provide access, as well as the timeframe within which such access must be provided, for the provider or supplier to fulfill their obligations set forth in the proposed § 424.516(f)(4). Proposed § 428.203(c)(1) would require that, beginning with claims with a date of service on or after January 1, 2027, a provider or supplier that is a covered entity as defined at § 10.3 must submit the data elements associated with each claim for a covered Part D drug billed to Medicare Part D for which such covered entity or its contractor(s) (such as contract pharmacies) dispensed units of a drug for which a manufacturer provides a discount under the 340B Program to such covered entity. This requirement would apply, for example, to claims for units of a drug covered under Part D and dispensed by contract pharmacies that the covered entity, its contractors, or its third-party administrators (TPAs) identify as 340B-eligible and for which the covered entity obtains a 340B discount, including through retrospective replenishment models. This requirement would also apply, for example, to claims for units of a drug covered under Part D and dispensed by the covered entity's in-house pharmacy.[235]

Specifically, we proposed to require that a provider or supplier that is a covered entity as defined at § 10.3 must submit the following data elements associated with each claim for units of a covered Part D drug billed to Medicare by such covered entity or its contractor(s) (such as contract pharmacies) for which a manufacturer provides a discount under the 340B Program to such covered entity: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); (4) Dispensing Pharmacy NPI; and (5) NDC–11. Additionally, we proposed at § 428.203(c)(2) that, in addition to submitting the data elements set forth in proposed § 428.203(c)(1), a provider or supplier that is a covered entity as defined at § 10.3 must submit its 340B ID and name as designated in the 340B OPAIS database.

We explained that we understood that reporting the data proposed at § 428.203(c) may impose new operational demands on 340B providers, potentially requiring the development of reporting processes where none currently exist and that 340B providers will need time to develop a process for collecting the 340B data elements to submit to the 340B repository and prepare the data in a form and manner prescribed by CMS. Additionally, given the variety in the scope of provider types and organizations that participate in the 340B Program, we recognized the amount of preparation time to submit data varies. We proposed at § 428.203(c)(3) to require that 340B providers report data on a quarterly basis (though they may choose to submit more frequently) within 1 calendar quarter following the close of the relevant calendar quarter. For example, for claims with dates of service between October 1, 2027, through December 31, 2027, 340B providers would submit the data elements from Part D 340B claims to the 340B repository no later than March 31, 2028. Quarterly submissions are necessary so CMS has timely information to assess the reliability of the data for potential future use in removing 340B units from Part D inflation rebate calculations. In addition, quarterly submissions may minimize the burden on 340B providers by reducing the amount of data in each submission and the amount of quality assurance necessitated for each submission. We received public comments on these proposals. For ease of reference and organization, we summarize comments received and our responses at the end of sections III.F.3.c.2.b. and III.F.3.c.2.c. of this final rule.

Specifically, at § 428.203(c)(3), we proposed that the data elements and information set forth in § 428.203(c)(1) and (c)(2) must be submitted on a quarterly basis and in a form and manner specified by us in accordance with the following timelines: data elements and information associated with claims with dates of service during the first calendar quarter must be submitted by the close of the second calendar quarter; data elements and information associated with claims with dates of service during the second calendar quarter must be submitted by the close of the third calendar quarter; data elements and information associated with claims with dates of service during the third calendar quarter must be submitted by the close of the fourth calendar quarter; and data elements and information associated with claims with dates of service during the fourth calendar quarter must be submitted by the close of the first calendar quarter of the immediately following calendar year.

These are the same data elements, information, and timing requirements that are specified in the CY 2026 PFS final rule (90 FR 49750) establishing the 340B repository with voluntary submission.

We noted in the proposed rule that we are issuing a revised collection of information (0938–1485) titled ''Information Collection Request (ICR) for the Medicare Prescription Drug Inflation Rebate Program under sections 11101 and 11102 of the Inflation Reduction Act (IRA)'' (CMS–10930, OMB 0938–1485) alongside this final rule to reflect the burden associated with a mandatory submission to the 340B repository. We are working to operationalize the 340B repository in a way that minimizes burden on 340B providers and have engaged with a range of interested parties, including covered entities and their staff responsible for pharmacy services management, and 340B TPAs, to consider the technical requirements that would facilitate lower burden for submission to the 340B repository. See section V.B.5. of this final rule for an updated estimate of burden associated with the collection of data for the 340B repository. The ICR contains more details regarding how covered entities would submit data to the 340B repository.

Under this proposal in the CY 2027 PFS proposed rule, the data submitted to the 340B repository would not be used to calculate inflation rebates. We will continue to use the Prescriber-

[235] CMS uses the term ''in-house pharmacy'' as it is defined in the OPAIS 340B Glossary. An ''in-house pharmacy'' is described as a pharmacy that is owned by and is a legal part of a 340B entity. Typically, in-house pharmacies are listed as shipping addresses of the entity and the entity owns the pharmacy license. See: *https://340bregistration.hrsa.gov/help/CoveredEntity/Links/340B_Glossary.htm.*

Pharmacy Methodology to remove 340B units from Part D inflation rebate calculations. Any future proposal to use the data reported to the 340B repository to remove 340B units from Part D inflation rebate calculations would undergo notice-and-comment rulemaking. We described our intention to analyze the data submitted to the 340B repository under this proposal to determine if they could be used reliably in the future to remove 340B units from Part D inflation rebate calculations in accordance with section 1860D–14B(b)(1)(B) of the Act. We would match the stored data elements in the 340B repository to PDE records for each Part D rebatable drug dispensed during the applicable period and would evaluate 340B repository data for: (1) data integrity, and (2) submission frequency and completeness across covered entity types and geographies, including through comparison to claims identified under the Prescriber-Pharmacy Methodology adopted in the CY 2026 PFS final rule to exclude 340B units starting on January 1, 2026, from Part D inflation rebates, including modifications established in this final rule. We noted in the proposed rule, we understand the importance of maintaining the confidentiality of data submitted to the 340B repository, and this data would not be made available to external parties, including manufacturers and Part D plan sponsors.

We solicited comments on the proposal at § 424.516(f)(4) that a provider or supplier that is a covered entity as defined at § 10.3 would be required to submit to CMS the documentation set forth at proposed § 428.203(c)(1) and (2) relating to covered Part D drugs written or ordered by such provider or supplier and comply with the submission requirements set forth at § 428.203(c)(3) and (4). We also solicited comments on the documentation and timing requirements proposed at § 428.203(c) to which a provider or supplier that is a covered entity would be required to adhere to fulfill their obligation at proposed § 424.516(f)(4). We also solicited comments on the scope of Part D 340B claims for which a provider or supplier that is a covered entity as defined at § 10.3 must submit data elements under the proposed regulation text.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposal to require submissions from 340B providers to the 340B repository. Many commenters stated that mandating submissions from 340B providers to the 340B repository is an important step in advancing program integrity, ensuring robust submissions with complete and accurate data, and fulfilling the statutory requirement at section 1860D–14B(b)(1)(B) of the Act to exclude 340B units from Part D inflation rebate calculations.

Response: We thank the commenters for the support.

Comment: Some commenters urged CMS to shift to using data collected through the 340B repository in Part D inflation rebate calculations as soon as possible since, in their view, the 340B repository would provide the most comprehensive and accurate method for identifying and excluding 340B units. A few commenters stated that the 340B repository will provide more accurate data than the Prescriber-Pharmacy Methodology but did not specifically recommend that we use 340B repository data in Part D inflation rebate calculations now or in the future.

Response: We thank the commenters for their feedback. As discussed elsewhere in this final rule, data submitted to the 340B repository will not be used in Part D inflation rebate calculations under this final rule. Before that data can be relied upon for that purpose, CMS must evaluate its completeness and representativeness, which requires the mandatory reporting we are finalizing here. We will continue to rely on the Prescriber-Pharmacy Methodology to exclude 340B units from Part D inflation rebate calculations while this evaluation is underway. Any future proposal to use 340B repository data for that purpose would be subject to separate notice-and-comment rulemaking.

Comment: Some commenters stated that a mandatory reporting requirement is necessary because covered entities lack sufficient incentive to submit data voluntarily, and that a voluntary approach would result in low or unrepresentative participation that would limit CMS' ability to evaluate the repository's suitability for use in Part D inflation rebate calculations.

Response: We appreciate the feedback and agree that requiring mandatory reporting allows us to avoid the methodological limitations that would result from building our evaluation on a data set shaped by which organizations chose to participate. Specifically, continuation of a voluntary reporting approach introduces a confounding factor into the data based on characteristics of organizations that choose to submit or not, which would limit our ability to evaluate the suitability of the data. To mitigate this limitation and support a robust analysis of 340B data submissions, we believe establishing a mandatory reporting requirement is necessary to help ensure sufficient and representative participation.

Comment: A commenter stated that mandatory reporting is particularly important for biosimilar manufacturers, who often lack the market leverage available to reference product manufacturers to protect against duplicate discounts, and mandatory 340B claims reporting is therefore essential to ensuring that the statutory exclusion operates in practice, not merely in principle.

Response: We thank the commenter for this feedback. We reiterate that the 340B repository will not be used in Part D inflation rebate calculations at this time. We will consider this feedback if we propose such a policy in future rulemaking.

Comment: A couple of commenters supported mandatory reporting to the 340B repository because contract pharmacies generally do not know the 340B status of a Part D drug at the point of sale and should not be expected to identify or report 340B status through pharmacy claim submission processes.

Response: We thank the commenters for this feedback and agree that reporting responsibility rests with 340B providers, not contract pharmacies. Sections 428.203(c) and 424.516(f)(4) apply to 340B providers, not to third-party entities such as contract pharmacies and TPAs. We recognize that contract pharmacies generally do not know a claim's 340B status at the point of sale, since that status is typically determined later through a covered entity's or its TPA's retrospective identification process. The reporting obligation therefore falls on the 340B provider, who may rely on data from TPAs and contract pharmacies to compile its submissions but remains responsible for the accuracy and completeness of the data submitted to the 340B repository. A 340B provider may arrange for a TPA or other vendor to submit on its behalf, but this does not shift the underlying reporting responsibility away from the covered entity.

Comment: Some commenters stated that CMS has not provided sufficient explanation as to why it proposed to mandate reporting to the 340B repository even though it has not identified deficiencies with the Prescriber-Pharmacy Methodology. These commenters stated that this policy shift is significant, and CMS must explain why the Prescriber-Pharmacy Methodology finalized last

year is no longer sufficient. Some commenters stated that CMS does not explain why mandatory reporting must begin in 2027 since CMS is not yet using 340B repository data in Part D inflation rebate calculations, and that requiring reporting so soon undermines the purpose of the voluntary reporting period. A commenter recommended that CMS not finalize the proposal unless it can provide a reasoned explanation demonstrating why mandatory reporting is necessary and why less burdensome alternatives are inadequate to avoid arbitrary and capricious challenges under the Administrative Procedure Act. A commenter questioned the necessity of mandatory reporting since CMS already receives Part D claims data through existing PDE reporting mechanisms.

Response: We thank the commenters for the feedback. We first note that, although CMS does receive Part D claims data through existing PDE reporting mechanisms, we do not currently receive information on the 340B status of all Part D claims through PDE reporting. In the current 340B landscape, only the 340B covered entity has visibility into all purchases under the 340B program and dispenses to individuals enrolled in Medicare Part D; thus, CMS believes there are no less burdensome alternative sources to obtain claim-level information on 340B dispenses to Part D enrollees from the 340B covered entity. Indeed, reporting to the 340B repository, whether submitted voluntarily in accordance with the submission periods established under the CY 2026 PFS final rule or, beginning in 2027, as required under this final rule, is structured to be minimally burdensome such that CMS can match the data elements stored in the 340B repository to PDE records for Part D rebatable drugs to test whether the 340B repository data could be used to identify 340B units in the future. The required data elements have not changed between the CY 2026 PFS final rule and the CY 2027 PFS final rule, meaning that the underlying data reporting tasks for the 340B covered entities are identical whether reporting is voluntary or mandatory.

Second, we note that, since publication of the CY 2026 PFS final rule, through engagement with a diverse range of interested parties, a consistent theme has emerged independent of the repository's launch: covered entities lack sufficient incentive to voluntarily report data, citing administrative burden without an offsetting benefit. We believe this feedback provides a reasonable basis for anticipating, prior to formally evaluating repository participation data, that voluntary reporting alone may not yield a data set that is sufficiently complete or representative of all providers and suppliers that are covered entities. We disagree with the commenter that CMS must find the Prescriber-Pharmacy Methodology deficient for CMS to propose mandatory reporting by 340B providers to the 340B repository. This is because mandatory reporting to the 340B repository is separate in authority and serves a distinct and independent purpose from the Prescriber-Pharmacy Methodology, which is to collect Part D 340B claims data from covered entities so that CMS can evaluate whether such data could satisfy the statutory requirement at section 1860D–14B(b)(1)(B) of the Act in the future. Voluntary reporting of 340B claims data to the 340B repository introduces a confounding factor based on the characteristics of the 340B providers that choose to participate, limiting CMS' ability to assess whether 340B repository data are sufficiently complete and representative of all 340B providers for this purpose. CMS is therefore adopting mandatory 340B claims data reporting to test a different data source for potential future use. This effort proceeds independent of whether the Prescriber-Pharmacy Methodology remains adequate for its current use; we will continue relying on that methodology to calculate Part D inflation rebates while this evaluation of 340B repository data is underway.

Third, we note that interested parties representing drug manufacturers and covered entities commented on the revised guidance for the Medicare Part D Drug Inflation Rebate Program and the CY 2025 PFS proposed rule recommending that we create a mechanism, such as a repository or a clearinghouse, through which covered entities would retrospectively submit data to us identifying 340B claims dispensed under Part D, and a couple of these commenters supported mandatory reporting to the 340B repository. Further, in comments on the CY 2026 PFS proposed rule, many commenters requested that we mandate covered entity reporting to the 340B repository so that CMS could—in the commenters' view—more quickly transition away from the Prescriber-Pharmacy Methodology and instead use 340B repository data in Part D inflation rebate calculations. Requiring participation in the 340B repository in this final rule is responsive to this feedback.

CMS has signaled its intent to move toward mandatory reporting over the course of several rulemaking cycles. In the CY 2025 PFS proposed rule (89 FR 61971), we solicited comments on potential authorities to require covered entities to submit data to a 340B repository. In response to comments received in support of such a requirement, we stated in the CY 2026 PFS final rule (89 FR 98293) that we would consider comments received for use in future rulemaking and continue to explore requiring that covered entities and their contracted TPAs report to the 340B repository. In the CY 2026 PFS proposed and final rules (90 FR 32642, 49750), we stated that we were actively considering options for mandatory reporting to the 340B repository in the near future and recommended that covered entities take advantage of the testing period to prepare for future policy development related to 340B repository reporting. Additionally, we noted in the CY 2026 PFS final rule (90 FR 49751) that many commenters requested that CMS make reporting to the repository mandatory for covered entities and their contractors, stating that, without a mandatory requirement for submission to a 340B repository, the 340B repository would not be able to be used to fulfill the legal requirement to remove 340B units from Part D inflation rebate calculations. We agree with these commenters. As discussed earlier in this response, voluntary reporting introduces a confounding factor based on the characteristics of covered entities that choose to participate, which limits CMS' ability to assess whether 340B repository data are sufficiently complete and representative of all covered Part D drugs that are purchased under the 340B Program to support identification of 340B units for purposes of calculating Part D inflation rebates. We believe that continuation of voluntary reporting to the 340B repository could force us to delay our evaluation of the 340B repository data until an undetermined number of covered entities opt in—with no guarantee they ever would—or draw conclusions from an incomplete record of submissions. A mandatory requirement is therefore necessary to produce data of the completeness and representativeness needed to evaluate that use.

Comment: Some commenters stated that CMS has not demonstrated clear statutory authority to compel reporting of Part D 340B data, and that the IRA charged CMS with calculating inflation rebate amounts but did not establish a corresponding requirement for 340B providers to report such data to CMS. These commenters stated that CMS' reliance on sections 1866(a)(1)(X) and 1842(h)(9) of the Act is unpersuasive, and that CMS has not sufficiently

explained how these statutory provisions authorize CMS to compel reporting of Part D 340B claim-level information that are not being used to support accurate processing of Medicare claims and payment. A few of these commenters stated that the most natural reading of section 6406(a) of the ACA is as an audit authority permitting the Secretary to obtain records when necessary, but it does not establish a prospective, permanent, nationwide authority to require routine submissions from 14,000 providers and suppliers. A commenter stated that CMS' proposal conflicts with Executive Order 14192, ''Unleashing Prosperity Through Deregulation,'' and the Unfunded Mandates Reform Act of 1995. A commenter asked CMS to explain how an enrollment documentation authority directed at the services a provider or supplier furnishes and bills reaches claims submitted by a different entity under a different part of the Medicare program (that is, Medicare Part D). By contrast, a couple of commenters stated that the proposed reporting requirement falls within CMS' statutory authority to establish documentation requirements for certain orders and referrals made by Medicare providers, which includes 340B claims. A few commenters asked CMS to confirm that the reporting obligation rests with 340B providers and not with authorized vendors such as contract pharmacies and TPAs, which are not enrolled parties subject to § 424.516(f)(4).

Response: Section 1860D–14B(b)(1)(B) of the Act requires CMS to remove 340B units from Part D inflation rebate calculations beginning with plan year 2026, and we reiterate that data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable from the data sources specified at section 1860D–14B(d) of the Act (that is, information submitted by manufacturers, States, and Part D plan sponsors), and we do not currently have access to this data through other means. We believe that requiring 340B provider participation in the 340B repository is necessary to ensure robust data submissions in 2027 to determine if data submitted to the 340B repository could be used reliably in the future to remove 340B units from Part D inflation rebate calculations in accordance with section 1860D–14B(b)(1)(B) of the Act.

We agree with the commenters who stated that the reporting requirement falls within CMS' statutory authority. As we explained in the CY 2027 PFS proposed rule (91 FR 44012), section 6406(a) of the ACA amended section 1842(h) of the Act by adding a new paragraph which establishes that the Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under Title XVIII of the Act, as specified by the Secretary. In addition, section 6406(b)(3) of the ACA amended section 1866(a)(1) of the Act to require that providers maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider, as specified by the Secretary. Although we acknowledged that § 424.516(f) has historically set forth documentation requirements for providers and suppliers for their Part A and Part B services, the statutory authorities underlying that provision, sections 1842(h)(9) and 1866(a)(1)(X) of the Act, do not expressly limit documentation requirements to services furnished under Part A and Part B. Sections 1842(h)(9) and 1866(a)(1)(X) of the Act collectively set forth that providers and suppliers must maintain and provide access to documentation relating to ''items or services written or ordered by the provider *under this title,* as specified by the Secretary'' (emphasis added). Both sections 1842(h)(9) and 1866(a)(1)(X) of the Act fall under Title XVIII (that is, the Medicare statute), which inherently includes Part D. As such, requiring providers and suppliers to maintain and provide access to documentation related to covered Part D drugs written or ordered by a provider or supplier is consistent with sections 1866(a)(1)(X) and 1842(h)(9) of the Act. By transitioning from voluntary submission to mandatory participation in the 340B repository, we will be able to ensure more complete and reliable data submissions, thereby improving our ability to accurately assess potential future use of the 340B repository to exclude 340B units from Part D inflation rebate calculations, consistent with our obligations under section 1860D–14B(b)(1)(B) of the Act. Finally, we affirm that the requirements at §§ 428.203(c) and 424.516(f)(4) apply to 340B providers and not to third-party entities such as contract pharmacies and TPAs.

Comment: A few commenters requested that CMS affirm that the 340B repository and the 340B Rebate Model Pilot Program (''340B Rebate Pilot'') serve different purposes, and that the existence of the 340B repository does not diminish the need for a rebate model in the 340B Program. Some commenters stated that an expanded version of the 340B Rebate Pilot would offer the most efficient, accurate, and transparent path to identifying and excluding 340B claims from both the Part B and Part D Drug Inflation Rebate Programs and requested that HHS consider implementing a rebate model for all products.

Response: We acknowledge that HRSA has announced the availability of a 340B Rebate Pilot, which would require covered entities to report an expanded set of data elements for selected drugs under the Medicare Drug Price Negotiation Program for initial price applicability years 2026 and 2027 during their price applicability periods purchased at the 340B price to manufacturers.[236] CMS will coordinate with HRSA to reduce burden on covered entities as feasible. However, the 340B repository mandatory reporting requirement and the 340B Rebate Pilot are distinct in terms of legal basis, scope of drugs, recipient of collected data, and program purpose. The 340B repository mandatory reporting requirement is part of a distinct, comprehensive effort involving claims for all drugs dispensed under Part D and covered by Part D plan sponsors to assess use of the 340B repository to exclude 340B units from Part D inflation rebate calculations, whereas the 340B Rebate Pilot is at this time limited to selected drugs for initial price applicability years 2026 and 2027.

Comment: Many commenters stated that the 340B repository requirement would be largely duplicative of information already being reported through other mechanisms, including the 340B Rebate Pilot, and recommended that CMS track duplicative reporting burdens and consider whether the Part D 340B claims data information needed can be obtained from existing data sources such as manufacturers, payers, or wholesalers. These commenters stated that the duplicative reporting requirements are wasteful, inefficient, and cause financial harm to covered entities. Many commenters stated that HHS should not impose two separate

[236] See: *https://www.federalregister.gov/documents/2026/08/03/2026–15633/notice-regarding-340b-rebate-model-pilot-program.*

and overlapping data submission requirements on covered entities under the 340B repository and the 340B Rebate Pilot and recommended that CMS and HRSA collaborate to unify reporting requirements. A commenter recommended that CMS only move forward with mandating participation in the 340B repository beginning in 2027 if HRSA delays implementation of the 340B Rebate Pilot until after implementation of the 340B repository since, in their view, the 340B repository would obviate the need for the 340B Rebate Pilot.

Response: We disagree that our proposal for mandatory reporting to the 340B repository is largely duplicative of the 340B Rebate Pilot. As explained, there are key differences between these two initiatives to include the purpose of 340B reporting and underlying authority, scope of reported drugs, data elements, frequency of reporting, duration of reporting, and recipient of reported information. Duplication of reporting burden by a covered entity in CY 2027 to both the 340B repository and the 340B Rebate Pilot is limited to those drugs that are a selected drug in initial price applicability year 2026 and initial price applicability year 2027 during their price applicability period.

Comment: Many commenters recommended that CMS use the information submitted to the 340B repository—or an expanded ''neutral claims clearinghouse'' version of the 340B repository that would collect data for Federal programs more broadly—in the administration of other Federal programs, including the Medicare Drug Price Negotiation Program, so that covered entities need not submit data to multiple sources, including to the 340B Rebate Pilot and manufacturers. A commenter recommended that CMS consider how the 340B repository could be expanded to capture Part B 340B claims.

By contrast, some commenters recommended that the 340B repository be used only in the Medicare Part D Drug Inflation Rebate Program and that any expanded use be subject to notice-and-comment rulemaking. A commenter requested clarity on how 340B repository information will interact with other methods of identifying 340B units and asked which source will be used when data conflicts.

Response: At this time, data submitted to the 340B repository will be used to begin testing usability of the data for the purpose of removing 340B units under the Medicare Part D Drug Inflation Rebate Program. As we stated in the revised collection of information (0938–1485) titled ''Information Collection Request (ICR) for the Medicare Prescription Drug Inflation Rebate Program under sections 11101 and 11102 of the Inflation Reduction Act (IRA)'' (CMS–10930, OMB 0938–1485), CMS may also use the information collected by CMS from 340B providers to conduct other internal program analyses, such as those related to the Medicare Drug Price Negotiation Program. We note that this use is distinct from the external disclosure discussed in section III.F.3.c.2.c. of this final rule. Internal program analyses, including those related to the Medicare Drug Price Negotiation Program, are conducted by CMS using data CMS already holds, and do not involve disseminating, distributing, or copying 340B repository data to manufacturers, Part D plan sponsors, or other parties outside the agency. If we were to decide to use data submitted to the 340B repository for purposes other than the Medicare Part D Drug Inflation Rebate Program and internal program analyses, we would undergo notice-and-comment rulemaking and provide interested parties an opportunity to comment before any such policy is finalized. We acknowledge the suggestion that we consider how to capture Part B 340B claims data but do not intend to expand the use of the 340B repository to collect Part B claims data at this time.

Comment: Many commenters recommended that the 340B Rebate Pilot and 340B repository remain distinct but that CMS explore how to use the data collected through the 340B Rebate Pilot to improve accuracy of and reduce burden in the 340B repository, such as using 340B Rebate Pilot data to validate 340B repository data or reduce duplicative reporting burdens on covered entities by establishing a mechanism through which 340B Rebate Pilot data are used to populate the 340B repository for participating drugs.

Response: We appreciate the feedback.

Comment: A few commenters recommended that CMS not move forward with mandatory participation in the 340B repository until the Administration takes action to stop what the commenters deemed to be unlawful denial of 340B pricing to covered entities that decline to submit data directly to drug manufacturers.

Response: We note that the comments recommending CMS delay implementation of a mandatory 340B repository until the Administration ensures that 340B pricing is made available to covered entities is outside the scope of this final rule. We are implementing the reporting requirement at § 428.203(c) consistent with our obligations under section 1860D–14B(b)(1)(B) of the Act.

Comment: A couple commenters stated that the reporting requirement is overinclusive because it would require submission of information relating to drugs that are not subject to Medicare Part D inflation rebates. The commenter stated that requiring 340B providers to report information relating to selected drugs under the Medicare Drug Price Negotiation Program expands the reporting burden beyond what is necessary for the 340B repository's stated purpose.

Response: We do not agree that the reporting requirement is overinclusive. Section 1860D–14B(b)(1)(B) of the Act requires CMS to remove 340B units from inflation rebate calculations for all Part D rebatable drugs. Because the status of a Part D rebatable drug can change over time (for example, a drug or biological may have average annual total costs below the applicable threshold set forth at § 428.101(b) in one applicable period but not another), we believe requiring 340B providers to submit data for all Part D 340B claims is less burdensome and will result in more complete data than if we were to require 340B providers to continually change the scope of drugs for which they are required to submit data. Additionally, we note that this final rule does not implement different or additional data requirements specific to selected drugs under the Medicare Drug Price Negotiation Program. As we stated in the CY 2025 PFS final rule (89 FR 98285), the Medicare Part D Drug Inflation Rebate Program applies to selected drugs notwithstanding the status of the drug as a selected drug. The reporting requirement at § 428.203(c) therefore applies no differently to a Part D rebatable drug that is a selected drug than to a Part D rebatable drug that is not a selected drug.

Comment: Many commenters expressed concern that CMS proposed to enforce the 340B repository reporting requirement through its Medicare enrollment authority, including that CMS would reserve the right to revoke a hospital's Medicare enrollment for noncompliance while simultaneously acknowledging that the data collected has not yet been tested nor would be used to calculate Part D inflation rebates at this time. These commenters stated that this enforcement approach could create substantial financial and patient-access consequences unrelated to the underlying reporting deficiency, and that loss of Medicare enrollment is an extraordinary sanction disproportionate to a reporting process CMS is using only

to evaluate the feasibility of a future alternative methodology. A few of these commenters also expressed concern that what they described as severe penalty could apply even if noncompliance was due to reporting by a TPA or other third-party and stated the challenges of bearing ultimate legal accountability across a multi-vendor ecosystem. A commenter stated that CMS has not built a sufficient record to justify using such a severe enforcement mechanism since, in their view, CMS significantly underestimated the burdens associated with reporting to the 340B repository. A commenter expressed concern that notice and appeal provisions of 42 CFR part 424, subpart P appear designed to accommodate individual, discrete issues rather than an ongoing data reporting program. A commenter stated that CMS has not established a sufficiently clear procedural framework for imposing enforcement consequences.

Response: We do not agree that the enforcement consequence for non-compliance is disproportionate to the reporting requirement. We note that, in accordance with § 424.535(a)(10)(ii), a provider or supplier that meets the revocation criteria specified in § 424.535(a)(10)(i) is subject to revocation for a period of not more than 1 year for each act of noncompliance. As we stated elsewhere in this section, continuation of a voluntary reporting approach, which introduces a confounding factor into the data based on characteristics of organizations which choose to submit or not, would present a methodological limitation in our evaluation of the suitability of the 340B repository data. To mitigate this limitation and avoid constraints on our ability to conduct a robust analysis of 340B data submissions, we believe that establishing a mandatory reporting requirement would help ensure sufficient participation and alleviate these concerns, consistent with our obligations under section 1860D–14B(b)(1)(B) of the Act. In response to the comment that CMS underestimated associated burdens, we refer readers to section V.B.5. of this final rule.

We also do not agree that we have not established a sufficiently clear procedural framework for enforcement. As we stated in the CY 2027 PFS proposed rule (91 FR 44013), we reserve the right to revoke, in accordance with existing § 424.535(a)(10), a currently enrolled provider or supplier's Medicare enrollment and any corresponding provider agreement or supplier agreement for failure to comply with the requirements for maintaining and providing access to documentation specified in proposed and finalized § 424.516(f)(4). The procedural framework previously established at existing § 424.535(a)(10) would apply no differently to failures to comply with the requirements specified in proposed and finalized § 424.516(f)(4).

Comment: Many commenters recommended that, if CMS finalizes a mandatory reporting requirement, CMS establish a graduated compliance pathway—including a corrective-action process, a materiality threshold, technical assistance, a temporary safe harbor period as 340B providers transition systems to align with the requirement, and a permanent safe harbor for good-faith reporting errors, particularly when errors are due to third parties such as TPAs or contract pharmacies—before taking enforcement action, stating these safeguards would prevent disproportionate penalties for technical or inadvertent errors in complex claim-level submissions. Separately, a commenter stated that CMS should not impose Medicare enrollment sanctions without a separate finding of fraud, diversion, duplicate discounts, or improper billing. A commenter recommended that CMS tailor reporting expectations to scale with a hospital's actual capacity to comply, stating that applying a national standard disproportionately impacts small and rural hospitals. A couple of commenters recommended that CMS create a hardship exemption, with a commenter recommending that CMS exclude smaller 340B providers and another commenter recommending that CMS exempt Critical Access Hospitals, Sole Community Hospitals, Medicare Dependent Hospitals, rural referral centers, and low-volume covered entities from the mandatory reporting requirement.

In contrast, a few commenters recommended that CMS couple the mandatory reporting requirement with strong enforcement action, education, and auditing to ensure CMS is receiving complete and accurate data. These commenters stated that CMS should establish clear consequences for noncompliance, including penalties for inaccurate or incomplete reporting. A couple of commenters recommended that CMS suspend covered entities from the 340B Program for failure to comply with the reporting requirements. A commenter requested clarity on the consequences for non-reporting or misreporting but did not express preferences on types of enforcement actions. A commenter recommended that CMS ensure the reporting framework does not permit selective reporting by 340B providers that would reduce manufacturer inflation rebate liability for some products but not others.

Response: We acknowledge commenters' concerns about consequence of non-compliance with the mandatory reporting requirement due to technical or inadvertent errors in claim-level submissions, including errors caused by third parties such as TPAs or contract pharmacies. We believe that allowing 340B providers to make corrections to previously submitted claims as outlined in the Medicare Part D Claims Data 340B Repository Companion Guide,[237] together with the existing enforcement framework at § 424.535(a)(10), distinguishes good-faith, correctable errors from conduct that would warrant enrollment revocation. We therefore do not believe a separate materiality threshold or permanent safe harbor is needed at this time. We also do not agree that revocation under § 424.535(a)(10) requires a separate finding of fraud, diversion, duplicate discounts, or improper billing; that authority addresses documentation failures independently of other violations.

We additionally emphasize our commitment to engaging with 340B providers to provide the education and resources necessary for them to adhere to their reporting obligations to ensure we are receiving complete and accurate data. Several resources related to the 340B repository are available on the CMS website, including Frequently Asked Questions, a Medicare Part D 340B Repository Companion Guide, and Medicare Part D 340B Repository Data Submission Template examples in Excel and CSV formats.[238] The Medicare Part D Claims Data 340B Repository Help Desk is also available to assist 340B providers.[239] The comment recommending that CMS suspend covered entities from the 340B Program for failure to comply with the reporting requirement is out of scope.

Comment: A commenter stated that submitting data to the 340B repository would not be overly burdensome based on the data requirements and guidelines outlined in the CY 2027 PFS proposed rule. Another commenter stated that they perform analogous reporting for manufacturers and therefore have established the internal processes needed to support a Federal reporting

[237] See: *https://www.cms.gov/files/document/cms-medicare-part-d-340b-repository-companion-guide.pdf.*

[238] See: *https://www.cms.gov/initiatives/medicare-prescription-drug-affordability/overview/medicare-inflation-rebate-program.*

[239] See: *https://bosc.helpdesk.cms.gov/medicare340breporting/home.*

requirement. A commenter stated that their health system could successfully submit Part D 340B claims data retrospectively on a quarterly basis. A couple of commenters supported the proposal to allow TPAs to transmit data to the 340B repository on behalf of 340B providers.

Conversely, many commenters noted concern that mandatory 340B repository submissions would create significant burdens for 340B providers, stating that implementing the requirement could require fees to software vendors and TPAs, additional staff time, and could divert resources away from patient care. A couple of commenters stated that the requirement would be particularly challenging for small and rural covered entities and recommended a hardship exemption or flexibilities for such entities. A few commenters described challenges of consolidating data and standardizing reporting across multiple contract pharmacies, TPAs and outpatient drug delivery settings (such as outpatient retail pharmacies and child site infusion clinics) with different operational and IT ecosystems.

A few commenters recommended that CMS engage with interested parties to test the 340B repository and identify ways to minimize reporting burdens before the 340B repository becomes mandatory, stating that interested parties' engagement will help identify operational challenges early and improve the accuracy and usability of the 340B repository over time. A commenter recommended that CMS work with interested parties to identify ways to improve the methodology for identifying Part D 340B drug units without adding additional reporting obligations.

Response: We appreciate the commenters who stated that submitting data to the 340B repository would not be overly burdensome given the data requirements and guidelines outlined, that they already perform analogous reporting for manufacturers and have established internal processes that can support a Federal reporting requirement, and that permitting TPAs to transmit data to the 340B repository on behalf of 340B providers would ease compliance.

In developing the data elements for submission and process for voluntary submission to the 340B repository, we considered how to minimize burden on 340B providers. We are collecting the minimal number of data elements necessary to match 340B repository data to PDE records for Part D rebatable drugs, and we are providing quarterly submission deadlines and additional time for 340B providers to submit corrections to their Part D 340B data. We believe these decisions will lower burden on 340B providers to the extent possible. As we stated in the CY 2027 PFS proposed rule (91 FR 44014), we understand covered entities typically contract with vendors, such as TPAs, to determine 340B eligibility of claims using data submitted by covered entities and their contractors. We will allow covered entities that choose to submit data to the 340B repository to arrange for their TPAs or other vendors to submit certain data elements to the 340B repository on their behalf if they would like to do so. We note that there are no hardship exemptions or other reporting flexibilities for 340B providers that are small covered entities, rural covered entities, or both. We believe that permitting covered entities to rely on their TPAs or other vendors for data submission, as previously described, appropriately mitigates burden for all 340B providers, including small and rural covered entities, without the need for a separate exemption based on characteristics of a 340B provider.

Finally, we have engaged extensively with interested parties to develop the 340B repository in ways that minimize burden on 340B providers to the extent possible in an evolving 340B landscape. In addition to meeting with interested parties on specific issues, we have held broad discussions and technical calls open to all 340B entities and related parties to hear feedback and input on ways to minimize burden and share technical specifications in time for interested parties to participate in voluntary submissions this fall. We welcome continued feedback and remain committed to continued engagement with interested parties as we develop and test the 340B repository.

Comment: A couple of commenters appreciated CMS' commitment to seeking public input through rulemaking before relying on 340B repository data for Part D inflation rebate calculations and recommended that CMS continue to seek public input through future rulemaking before adopting any methodology that relies on 340B repository data for such calculations.

Response: We appreciate the support and affirm that any future proposal to use the data reported to the 340B repository to remove 340B units from Part D inflation rebate calculations would undergo notice-and-comment rulemaking, and we will continue to provide interested parties an opportunity to comment before any such policy is finalized.

Comment: Many commenters urged CMS to delay mandatory reporting to the 340B repository, stating that the 340B repository has not yet launched and is not expected to become operational until Fall 2026, leaving insufficient time to identify problems, train staff, and validate submissions before mandatory reporting begins for claims with dates of service on or after January 1, 2027. Many commenters similarly urged CMS not to mandate reporting into an untested system, stating that the 3-month testing period in 2026 is insufficient to support a transition from voluntary to mandatory reporting and will not provide enough time to evaluate the quality and completeness of the data or fully assess the operational burden on covered entities. Many commenters opposed that the proposal to require 340B providers to report data would be used only for testing purposes, stating that the benefits of the proposal do not outweigh the costs to 340B providers since CMS will not yet be using the data in Part D inflation rebate calculations, and that CMS should delay mandatory reporting until it has assessed the feasibility of using voluntarily-reported data.

Many commenters recommended that CMS delay implementation of mandatory reporting by, for example, providing 340B providers a specific minimum period—such as at least 6 months, or sufficient time after publication of final technical specifications—to configure, test, and validate submission systems before mandatory reporting begins. Relatedly, many commenters recommended a phased-in approach rather than a single compliance date, so CMS could assess data quality and refine specifications collaboratively with 340B providers; suggestions included phasing in or simplifying reporting with technical assistance and a hardship exemption for smaller 340B providers and continuing voluntary reporting while evaluating participation and data quality before imposing any mandatory requirement.

Many commenters stated that the proposed compliance date would require covered entities to implement mandatory 340B repository reporting while simultaneously preparing for the 340B Rebate Pilot, also effective January 1, 2027, compounding financial and operational pressures and diverting resources from patient care, and recommended delaying implementation to July 1, 2027, or January 1, 2028 given these concurrent obligations.

Response: We agree that 340B providers need adequate time following the 340B repository's launch to test workflows, train staff, and validate

submissions, and we recognize commenters' concerns that the originally proposed timeline could compress this preparation period, particularly given other data reporting obligations 340B providers face beginning in 2027.

As described in the CY 2027 PFS proposed rule (91 FR 44013), we proposed at § 428.203(c) to require 340B providers to submit Part D 340B data to the 340B repository beginning in 2027, with the data elements and information set forth in proposed paragraphs (c)(1) and (2) of that section submitted on a quarterly basis as required under proposed paragraph (c)(3). Under this proposal, data for a given calendar quarter would be due within 1 calendar quarter following the close of that quarter, meaning that data for claims with dates of service in Q1 2027 would have been due by June 30, 2027. We also noted in the proposed rule that we expected the 340B repository to become operational for voluntary submissions in Fall 2026, consistent with the CY 2026 PFS final rule (90 FR 49748), and we strongly encouraged 340B providers to begin submitting data voluntarily during that period to test operational processes ahead of the 2027 mandatory requirement, should such requirement be finalized. The 340B repository launched on October 1, 2026, and covered entities have begun successfully submitting Part D 340B data.

We also agree delaying the deadline for the first mandatory quarterly submission to the 340B repository would allow 340B providers additional time to configure, test, and validate their submission system. We believe this additional time will provide 340B providers a meaningful opportunity to configure and test their systems, consolidate necessary data, and validate submissions before mandatory reporting begins, while still allowing CMS to begin timely evaluation of the feasibility of using 340B repository data for purposes of the Part D inflation rebate calculation under section 1860D–14B(b)(1)(B) of the Act. We are finalizing a delayed deadline of September 30, 2027, for 340B providers to submit data for claims with dates of service from January 1, 2027 through March 31, 2027. The first mandatory submission will cover two calendar quarters of data (the first and second quarter of 2027) and will be due September 30, 2027. 340B providers may choose to submit data earlier than the September 30, 2027 deadline, including submitting first-quarter data separately before second-quarter data becomes available.

We note that this delay applies only to the deadline for the first mandatory quarterly submission. Beginning with the second reporting period, 340B providers must submit data within 1 calendar quarter following the close of each applicable quarter, consistent with the quarterly submission cadence proposed at § 428.203(c)(3). Because the deadline for the first mandatory submission will cover 2 calendar quarters (Q1 and Q2 2027), the next reporting period will consist of Q3 2027 data, which will be due by the end of the following quarter, December 31, 2027. These deadlines are listed in Table B–F1. After the submission due date for a given quarter, the 340B repository will remain open to receive additional submissions for that quarter in accordance with § 428.203(c)(4), which requires that data elements and information that are either incomplete or contain invalid data must be resubmitted at a later time in a form and manner specified by CMS, consistent with the resubmission process described in the CY 2027 PFS proposed rule (91 FR 44012 through 44015).

TABLE B-F1: Medicare Part D 340B Claims Submission Due Dates for Dates of Service in 2027

Medicare Part D 340B Claims Date of Service Timeframe	Medicare Part D 340B Claims Submission Due Dates
January 1 – March 31, 2027	September 30, 2027
April 1 – June 30, 2027	September 30, 2027
July 1 – September 30, 2027	December 31, 2027
October 1 – December 31, 2027	March 31, 2028

Comment: A few commenters stated that ADAPs are covered entities under 42 CFR 10.3 but are not Medicare-enrolled providers or suppliers, creating ambiguity as to whether the proposed requirement for ''a provider or supplier that is a covered entity'' to submit data to the 340B repository applies to ADAPs. These commenters stated that ADAP eligibility as a covered entity is tied to receipt of RW Part B funding rather than to health care service delivery or Medicare enrollment, and that the proposed enforcement mechanism has no application to an entity that holds no such enrollment. These commenters recommended that CMS clarify in the final rule whether and how ADAPs are required to submit data to the 340B repository and recommended that, if ADAPs are not intended to be subject to the requirement, CMS state so explicitly.

A commenter stated that several operational barriers would prevent ADAPs from complying with 340B repository reporting, even if the requirement were intended to reach them. This commenter stated that ADAP claims processing is often administered through third-party systems that do not capture the specific data elements the 340B repository would require, since the 340B repository data elements are structured around covered entities that directly operate or contract with a registered 340B contract pharmacy rather than the rebate model most ADAPs use. This commenter also stated that ADAPs' rebate claim cycles do not align with the proposed quarterly reporting timeline. This commenter recommended that CMS address this timing mismatch and precede any ADAP reporting requirement with a voluntary testing period of at least 1 year. Another commenter similarly recommended that CMS provide a longer submission timeline for ADAPs, stating that ADAP rebate data often reaches manufacturers up to 12 months after the end of a calendar quarter, and that manufacturers then have 3 months to reconcile and pay rebates, meaning some ADAP rebates may not be reconciled until 15 months after the applicable dispensing quarter.

Response: We appreciate this input. We proposed at § 428.203(c) that providers and suppliers that are covered entities as defined under § 10.3 submit Part D 340B data to the 340B repository beginning in 2027. We recognize that

the documentation requirement we proposed and are finalizing at § 424.516(f)(4), as well as the enforcement mechanism we proposed and are finalizing in accordance with existing § 424.535(a)(10), relies on Medicare enrollment, and that this mechanism has no application to an ADAP that holds no such enrollment. However, we strongly encourage ADAP participation in the 340B repository. ADAPs are covered entities under the 340B Program, and although the mandatory reporting requirement finalized in this rule does not extend to ADAPs because ADAPs are not providers or suppliers enrolled in Medicare, we continue to strongly encourage ADAPs to submit their Part D 340B claims data to the 340B repository on the same basis as other covered entities. We acknowledge commenters' concerns regarding potential mismatches between ADAP rebate cycles and the proposed quarterly reporting timeline. As we outlined in the CY 2027 PFS proposed rule, data submitted to the 340B repository will not be used to exclude 340B units from inflation rebate calculations at this time. If we propose and finalize such a policy in the future, we would provide additional guidance to ADAPs at that time.

Comment: Many commenters supported the data elements CMS proposed for the 340B repository, stating that the five proposed elements (date of service, prescription or service reference number, fill number, dispensing pharmacy NPI, and NDC–11) are appropriate.

Commenters stated that these elements did not present overly burdensome requirements or Protected Health Information (PHI) risks. Many commenters also supported the proposed quarterly submission timeline. These commenters stated that it was more efficient than the more frequent data demands covered entities currently face. Some commenters recommended that CMS instead align the 340B repository's data elements and reporting timeline with those required under the 340B Rebate Pilot. These commenters stated that this would improve efficiency and support future expansion of the 340B Rebate Pilot to the Medicare Part D Drug Inflation Rebate Program. These commenters recommended that CMS expand the data elements collected. Suggested additions included product serial number, prescribed date, quantity dispensed, bank identification number (BIN)/processor control number (PCN), prescriber identification number, and claims adjustment/paid date. These commenters stated that without common data elements, the 340B repository would have limited utility for cross-program validation. A few commenters recommended that CMS require more frequent submissions than the proposed quarterly timeline. These commenters stated that timelier data is critical to identifying 340B claims and administering the Medicare Part D Drug Inflation Rebate Program. A commenter stated that quarterly reporting may be sufficient for calculating Part D inflation rebate liability specifically. This commenter stated that quarterly reporting would not support other use cases requiring more timely identification of 340B claims.

Response: We designed the 340B repository to assess whether covered entity-submitted data can reliably identify units of Part D rebatable drugs for which a manufacturer provided a 340B discount, to determine if such data could be used reliably in the future to remove 340B units from Part D inflation rebate calculations in accordance with section 1860D–14B(b)(1)(B) of the Act. We proposed the five required data elements (date of service, prescription or service reference number, fill number, dispensing pharmacy NPI, and NDC–11) because we determined these elements are necessary and sufficient to identify a unique PDE record. We agree with the commenters that stated requiring additional fields, such as product serial number and prescribed date, is not necessary. Based on our current review, we believe requiring these fields would impose burden on 340B providers without a corresponding benefit to the program.

We do not agree that we should, at this time, expand the required data elements or align them with the data fields required under 340B Rebate Pilot. The 340B repository serves a distinct purpose from 340B Rebate Pilot: the 340B repository exists to allow CMS to assess whether submitted data can support our statutory obligation under section 1860D–14B(b)(1)(B) of the Act to exclude 340B units from Part D inflation rebate calculations, not to facilitate manufacturer-level claims verification or cross-program reconciliation with the 340B Rebate Pilot. We intend to minimize burden on 340B providers while collecting the minimum elements necessary to match a submission to a PDE record to exclude 340B units from inflation rebate calculations, were the 340B repository to be used for such purpose in the future. We do not agree that we should require more frequent than quarterly submission of Part D 340B claims data at this time. Quarterly submissions provide CMS with timely information to assess the reliability of the data for potential future use in removing 340B units from Part D inflation rebate calculations. Quarterly submissions also minimize burden on 340B providers by reducing the amount of data and quality assurance required for each submission. Given the variety in the scope of provider types and organizations that participate in the 340B Program, the amount of preparation time needed to compile, certify, and submit complete and accurate claims data varies. The quarterly timeline provides 340B providers sufficient time to meet these requirements without imposing the additional burden that more frequent reporting would create.

Comment: A couple of commenters recommended that CMS require 340B and non-340B claims indicators on Part D claims. One of these commenters stated that claims indicators would improve the effectiveness of the 340B repository because CMS lacks visibility into the full universe of 340B claims and therefore cannot reliably assess the extent of underreporting or identify gaps in 340B repository data. In contrast, a few commenters re-emphasized points made in their previous comments on the CY 2025 PFS proposed rule (which we summarized and responded to in the CY 2025 PFS final rule (89 FR 98294)) that adding 340B claims indicators to Part D claims would be infeasible due to operational challenges.

Response: We note that 340B claims indicators are not currently required from CMS for Part D 340B claims and acknowledge feedback received on the CY 2025 PFS proposed rule that requiring such a claims indicator has the potential to pose operational challenges and increase pharmacy burden because 340B status may not be known at the point of sale and may not always be accurate. In this final rule, we maintain that reporting of a 340B claims indicator on Part D claims submitted by dispensing entities remains voluntary.

After consideration of the comments received, we are finalizing the proposal at § 428.203(c) to require providers and suppliers that are covered entities, as defined under § 10.3, to submit Part D 340B data to the 340B repository beginning in 2027, with modification. Specifically, at § 428.203(c)(1) we are finalizing without modification the five data elements proposed for each Part D 340B claim submitted to the 340B repository: (1) date of service, (2) prescription or service reference number, (3) fill number, (4) dispensing pharmacy National Provider Identifier (NPI), and (5) National Drug Code (NDC–11). At § 428.203(c)(2), we are finalizing, without modification, that

the 340B provider must submit its 340B ID and name as designated in the 340B OPAIS database. At § 428.203(c)(3), we are finalizing the requirement that 340B providers report data on a quarterly basis (though they may choose to submit more frequently) within 1 calendar quarter following the close of the relevant calendar quarter, with modification at § 428.203(c)(3)(i)(B) to delay the first mandatory reporting deadline by one quarter. We also made a minor technical modification to § 428.203(c)(3) to more precisely describe an applicable quarter as a ''quarter of a calendar year'' rather than a ''calendar quarter.'' We are finalizing § 428.203(c)(4) as proposed and adding new § 428.203(c)(5) to clarify the certification requirement; § 428.203(c)(4) and (5) are described in further detail in section F.3.c.2.c. of this final rule. We are also finalizing, with a conforming modification to reflect new § 428.203(c)(5), our proposal at § 424.516(f)(4) that such reporting would fulfill a 340B provider's obligation to provide access to documentation relating to covered Part D drugs written or ordered by such 340B provider to maintain enrollment in Medicare.

(c) Submitting Part D 340B Claims Data to the 340B Repository (§ 428.203(c))

We stated in the CY 2027 PFS proposed rule that we expect that the 340B repository will be operational by Fall 2026 for voluntary submissions from covered entities, as we adopted in the CY 2026 PFS final rule (90 FR 49748). Since publication of the CY 2027 PFS proposed rule, the 340B repository launched on October 1, 2026, and 340B providers may now create an account and begin submitting Part D 340B data.[240] As we stated in the proposed rule, we proposed to require all 340B providers to submit certain data elements associated with Part D 340B claims beginning in 2027. We strongly encouraged 340B providers to begin submitting data to the 340B repository voluntarily in 2026 to test operational processes, as we proposed here to adopt the requirement that 340B providers submit data elements from their Part D 340B claims starting in 2027. The rest of this section proposed the form and manner by which, starting in 2027, under the proposed § 428.203(c), 340B providers would submit data to the 340B repository.

As stated in section III.F.3.c.b. of this final rule, under the 340B mandatory reporting proposal, the data elements and information set forth in paragraphs (c)(1) and (2) of § 428.203 would be submitted on a quarterly basis. We proposed here that we would rely upon the completeness and accuracy of the data submitted by 340B providers to the 340B repository, consistent with the 340B provider requirement to certify the accuracy of such submissions described later in this section, to consider all data elements received by the 340B repository to be associated with Part D 340B claims. That is, CMS would rely on the accuracy and completeness of the submitted, certified data to the 340B repository to verify the 340B status of a claim.

We solicited comments on this proposal. For ease of reference and organization, we summarize comments received and our responses at the end of this section III.F.3.c.2.c.

We also proposed, as part of every submission, to require 340B providers (or an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification) to certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, its submissions include all Part D 340B claims for the 340B provider at the time of submission for the relevant period. 340B providers or their authorized representative would be required to certify the completeness and accuracy of the data submitted and to certify that the submitter is authorized to submit on behalf of the 340B provider.

We solicited comments on this proposal. For ease of reference and organization, we summarize comments received and our responses at the end of this section III.F.3.c.2.c of this final rule.

In the CY 2026 PFS final rule (90 FR 49750), describing the proposal for voluntary data submission, we noted that we understand covered entities typically contract with vendors, such as 340B TPAs, to determine 340B-eligibility of claims using data submitted by covered entities and their contract pharmacies. We continue to acknowledge these contracts and, therefore, we proposed that 340B providers could arrange for TPAs or other vendors to submit the required data elements to the 340B repository on their behalf. 340B providers would ultimately be responsible for the accuracy of the data submitted to the 340B repository, even if a 340B provider has an arrangement with a vendor to submit on its behalf.

We solicited comments on this proposal. For ease of reference and organization, we summarize comments received and our responses at the end of this section III.F.3.c.2.c of this final rule.

In section III.F.3.c.b. of the proposed rule, we proposed to require that 340B providers report data on a quarterly basis. We separately proposed that 340B providers would have additional time to submit data to reflect a revision to the 340B determination of claims with dates of service throughout an applicable period. A revision could come in one of two forms: (1) resubmission of data for a claim that the 340B provider previously submitted to the 340B repository in error or with errors in the requested data fields, or (2) new submission of data for a claim for a drug that the 340B provider had previously determined was not purchased under the 340B Program but later identified was purchased under such program. In instances where the 340B provider submits Part D 340B claims data to the repository that is either (1) incomplete or (2) contains invalid data, we may inform the 340B provider of such error and request that the 340B provider resolve and resubmit the Part D 340B claims data to process the submission successfully. As noted in the CY 2026 PFS final rule (90 FR 49754), we will provide details on the process and timing for covered entities to submit revised data to the 340B repository after the end of the reporting period in the future, and we anticipate that this same timing would apply to claims with dates of service in 2027. Specifically, at § 428.203(c)(4), we proposed that data elements and information submitted in accordance with paragraph (c)(3) of such section that is either incomplete or contains invalid data must be resubmitted at a later time in a form and manner specified by CMS.

We solicited comments on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported CMS operating the 340B repository directly rather than through a third-party vendor, stating that, from a compliance and data-privacy standpoint, a neutral, government-operated platform is preferable to a vendor with commercial interests. These commenters recommended that CMS develop and operate the 340B repository itself, or, if it engages a contractor, ensure the contractor has no ownership, governance, or financial

[240] See here to create an account with the 340B repository: *https://medicare340breporting.cms.gov/sec340b/login.* See here to access instructions and technical specifications on the 340B repository: *https://www.cms.gov/initiatives/medicare-prescription-drug-affordability/overview/medicare-inflation-rebate-program.*

relationship that could allow, or appear to allow, manufacturers, pharmacy benefit managers (PBMs), Part D plan sponsors, or other interested parties to influence the 340B repository's operation or access its data, since covered entities should not have to submit sensitive claims-level information through systems controlled by parties with a financial interest in the 340B Program.

Some commenters urged CMS to collect only data necessary for Part D inflation rebate calculations and clarify the scope of permissible data use, access, and retention. These commenters recommended that CMS establish transparent policies governing which government agencies and contractors may access submitted data, how long it will be retained, and how it will eventually be destroyed; and limit use of the data to administration of the Medicare Part D Drug Inflation Rebate Program. A commenter recommended that CMS clarify data security and proprietary-information protections for claim-level 340B data, particularly where contract pharmacy relationships are involved.

Some commenters urged CMS to confirm that 340B repository data will not be shared with manufacturers on a claims-level basis and to retain this safeguard if CMS moves forward with the 340B repository. These commenters anticipated that manufacturers would request additional data elements or broader data sharing and urged CMS to reject such requests, stating that CMS has already determined the proposed data elements are sufficient to identify and exclude 340B units without manufacturer data sharing. Where manufacturer access to information is necessary for rebate calculation or verification, these commenters recommended that CMS provide only aggregate or otherwise limited data rather than access to individual claims, and, if CMS shares any data with manufacturers or other interested parties, explicitly conduct notice-and-comment rulemaking before doing so and prohibit its use for purposes unrelated to duplicate-discount prevention and prohibit further redisclosure. A commenter added that claims data submitted to the 340B repository is sensitive and proprietary, and recommended that CMS ensure manufacturers lack access to it and that strong data security standards be clearly set forth in user agreements. A couple of commenters recommended that CMS codify data protections from third parties into regulatory text.

In contrast, many commenters urged CMS to share 340B repository data with manufacturers to support validation of Part D (and, in one case, Part B) inflation rebate calculations, stating that manufacturers currently have no reliable way to confirm whether a claim was 340B-eligible, which limits their ability to verify rebate invoices, creates duplicate-discount risk, and prevents them from catching reporting anomalies, inconsistencies, and missing claims. A few commenters disputed CMS' confidentiality rationale for withholding this data, stating that the data elements do not constitute PHI, manufacturers already receive comparable claim-level data under the Medicare Drug Price Negotiation Program and the 340B Rebate Pilot without it constituting PHI, and drew analogies to the Medicaid Drug Rebate Program and Medicare Drug Price Negotiation Program, where manufacturers receive utilization or claims data—and, in the Medicaid program, a statutory audit right—to validate payment obligations; a commenter urged CMS to extend this approach to Part B inflation rebates as well. A commenter recommended that CMS share 340B repository data with researchers, and a commenter recommended that CMS provide Part D plan sponsors with timely, preferably near real-time, access to 340B repository data related to their beneficiaries and pharmacy claims.

Response: As we stated in the CY 2027 PFS proposed rule (91 FR 44014), we understand the importance of maintaining the confidentiality of data submitted to the 340B repository. Therefore, this data—irrespective of whether it is submitted to CMS directly from the 340B provider or from a vendor submitting on their behalf—will be for official use only and will not be disseminated, distributed, or copied to unauthorized persons, including manufacturers and Part D plan sponsors. We reaffirm our commitment to protecting sensitive and confidential data submitted by 340B providers and continue to acknowledge the importance of data security. The 340B repository will be designed to comply with all applicable Federal security laws, regulations, and HHS policies, including but not limited to those related to data protection and information security. Any third party that CMS engages to support the 340B repository will be required to follow protocols to address conflicts of interest. For example, CMS will implement safeguards such as firewalls or contractual limitations on usage of information to ensure that any third party supporting the 340B repository does not misuse information to which it obtains access in its role supporting the 340B repository. We decline to provide claim-level data, such as 340B repository data, to manufacturers regarding the 340B Program or other statutory exclusions of units from inflation rebate calculations as we do not believe this is necessary to operate the program at this time. First, we disagree with the premise that 340B repository data, if shared by CMS with manufacturers, could or should be used to verify manufacturers' rebate reports because 340B repository data is not relevant to Part D inflation rebate reports at this time since the current purpose of the 340B repository is to evaluate the completeness and accuracy of the data. In addition, section 1860D–14B(f) of the Act, codified at § 428.403(a)(1), precludes administrative or judicial review of the determination of units as set forth at § 428.203, the determination of whether a drug is a Part D rebatable drug as set forth at § 428.101, and the calculation of the rebate amount as set forth at § 428.201(a), inclusive of any reconciled rebate amount. As explained in the CY 2025 final rule (89 FR 98307), the Suggestion of Error process is limited to mathematical steps involved in determining the rebate amount, and the elements precluded from administrative or judicial review will not be considered in-scope for the Suggestion of Error process. Although we affirm that we will not share 340B repository data, we decline the suggestion to incorporate this detail into regulatory text as we do not believe such a step is necessary.

Comment: A commenter stated that CMS has not adequately addressed the Privacy Act implications of the 340B repository and should consider issuing a public notice to members of the public describing its information collection before creating a system of records containing patient data. This commenter also stated that, in their view, the 340B repository constitutes a system of records, and CMS must therefore satisfy the Privacy Act's substantive limitations and notice requirements regarding information collection. The commenter stated that CMS has not demonstrated that the 340B repository satisfies this standard since CMS has stated that the purpose of the 340B repository is to test the data rather than use it in Part D inflation rebate calculations. Additionally, some commenters stated that several of the required data elements constitute PHI under HIPAA's Privacy Rule but did not specify which data elements. A commenter recommended that CMS clearly identify the legal authority supporting the

disclosure of PHI from covered entities to the 340B repository, explain how the proposal interacts with the HIPAA Privacy Rule, and provide 340B providers with operational guidance sufficient to ensure compliant disclosures. A commenter stated that its members have expressed general privacy concerns about submitting data to the 340B repository.

Response: We appreciate this comment and acknowledge some of the required data elements may constitute PHI. In cases where a 340B provider is also a HIPAA covered entity and submits information that constitutes PHI, or is the business associate of a HIPAA covered entity [241] and submits information that constitutes PHI on the covered entity's behalf, disclosure of this PHI to the 340B repository must be for a purpose permitted by an applicable disclosure permission under the HIPAA Privacy Rule (45 CFR part 160 and subparts A and E of part 164). For example, the HIPAA Privacy Rule allows HIPAA covered entities to disclose PHI without an individual's authorization when that disclosure is required by law and the disclosure complies with the requirements of that law (45 CFR 164.512(a)). CMS' use and disclosure of Part D data is governed by the Privacy Act of 1974, requiring that we establish and maintain a System of Records Notice (SORN). Per the Privacy Act of 1974, CMS intends to issue a SORN in the **Federal Register** for the 340B repository. (Currently, CMS does not have a standalone SORN issued specifically for the 340B repository.)

Comment: A few commenters stated that new reporting requirements create a risk of good-faith technical errors arising from TPAs, contract pharmacies, or discrepancies between data sources. These commenters recommended that CMS define all required reporting elements, file specifications, and validation standards sufficiently in advance of the effective date. Many commenters recommended that CMS establish a defined timeline for correcting or revising 340B claims status after the reporting deadline. A few of these commenters recommended a hard cap of 45 to 90 days, stating that additional time would create administrative complexity and inaccurate inflation rebate calculations. By contrast, a few other commenters recommended adequate lead time, practical reconciliation tools, hardship exemptions, and a dispute process instead of fixed time frame for submission of corrections. A commenter noted that a change in 340B status of a Part D claim may occur months or even years after the initial dispense date with a consequence being that a 340B claim's status is never final. Several commenters recommended a reconciliation mechanism to adjust manufacturers' rebate liability whenever a claim's 340B status is revised after an invoice has been issued, stating that manufacturers should not pay inflation rebates on units later determined to be 340B units.

A few commenters recommended that CMS establish validation and audit processes rather than rely solely on self-reported data and that CMS require complete reporting of all Part D 340B claims, including contract pharmacy claims. These commenters stated that the 340B repository will only succeed if all eligible covered entities submit data, including data originating from contract pharmacies, since any covered entity that fails to report would result in an undercount of 340B units and inflated Part D inflation rebate invoices. Some commenters also recommended that CMS be transparent about its process for evaluating the 340B repository, including sharing its assessment results publicly in future rulemaking and consulting interested parties with experience in 340B claims validation, such as manufacturers. A commenter stated that adding another repository risks creating mismatched claim records and additional burden. By contrast, a few other commenters supported the 340B repository's design, which enables covered entities to leverage existing data and TPAs.

Response: As we stated in the proposed rule, our 340B repository instructions already define the required data elements, specifications, and submission process in sufficient detail for 340B providers to prepare for the 2027 start date. Additionally, CMS has published technical specifications for the 340B repository on the CMS website.[242] As proposed, 340B providers would submit Part D 340B claims data quarterly, within one calendar quarter following the close of the applicable quarter (for example, data for the fourth quarter is due by March 31 of the following year). As discussed earlier in this final rule and detailed in Table B–F1, we are finalizing a delayed deadline of September 30, 2027 as the first deadline for mandatory submissions, which applies to data for claims with dates of service from January 1, 2027 through June 30, 2027.

As outlined in this final rule, a 340B provider may submit a revision to the repository in one of two forms: (1) resubmission of data for a claim(s) that the 340B provider previously submitted to the 340B repository in error or with errors in the requested data fields, or (2) new submission of data for a claim for a drug that the 340B provider had previously determined was not purchased under the 340B Program but later identified was purchased under such program. In instances where the 340B provider submits Part D 340B claims data to the repository that is either (1) incomplete or (2) contains invalid data (for example, if the NDC–11 field contains fewer than 11 characters), we will inform the 340B provider of such error and request that the 340B provider resolve and resubmit the Part D 340B claims data to process the submission successfully as soon as practically possible. CMS has provided instructions for how a 340B provider can resubmit a previously submitted claim in the Medicare Part D 340B Repository Companion Guide available to 340B providers on the CMS website. CMS will provide further instruction on the reporting deadline to submit corrections on 340B claims with dates of service in 2027 through future technical instruction. As we have outlined in the CY 2027 PFS proposed rule, data submitted to the 340B repository will not be used to calculate inflation rebates unless and until we propose and finalize a policy to use such data to exclude 340B units from inflation rebate calculations in the future. However, it is necessary that we establish a deadline to receive any and all corrections for submissions of 340B claims with dates of service in 2027, to allow CMS to assess the usability of 340B claims data submitted to the 340B repository. This correction process is separate from the quarterly deadlines for submitting 340B claims data, which are fixed.

[241] HIPAA covered entities are defined as a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a transaction covered by the HIPAA administrative simplification regulations (45 CFR parts 160—164). *See* 45 CFR 160.103 (definition of ''Covered entity''). Business associates of HIPAA covered entities include persons that perform certain functions or activities regulated by the HIPAA administrative simplification regulations on behalf of a covered entity that involve creating, receiving, maintaining, or transmitting PHI; or that provide certain services to or for a covered entity involving the disclosure of PHI to that person. A business associate also is any subcontractor that creates, receives, maintains, or transmits PHI on behalf of another business associate. *See* 45 CFR 160.103 (definition of ''Business associate'').

[242] See: *https://www.cms.gov/initiatives/medicare-prescription-drug-affordability/overview/medicare-inflation-rebate-program.*

We will consider all data elements received by the 340B repository to be associated with Part D 340B claims. 340B providers must report all Part D 340B claims, including contract pharmacy claims. The 340B repository does not independently verify the 340B status of a claim but rather serves to store these data. As described in the CY 2027 PFS proposed rule, we intend to analyze the data submitted to the 340B repository to determine if it could be used reliably in the future to remove 340B units from Part D inflation rebate calculations in accordance with section 1860D–14B(b)(1)(B) of the Act. We will evaluate 340B repository data for: (1) data integrity, and (2) submission frequency and completeness across covered entity types and geographies, including through comparison to claims identified under the claims-based methodology adopted in the CY 2026 PFS final rule. In instances where a 340B provider submits data that is incomplete or contains invalid data, we will inform the 340B provider of the error and require resubmission in a form and manner specified by CMS. We intend to leverage existing processes and systems, including submission infrastructure designed to minimize reporting burden, whenever possible. We designed the 340B repository to let covered entities leverage existing data and TPAs, which we expect will minimize discrepancies with other reporting platforms.

Comment: A few commenters supported requiring 340B providers to certify that repository submissions are complete, accurate, and include all Part D 340B claims for the relevant period. Another commenter also supported this certification requirement and recommended that CMS strengthen the policy by clarifying that 340B providers may face False Claims Act risk for improper certifications. A few commenters recommended that CMS qualify this certification standard to reflect reasonable diligence and good-faith reliance on available claims and internal 340B records, rather than an absolute guarantee, stating that 340B status is often refined through retrospective reconciliation and that a stricter standard could create compliance risk even for entities acting in good faith. One of these commenters noted that CMS should establish clear correction procedures and provide notice and opportunity to cure before imposing penalties. Another commenter recommended that CMS allow certification by any authorized representative with delegated oversight of the underlying data rather than limiting the role to a 340B provider's chief executive officer or chief financial officer.

Response: We appreciate commenters' feedback. We would rely upon the completeness and accuracy of the data submitted by 340B providers to the 340B repository, consistent with the 340B provider requirement to certify the accuracy of such submissions and would consider all data elements received by the 340B repository to be associated with Part D 340B claims. That is, CMS would rely on the accuracy and completeness of the submitted, certified data in the 340B repository to verify the 340B status of a claim. We note that 340B providers are required to certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, its submission includes all Part D 340B claims for the 340B provider at the time of submission for the relevant period reflecting a reasonable level of diligence on behalf of the 340B provider. 340B providers may rely in good faith on available claims, TPA, contract pharmacy, and other internal 340B records. Claims data may require correction as additional information becomes available and a revision may take one of two forms: (1) resubmission of data for a claim previously submitted to the 340B repository in error or with errors in the requested data fields, or (2) new submission of data for a claim for a drug the covered entity had previously determined was not purchased under the 340B Program but later identified was purchased under such program. 340B providers may designate TPAs to submit data on their behalf, but the 340B provider remains responsible for the accuracy of that submission. In instances where a 340B provider submits Part D 340B claims data that is either incomplete or contains invalid data, we may inform the 340B provider of such error and request resolution and resubmission in order to process the submission successfully.

Based on the provision we are finalizing at § 428.203(c) to require 340B providers to submit Part D 340B data to the 340B repository beginning in 2027, with the data elements and information set forth in paragraphs (c)(1) and (2) of that section submitted on a quarterly basis as required under paragraph (c)(3), nothing in this provision limits or otherwise affects the applicability of the False Claims Act, 31 U.S.C. 3729–3733. Depending on the facts and circumstances, the knowing submission of false or fraudulent information in connection with this reporting requirement may give rise to liability under the False Claims Act where the statutory requirements for such liability are satisfied.

Certification is not limited to a 340B provider's chief executive officer or chief financial officer and can be executed by an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification on behalf of the 340B provider. 340B providers may use TPAs to submit data on their behalf, but they remain responsible for its accuracy. Additionally, any individual or contractor with delegated authority as an authorized representative of the 340B provider may provide this certification. In response to the requests that CMS strengthen the certification requirement, as well as the requests for clarity regarding who is able to complete the certification, we are finalizing new § 428.203(c)(5) to specify that the data elements and information submitted in accordance with § 428.203(c)(3) must be certified by one of the following: (1) the CEO of the provider or supplier that is a covered entity; (2) the CFO of the provider or supplier that is a covered entity; (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or (4) an individual or contractor with the delegated authority as an authorized representative of the provider or supplier that is a covered entity to perform the certification on behalf of one of the individuals mentioned in § 428.203(c)(5)(i) through § 428.203(c)(5)(iii) and is authorized to submit the data elements in this submission on behalf of such provider or supplier. Nothing in new § 428.203(c)(5) modifies the substance of the certification requirement described in the CY 2027 PFS proposed rule but rather serves to improve clarity of this final rule.

Comment: A commenter emphasized challenges in identifying Medicare Part D claims. The commenter explained that 340B providers do not receive complete information from PBMs, including the BIN and PCN, from all TPAs, and therefore would need additional information from some TPAs to reliably identify Medicare claims. Additionally, the commenter stated that Medicare Part D and commercial payer BINs/PCNs can sometimes be identical, making it impossible for 340B providers to distinguish between Medicare and commercial claims based solely on this information. A commenter stated that PBMs frequently alter BINs/PCNs post-adjudication. Similarly, a commenter appreciated that BINs/PCNs are not

required data elements for the 340B repository because 340B providers would be greatly challenged in providing that information.

Response: We believe there are public resources, in addition to the BIN/PCN file available on the CMS website,[243] available to 340B providers to help identify Part D claims. For example, Part D plan sponsors typically publish payer sheets with claims processing instructions which include the BINs/PCNs for the sponsor's Part D plans. We also understand that covered entities already commonly submit BINs/PCNs as a part of other 340B reporting requirements, so we believe BIN/PCN identification for Part D plans is feasible. We also note that any data submitted to the 340B repository that is associated with payors other than Part D plans will not be used by CMS (although any additional data submitted will be subject to relevant CMS data retention policies and legal requirements), and 340B providers will not be penalized for submitting such additional data. We will match the stored data elements in the 340B repository to PDE records for each Part D rebatable drug dispensed during the applicable period, which will allow CMS to test whether data submitted to the 340B repository can be used to accurately identify and exclude Part D 340B units from inflation rebate calculations.

Comment: A few commenters requested that CMS publish finalized technical specifications and facilitate testing environments before launching the 340B repository. A few commenters provided specific operational recommendations and requests for information, such as a recommendation that the 340B repository include a contingency process for system outages and recommendations for rejected submissions.

Response: As previously mentioned, the 340B repository is live as of October 1, 2026, and we have provided technical specifications that are available on the CMS website. The specific technical details are outside the scope of this final rule. We direct readers to technical information about the 340B repository available on the CMS Inflation Rebate website, including information on how to contact the 340B Repository Help Desk for technical assistance.[244]

Comment: A commenter recommended that CMS use 340B repository data to evaluate whether the program is improving patient affordability, access, or services, while avoiding operational changes that disrupt pharmacy access or dispensing.

Response: The purpose of the 340B repository at this time is for the Medicare Part D Drug Inflation Rebate Program. CMS will use the data to assess the usability of the data received and feasibility of CMS removing 340B units from the total number of units used to calculate the total Part D rebate amount in the future based on the data submitted.

Comment: A commenter recommended that CMS articulate a clear preemption principle that prevents State laws from prohibiting, penalizing, or materially interfering with mandatory reporting to the 340B repository.

Response: We are not aware of any State laws that purport to prohibit, penalize, or interfere with the 340B repository.

After consideration of the comments received, we are finalizing at § 428.203(c)(4) the requirement that data elements and information that are incomplete or contain invalid data must be resubmitted at a later time, in a form and manner specified by CMS. We are also finalizing our proposal to require 340B providers (or an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification) to certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, its submissions include all Part D 340B claims for the 340B provider at the time of submission for the relevant period. As described earlier in this section, we are finalizing new § 428.203(c)(5) detailing this certification requirement. We are adopting our proposal that we would rely upon the completeness and accuracy of the data submitted by 340B providers to the 340B repository, consistent with the 340B provider requirement to certify the accuracy of such submissions. We are also adopting our proposal that 340B providers could arrange for TPAs or other vendors to submit the required data elements to the 340B repository on their behalf. 340B providers would ultimately be responsible for the accuracy of the data submitted to the 340B repository.

d. Clarification of Date of Receipt for Rebate Reports

As stated in the CY 2025 PFS final rule (89 FR 98305) which was effective on January 1, 2025 and appeared in the December 8, 2024 **Federal Register**, § 428.400 defines the date of receipt as the calendar day following the day in which a report of a rebate amount (as set forth in § 428.401(b), (c), and (d) and § 428.402(b) and (c)) is made available to the manufacturer of a Part D rebatable drug by CMS. The date of receipt starts the clock for calculation of deadlines at multiple points in the rebate reporting process, including for manufacturer submission of a suggestion of error and for payment of rebate amounts owed. For example, as set forth in § 428.405(a)(1), a rebate amount owed is due no later than ''the 30th calendar day after the date of receipt of information regarding the rebate amount.''

For clarity and transparency, in the CY 2027 PFS proposed rule (91 FR 44014 through 44015), we made technical corrections to the examples provided in CY 2025 PFS final rule of the calculation of due dates based on the ''date of receipt''. In the CY 2025 PFS final rule (89 FR 98306), we provided examples of the ''date of receipt'', including: (1) ''if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, will be the date of receipt and, therefore, day one of the 10-calendar-day period to submit a Suggestion of Error; the Suggestion of Error would be due by 11:59 p.m. PT on June 10, 2026[ ]''; and (2) ''if the Rebate Report is provided on June 30, 2026, then July 1, 2026, would be the date of receipt and therefore day one of the 30-calendar-day payment period; payment would be due no later than 11:59 p.m. PT on July 30, 2026.'' In the CY 2027 PFS proposed rule (91 FR 44014 through 44015), we corrected these examples to be consistent with the definition of ''date of receipt'' in § 428.400. Specifically, in each example provided, the ''date of receipt'' should be day 0 of the relevant calendar period, not day one. Therefore, if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, will be the ''date of receipt'' and day zero of the 10-calendar-day period to submit a Suggestion of Error, such that Suggestions of Error would be due by 11:59 p.m. PT on June 11, 2026. Likewise, if a Rebate Report is provided on June 30, 2026, then July 1, 2026, will be the date of receipt and day zero of the 30-calendar-day payment period, such that payment would be due no later than 11:59 p.m. PT on July 31, 2026.

We did not receive public comments on this clarification.

e. Enforcement of Manufacturer Payment of Rebate Amounts (§ 428.500)

In accordance with section 1860D–14B(a)(2) of the Act, the manufacturer of a Part D rebatable drug is required to

[243] See: *https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers.*

[244] *See: https://www.cms.gov/initiatives/medicare-prescription-drug-affordability/overview/medicare-inflation-rebate-program.*

provide a rebate equal to the rebate amount specified in section 1860D–14B(b) for the rebatable drug for the applicable period within 30 calendar days after receipt of the rebate amount from CMS. Section 1860D–14B(e) of the Act gives us the authority to impose a CMP equal to 125 percent of the rebate amount specified at section 1860D–14B(b) for each drug for each applicable period on a manufacturer that fails to pay the specified rebate amount. Subpart F implements this section of the Act and establishes the procedures for determining and collecting a CMP.

In the CY 2027 PFS proposed rule (91 FR 44015), we clarified that the imposition of CMPs under section 1860D–14B(e) of the Act, in accordance with § 428.500, is not the exclusive remedy for a manufacturer's failure to comply with its rebate payment obligations described in § 428.405(a), nor the exclusive remedy for other conduct that may impact obligations, such as rebate amounts owed, under the Medicare Part D Drug Inflation Rebate Program. For example, whether imposing CMPs under section 1860D–14B(e) of the Act or not, when we deem it appropriate, we may refer manufacturers to the Department of Justice, the Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation.

We did not receive public comments on this clarification.

G. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

As of January 1, 2026, the Medicare Shared Savings Program (Shared Savings Program) has 511 accountable care organizations (ACOs) with over 700,000 healthcare providers and organizations providing care to over 12.6 million assigned beneficiaries.[245] Eligible groups of providers and suppliers, such as physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or joining an ACO and in so doing agree to become accountable for the total cost and quality of care provided to an assigned population of Medicare FFS beneficiaries[246] (herein also referred to as ''Original Medicare beneficiaries'').

Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive Original Medicare (OM) payments under Parts A and B,[247] and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases healthcare spending.

As part of our effort to align spending and value in OM, we are focused on developing policies that would grow the number of healthcare providers and beneficiaries in accountable care relationships and grow savings to the Medicare Trust Funds. To achieve these goals, we proposed changes to the Shared Savings Program and sought comments on potential future policy developments in several requests for information, informed by the following strategic objectives:

- Strengthen financial incentives to participate and drive savings while minimizing ''gaming'' [248] opportunities in the Shared Savings Program.
- Grow participation in the Shared Savings Program through more meaningful participation and through beneficiary engagement, including beneficiary incentives.
- Simplify Shared Savings Program requirements and reduce participant burden in the Shared Savings Program, including through advancing ACO use of digital quality measures.

More specifically, our changes to the Shared Savings Program's financial methodology will strengthen financial incentives for ACOs to participate in the program while mitigating selection issues and benchmark rebasing concerns. Our changes to the Shared Savings Program's beneficiary assignment methodology are expected to expand the population of Medicare FFS beneficiaries for which ACOs are accountable for quality and cost of care, while minimizing potential gaming opportunities in connection with the assignment methodology. The changes to the Shared Savings Program quality performance standard and other quality reporting requirements will support ACO advancement toward digital quality measurement and reduce participant burden. Our proposal to allow flexibility for Shared Savings Program ACOs to reduce or eliminate Part B cost sharing for eligible beneficiaries, and therefore expand availability of this flexibility beyond ACOs participating in the prepaid shared savings payment option (which we proposed to discontinue), is intended to increase beneficiary engagement. Our changes to simplify the Shared Savings Program Certified Electronic Health Record Technology (CEHRT) use requirements and beneficiary information notice requirements will reduce burden for ACOs. Other modifications to the Shared Savings Program regulations addressed in the CY 2027 PFS proposed rule included: proposed changes to the definition of primary care services for the purpose of determining beneficiary assignment, and proposed modifications to definitions of experienced and inexperienced with performance-based risk Medicare ACO initiatives used in determining an ACO's eligibility for participation options, and proposed changes to the methodology for determining quarterly payment amounts received by eligible ACOs participating under the Advance Investment Payment (AIP) option. Further, through the CY 2027 PFS proposed rule, we sought comment on specialty care in the Shared Savings Program. We provided a more detailed summary of the proposed changes to the Shared Savings Program and the topics on which we sought comment in a Request for Information (RFI) in section III.G.1.c. of the proposed rule.

We received public comments on these proposals. Our summary of the comments we received and our responses can be found in each section of III.G.

b. Statutory and Regulatory Background on the Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended title XVIII of the Act (42 U.S.C. 1395 et seq.) by adding section 1899 of the Act to establish the Medicare Shared Savings Program to facilitate coordination and cooperation among healthcare providers to improve

[245] See ''Shared Savings Program Fast Facts—As of January 1, 2026'', available at *https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf*.

[246] ''Medicare fee-for-service beneficiary'' is defined under section 1899(h)(3) of the Act, and a related definition was codified at 42 CFR 425.20.

[247] Over time, in Shared Savings Program rulemaking, we have used various phrases to refer to payments under the original Medicare fee-for-service program. Herein, we sometimes refer to Medicare fee-for-service (FFS) payments under Parts A and B as ''Original Medicare payments.'' More generally, we use the terms ''Traditional Medicare'' and ''Original Medicare'' interchangeably and consider the terms to be synonymous.

[248] For instance, in section III.G.2.a of this final rule, we describe the potential for Shared Savings Program assignment policies to be exploited in a manner that results in differences in outcomes that could advantage the ACO's financial performance.

the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj).

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (Pub. L. 114–255). The Bipartisan Budget Act of 2018 (Pub. L. 115–123), further amended section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011, **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent update to the program rules appeared in the June 9, 2015, **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016, **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017,'' appeared in the December 31, 2018, **Federal Register** ((83 FR 67816) (hereinafter referred to as the ''December 2018 final rule'')).

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020, **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), and the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which was effective on May 8, 2020, and appeared in the May 8, 2020, **Federal Register** (85 FR 27550) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we updated quality requirements, financial calculations, eligibility requirements, and assignment methodology due to the to the public health emergency (PHE) for coronavirus disease 2019 (COVID–19).

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. For summaries of certain policies finalized in prior PFS rules, refer to the CY 2019 PFS final rule (also referred to as the ''November 2018 final rule'') (83 FR 59452), CY 2020 PFS final rule (84 FR 62568), the CY 2021 PFS final rule (85 FR 84717), the CY 2022 PFS final rule (86 FR 65253 and 65254), the CY 2023 PFS final rule (87 FR 69779 and 69780), the CY 2024 PFS final rule (88 FR 79094 and 79095), the CY 2025 PFS final rule (89 FR 98082 and 98083), and the CY 2026 PFS final rule (90 FR 49757 through 49759). In the CY 2026 PFS final rule (90 FR 49757 through 49836), we finalized changes to Shared Savings Program policies, including to: limit participation in a one-sided model to an ACO's first agreement period under the BASIC track's glide path (if eligible), for a maximum of 5 PYs instead of 7 PYs; modify the Shared Savings Program eligibility and financial reconciliation requirements in connection with the statutory requirement that ACOs have at least 5,000 assigned Medicare FFS beneficiaries; make changes to the Shared Savings Program quality performance standard and other quality reporting requirements; expand the application of the Shared Savings Program quality and finance extreme and uncontrollable circumstances (EUC) policies to an ACO that is affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program; and to make changes to other programmatic areas, including changes to Shared Savings Program eligibility requirements and change request procedures, updates to the beneficiary assignment methodology to revise the definition of primary care services to align with payment policy changes, and to revise the Shared Savings Program's quality reporting monitoring policies.

Aside from CY PFS rulemaking, we also note that in a final rule entitled ''Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023,'' which was effective on October 15, 2024, and appeared in the September 27, 2024, **Federal Register** (89 FR 79152) (hereinafter referred to as the ''SAHS billing activity final rule''), we finalized an approach to address the SAHS billing activity CMS identified for CY 2023 to protect the accuracy, fairness, and integrity of Shared Savings Program financial calculations.

Policies applicable to Shared Savings Program ACOs for purposes of quality reporting for other programs have also continued to evolve based on changes in statute, such as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), which established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the MIPS and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Provisions in This Final Rule

In sections III.G.2. through III.G.9. of this final rule, we summarize and respond to public comments received on the proposed modifications to the Shared Savings Program's policies discussed in section III.G. of the CY 2027 PFS proposed rule (91 FR 44015 through 44134). Some commenters' suggestions for modifications to Shared Savings Program policies went beyond the scope of the proposals discussed in section III.G. of the CY 2027 PFS

proposed rule and will not be addressed in this section of this final rule. As a general summary, we are finalizing the following changes to Shared Savings Program policies to:

• Revise the Shared Savings Program assignment methodology (section III.G.2. of this final rule):

++ Exclude from assignment calculations allowed charges for primary care services billed through a non-ACO Taxpayer Identification Number (TIN) by an ACO professional used in assignment (section III.G.2.a.(2)(a) of this final rule).

++ Modify assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status (section III.G.2.a.(2)(b) of this final rule).

++ Revise the definition of primary care services used in Shared Savings Program beneficiary assignment (section III.G.2.b. of this final rule).

• Revise the quality performance standard and other quality reporting requirements, including the following (section III.G.3. of this final rule):

++ Extend the availability of the MIPS CQMs collection type and the MIPS CQM reporting incentive for Shared Savings Program ACOs (section III.G.3.b. of this final rule).

++ Extend the scoring of Shared Savings Program ACOs reporting Medicare CQMs using flat benchmarks (section III.G.3.c. of this final rule).

++ Address Shared Savings Program ACOs' challenges with meeting the MIPS data completeness requirement (section III.G.3.d. of this final rule):

— Revise the Shared Savings Program quality reporting requirements beginning in PY 2026 (section III.G.3.d.(2) of this final rule).

— Establish the Medicare eCQMs Collection Type for Shared Savings Program ACOs (section III.G.3.d.(3) of this final rule).

— Revise the definition of a ''Beneficiary Eligible for Medicare CQMs'' (section III.G.3.d.(4) of this final rule).

++ Revise the Shared Savings Program scoring policy for excluded APP Plus measures and APP Plus measures that lack a benchmark (section III.G.3.e. of this final rule).

++ Update the APP Plus quality measure set (section III.G.3.f. of this final rule).

• Revise Shared Savings Program Certified Electronic Health Record Technology (CEHRT) Use Requirements (section III.G.4. of this final rule).

++ Simplify Shared Savings Program CEHRT use requirements (section III.G.4.b. of this final rule).

— Allow ACOs the option to meet Shared Savings Program CEHRT use requirement by completely reporting at least one ACO-reported measure through the eCQMs or Medicare eCQMs collection types (section III.G.4.b.(1) of this final rule).

— Allow ACOs the option to meet Shared Savings Program CEHRT use requirements by completely reporting at least one measure in the APP Plus quality measure set and meeting the applicable data completeness requirement using CEHRT and attesting to using FHIR capabilities in certified health IT to support reporting of at least one of the five ACO-reported measures (section III.G.4.b.(2) of this final rule).

— Allow ACOs the option to meet Shared Savings Program CEHRT use requirements by attesting to one of three ACO CEHRT use metrics (section III.G.4.b.(3) of this final rule).

— Revise public reporting requirements (section III.G.4.b.(4) of this final rule).

— Require compliance with Shared Savings Program CEHRT use requirements (section III.G.4.b.(5) of this final rule).

• Revise policies for the Shared Savings Program's financial methodology, including the following (section III.G.5. of this final rule):

++ Change the Shared Savings Program financial methodology to encourage additional savings in two-sided risk (section III.G.5.c. of this final rule):

— Increase the sharing rate under Level E of the BASIC track (section III.G.5.c.(1) of this final rule).

— Reduce the maximum weight on the regional adjustment for ACOs under the ENHANCED track (section III.G.5.c.(2) of this final rule) for ACOs that are lower spending compared to their regional service area.

++ Increase the prior savings adjustment by increasing the scaling factor (section III.G.5.d. of this final rule).

++ Risk adjust the 5 percent cap on upward adjustments to the historical benchmark (section III.G.5.e. of this final rule).

++ Incentivize new participation through a growth adjustment to the historical benchmark (section III.G.5.f. of this final rule).

++ Reform the Accountable Care Prospective Trend (ACPT) component of the benchmark update factor (section III.G.5.g. of this final rule).

• Increase beneficiary engagement by allowing ACOs to reduce or eliminate Part B cost sharing for beneficiaries (section III.G.6.a. of this final rule), and discontinue availability of the option for prepaid shared savings (section III.G.6.b. of this final rule).

• Modify the calculation methodology for setting quarterly advance investment payment amounts and revise the terminology on allowable uses of advance investment payments (section III.G.7. of this final rule).

• Revise the approach to determining whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives (section III.G.8. of this final rule).

• Modify Shared Savings Program beneficiary notification requirements (section III.G.9. of this final rule):

++ Revise distribution timing of standardized written notices (section III.G.9.b.(1) of this final rule).

++ Remove the requirement to provide a beneficiary follow-up notice (section III.G.9.b.(2) of this final rule).

Additionally, in section II.D. of the final rule we are finalizing a policy to replace office/outpatient evaluation and management (O/O E/M) visit complexity add-on code, HCPCS code G2211 with modifiers that would allow for differential payment for ACO participants.

Taken together, the Shared Savings Program policy provisions in this final rule are projected to reduce Trust Fund expenditures by $5.5 billion in total through the end of the 10-year period 2027 through 2036, ranging from approximately $8.9 billion lower spending at the 10th percentile to $2.3 billion lower spending at the 90th percentile, as described in the Regulatory Impact Analysis in section VI. of this final rule.

Certain policies, including both existing policies and finalized policies described in the CY 2027 PFS final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following policies require the use of our authority under section 1899(i) of the Act: modifications to the ACPT component of the three-way blended benchmark update factor (described in section III.G.5.g. of this final rule); discontinuing availability of the option for prepaid shared savings (described in section III.G.6.b. of this final rule); and changes to the calculation methodology for quarterly advance investment payments (described in section III.G.7. of this final rule). As described in the Regulatory Impact Analysis in section VI. and elsewhere in this final rule, these policy changes to the Shared Savings Program

are expected to improve the quality and efficiency of care under the Medicare program and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies we have adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

We will continue to reexamine this projection in the future to ensure that an alternative payment model does not result in additional program expenditures and so continues to satisfy the requirement under section 1899(i)(3)(B) of the Act. If we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we will undertake notice and comment rulemaking to adjust the payment model to ensure continued compliance with the statutory requirements.

d. PY 2027 Application Cycle Flexibility

Some of the financial methodology changes described in section III.G. of this final rule may be consequential for ACOs' decisions to enter an agreement period under Level E of the BASIC track or the ENHANCED track. We anticipate a significant number of renewal applications for the January 1, 2027 agreement period start date. There are currently 96 ACOs that entered an agreement period beginning on January 1, 2022, that need to apply to renew to continue their participation in the Shared Savings Program by entering an agreement period beginning on January 1, 2027. Considering the timing of CY PFS rulemaking and the Shared Savings Program application cycle for the January 1, 2027 start date (occurring in CY 2026), ACO applicants received notice of the proposed changes after the deadline for submitting their applications to continue their participation. Additionally, under a previously established timeline for application actions and deadlines, the application cycle required ACO applicants to finalize their selection of track/level of participation by early September 2026,[249] which is before this CY 2027 PFS final rule was issued. ACO applicants had to make their final selection between the BASIC track and ENHANCED track before this CY 2027 PFS final rule was issued. To mitigate the potential impact on ACO applicants in making their final selection of track/level of participation in the Shared Savings Program, we are providing ACOs applying for an agreement start date of January 1, 2027, with a time-limited opportunity to change their final selection between the BASIC track and ENHANCED track (if eligible). We also noted in the CY 2027 PFS proposed rule that an ACO applicant that has not submitted an application for a January 1, 2027 agreement start date as of the date of display of the CY 2027 PFS proposed rule that wishes to enter a new agreement in the Shared Savings Program, may apply to enter a new agreement period beginning on January 1, 2028, during the application cycle occurring in CY 2027.

2. Beneficiary Assignment Methodology

a. Modifications to the Shared Savings Program Assignment Methodology

(1) Background

Under section 1899(b)(2)(A) of the Act, an ACO must ''be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it.'' As defined in section 1899(h)(3) of the Act and in the Shared Savings Program's regulations at § 425.20, the term ''Medicare fee-for-service beneficiary'' means an individual who is enrolled in the original Medicare FFS program under Parts A and B and is not enrolled in a Medicare Advantage (MA) plan under Part C, an eligible organization under section 1876 of the Act, or a Program of All-Inclusive Care for the Elderly (PACE) program under section 1894 of the Act. Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act (Pub. L. 114–255) and the Bipartisan Budget Act of 2018 (Pub. L. 115–123), provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided by physicians in the ACO who are ACO professionals and, in the case of PYs beginning on or after January 1, 2019, services provided by a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). In the context of the Shared Savings Program, ''assignment'' (as defined in § 425.20) refers to an operational process by which we determine whether a beneficiary has chosen to receive a sufficient level of certain primary care services from physicians and other healthcare practitioners associated with a specific ACO so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care during a given benchmark year or PY.[250] We refer to the process by which we determine assignment under section 1899(c)(1) of the Act as ''claims-based assignment''.

Further, under section 1899(c)(2)(B) of the Act, a non-claims-based process for voluntary alignment applies to all Shared Savings Program ACOs and is used to supplement claims-based assignment. In accordance with section 1899(c)(2)(B)(iii) of the Act, voluntary alignment supersedes claims-based assignment.

The regulations governing the assignment methodology under the Shared Savings Program, with provisions on claims-based assignment and voluntary alignment, are in 42 CFR part 425, subpart E. In the sections that follow we provide additional regulatory background about the Shared Savings Program's step-wise claims-based assignment methodology (section III.G.2.a.(1)(a) of this final rule) and criteria based on Medicare enrollment status that we use to determine a beneficiary's eligibility for assignment (section III.G.2.a.(1)(b) of this final rule), provide an overview of assignment-based program operations (section III.G.2.a.(1)(c) of this final rule), and describe beneficiaries excluded from the assigned population under the current assignment methodology (section III.G.2.a.(1)(d) of this final rule).

(a) Background on Step-Wise Assignment Methodology

As we have described in the CY 2024 PFS final rule (88 FR 79136), under claims-based assignment, we determine a Medicare FFS beneficiary is assigned to an ACO if the beneficiary meets the criteria in § 425.401(a) to be eligible for assignment to an ACO, and the beneficiary's utilization of primary care services [251] meets the criteria established under the assignment methodology specified in § 425.402 (specifying the basic assignment methodology) and § 425.404 (specifying special assignment conditions for ACOs including FQHCs and RHCs). Section

[249] See CMS, Medicare Shared Savings Program, ''Key Application Actions and Deadlines For Agreement Periods Beginning on January 1, 2027'', available at *https://www.cms.gov/files/document/key-application-actions-deadlines.pdf https://www.cms.gov/files/document/key-application-actions-deadlines.pdf.*

[250] As we have explained in earlier rulemaking (see 88 FR 79136; see also 76 FR 67851, and 83 FR 67863), the term ''assignment'' for purposes of the Shared Savings Program in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other healthcare practitioners from whom they receive covered services.

[251] As described in section III.G.2.b. of this final rule, we define primary care services for purposes of the Shared Savings Program in § 425.20 as a set of services identified by HCPCS codes and CPT codes, as specified under § 425.400(c).

425.402 specifies a step-wise assignment methodology for determining an ACO's assigned beneficiary population based on beneficiaries' use of primary care services. Section 425.402(b) of the Shared Savings Program regulations specifies the step-wise methodology we use to assign Medicare FFS beneficiaries to an ACO based on available claims information, for PY 2016 and subsequent PYs. In accordance with § 425.404(b), for PYs starting on January 1, 2019, and subsequent PYs, under the assignment methodology in § 425.402, we treat a service reported on an FQHC or RHC claim as a primary care service performed by a primary care physician.

The Shared Savings Program step-wise assignment process is offered in two similar, but distinct, claims-based assignment methodologies: prospective assignment as specified under § 425.400(a)(3); and preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2). Consistent with the requirements of section 1899(c)(2)(A) of the Act, we offer all Shared Savings Program ACOs the opportunity to select their assignment methodology annually, starting with agreement periods beginning on July 1, 2019, in accordance with §§ 425.400(a)(4)(ii) and 425.226(a)(1). We use the same step-wise assignment methodology under § 425.402 to assign beneficiaries to ACOs under prospective assignment and ACOs under preliminary prospective assignment with retrospective reconciliation.

The step-wise assignment methodology was initially established with the November 2011 final rule and was modified through subsequent rulemaking. For a discussion of the relevant background and related considerations, we refer readers to the November 2011 final rule (76 FR 67853 through 67858), June 2015 final rule (see 80 FR 32699 through 32701, and 32748 through 32755), CY 2023 PFS final rule (87 FR 69825 through 69829), and the CY 2024 PFS final rule (88 FR 79136 through 79163). We have detailed how we perform claims-based assignment in programmatic material, including publicly available specifications documents. See, for example, Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (Section 2.3 Claims-Based Assignment).

In the discussion that follows, we first describe our use of the ACO participant list to identify primary care services billed by ACO professionals and CMS certification numbers (CCNs) used in the assignment methodology, and then we describe the steps of the claims-based assignment process.

(i) Use of ACO Participant List To Identify Primary Care Services Billed by ACO Professionals and CCNs Used in Assignment Calculations

As we described in the CY 2023 PFS final rule (87 FR 69825), under the Shared Savings Program, ACOs are accountable for the quality, cost, and overall care of the Medicare FFS beneficiaries that are assigned to the ACO (§ 425.100(a)). ACOs are formed by one or more ''ACO participants,'' which are responsible for managing and coordinating care for the assigned beneficiary population. The Shared Savings Program regulations define ''ACO participant'' at § 425.20 as an entity identified by a Medicare-enrolled billing Taxpayer Identification Number (TIN) through which one or more ''ACO providers/suppliers'' (as defined at § 425.20) bill Medicare, that alone or together with one or more other ACO participants compose an ACO, and that is included on the list of ACO participants that is required under § 425.118 (herein ''ACO participant list''). An ''ACO provider/supplier'' is an individual or entity that: (1) is a provider (as defined at § 400.202) or supplier (as defined at § 400.202); (2) is enrolled in Medicare; (3) bills for items and services furnished to Medicare FFS beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and (4) is included on the list of ACO providers/suppliers that is required under § 425.118 (herein ''ACO provider/supplier list'').[252] We require each ACO to execute contractual agreements with each of its ACO participants (''ACO participant agreements''), to ensure that the ACO participant and each ACO provider/supplier billing through the TIN of the ACO participant agree to the requirements of the Shared Savings Program (see 87 FR 69825, and see also § 425.116).

As we explained in the CY 2023 PFS final rule (87 FR 69825 through 69826), under § 425.118(a), an ACO must maintain, update, and submit to us an accurate and complete list identifying each ACO participant (including its Medicare-enrolled TIN) and each ACO provider/supplier (including its National Provider Identifier (NPI), CCN, or other identifier). More specifically, an ACO must submit a draft ACO participant list before the start of an agreement period and before each performance year thereafter. In accordance with § 425.118(a)(3), the ACO must certify the accuracy of its ACO participant list before the start of its agreement period and before each performance year thereafter. An ACO must maintain and periodically update its ACO participant list. For additional background on development and maintenance of the ACO participant list we refer readers to the CY 2023 PFS final rule at 87 FR 69826, and CY 2026 PFS final rule at 90 FR 49775 through 49778.

More generally, in accordance with § 425.102(a), an ACO may be formed from the following ACO participants or combinations of ACO participants: (1) ACO professionals in group practice arrangements; (2) networks of individual practices of ACO professionals; (3) partnerships or joint venture arrangements between hospitals and ACO professionals; (4) hospitals employing ACO professionals; (5) Critical Access Hospitals (CAHs) that bill under Method II (as described in § 413.70(b)(3)); (6) RHCs; (7) FQHCs; and (8) teaching hospitals that have elected under § 415.160 to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians (herein referred to as electing teaching amendment (ETA) hospitals).

Under § 425.20, ''ACO professional'' is defined to mean an individual who is Medicare-enrolled and bills for items and services furnished to Medicare FFS beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations and who is either of the following: (1) a physician legally authorized to practice medicine and surgery by the State in which he or she performs such function or action; or (2) a practitioner who is a physician assistant (PA), a nurse practitioner (NP), or a clinical nurse specialist (CNS).[253] As detailed in section III.G.2.a.(1)(ii) of this final rule, the step-wise assignment methodology considers primary care services furnished by the following ACO professionals: primary care physicians

[252] For additional background on development and maintenance of the ACO provider/supplier list, we refer readers to the CY 2023 PFS final rule at 87 FR 69826.

[253] Sometimes we refer to NPs, PAs, and CNSs who are ACO professionals in the ACO as ''non-physician ACO professionals''.

(as defined in § 425.20), physicians with specialty designations included in § 425.402(c), and non-physician ACO professionals (NPs, PAs, CNSs) (herein collectively referred to as ''ACO professionals used in assignment'' for brevity).

Under the claims-based assignment process we identify allowed charges for a beneficiary's primary care services received in an ACO (furnished by ACO professionals used in assignment billing through the TIN of an ACO participant or an FQHC, RHC, Method II CAH, or ETA hospital identified by a CCN enrolled under the TIN of an ACO participant), in any other ACO, or other individual practitioners, or groups of practitioners identified by Medicare-enrolled billing TINs or CCNs that are not participating in the Shared Savings Program. We use the ACO participant list certified by the ACO to identify ACO professionals used in assignment that are billing primary care services, and to identify CCNs enrolled under the TIN of an ACO participant, for purposes of performing claims-based assignment for the PY, and, if applicable, assignment for the ACO's benchmark years in the case of establishing or adjusting the ACO's historical benchmark under subpart G (see § 425.652(a)).

We use different approaches to identifying primary care services furnished by ACO professionals and CCNs enrolled under the TIN of an ACO participant. Because of the billing relationship between an ACO professional and an ACO participant, any claims for primary care services billed by an ACO professional through the TIN of an ACO participant would be used for assignment. We note that operationally we identify an ACO professional based on the physician's or non-physician practitioner's NPI. As we explained in the CY 2023 PFS final rule (87 FR 69826), for purposes of beneficiary assignment, we identify claims for services furnished by Method II CAHs, ETA hospitals, FQHCs, and RHCs using the CCN assigned to the facility. Section 425.402(f) includes provisions on how we identify services furnished by FQHCs, RHCs, Method II CAHs, and ETA hospitals, based on CCNs enrolled under the TIN of an ACO participant, for purposes of beneficiary assignment for PY 2023 and subsequent PYs. Under this approach, we use the Provider Enrollment, Chain, and Ownership System (PECOS) to determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant prior to the start of performance year, and periodically during the performance year, and account for changes in CCN enrollment status during the PY.[254] We also note that the claims data used for assignment for FQHCs, RHCs, Method II CAHs, and ETA hospitals are limited to outpatient facility claims, and have specified in program specifications additional steps we use to identify data on outpatient facility claims for these four provider types.[255]

As specified in § 425.306, each ACO participant that submits claims for services used to determine the ACO's assigned population under subpart E of part 425 must be exclusive to one Shared Savings Program ACO. In initially establishing exclusivity requirements for ACO participants in the November 2011 final rule (76 FR 67811), we explained that individual NPIs are free to participate in multiple ACOs if they bill under several different TINs. We explained that when providers whose services are the basis of assignment bill under two or more TINs, each TIN would be exclusive to only one ACO, assuming both TINs have both joined as participants, but the provider billing under the TINs would not have to be exclusive to one ACO. In the February 2016 proposed rule (81 FR 5824, 5849), we recognized there may be cases where a beneficiary is receiving primary care services from ACO participants in multiple ACOs or from both ACO participants and non-ACO providers and suppliers. We explained that in such cases, the composition of each ACO is important in determining whether the beneficiary is assigned to an ACO at all, and in determining to which ACO (among several) the beneficiary may be assigned. As we explained in the CY 2023 PFS final rule (87 FR 69828), our policies for accounting for changes in CCN enrollment status, for identifying services furnished by FQHCs, RHCs, Method II CAHs, and ETA hospitals for purposes of beneficiary assignment, reflect our operational approach to treat CCNs in a similar fashion to ACO participant TINs and not allow a CCN to switch between ACOs during the performance year (see § 425.402(f)(3)(iii)). In earlier rulemaking, we have not more generally sought to address the impact on assignment of an ACO professional used in assignment (NPI) billing primary care services for a beneficiary through an ACO participant TIN and non-ACO TIN, and related policy considerations.

(ii) Steps of the Claims-Based Assignment Process

In each step of the claims-based assignment process, we determine whether the allowed charges for a beneficiary's primary care services in an ACO are greater than allowed charges for the beneficiary's primary care services in any other ACO, or other individual practitioners, or groups of practitioners identified by Medicare-enrolled billing TINs or CCNs that are not participating in the Shared Savings Program (that is, a non-ACO individual or group TIN or non-ACO CCN). In doing so, we determine which ACO or non-ACO entity provided a beneficiary's plurality of allowed charges for primary care services for purposes of assignment. Herein, for brevity, we sometimes refer to this stage of the assignment process as ''plurality competition''.[256]

To follow is a summary of the steps used in the claims-based assignment methodology under § 425.402(b):

In accordance with § 425.402(b)(1), as a ''pre-step'' to the first and second step of the claims-based assignment process, CMS identifies all beneficiaries who had at least one primary care service during the applicable assignment window [257] with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or has one of the primary specialty designations specified in § 425.402(c). This pre-step is designed to satisfy the statutory requirement under section 1899(c)(1) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians participating in the ACO. Beneficiaries

[254] We refer readers to the discussion in the CY 2023 PFS final rule at 87 FR 69825 through 69829.

[255] See Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (Appendix D: Outpatient Facility Claims Used in Beneficiary Assignment).

[256] We have infrequently made references to ''competition'' in claims-based assignment in earlier rulemaking. See, for example, 85 FR 84790 (in describing observations based on internal analysis of the rate at which beneficiaries are assigned to an ACO and subsequently not assigned to that ACO), and 89 FR 98197 through 98198 (in generally referring to the ACOs included in the claims-based assignment competition).

[257] As defined in § 425.20, ''assignment window'' means the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both. As we explained in the CY 2024 PFS final rule (88 FR 79137, see also 83 FR 67860), the assignment window for ACOs under prospective assignment is a 12-month period offset from the calendar year (for example, October through September preceding the calendar year), while for ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window is the 12-month period based on the calendar year.

who meet the pre-step requirement are then assigned to an ACO through either the first or second step of the assignment methodology specified in § 425.402(b)(3) and (b)(4).

As described in § 425.402(b)(2), for beneficiaries who meet the pre-step requirement under § 425.402(b)(1), CMS identifies all primary care services furnished by ACO professionals of that ACO who are primary care physicians as defined under § 425.20, non-physician ACO professionals, and physicians with specialty designations included in § 425.402(c) during the applicable assignment window. This provision reflects an operational step necessary to identify the sum of allowed charges for primary care services for a beneficiary received in an ACO (furnished by ACO professionals used in assignment billing through the TIN of an ACO participant or CCNs enrolled under the TIN of an ACO participant), as compared to any other ACO, non-ACO CCN, or non-ACO individual or group TIN, for determining the outcome of the plurality competition under step 1 and step 2 of the assignment methodology.

Under the first step of the assignment process, specified at § 425.402(b)(3), a beneficiary who is eligible for assignment and meets the pre-step requirement is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for primary care services furnished during the assignment window by primary care physicians, NPs, PAs, or CNSs who are ACO professionals in any other ACO, or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN (that is, a non-ACO CCN, or non-ACO individual or group TIN).

The second step of the assignment methodology, specified at § 425.402(b)(4), applies to the remainder of the beneficiaries who are eligible for assignment and meet the pre-step requirement, who have not had a primary care service rendered during the assignment window by any primary care physician, NP, PA, or CNS, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by physicians who are ACO professionals with specialty designations specified in § 425.402(c) are greater than the allowed charges for primary care services furnished during the assignment window by physicians with such specialty designations who are ACO professionals in any other ACO, or who are unaffiliated with an ACO and are identified by a Medicare-enrolled billing TIN (that is, a non-ACO CCN, or non-ACO individual or group TIN).

For PY 2025 and subsequent PYs, as specified in § 425.402(b)(5), we employ a third step to assign eligible Medicare FFS beneficiaries who are not identified by the ''pre-step'' criterion specified under § 425.402(b)(1). In this step, we identify all beneficiaries who had at least one primary care service with a non-physician ACO professional in the ACO during the applicable assignment window, and had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician or who has one of the primary specialty designations included in § 425.402(c) during the applicable expanded window for assignment (see § 425.402(b)(5)(i) through (ii)).[258] As described in § 425.402(b)(5)(iii), for a beneficiary meeting the aforementioned criteria in § 425.402(b)(5)(ii), we identify all primary care services furnished by ACO professionals in the ACO who are primary care physicians, non-physician ACO professionals, and physicians with specialty designations included in § 425.402(c) during the applicable expanded window for assignment. The identification of primary care services described in § 425.402(b)(5)(iii) serves as an operational step which is similar to the step described in § 425.402(b)(2). This operational step is necessary to identify the sum of allowed charges for primary care services for a beneficiary received in an ACO (furnished by ACO professionals used in assignment billing through the TIN of an ACO participant or CCNs enrolled under the TIN of an ACO participant), as compared to any other ACO, non-ACO CCN, or non-ACO individual or group TIN, for determining the outcome of the plurality competition under step 3.

In accordance with § 425.402(b)(5)(iv), a beneficiary identified in § 425.402(b)(5)(ii) who is eligible for assignment is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, physicians with specialty designations included in § 425.402(c), or non-physician ACO professionals during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations included in § 425.402(c), NPs, PAs, and CNSs who are ACO professionals in any other ACO, or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN (that is, a non-ACO CCN, or non-ACO individual or group TIN).

As previously described, under § 425.402(b)(3), (b)(4), (b)(5)(iv), the plurality competition which occurs in each step of assignment compares allowed charges for primary care services furnished to a beneficiary by certain ACO professionals in an ACO with allowed charges for primary care services furnished by the same type of healthcare providers who are either (1) ACO professionals in any other ACO, or (2) not affiliated with any ACO and identified by a Medicare-enrolled billing TIN. Under the existing provisions, for purposes of plurality competition, we attribute to a non-ACO TIN the allowed charges for primary care services for a beneficiary furnished by an ACO professional that are billed through the non-ACO TIN. In determining the outcome of plurality competition for a beneficiary we consider both: (1) allowed charges for primary care services for the beneficiary received inside the ACO (furnished by an ACO professional or FQHC, RHC, Method II CAH or ETA hospital that has enrolled under the TIN of an ACO participant), and (2) allowed charges for primary care services for the same beneficiary being billed by the same ACO professional outside the ACO to a non-ACO TIN. As a result, a beneficiary may be identified as receiving the plurality of their primary care services outside an ACO based on a difference in the TIN to which the services are being billed by their healthcare provider who is an ACO professional used in assignment. Under these circumstances, when the plurality of allowed charges for primary care services is attributed to a non-ACO TIN, the ACO whose ACO professionals are furnishing services to the beneficiary would not be held accountable for the beneficiary's quality and cost of care.

(b) Background on Criteria Based on Medicare Enrollment Status Use To Identify Beneficiaries Eligible for Assignment and the Assignable Beneficiary Population

With the June 2015 final rule (see 80 FR 32743 through 32746, 32774 through 32775, and 32840 through 32841), we added § 425.401, establishing criteria for a beneficiary to be assigned to an ACO, which included assignment eligibility

[258] As defined in § 425.20, ''expanded window for assignment'' means the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window and the preceding 12 months.

criteria under § 425.401(a), and exclusion criteria for prospectively assigned beneficiaries under § 425.401(b).[259] These criteria included requirements based on a beneficiary's Medicare enrollment status. Additional background on considerations in establishing the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status is provided in section III.G.2.a.(2)(b) of this final rule.

In subsequent rulemaking, we finalized amendments to § 425.401(b) introductory text, to apply the prospective assignment exclusion criteria in determining beneficiaries that would remain prospectively assigned at the end of CY 2019 to an ACO participating in a 6-month PY or performance period during 2019. Refer to the CY 2019 PFS final rule at 83 FR 59946 through 59947, and 60093; and the December 2018 final rule at 83 FR 67951, and 68069. We note that the criteria for determining a beneficiary's eligibility for assignment under § 425.401(a), and the prospective assignment exclusion criteria specified under § 425.401(b)(1) through (3), have remained unchanged since being finalized with the June 2015 final rule.

Currently, in accordance with § 425.401(a), a beneficiary may be assigned to an ACO under the assignment methodology in §§ 425.402 and 425.404, for a performance or benchmark year, if the beneficiary meets all of the following criteria during the assignment window:

(1) Has at least 1 month of Part A and Part B enrollment, and does not have any months of Part A only or Part B only enrollment.

(2) Does not have any months of Medicare group (private) health plan enrollment.

(3) Is not assigned to any other Medicare shared savings initiative.

(4) Lives in the United States (U.S.) or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

If a beneficiary meets the criteria noted previously, and then is assigned to an ACO that is participating under prospective assignment, the beneficiary may be later excluded from the ACO's prospective assignment list if they no longer meet these eligibility criteria. In accordance with § 425.401(b), a beneficiary is excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each PY consistent with § 425.400(a)(3)(ii), if the beneficiary meets any of the following criteria during the performance or benchmark year: [260]

(1) Does not have at least 1 month of Part A and Part B enrollment, and has any months of Part A only or Part B only enrollment.

(2) Has any months of Medicare group (private) health plan enrollment.

(3) Did not live in the U.S. or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residency at the end of the year.

We have also applied the eligibility criteria established at § 425.401(a) and the prospective assignment exclusion criteria at § 425.401(b) in determining whether a beneficiary is eligible to be assigned to an ACO through voluntary alignment. We refer readers to discussions in earlier rulemaking (see 81 FR 80501 through 80510, 83 FR 59959 through 59964, and 89 FR 98097 through 98101), on the establishment of and modifications to these policies. With the CY 2025 PFS final rule (89 FR 98097 through 98101), we finalized the voluntary alignment policies applicable for PY 2025 and subsequent PYs under § 425.402(e)(2)(iii).

In accordance with § 425.402(e)(2)(iii)(A), among other conditions that must be satisfied for a beneficiary to be prospectively assigned to an ACO through voluntary alignment for PY 2025 and subsequent PYs, the beneficiary must meet the eligibility criteria established at § 425.401(a), and must not be excluded by the criteria at § 425.401(b). Further, as specified under § 425.402(e)(2)(iii)(A), the exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for voluntary alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under § 425.402(e), regardless of the ACO's assignment methodology selection under § 425.226(a)(1).

There is currently asymmetry in the requirements used to identify the ACO assigned population under criteria in § 425.401 based on Medicare enrollment status, and the broader ''assignable beneficiary'' population (as defined in § 425.20), used in determining factors based on national and regional Medicare FFS expenditures.[261] As we have explained in earlier rulemaking, the assignable population is a subset of the larger population of Medicare FFS beneficiaries (see, for example, 88 FR 79138). Under our operational approach to identifying the assignable beneficiary population, we require that the beneficiary have at least 1 month of Part A and Part B enrollment and no Medicare group health plan enrollment (including MA) during that same month during the applicable 12-month assignment window. In comparison, for a beneficiary to be eligible to be assigned to an ACO under the criteria in § 425.401(a)(1) through (2) the beneficiary must: (1) have at least 1 month of Part A and Part B enrollment, and not have any months of Part A only or Part B only enrollment during the assignment window; and (2) not have any months of Medicare group (private) health plan enrollment during the assignment window. As a result, beneficiaries with one or more month of Part A only or Part B only enrollment, or Medicare group health plan enrollment during the assignment window could be included in the assignable beneficiary population, while beneficiaries with such Medicare enrollment status are ineligible for assignment to an ACO.

With the June 2016 final rule (see 81 FR 37985 through 37989), we established the use of the assignable population, rather than the broader Medicare FFS population in certain financial calculations based on national and regional FFS expenditures. In the June 2016 final rule (81 FR 37961), we explained that this approach to use the assignable population ensured these calculations were based on beneficiaries that have some chance of being assigned to the ACO. We also clarified that some beneficiaries who meet the definition of ''assignable beneficiary'' will ultimately be excluded from assignment to an ACO for purposes of determining the ACO's benchmark year or PY expenditures because they fail to meet the assignment criteria specified under § 425.401(a). In subsequent rulemaking we have established policies to ensure alignment

[259] We also refer readers to the related discussion in the proposed rule entitled ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations'', which appeared in the December 8, 2014 **Federal Register** (79 FR 72760, 72790 through 72792, and 72811).

[260] We note the introductory text of § 425.401(b) includes a reference to applicability of the prospective assignment exclusion criteria for determining assignment to ACOs participating under a 6-month performance year or performance period during CY 2019, under § 425.609(b)(1)(ii) and (c)(1)(ii).

[261] With the June 2016 final rule (see, for example, 81 FR 37985 through 37989, and 38013), we finalized the definition for ''assignable beneficiary'' under § 425.20, which we subsequently amended with the CY 2024 PFS final rule (88 FR 79143 through 79144, and 79162 through 79163).

between the assigned and assignable populations [262] or calculations based on these populations.[263] However, we did not previously seek to address the differences in Medicare enrollment status of beneficiaries in the assignable population and the assigned population.

(c) Overview of Assignment-Based Program Operations

Various Shared Savings Program operations are based on the ACO's assigned population, or consider the size of the ACO's assigned population, as described in prior rulemaking (see, for example, 88 FR 79137 through 79138). To follow is a summary of these policies, including references to changes to Shared Savings Program policies elsewhere in section III.G. of this final rule.

Various aspects of the Shared Savings Program's financial methodology under subpart G depend on the size or composition of the ACO's assigned population, including calculating the ACO's benchmark and performance year expenditures, and adjusting and updating the ACO's benchmark. For each performance year, we determine whether the estimated average per capita Medicare Parts A and B FFS expenditures for Medicare FFS beneficiaries assigned to the ACO are above or below the ACO's updated benchmark, to determine whether the ACO qualifies for a shared savings payment or is responsible for sharing losses with CMS (as applicable) (§§ 425.605(a) and 425.610(a)). In computing an ACO's historical benchmark, we determine the per capita Parts A and B FFS expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the ACO's agreement period, in accordance with § 425.652(a) and (c). In benchmark calculations, the assigned population is the basis for determining the ACO's regional service area used in calculating the two-way blend of national and regional growth rates applied in trending and updating the ACO's benchmark (§ 425.652(a)(5)(iv)–(v), and (b)(2)), and the regional adjustment to the benchmark (§ 425.656). The assigned population is also used in calculating a proration factor applied in the prior savings adjustment (§ 425.658(b)(3)), and in determining an ACO's eligibility for and the amount of the population adjustment to the historical benchmark (§ 425.662(b)). The average prospective HCC risk scores for the ACO's assigned beneficiaries are used to risk adjust the ACO's benchmark expenditures (§§ 425.652(a)(3) and (10); 425.605(a)(1); 425.610(a)(2)), and other benchmark calculations (see, for example, § 425.656(b)(3) and (4) on calculating the regional adjustment, and § 425.660(b)(4) on calculating the ACPT component of the three-way blended benchmark update factor). As another example, as described in section III.G.5.e of the CY 2027 PFS proposed rule, we proposed to risk adjust the 5 percent cap on upward adjustments to the benchmark, based on average CMS–HCC risk scores for the ACO's assigned beneficiary population. In addition, we used the size of the ACO's assigned population in other financial calculations, including: determining the MSR/MLR threshold based on the ACO's number of assigned beneficiaries (§§ 425.605(b)(2)(i)(C) and 425.610(b)(1)(iii)); determining the eligibility of a low revenue ACO participating in the BASIC track for an opportunity to share in savings even if it does not meet the MSR (§ 425.605(h)); and determining the applicability of an alternative performance payment limit or loss recoupment limit for an ACO with fewer than 5,000 assigned beneficiaries in any benchmark year (§§ 425.605(i) and 425.610(l)).

The size of the ACO's assigned population is the basis for our determinations related to participation requirements and payment methodologies. For instance, we evaluate whether an ACO meets the requirement to have at least 5,000 assigned beneficiaries to be eligible to participate in the Shared Savings Program (§§ 425.110 and 425.600(h)(3)). We also use the ACO's number of assigned beneficiaries in repayment mechanism amount calculations (§ 425.204(f)), and in determining expenditures based on the ACO's assigned population when identifying if the ACO is a high revenue or low revenue ACO (as defined under § 425.20) for purposes of determining an ACO's eligibility for the Advance Investment Payment option (§ 425.630(b)(4)).

The ACO's assigned population informs the amount of quarterly advance investment payments (§ 425.630(b) and (f)) and prepaid shared savings (§ 425.640(f) and (h)) for eligible ACOs. Elsewhere in this final rule we are amending the quarterly advance investment payment calculation methodology (section III.G.7.) and discontinuing availability of the option for prepaid shared savings (section III.G.6.b.).

The assigned population is central to other programmatic areas, including quality and financial extreme and uncontrollable circumstances policies (see § 425.512(c)(1)(i); see also §§ 425.605(f)(1) through (2) and 425.610(i)(1) through (2)), and CMS's provision of beneficiary-identifiable data and aggregate reports to ACOs under subpart H.

(d) Beneficiaries Excluded From the Assigned Population Under the Current Assignment Methodology Based on the Assignment Calculations and Medicare Enrollment Status

As previously noted in the background discussion in section III.G.2.a.(1) of this final rule, current policies exclude beneficiaries from assignment when, for example, a non-ACO TIN is determined to provide the plurality of a beneficiary's primary care services as a result of ACO professionals billing primary care services for the beneficiary inside and outside the ACO, or when we determine a beneficiary is ineligible for assignment based on Medicare enrollment status. Our estimates, based on simulations using PY 2024 data, suggest the former leads to approximately 97,800 beneficiary person years not being assigned to an ACO due to non-ACO TIN being identified as providing the plurality of the beneficiary's primary care services, and the latter leads to approximately 248,000 beneficiary person years not being assigned due only to their Medicare enrollment status.[264]

We sought approaches to expand the population of Medicare FFS beneficiaries for which ACOs are accountable for quality and cost of care. ACOs provide high-quality care to people with Medicare, and they are a critical tool to help Make America Healthy Again by supporting whole person care that addresses prevention, chronic illness and the root causes of disease, and achieving savings for the

[262] We refer readers to the CY 2024 PFS final rule (88 FR 79136 through 79163), in which we finalized use of an expanded window for assignment in both step 3 of the assignment methodology, and the definition of an assignable beneficiary, which we explained was necessary to maintain symmetry between the two approaches (see, for example, 88 FR 79158).

[263] We refer readers the CY 2023 PFS final rule (87 FR 69929 through 69932), in which we finalized modifications to our methodology for calculating county FFS expenditures to provide for the use of separate assignment windows for ACOs depending on their selected assignment methodology, to address and protect against bias in the calculations.

[264] Person years represents the sum of fractions of the year during which beneficiaries were enrolled in one of four Medicare enrollment types (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries). In section III.G.2.a.(2)(b) of this final rule, we describe in greater detail our consideration of Shared Savings Program-eligible months in identifying beneficiaries eligible for assignment.

Medicare Trust Funds.[265] As described in section III.G.1.a. of this final rule, as part of our effort to align spending and value in OM, we are focused on developing policies that would grow the number of Medicare FFS beneficiaries in accountable care relationships and grow savings to the Medicare Trust Funds.

Since PY 2024, we have seen the number of beneficiaries assigned to Shared Savings Program ACOs steadily increase.[266] As of January 1, 2024, 10.8 million beneficiaries were initially assigned to 480 ACOs. As of January 1, 2025, 11.2 million beneficiaries were initially assigned to 477 Shared Savings Program ACOs. As of January 1, 2026, Shared Savings Program ACOs are serving 12.6 million beneficiaries that were initially assigned to 511 ACOs, a 12.3 percent increase from 2025, and the largest number ever served by the Shared Savings Program.[267] However, the number of beneficiaries assigned to Shared Savings Program ACOs remains a fraction of the larger OM population. Based on an internal analysis, for PY 2024, about one-third (10.3 million) of the OM population (30.8 million) was assigned to an ACO participating under the Shared Savings Program.[268] [269]

As noted in the CY 2027 PFS proposed rule (91 FR 44024), our proposals to modify the Shared Savings Program assignment policies on plurality competition and assignment eligibility criteria based on Medicare enrollment status represent an opportunity to make meaningful steps toward achieving our stated goals around growing the number of Medicare FFS beneficiaries involved in accountable care relationships and also to further strengthen Shared Savings Program policies. Regarding the latter, as described further in section III.G.2.a.(2)(a) of this final rule, our proposed changes to assignment calculations would reduce the potential for ACO professionals' billing patterns inside and outside the ACO for the care of the same beneficiaries to result in differences in assignment outcomes that advantage the ACO's financial performance. As described in section III.G.2.a.(2)(b) of this final rule, our changes to the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status to align with the approach to identifying the assignable population would allow for greater symmetry between the ACO assigned population and the assignable population, and help ensure consistency between Shared Savings Program calculations used in determining ACO financial performance.

(2) Revisions

(a) Exclude From Assignment Calculations Allowed Charges for Primary Care Services Billed Through a Non-ACO TIN by an ACO Professional Used in Assignment

As described in section III.G.2.a.(1)(a)(ii) of this final rule, in claims-based assignment calculations for a beneficiary we consider allowed charges for primary care services furnished by an ACO professional billed through an ACO participant TIN (that is, inside the ACO), and allowed charges for primary care services furnished by the same ACO professional billed through a non-ACO TIN (that is, outside the ACO). Under current assignment policies, it is possible that a beneficiary may not be assigned to an ACO, despite choosing to receive care from the same physician or non-physician practitioner, only because of a difference in the TIN through which the services are being billed.

We proposed to amend the Shared Savings Program assignment methodology to address the circumstance under which ACO professionals used in assignment bill primary care services for a beneficiary through an ACO participant TIN and non-ACO TIN. More specifically, we proposed to remove from assignment calculations for purposes of plurality competition in step 1 under § 425.402(b)(3), step 2 under § 425.402(b)(4), and step 3 under § 425.402(b)(5)(iv), allowed charges for a beneficiary's primary care services billed through a non-ACO TIN by an ACO professional used in assignment if that beneficiary also had primary care services billed by an NPI under an ACO TIN.

This change will only impact the determination of assignment under the Shared Savings Program, and will not change how assigned beneficiary expenditures are calculated under the Shared Savings Program's financial methodology, for a benchmark year (in accordance with § 425.652(a)) or performance year (in accordance with §§ 425.605(a) and 425.610(a)). We noted in the CY 2027 PFS proposed rule (91 FR 44025), that under this proposal, assigned beneficiary expenditures for purposes of Shared Savings Program financial calculations would continue to include payment amounts for primary care services furnished to an assigned beneficiary billed through an ACO participant or non-ACO TIN, among other payment amounts.

We also noted in the CY 2027 PFS proposed rule (91 FR 44025) that under this approach, ACO professionals may continue to bill under several different TINs, such as ACO participants in multiple ACOs or both ACO participants and non-ACO providers and suppliers. This change will not impact an ACO professional's ability to receive FFS payment for primary care services billed through an ACO participant or non-ACO TIN.

We provided the following hypothetical examples to illustrate the outcome of plurality competition under the current approach and the revised approach. In these illustrations, for simplicity, we assumed the beneficiary meets the assignment eligibility criteria and therefore could be assigned to an ACO based on the outcome of plurality competition.

As one example, consider a beneficiary for which ACO professionals used in assignment billed primary care services through an ACO participant in ACO A and a non-ACO TIN, and the sum of allowed charges for this beneficiary for these services is greater for the billings through the non-ACO TIN than through the ACO. For instance, ACO professionals billed primary care services through an ACO participant in ACO A, resulting in allowed charges of $100 for each of three services, totaling $300. For this same beneficiary, ACO professionals in

[265] See CMS, Fact Sheet, ''2026 Medicare Accountable Care Organization Initiatives Participation Highlights'' (February 4, 2026), available at *https://www.cms.gov/newsroom/fact-sheets/2026-medicare-accountable-care-organization-initiatives-participation-highlights*.

[266] See ''Shared Savings Program Fast Facts—As of January 1, 2026'', available at *https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf* (specifying the count of beneficiaries initially assigned to ACOs for each performance year). Performance year specific ''Fast Facts'' are available through the Medicare Shared Savings Program website, Program Data web page at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/data*. See also the ''Fast Facts Archives'' (zip file), available at *https://www.cms.gov/files/zip/fast-facts-archives.zip*.

[267] CMS, Fact Sheet, ''2026 Medicare Accountable Care Organization Initiatives Participation Highlights'' (February 4, 2026), available at *https://www.cms.gov/newsroom/fact-sheets/2026-medicare-accountable-care-organization-initiatives-participation-highlights*.

[268] See, for example, Medicare Shared Savings Program, Performance Year Financial and Quality Results, Public Use File for PY 2024, available at *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results* (including a variable ''Total Assigned Beneficiaries'', specifying number of assigned beneficiaries for PY 2024, which summed across ACOs reconciled for PY 2024 totals 10,326,340).

[269] For purposes of this analysis, the total population of 30.8 million includes all beneficiaries with at least 1 month of Part A and Part B enrollment and no Medicare group (private) health plan enrollment (including MA) in that same month during the year.

ACO A also billed primary care services to a non-ACO TIN, resulting in allowed charges of $100 for each of four services, totaling $400. Under our existing policy, we would determine that the non-ACO TIN provided the plurality of the beneficiary's primary care services, because it provided the greatest amount of allowed charges for the beneficiary, and as a result the beneficiary would not be assigned to ACO A. Under this approach, we will exclude from plurality competition the allowed charges of $400 which the ACO professionals in ACO A billed through the non-ACO TIN. As a result, under this approach, ACO A will be determined to have provided the plurality of allowed charges for primary care services for the beneficiary, and we will assign the beneficiary to ACO A.

As a second example, consider a beneficiary for which ACO professionals used in assignment billed primary care services through ACO participants in two different ACOs (ACO A and ACO B), and a non-ACO TIN, and the sum of allowed charges for this beneficiary for these services is greater for the billings through the non-ACO TIN than through either ACO. For instance, ACO professionals billed primary care services for the beneficiary through an ACO participant in ACO A, resulting in allowed charges of $100 for each of three services, totaling $300. These ACO professionals also billed primary care services for the beneficiary through an ACO participant in ACO B, resulting in allowed charges of $100 for each of two services, totaling $200. These same ACO professionals billed primary care services for the beneficiary to a non-ACO TIN, resulting in allowed charges of $100 for each of four services, totaling $400. Under our existing policy, we would determine that the non-ACO TIN provided the plurality of the beneficiary's primary care services, and as a result the beneficiary would not be assigned to an ACO. Under this approach, we will exclude from plurality competition the allowed charges of $400 which the ACO professionals in ACO A and ACO B billed through the non-ACO TIN. As a result, we will decide the outcome of plurality competition between ACO A ($300 in allowed charges) and ACO B ($200 in allowed charges), and determine that ACO A provided the plurality of allowed charges for primary care services for the beneficiary, and we will assign the beneficiary to ACO A.

As a third example, consider a beneficiary for which an ACO professional used in assignment billed primary care services through an ACO participant in ACO A and a non-ACO TIN, and for which other healthcare providers unaffiliated with an ACO are also billing primary care services for the beneficiary through a non-ACO TIN, and the sum of allowed charges for this beneficiary for these services is greater for the billings through the non-ACO TIN than the ACO. For instance, an ACO professional billed primary care services through an ACO participant in ACO A, resulting in allowed charges of $100 for each of three services, totaling $300. For this same beneficiary, an ACO professional in ACO A also billed primary care services to a non-ACO TIN, resulting in allowed charges of $100 for one service. Additionally, allowed charges of $100 for each of five services, totaling $500, were billed through the non-ACO TIN by a primary care physician who is unaffiliated with any ACO. Under our existing policy, we would determine that the non-ACO TIN provided the plurality of allowed charges for primary care services for the beneficiary, and as a result the beneficiary would not be assigned to ACO A. Under this approach, we will exclude from plurality competition the allowed charges of $100 which the ACO professional billed through the non-ACO TIN. In this hypothetical example, the outcome of plurality competition would not change under the approach, as we will still determine that the non-ACO TIN provided the plurality of allowed charges for primary care services for the beneficiary, and the beneficiary will not be assigned to ACO A.

We noted in the CY 2027 PFS proposed rule that if an ACO professional bills under ACO participants in multiple ACOs, but not to a non-ACO TIN, we do not anticipate the change will impact the outcome of the plurality competition (compared to our current approach).

As illustrated in the examples previously described, this approach will reduce the likelihood that we will determine the beneficiary's plurality of allowed charges for primary care services to be attributed to a non-ACO TIN or non-ACO CCN and increase the likelihood that a beneficiary is assigned to an ACO. Based on our simulations of this approach described in section III.G.2.a.(2)(c) of this final rule, we observed that nearly all ACOs (462 of 476 ACOs or 97 percent) would experience a relatively small increase in their assigned population (less than 1 percent growth). We observed the remaining 3 percent of ACOs would experience growth in their assigned population ranging from 4 percent to 12 percent. We also observed that on average the beneficiaries added to assignment with this proposed change have higher cost and higher risk scores. This latter point highlights that the existing assignment methodology includes vulnerabilities that could lead ACOs, ACO participants or their ACO professionals to avoid at-risk beneficiaries (as defined in § 425.20). We explore related considerations in the discussion that follows.

Shared Savings Program policies include certain safeguards against ACO avoidance of at-risk beneficiaries. Specifically, section 1899(d)(3) of the Act, and related regulations under § 425.316(b), authorize us to monitor for ACO avoidance of at-risk beneficiaries. If we discover that an ACO has engaged in the avoidance of at-risk beneficiaries, we can impose remedial action or terminate the ACO, in accordance with § 425.316(b)(2).

There may be multiple possible pathways for an ACO to engage in strategic patient risk selection.[270] In recent years, we have engaged in monitoring to identify potential patient risk selection behavior by ACOs. Our monitoring and compliance processes for identifying and addressing ACO avoidance of at-risk beneficiaries can be resource intensive. We believe that the change to determining the outcome of plurality competition within the assignment methodology will allow for a more efficient solution to mitigate a mechanism for ACOs, ACO participants, or their ACO professionals to avoid accountability for the quality and cost of care for high-cost at-risk beneficiaries. A pattern of billing by ACO professionals used in assignment resulting in a population of relatively higher costs beneficiaries not being assigned to the ACO could provide a mechanism for the ACO to achieve lower PY expenditures as compared to its historical benchmark, thereby potentially increasing its savings or decreasing its losses. An ACO avoiding assignment of high-cost beneficiaries under the Shared Savings Program reduces the cost effectiveness of coordinated care and shared savings initiatives, limiting savings for the Trust Funds, and potentially limiting improvements in quality of care and outcomes that could result for the patient. We are concerned that the provisions addressing avoidance of at-risk beneficiaries under section 1899(d)(3) of the Act and § 425.316(b), entail an ACO-specific analysis which

[270] See, for example, McWilliams JM, et al. ''Savings or Selection? Initial Spending Reductions in the Medicare Shared Savings Program and Considerations for Reform.'' *Milbank Q.* 2020 Sep;98(3):847–907, available at *https://onlinelibrary.wiley.com/doi/10.1111/1468-0009.12468*.

may not serve as an adequate deterrent against the aforementioned concerns about ACO professionals billing patterns for the care of the same beneficiaries resulting in differences in assignment outcomes that advantage the ACO's financial performance. In comparison, the approach to modifying plurality competition would result in a program-wide change which will be implemented with each assignment run, which we believe will largely resolve our concerns.

We believe the proposal to exclude from assignment calculations allowed charges for primary care services furnished by an ACO professional used in assignment billed through a non-ACO TIN offers a tailored approach to reduce the potential for ACO professionals' billing patterns, inside and outside the ACO for care of the same beneficiaries, to result in differences in assignment outcomes that advantage the ACO's financial performance. We recognize that the approach can result in assignment of beneficiaries for which ACO professionals may be billing a greater amount of primary care services through non-ACO TINs, compared to ACO participant TINs. We recognize there can be appropriate billings by ACO professionals through multiple different TINs (inside and outside the ACO) for services furnished to a beneficiary, such as a result of the physician or non-physician practitioner working in more than one practice location, or reflective of multiple employment arrangements. Nonetheless, we believe it is appropriate to assign the beneficiary to an ACO under such circumstances. We believe that beneficiaries added to ACOs' assigned populations under the proposed changes in assignment would benefit from better care coordination and quality improvement activities through ACOs participating under Shared Savings Program requirements, and the proposed changes to assignment are estimated to result in higher net Federal savings (as described in section III.G.2.a.(2)(c) of this final rule). These potential benefits outweigh potential concerns that this approach minimizes our consideration of billing arrangements of ACO professionals through non-ACO TINs.

We acknowledge a possibility that ACOs, ACO participants, or their ACO professionals, and non-ACO TINs may have relied on the existing program policy to structure arrangements in which ACO professionals bill inside and outside the ACO for the care of the same beneficiary. However, we do not believe any such reliance interests outweigh our concerns about the potential for ACOs and other providers/suppliers to exploit a vulnerability with the existing Shared Savings Program assignment methodology, and the potential benefits for beneficiaries and the Trust Funds of the modifications to the plurality competition, as we describe elsewhere in section III.G.2.a. of this final rule.

We proposed to apply this revised approach to determining assignment for the PY starting on January 1, 2028, and subsequent PYs. We discuss the proposed timing of applicability further in section III.G.2.a.(2)(d) of this final rule, including use of the same assignment rules in determining beneficiary assignment for purposes of benchmark calculations as would apply in the PY.

We proposed to revise and republish § 425.402(b)(3), (b)(4), and (b)(5)(iv), with new provisions added to steps 1, 2, and 3 of the claims-based assignment methodology (respectively). As proposed, these provisions would continue to specify the existing approach to comparing allowed charges for primary care services furnished to a beneficiary by certain ACO professionals in an ACO with allowed charges for primary care services furnished by the same type of healthcare providers who are either (1) ACO professionals in any other ACO, or (2) not affiliated with any ACO and identified by a Medicare-enrolled billing TIN. We proposed to revise these paragraphs to add provisions, applicable for performance year 2028 and subsequent performance years, specifying how we identify and exclude from assignment allowed charges for primary care services billed by an ACO professional used in assignment under a Medicare-enrolled billing TIN unaffiliated with any ACO (for brevity referred to in the proposed regulation as a ''non-ACO TIN'') during the applicable assignment window. To follow is a summary of the amendments to § 425.402(b)(3), (b)(4), and (b)(5)(iv).

We proposed to revise § 425.402(b)(3), specifying assignment step 1 as follows:

- We proposed to specify the existing provisions of assignment step 1 under paragraph (b)(3) in new paragraph (b)(3)(i), and also redesignate existing paragraphs (b)(3)(i) and (ii) as paragraphs (b)(3)(i)(A) and (B) (respectively).
- Under new paragraph (b)(3)(ii), we proposed to specify that for performance year 2028 and subsequent performance years, if an ACO professional for which we identify a primary care service under § 425.402(b)(2) also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then we would exclude from consideration in assignment under proposed new § 425.402(b)(3)(i) the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable assignment window.

We proposed to revise § 425.402(b)(4), specifying *assignment* step 2 as follows:

- We proposed to specify the existing provisions of assignment step 2 under paragraph (b)(4) in new paragraph (b)(4)(i), and also redesignate existing paragraphs (b)(4)(i) and (ii) as paragraphs (b)(4)(i)(A) and (B) (respectively).
- Under new paragraph (b)(4)(ii), we proposed to specify that for performance year 2028 and subsequent performance years, if an ACO professional for which we identify a primary care service under § 425.402(b)(2) also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then we would exclude from consideration in assignment under proposed new § 425.402(b)(4)(i) the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable assignment window.

We proposed to revise § 425.402(b)(5)(iv), the provision of assignment step 3 in which we determine which ACO or non-ACO entity provided a beneficiary's plurality of allowed charges for primary care services, as follows:

- We proposed to specify the existing provisions of under paragraph (b)(5)(iv) in new paragraph (b)(5)(iv)(A), and also redesignate existing paragraphs (b)(5)(iv)(A) and (B) as paragraphs (b)(5)(iv)(A)(*1*) and (*2*) (respectively).
- Under new paragraph (b)(5)(iv)(B), we proposed to specify that for performance year 2028 and subsequent performance years, if an ACO professional for which we identify a primary care service under § 425.402(b)(5)(iii) also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then we would exclude from consideration in assignment under proposed new § 425.402(b)(5)(iv)(A) the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable expanded window for assignment.

As we have described in section III.G.2.a.(1) of this final rule, in determining claims-based assignment, we consider allowed charges for primary care services billed through physicians and non-physician practitioners, as well as FQHCs, RHCs, Method II CAHs, and ETA hospitals (as identified by CCN). The more general

language of the proposed new provisions of the regulations in § 425.402(b)(3), (b)(4), and (b)(5)(iv) describing exclusion from assignment calculations of allowed charges for primary care services billed by an ACO professional (physicians and non-physician practitioners) used in assignment through a non-ACO TIN is inclusive of primary care services billed through a non-ACO CCN enrolled under the non-ACO TIN. To the extent the ACO professional is billing primary care services through an ACO participant TIN and a non-ACO CCN, this approach will also exclude from plurality competition the allowed charges billed through the non-ACO CCN.

We sought comment on the proposed change to the step-wise assignment methodology under which we would exclude allowed charges for primary care services billed through a non-ACO TIN by an ACO professional used in assignment, and related proposed changes to the Shared Savings Program regulations at § 425.402(b)(3) (applicable to step 1), (b)(4) (applicable to step 2), and (b)(5)(iv) (applicable to step 3), as revised and republished. We sought comment on the proposal to apply this approach in determining Shared Savings Program assignment for the PY starting on January 1, 2028, and subsequent PYs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposed policy to exclude allowable charges to non-ACO TINs by ACO professionals. In addition to the general support received from these commenters, many commenters included specific reasons for their support.

A commenter stated that the proposal will help mitigate unwarranted shared saving payments that result from large changes between ACOs' historical benchmark population and performance year populations. A few commenters noted that the proposed policy could benefit the most vulnerable (highest risk and costliest) beneficiaries that may be excluded from ACO assignment. Many commenters supported the policy citing that it advances the goal of connecting more Medicare beneficiaries with coordinated, accountable care. Many commenters supported the policy because it would ensure that assignment reflects the relationship with the provider responsible for their care. A commenter supported the policy and shared their belief that it protects ACOs from assigning beneficiaries based on care they received at facilities where ACOs do not have oversight. A couple of commenters acknowledged that ACOs may influence assignment to their advantage through billing to unaffiliated TINs and additionally recommend CMS extend the policy by routinely auditing ACOs' participant lists, publishing the amount of participant turn-over, and evaluating savings using fixed provider lists while using the current assignment rules.

Response: We appreciate the comments in support of the proposal and the additional considerations they included. Many of the comments highlighted additional positive impacts that the policy may have on ACOs, providers, and beneficiaries, such as greater benefits for vulnerable populations, more accurate reflections of patient-provider relationships, and fewer unwarranted payments caused by changes between historical benchmark and performance year populations. These additional details provide further support and reasoning for implementing the policy change.

Comment: A few commenters opposed the proposed policy. A commenter opposed being held accountable for beneficiaries that receive care provided by non-ACO TINs, as these non-ACO TINs may not have incentives to control cost and quality of care. Another commenter opposed any policy that disrupts genuine patient-physician relationships and expressed that CMS should provide sufficient assignment data to ACOs to identify and correct unusual results. Another commenter did not support the goal of expanding the number of beneficiaries in ACOs, but did not specify any reasons for this opposition.

Response: We acknowledge the concerns with the proposed policy expressed in comments. CMS agrees with the concern that non-ACO TINs are less likely to control the cost and quality of care provided, however, the policy would only add beneficiaries to an ACO's assignment if the beneficiary also had primary care services billed under the ACO TIN. This proposed policy will work to address vulnerabilities within the current assignment methodology to ensure beneficiaries are not excluded from assignment due to avoidance, ultimately increasing the assigned population. CMS believes that in doing so, ACOs and their professionals that do have an incentive to control costs and quality will be held accountable for these beneficiaries.

With regard to the opposition to increasing the assigned population, we emphasize that the purpose of doing so through this policy is to provide a greater number of beneficiaries with access to the benefits of accountable care via the Shared Savings Program. For commenters concerned about disruption to genuine patient-physician relationships, we note that the policy does not prevent healthcare providers and patients from continuing existing relationships. Beneficiaries assigned to ACOs as a result of this policy would have received services from ACO professionals billing through their ACO TIN. Additionally, in regards for the request to provide sufficient assignment data to ACOs, we note that we will continue to provide ACOs with annual and quarterly reports, such as the Assignment List Report, Assignment Summary Report, and Beneficiary and Expenditure Utilization Report, and monthly Claim and Claim Line Feed Files that provide additional information related to each assigned beneficiary and the services they receive. We will also continue to monitor for opportunities to provide ACOs with additional assignment related data that can assist with better understanding of the relationships between providers and assigned beneficiaries. We believe the potential benefits of implementing the proposed policy on beneficiaries outweigh their concerns regarding adjustments to billing arrangements.

Comment: Some commenters expressed their support for finalizing the policy, but recommended CMS provide continued monitoring and supporting data on expected beneficiary growth and characteristics. Many other commenters urged CMS to conduct further analysis of the policy's impact on participating ACOs prior to finalizing despite supporting the policy's goals in concept. Many commenters requested additional analysis and monitoring due to specific concerns about a negative financial impact based on the type of ACO, geographic location, or patient population, such as rural ACOs, ACOs that serve populations with higher needs, or the circumstances unique to nursing facilities and patients. Specifically, regarding long-term care, a commenter was concerned about situations where billing under different TINs occurs for legitimate purposes, such as for long-stay versus short-say patients in nursing facilities. Another commenter urged CMS to evaluate the impact on long-stay nursing facility patients to ensure they are not being assigned to an ACO based on historical primary care charges that no longer represents the delivery of their care. Some commenters requested analyses prior to finalizing or a delay in the

policy until more impacts were understood.

Response: We appreciate comments with recommendations for further analysis to ensure the implementation of the proposed policy has the intended effect, without negatively impacting certain ACOs, providers, or beneficiary populations.

In updated simulations of PY 2025 data, we found similar results regarding the average number of added beneficiaries, and average impact on aggregate and per capita gross savings and losses as reported in the CY 2027 PFS proposed rule. Specifically, we found that most ACOs (304 of 472 or 64 percent) would experience a small increase in their assigned population (less than 1 percent growth). Additionally, we found that nearly all ACOs (459 of 472 or 97 percent) would experience a relatively small increase in their assigned population (less than 5 percent growth). We observed the remaining 3 percent of ACOs would experience growth in their assigned population ranging from 6 percent to 43 percent.

We also compared financial performance of ACOs by different types of ACO characteristics. In PY 2025 simulations comparing rural ACOs to non-rural ACOs, we found that rural ACOs experienced a $17 lower average per capita gross savings/losses (-4.69 percent), compared to non-rural ACOs that saw $24 lower average per capita gross savings/losses (-4.09 percent). In comparing ACOs with a higher versus lower proportion of beneficiaries with Long-Term Institutionalized (LTI) Status, we found that these ACOs with higher proportion of beneficiaries with LTI status experienced $31 lower average per capita gross savings/losses (-4.56 percent). ACOs with a lower proportion of beneficiaries with LTI Status experienced $21 lower average per capita gross savings/losses (-3.98 percent) as a result of the policy. We also compared financial performance for ACOs that had a higher average Hierarchical Condition Category (HCC) score among their beneficiaries. We found that these ACOs experienced $31 lower average per capita gross savings/losses (-3.71 percent), while ACOs with lower average HCC scores experienced $21 lower average per capita gross savings/losses (-4.42 percent). Although estimated impacts differed across these groups, differences between groups were relatively small and not statistically significant and therefore do not provide evidence that the policy would have different effects across the groups examined.

Given that we do not see statistically significant differences between the different types of ACOs and patient populations examined, and considering the policy's potential to provide safeguards against ACO avoidance of at-risk beneficiaries and the potential to increase beneficiaries assigned to ACOs improving beneficiary care coordination, CMS declines to delay implementation of this policy. CMS will continue to monitor the impact of the proposed policy on ACOs as additional performance data becomes available.

With respect to concerns about billing under multiple TINs for legitimate purposes, we note that the policy only impacts beneficiaries that are already seen at the ACO for primary care services. Therefore, it would only pull beneficiaries billed to the non-ACO TIN if they also had primary care services billed by an ACO professional to the ACO TIN. Similarly, with regards to impacts on long-stay nursing facility patients being assigned to an ACO based on historical primary care charges, we would not expect historical charges to have differing impacts under the existing assignment methodology compared to the proposed policy, and the proposed policy is intended to be incorporated throughout the window used for assignment.

Comment: Many commenters urged CMS to implement guardrails or protections to reduce the possibility of unintended negative consequences. Specifically, some commenters asked for guardrails to protect against negative impacts on gross savings/losses, especially for the small number of ACOs that would experience a larger impact from this policy. Others asked for guardrails to ensure established relationships are not disrupted where billing patterns may reflect legitimate arrangements or needs, such as in rural areas.

Response: We appreciate the concern for ACOs expressed in the comments, but we do not believe guardrails are needed at this time based on the relatively small impact observed in multiple performance years of our analysis which we believe would be outweighed by the potential benefits of this policy to strengthen safeguards against possible ACO avoidance of at-risk beneficiaries. Additionally, based on PY 2025 data we observed that most clinicians do not bill through multiple billing TINs/CCNs (81.9% of NPIs bill primary care services through a single TIN/CCN, and 87.5% of NPIs bill 95% or greater of the primary care services they provide through a single TIN/CCN).

Additionally, providers should continue to provide care for their patients as they normally would, and beneficiaries can continue to see the healthcare providers of their choice. This policy only impacts beneficiaries who receive healthcare from an ACO professional and also received care that was billed by the same ACO professional under a non-ACO TIN. Therefore, care relationships should not be disrupted. As reported previously, differential impacts on financial performance for rural ACOs or ACOs with a higher proportion of beneficiaries with high HCC scores were not statistically significant.

We will continue monitoring the impact of the proposed policy on ACOs for possible unintended consequences as additional performance data becomes available.

Comment: A commenter asked that CMS clarify the existing assignment methodology in which CMS excludes certain primary care services provided during short-term SNF stays (including when billed via FQHCs/RHCs) from the Shared Savings Program's beneficiary assignment calculation, preventing short-term SNF stays from skewing primary care assignment (42 CFR 425.400(c)(1)(v)–(ix)).

Another commenter shared concerns regarding the effect of expanded assignment on independent specialists whose patients are assigned to an ACO. Specifically, the commenter raised concerns that the proposed policy could pull beneficiaries into an ACO's cost and quality measures even when a meaningful part of their care comes from an independent specialist outside the ACO. The commenter noted that these specialists currently have limited ways to coordinate with the ACO or share in savings tied to that care and recommended that CMS establish additional methods to improve specialist integration into ACOs.

A commenter suggested that CMS should provide examples of how this policy might play out for providers with various billing structures, such as academic medical centers, hospital-based primary care, and multi-TIN organizations.

A commenter conducted their own simulation analyses of the policy and found differing results from what CMS outlined in the CY 2027 PFS proposed rule, and therefore asked CMS to clarify how they intend to implement the policy. Based on the commenter's results and comparison to CMS' simulated results in the CY 2027 PFS proposed rule, they suggested that CMS is proposing a broader approach to assignment than the commenter's initial interpretation of the proposal. Specifically, they believed CMS's

simulation results point to excluding a claim billed for any beneficiary to a non-ACO TIN by an ACO provider, even if the beneficiary did not also have care billed to an ACO TIN by the provider.

Response: We appreciate the concerns raised in comments about impacts on different providers and suppliers and the additional analyses that a commenter conducted.

While we recognize there could be a variety of reasons why healthcare provider organizations structure their use of billing TINs and CCNs, we note that the proposed policy would act to ensure beneficiaries are assigned to an ACO if the ACO professionals provide the plurality of the beneficiary's primary care services. The proposed change ensures if an ACO professional's services are billed to external TINs, the external TIN cannot pull otherwise eligible and assignable beneficiaries outside of the ACO. The impact from the proposed policy will primarily impact beneficiaries receiving primary care services from the same set of healthcare providers (NPIs) but through multiple billing TIN/CCNs, and where some of those TINs/CCNs are part of an ACO's participant list and others are not.

We appreciate the comment raised about the potential impact of these proposals on specialists not associated with ACOs. We wish to clarify that for beneficiaries that receive a plurality of their primary care from independent specialists outside of the ACO, the proposed policy would only pull such beneficiaries into the ACO if those independent specialists also bill for those beneficiaries through the ACO's participant TINs. Otherwise, if those independent specialists do *not* bill primary care services for those beneficiaries through the ACO, then no claims from those specialists are excluded during the plurality competition, and those beneficiaries would likely continue to have their care associated with the external specialist TIN and not be assigned to the ACO. Additionally, many ACOs have found methods to efficiently incorporate specialists into their ACO operations which have led to improvements in quality of care and cost reductions, and the proposed policy should not impact the existing methods of ACO specialist integration. However, we also recognize there are opportunities to improve how specialists are incorporated into ACOs, and we will be reviewing the comments we received related to the Request for Information (RFI) for Specialty Care in the Shared Savings Program that was included in the CY 2027 PFS proposed rule.

We appreciate the commenter that conducted their own simulation analysis of the policy, however we believe this commenter may misunderstand how the policy will be implemented. They described their belief that CMS's policy would exclude a claim billed for any beneficiary to a non-ACO TIN by an ACO provider, even if the beneficiary did not also have care billed to an ACO TIN by the provider. This does not accurately reflect the policy, as CMS would only exclude allowed charges for primary care services provided by NPI's billing through non-ACO TINs when those beneficiaries also had primary care services billed by an NPI within an ACO TIN.

With respect to the request for clarification surrounding assignment methodology as it relates to short-stay SNFs, it is not within scope of the current proposed policy. We refer readers to additional information related to the Assignment Methodology and related CPT code exclusions related to SNF stays in Section 2 and Appendix C of the Medicare Shared Savings Program Shared Savings and Losses, and Assignment and Quality Performance Standard Methodology Specifications Version 14.[271]

Comment: A commenter supported the proposal but expressed concern that even with this policy, claims-based assignment would not go far enough to engage enough beneficiaries in accountable care, and that beneficiaries should have an accessible way to choose the provider that they wish to coordinate their care. Additionally, a couple of commenters pointed to the need to improve and expand voluntary alignment and a commenter raised concerns that the voluntary alignment process is challenging to navigate for beneficiaries and suggested CMS provide ACOs the ability to align beneficiaries by paper as an addition to the current electronic voluntary alignment process. These comments did not specifically relate to this proposed policy, but rather more broadly to the assignment methodology.

Response: We appreciate the recommendation made in comments, however this is beyond the scope of the current proposal. We note that beneficiaries are currently able to proactively designate a primary clinician or practice as their main source of care and voluntarily align to an ACO. We are currently researching additional ways CMS can support beneficiary education and enhance the accessibility of voluntary alignment.

After consideration of public comments, we are finalizing our proposal to amend the Shared Savings Program assignment methodology to address the circumstance under which ACO professionals used in assignment bill primary care services for a beneficiary through an ACO participant TIN and non-ACO TIN, and to revise and republish § 425.402(b)(3), (b)(4), and (b)(5)(iv), with new provisions added to steps 1, 2, and 3 of the claims-based assignment methodology (respectively) as proposed.

(b) Modify Assignment Eligibility Criteria and Prospective Assignment Exclusion Criteria Based on Medicare Enrollment Status

In this section, we provide additional background on the development of the Shared Savings Program's assignment eligibility criteria and prospective assignment exclusion criteria; revisit key considerations informing the development of our existing policies, and discuss factors informing our proposal to modify these policies; and describe our proposal to modify the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status.

As we explained in the December 2014 proposed rule (79 FR 72790 through 72791) and June 2015 final rule (80 FR 32743 through 32744), the assignment eligibility criteria we proposed and finalized were consistent with criteria we established to operationalize the Shared Savings Program's assignment methodology finalized with the November 2011 final rule. We referenced a detailed specifications document, which included information regarding the beneficiary assignment process, that we made available to the public on the CMS website.[272] [273]

[271] Please see *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0.*

[272] Between May 2012 and December 2014, CMS issued and updated the initial versions of the Shared Savings Program's ''Shared Savings and Losses and Assignment Methodology Specifications'', which included specifications for beneficiary assignment and the shared savings and losses calculations under the program. The specifications, and the CMS webpage where the document has been posted, have been updated over time. The earlier versions of the document are maintained in the ACO Management System (ACO–MS) Knowledge Library (accessible to ACOs) at *https://acoms.cms.gov/knowledge-management/view/8320.* The ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' documents for current years are available on ''Program Guidance & Specifications'' webpage of the Shared Savings Program's website at *https://www.cms.gov/*

In the December 2014 proposed rule (79 FR 72791), we explained that to determine whether a beneficiary is eligible to be assigned to an ACO, we must have information about the beneficiary's Medicare enrollment status. We explained that as required by section 1899(h)(3) of the Act, and consistent with the definition of Medicare FFS beneficiary in § 425.20, only beneficiaries enrolled in traditional Medicare FFS under Parts A and B are eligible to be assigned to an ACO participating in the Shared Savings Program. In the December 2014 proposed rule (79 FR 72791), we proposed that beneficiaries who have coverage under only one of these parts (Part A or Part B) would not be eligible to be assigned to an ACO, because of the statutory definition for Medicare FFS beneficiary and because an important objective of the Shared Savings Program is to help align incentives between Part A and Part B.

Further, in the December 2014 proposed rule (79 FR 72791), we explained that beneficiaries enrolled in a group health plan including beneficiaries enrolled in MA plans under Part C, eligible organizations under section 1876 of the Act, and Programs of All-Inclusive Care for the Elderly (PACE) under section 1894 of the Act are also not eligible to be assigned. In the June 2015 final rule (80 FR 32745), we summarized and responded to comments suggesting that the criterion that a beneficiary not have any months of Medicare group (private) health plan enrollment during the assignment window be revised to not more than 3 to 6 months, to account for certain situations where beneficiaries, such as dual eligible beneficiaries, might change, enroll in or disenroll from plans more frequently. The comments explained that this would allow such beneficiaries to remain attributed to the ACO. In our response we explained that section 1899(c) of the Act requires the Secretary to determine an appropriate method to assign Medicare FFS beneficiaries to an ACO. We then explained that as required by section 1899(c) of the Act, and consistent with the definition of Medicare FFS beneficiary under section 1899(h)(3) of the Act and § 425.20 of the Shared Savings Program regulations, our policy provided that only beneficiaries enrolled in traditional Medicare FFS under Parts A and B are eligible to be assigned to an ACO participating in the Shared Savings Program. We explained our belief that such policy was consistent with these requirements because under such approach only beneficiaries enrolled in traditional Medicare FFS under Parts A and B ''throughout the full performance year'' would be eligible to be assigned to an ACO. At the time, we declined to revise our policy in response to the commenters' concerns, but specified our plan to consider this issue further, and potentially address the issue in future rulemaking. We have not revisited these topics in subsequent rulemaking.

We have continued to consider our approach to determining the eligibility of Medicare FFS beneficiaries for assignment. In considering whether to propose revising our approach, we revisited key considerations informing the development of these policies.

The first consideration informing the development of our eligibility criteria was consistency with the definition of a Medicare FFS beneficiary under section 1899(h)(3) of the Act. While we maintain that our existing policies for determining eligibility for assignment are consistent with such definition, we acknowledge that these eligibility criteria potentially operate to exclude from eligibility for assignment beneficiaries that may satisfy this definition.

Section 1899(h)(3) of the Act defines a ''Medicare fee-for-service beneficiary'' as an individual who is enrolled in the original Medicare FFS program under Parts A and B and is not enrolled in an MA plan under Part C, an eligible organization under section 1876 of the Act, or a PACE program under section 1894 of the Act. In the prior rulemaking discussed previously in this section, we adopted restrictive eligibility criteria under the assignment methodology we established under section 1899(c) of the Act. Under this approach, a beneficiary is eligible for assignment only if, during the 12-month assignment window (as defined under § 425.20, and described in section III.G.2.a.(1) of this final rule), the beneficiary has at least 1 month of Part A and Part B enrollment, but no month of Part A only or Part B only enrollment, and no month of Medicare group health plan enrollment. The requirements excluding from eligibility for assignment Medicare FFS beneficiaries that have a month of Part A only or Part B only enrollment, or Medicare group health plan enrollment during the assignment window are consistent with, but not required by, section 1899(h)(3) of the Act. In our response to comments included in the June 2015 final rule (80 FR 32745), we did not disagree that it could be permissible under section 1899(h)(3) of the Act for beneficiaries with some months of Medicare group health plan enrollment to be eligible for assignment by noting our intention to potentially address this issue in future rulemaking. Moreover, in earlier rulemaking, we did not specify that the more restrictive view we took towards identifying beneficiaries eligible to be assigned based on Medicare enrollment status was the only possible approach to operationalizing identification of a Medicare FFS beneficiary under the definition of section 1899(h)(3) of the Act for assignment under section 1899(c) of the Act.

The second consideration was that an objective of the Shared Savings Program is to help align incentives between Part A and Part B. The Shared Savings Program's financial methodology similarly reflects the alignment of Part A and Part B incentives and the composition of the ACO's assigned population, in that we only consider expenditures for months during which the beneficiary was enrolled under both Parts A and B [274] in determining benchmark year and performance year expenditures. We acknowledge that the existing assignment eligibility criteria based on Medicare enrollment status, in which we require a beneficiary to have at least 1 month of Part A and Part B enrollment, but no month of Part A only or Part B only enrollment, and no month of Medicare group health plan enrollment during the assignment window, is not the only way to further the objective to align incentives between Parts A and B. For instance, this alignment will be achieved under an approach that allows for beneficiaries to be eligible for assignment if they have at least 1 month of Part A and B enrollment during the assignment

medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations.

[273] The Physician Group Practice (PGP) demonstration, authorized under section 1866A of the Act, was implemented by CMS from April 2005 through March 2010, and served as a model for many aspects of the Shared Savings Program (see, for example, 76 FR 67833). Although not expressly stated in earlier rulemaking, the assignment eligibility criteria initially established under the Shared Savings Program closely tracked the parameters for the assignment methodology under the PGP demonstration. See for example, Kautter, J. et al. (RTI International), ''Physician Group Practice Demonstration Bonus Methodology Specifications'' (December 20, 2004), available at *https://www.cms.gov/priorities/innovation/files/x/pgp-payment.pdf* (Section 3.1 Assignment Criteria, pages 9–10).

[274] For a description of how CMS annualizes the assigned beneficiary's expenditures, refer to Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (Section 3.1.2 Annualizing Assigned Beneficiary Expenditures).

window in combination with the existing approach to determining the beneficiary's expenditures for the same month(s) the beneficiary was enrolled in Part A and B.

Based on this reconsideration and to increase the number of Medicare FFS beneficiaries in accountable care relationships, we proposed to expand the criteria for assignment eligibility to permit assignment of a Medicare FFS beneficiary with at least 1 month of Part A and Part B enrollment during the assignment window and no Medicare group health plan enrollment during that same month. We believe this approach will retain consistency with section 1899(h)(3) of the Act and further the Shared Savings Program's stated objective of aligning incentives between Part A and Part B. This modification to the assignment eligibility criteria and prospective assignment exclusion criteria will incrementally increase the assigned population and be aligned with our goal of growing the number of Medicare FFS beneficiaries involved in accountable care relationships (described in section III.G.2.a.(1)(d) of this final rule). Additionally, as we address in the following discussion, this approach to identifying beneficiaries eligible for assignment based on Medicare enrollment status will align with our use of Shared Savings Program-eligible months in identifying beneficiaries eligible for assignment and calculation of assigned beneficiary expenditures using months of Part A and B enrollment, and bring greater symmetry to program calculations based on the assigned and assignable populations.

In determining assignment, we identify a beneficiary's Shared Savings Program-eligible months, in which the beneficiary is alive on the first of the month, enrolled in both Parts A and B, and not enrolled in a Medicare group health plan.[275] This results in assignment of beneficiaries with between 1 and 12 months of Parts A and B enrollment, so long as the remaining criteria under § 425.401(a) are met. There are various reasons for beneficiaries currently eligible for assignment to have fewer than 12 months of Parts A and B enrollment, including the timing of when the beneficiary becomes eligible for Medicare, and if a beneficiary dies during the period. We also use Shared Savings Program-eligible months for assigned beneficiaries in other Shared Savings Program operations, including to assign a monthly enrollment status to the beneficiary according to four Medicare enrollment types (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) and to calculate beneficiary person years.[276] [277] The approach to identifying beneficiaries as eligible for assignment if they have at least 1 month of Part A and Part B enrollment and no Medicare group health plan enrollment during that same month during the assignment window, will effectively expand the population of assigned beneficiaries who have fewer than 12 months of Parts A and B enrollment.

Under our existing approach we determine, based on the point in time assignment is run, whether a beneficiary meets the assignment eligibility criteria or must be excluded from the assigned population based on the criteria specified under § 425.401. In doing so we consider the beneficiary's eligibility throughout the applicable assignment window for the assignment run, using the relevant data available on Medicare enrollment status, overlap in assignment with other Medicare shared savings initiatives, and other factors.[278] We will maintain this approach, based on the point in time assignment is run, in implementing the revised assignment eligibility criteria and prospective assignment exclusion criteria.

We also noted in the CY 2027 PFS proposed rule that for beneficiaries assigned under the eligibility criteria based on Medicare enrollment status, we would apply the existing approach to determine expenditures used in benchmark year and performance year expenditure calculations in which we only consider expenditures for months during which the beneficiary was enrolled under both Parts A and B. That is, we would not consider expenditures for months in which the beneficiary was enrolled under Part A only or Part B only. We also noted in the CY 2027 PFS proposed rule that the Shared Savings Program financial calculations do not consider Part C claims data. We believe this modified approach would remain consistent with the program's objective to hold ACOs accountable for the total cost of the beneficiary's care as based in Parts A and B expenditures.

As described in section III.G.2.a.(1)(b) of this final rule, the assignable beneficiary population (as defined in § 425.20) is a subset of the larger population of Medicare FFS beneficiaries, as defined under section 1899(h)(3) of the Act and § 425.20. Operationally, this population includes beneficiaries that have at least 1 month of Part A and Part B enrollment and no Medicare group health plan enrollment during that same month during the applicable 12-month assignment window. This approach to identifying Medicare FFS beneficiaries who meet the criteria for inclusion in the assignable population is less restrictive compared to the existing assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status. Applying a similar approach to identifying Medicare FFS beneficiaries eligible for assignment could bring greater symmetry to the composition of the assignable beneficiary population and the assigned population and thereby allow for more comparable calculations between factors based on assignable beneficiary expenditures used in establishing, adjusting and updating the ACO's historical benchmark and factors based on the ACO's assigned population (including benchmark year and performance year expenditures).

As described in the Regulatory Impact Analysis, in section VI of this final rule, as enrollment in MA has grown over recent years,[279] so has the number of beneficiaries switching back to OM from MA.[280] Our current eligibility criteria

[275] In the June 2015 final rule (80 FR 32745), we specified that only beneficiaries enrolled in traditional Medicare FFS under Parts A and B ''throughout the full performance year'' are eligible to be assigned to an ACO. However, this statement from earlier rulemaking does not always accurately reflect the Shared Savings Program's assignment operations in which we allow for an eligible beneficiary who has fewer than 12 months of enrollment in Parts A and B to be assigned to an ACO.

[276] To calculate person years: We sum the number of Shared Savings Program-eligible months for each assigned beneficiary for each Medicare enrollment type; we then divide this number by 12 (the number of months in a calendar year).

[277] See Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (Section 3.1. Calculating ACO-Assigned Beneficiary Expenditures).

[278] The Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), includes among other information, selected characteristics of Shared Savings Program ACO reports for ACOs under preliminary prospective assignment with retrospective reconciliation and for ACOs under prospective assignment (see Appendix F, Tables 14 and 15.)

[279] See, for example, *Data.CMS.gov*, Medicare Enrollment Dashboard, Medicare Enrollment for March 2026, available at *https://data.cms.gov/tools/medicare-enrollment-dashboard* (showing yearly trend data for MA, FFS, and Total, from 2013 through 2025).

[280] See Xu L, et al. ''Medicare Switching: Patterns Of Enrollment Growth In Medicare Advantage, 2006–22''. *Health Affairs* (September 5, 2023), available at *https://doi.org/10.1377/*

based on Medicare enrollment status restricts and delays the eligibility of such beneficiaries for assignment to ACOs. Allowing beneficiaries with at least one month of Part A and Part B enrollment and no Medicare group health plan enrollment during that same month during the assignment window to be eligible for assignment would allow us to more accurately account for when this population qualifies as Medicare FFS beneficiaries and, in turn, is included in ACO assignment, and encompass various circumstances around the timing of a beneficiary's enrollment in Medicare and changes in enrollment that result in a beneficiary having one or more months of Part A only or Part B only enrollment, or Medicare group health plan enrollment.[281] We also note that the population of beneficiaries transitioning between MA and OM are captured in the assignable beneficiary population. In this respect, the approach to align the assignment eligibility criteria and prospective assignment exclusion criteria with the approach we use to identify the assignable beneficiary population based on Medicare enrollment status serves an important purpose in resolving the asymmetry between the assigned and assignable populations which has grown over time in light of changes to Medicare enrollment trends.

ACOs may rely on programmatic data included in program reports and data files we deliver to ACOs (described in section III.G.2.a.(2)(d) of this final rule) to understand their assigned population, and the reason for beneficiaries' ineligibility for assignment, among other factors. Additionally, ACOs may be accustomed to coordinating care, reporting quality measures, and considering approaches to lowering growth in expenditures for Medicare beneficiaries eligible for assignment, which presently includes beneficiaries with at least 1 month of Part A and Part B enrollment, but no month of Part A only or Part B only enrollment, and no month of Medicare group health plan enrollment during the assignment. As described in section III.G.2.a.(2)(d) of this final rule, we anticipate updating the Shared Savings Program's publicly available specification documents, programmatic resources, and program reports to include information that would help ACOs understand their assigned population and the population of beneficiaries eligible to be assigned under the revised assignment methodology. Although we recognize it may take ACOs time to update their data systems and models for analysis of Shared Savings Program data, we do not believe this potential concern outweighs the reasons for proposing this change described elsewhere in section III.G.2.a of this final rule. We noted in the CY 2027 PFS proposed rule that the proposal to apply the changes to the beneficiary assignment methodology for the PY starting on January 1, 2028, and subsequent PYs, provides time for ACOs to prepare for any related changes.

We proposed to revise the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status under § 425.401, and to apply the revised criteria in determining assignment for the PY starting on January 1, 2028, and subsequent PYs. We discuss the timing of applicability further in section III.G.2.a.(2)(d) of this final rule, including use of the same assignment rules in determining beneficiary assignment for purposes of benchmark calculations as would apply in the PY. The following is a description of the criteria for a beneficiary to be assigned to an ACO for a PY or benchmark year which would apply for the PY starting on January 1, 2028, and subsequent PYs. Later in this section of this final rule, we detail our proposal to revise and republish § 425.401, including to incorporate the following new provisions.

Under new § 425.401(a)(2), we proposed to specify the beneficiary assignment eligibility criteria applicable for the PY starting on January 1, 2028, and subsequent PYs. Accordingly, we proposed a beneficiary may be assigned to an ACO under the assignment methodology in §§ 425.402 and 425.404, for a performance or benchmark year, if the beneficiary meets all of the following criteria during the assignment window:

- Has at least 1 month of Part A and Part B enrollment and does not have Medicare group (private) health plan enrollment during that same month during the assignment window.
- Is not assigned to any other Medicare shared savings initiative.
- Lives in the U.S. or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

We noted in the CY 2027 PFS proposed rule that under the proposed approach to revising the assignment eligibility criteria based on Medicare enrollment status, we would continue to apply the existing criteria which ensure that a beneficiary is not assigned to any other Medicare shared savings initiative (consistent with § 425.401(a)(3)), and lives in the U.S. or U.S. territories and possessions (consistent with § 425.401(a)(4)).

Under new § 425.401(b)(2), we proposed to specify the prospective assignment exclusion criteria applicable for the PY starting on January 1, 2028, and subsequent PYs. Accordingly, we proposed a beneficiary would be excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each PY consistent with § 425.400(a)(3)(ii) if the beneficiary meets any of the following criteria during the performance or benchmark year: [282]

- Does not have at least 1 month of Part A and Part B enrollment without Medicare group (private) health plan enrollment during that same month during the assignment window.
- Did not live in the U.S. or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residency at the end of the year.

We noted in the CY 2027 PFS proposed rule that under the proposed approach to revising the prospective assignment exclusion criteria, we would continue to apply the existing criterion to exclude from prospective assignment a beneficiary that did not live in the

hlthaff.2023.00224 (finding only slightly increasing number of switchers from MA to OM over 2020 to 2023 compared to earlier years, and includes Exhibit 3 indicating higher rates of switching from MA to FFS for disabled beneficiaries, full dual eligible beneficiaries, and beneficiaries with >3 HCC diagnostic codes in 2022). See also, Mackleby G, Liu A, and Trish E. ''Switching Medicare Plans Outside Open Enrollment Was Increasingly Common, Especially Among Sicker Enrollees, 2015–22''. *Health Affairs* (February 2, 2026), available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2025.00915* (among MA enrollees, finding compared with Medicare open enrollment period switchers, alternative enrollment period switchers tended to have higher risk scores and hospitalization rates before switching).

[281] We note that there are a multitude of factors impacting the timing for when a beneficiary enrolls in OM or a MA plan, and the timing of when a beneficiary may change to a different MA plan or switch back to OM. Information on initial enrollment in OM and timing for when a beneficiary can join, switch, drop or make changes in their MA plan, is included in the Medicare & You Handbook (2026), available at *https://www.medicare.gov/publications/10050-medicare-and-you.pdf.*

[282] We omitted from this description the reference to applicability of the prospective assignment exclusion criteria for determining assignment to ACOs participating under a 6-month PY or performance period during CY 2019, under § 425.609(b)(1)(ii) and (c)(1)(ii) which is otherwise retained for completeness in the introductory text of § 425.401(b) (under the proposed amendments).

U.S. or U.S. territories and possessions (consistent with § 425.401(b)(3)).

More generally, we note that the assignment eligibility criteria and prospective assignment exclusion criteria under § 425.401 apply in determining beneficiaries assigned under claims-based assignment and voluntary alignment. We anticipate the proposed changes in criteria based on Medicare enrollment status would increase the population assigned under both methods.

We proposed to revise and republish § 425.401, to specify the existing criteria for a beneficiary to be assigned to an ACO for a performance or benchmark year apply to PYs starting prior to January 1, 2028 (as applicable), and to specify the proposed criteria applicable for the performance year starting on January 1, 2028, and subsequent performance years. The following list summarizes the proposed amendments to § 425.401:

- We proposed to add subject headings to the introductory text of paragraphs (a) and (b) of § 425.401 to specify the following: paragraph (a) includes provisions with ''Assignment eligibility criteria''; and paragraph (b) includes provisions with ''Prospective assignment exclusion criteria''.
- We proposed to revise § 425.401(a)(1) to specify the provisions with assignment eligibility criteria applicable for PYs starting prior to January 1, 2028 (as applicable), by making the following amendments:

++ Redesignating paragraphs (a)(1)(i) and (ii) as paragraphs (a)(1)(i)(A) and (B) (respectively), and redesignating paragraphs (a)(2) through (a)(4) as paragraphs (a)(1)(ii) through (a)(1)(iv) (respectively).

++ Adding the following heading to introductory text of paragraph (a)(1), specifying the timing of applicability for the provisions: ''For performance years starting prior to January 1, 2028 (as applicable)''.

- We proposed to add new paragraph (a)(2) with the assignment eligibility criteria applicable for the performance year starting on January 1, 2028, and subsequent performance years (previously described in this section of this final rule).
- We proposed to revise § 425.401(b)(1) to specify the provisions with prospective assignment exclusion criteria applicable for performance years starting prior to January 1, 2028 (as applicable), by making the following amendments:

++ Redesignating paragraphs (b)(1)(i) and (ii) as paragraphs (b)(1)(i)(A) and (B) (respectively), and redesignating paragraphs (b)(2) and (b)(3) as paragraphs (b)(1)(ii) and (b)(1)(iii) (respectively).

++ Adding the following heading to introductory text of paragraph (b)(1), specifying the timing of applicability for the provisions: ''For performance years starting prior to January 1, 2028 (as applicable)''.

- We proposed to add new paragraph (b)(2) with the prospective assignment exclusion criteria applicable for the PY starting on January 1, 2028, and subsequent PYs (previously described in this section of this final rule).

We also proposed a technical and conforming change to cross-references to provisions of § 425.401 within § 425.612(a)(1)(iv)(A)(*2*), which describes certain conditions under which we make payments for SNF services furnished to a beneficiary preliminarily prospectively assigned to an ACO for which a waiver of the SNF 3-day rule was approved.

We sought comment on the proposed changes under which we would apply modified assignment eligibility criteria and prospective assignment exclusion criteria based on a beneficiary's Medicare enrollment status in determining assignment to an ACO for the performance year starting on January 1, 2028, and subsequent PYs. Under the proposed approach more beneficiaries would be eligible for assignment, and remain prospectively assigned to ACOs, under both claims-based assignment and voluntary alignment, than under current program policies. We sought comment on the proposed amendments to § 425.401 (as revised and republished), specifying the assignment eligibility criteria and prospective assignment exclusion criteria that would apply by PY, and the proposed technical and conforming change to cross-references to provisions of § 425.401 within § 425.612(a)(1)(iv)(A)(2).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed general support for the proposed change to assignment eligibility criteria. Many other supporting commenters cited the policy as a means of growing the Shared Savings Program and increasing beneficiaries in accountable care relationships.

A couple of commenters supported the policy emphasizing the importance of ensuring assignment policy accurately reflects beneficiaries that ACOs can manage. Another commenter stated that the proposed changes will contribute towards improved management and quality of care their ACO provides and emphasizes the importance of ensuring the Shared Savings Program beneficiaries are aligned with providers that meet the program goals. Another commenter expressed support, stating that improved consistency and clarity in beneficiary assignment standards will be especially helpful for organizations in long-term value-based payment arrangements.

A couple of commenters expressed their support of the policy and recommended that CMS provide supporting data regarding the expected impacts on assignment growth and beneficiary characteristics.

Response: We appreciate comments in support of the proposed policy, which is intended to increase the Shared Savings Program assigned beneficiary population and improve symmetry between the definitions of the assigned and assignable populations. We appreciate that these comments recognize and support this intent, while also highlighting other potential beneficial impacts of the policy (for example, improving quality of care provided by ACOs, and consistency in assignment standards).

Comment: We received several comments expressing opposition to the proposed assignment methodology. A commenter stated that ACO clinicians should not be required to assume the care, cost, and risk for patients who delay care until they are covered by Medicare. Another commenter does not support the goal of expanding the number of beneficiaries in ACOs.

Many comments expressed conceptual agreement with the policy and CMS' goals but cited various concerns. For example, a commenter warned that the policy could result in fewer beneficiaries in the Shared Savings Program if fewer ACOs decide to participate. Several commenters warned of an influx of hospice patients who transition to Traditional Medicare once they need the hospice benefit. A commenter expressed concern that ACOs do not have time to reach out to beneficiaries or engage them properly in care when they transition to Traditional Medicare mid-year. A commenter urged CMS to assess the impact of the interaction between this policy and recent changes to the enrollment pathways for dually-eligible special needs plans (D–SNPs), due to significant risk of beneficiaries transitioning in and out of Medicare Advantage while remaining assigned to an ACO. A commenter asked CMS to monitor the impact on beneficiaries in long-term care (LTC) who transition between FFS

Medicare and Medicare Advantage for any instability in their assignment population and to ensure that ACO and LTC providers have up-to-date information on these beneficiaries. Some commenters recommended that CMS implement guardrails to mitigate unintended negative consequences and adverse impacts on gross savings/losses, particularly for the small number of ACOs expected to experience larger impacts and those that serve populations with higher cost and higher risk.

Response: We appreciate concerns raised in comments about decreased ACO participation in the Shared Savings Program. We acknowledge the commenter's suggestion that it is possible that a small decrease in the number of participating ACOs could occur, however, as a result of this policy we expect the overall number of assigned beneficiaries to increase, which is expected to increase savings and aligns with program goals, see discussion of program impacts in the Regulatory Impact Analysis in section VI.8.(a) of this final rule. CMS feels that this outweighs the possibility of fewer ACOs participating in the Shared Savings Program. We appreciate the comments concerning being held accountable for beneficiaries who are newly transitioning from Medicare Advantage and the potential complications, including, an influx of patients receiving hospice care, ACOs not having time to engage new beneficiaries in care, and changes to the dually-eligible special needs plans enrollment pathways. With respect to commenters' concerns about an increase in hospice beneficiaries or other special populations with high costs of care, the policy is intended to bring greater symmetry to program calculations between the assigned and assignable populations. This will allow for better comparison between factors based on assignable beneficiary expenditures. In other words, the assignable population already allows for beneficiaries who transition from Medicare Advantage mid-year and includes beneficiaries who joined Traditional Medicare in order to choose Medicare's hospice benefit or for other similar reasons. Therefore, any increases that ACOs see in assigned beneficiary populations under the proposed policy would align with populations already included in the assignable population, which would serve to improve symmetry in comparing expenditures to benchmarks. Additionally, the policy would be implemented in the same manner between benchmark and performance years, making changes as a result of the policy comparable. CMS believes that by improving alignment in the methodology used to determine the ACO-assigned and assignable populations, and symmetry in application of the policy in benchmark and performance years, ACOs will be fairly held accountable for care and expenditures that they have previously not been subject to. Financial impacts to ACOs are expected to be relatively modest, with average change in aggregate gross savings/losses of less than 1% based on PY 2025 simulations.

A similar line of reasoning applies to concerns about having time to reach out to beneficiaries newly transitioned from Medicare Advantage. The policy only brings in beneficiaries who would already be eligible for the assignable population and allows them to enter the assigned population, and some ACOs may already be aware of providing care for these beneficiaries before being assigned. Additionally, ACOs often have beneficiaries assigned to their ACO late in the performance year, and this policy likely only marginally increases this already existing circumstance.

In simulations of the policy using PY 2025 data, we found that ACOs with a higher proportion of beneficiaries with LTI status experienced $11 lower average per capita gross savings/losses (-1.82 percent). ACOs with a lower proportion of beneficiaries with LTI Status that saw $15 lower average per capita gross savings/losses (-3.17 percent) as a result of the policy.

In simulations using PY 2025 data, ACOs with a higher proportion of beneficiaries with hospice status saw a $5 lower average per capita gross savings/losses (−1.05 percent) as an impact of the policy, while other ACOs had $17 lower average per capita gross savings/losses (−3.37 percent). Hospice status was determined by whether a beneficiary began hospice coverage during the benchmark or performance year.

Although estimated impacts of the policy differed across ACOs by proportions of beneficiaries with LTI status or with hospice status, these differences were not statistically significant and therefore do not provide evidence that the policy would have different effects across the groups examined.

With regard to the request that CMS implement guardrails to mitigate unintended negative consequences, while we appreciate the comments concerning the disproportionate impacts on ACOs that serve beneficiaries with higher risk, we believe this would add unnecessary additional complexity relative to the impacts and benefits from the proposed policy. In simulations of PY 2025 data, we compared ACOs whose assigned beneficiaries had higher average Hierarchical Condition Category (HCC) scores. ACOs in the top quartile of HCC scores had a non-statistically significant impact on average gross savings/losses than ACOs with lower average HCC scores. Instead of guardrails we will continue monitoring the impact of the policy on ACOs for possible unintended negative consequences as performance data becomes available.

Comment: Many commenters expressed concerns that the Shared Savings Program risk adjustment isn't built to handle beneficiaries with incomplete or transitional Medicare enrollment histories, causing risk scores to potentially understate true expected costs. As a result, ACOs could be held accountable for higher-cost or higher-risk beneficiaries whose expenditures aren't fully captured in risk-adjusted benchmarks—whether the transition stems from mid-year Medicare Advantage-to-hospice disenrollment or from having under 12 months of traditional Medicare enrollment, such as those newly aging in or coming from Medicare Advantage.

Response: We appreciate concerns raised in comments about risk adjustment not accounting for beneficiaries who have incomplete or transitional Medicare enrollment histories, or who have mid-year transitions from Medicare Advantage (MA). We disagree, however, that the CMS–HCC risk adjustment model, which is used in the Shared Savings Program for risk adjustment, is poorly suited to these populations or that it would systematically understate expected costs for ACOs. The CMS–HCC risk adjustment model is designed for and calibrated on claims and enrollment data taken from a sample of the national Medicare FFS population, including Medicare beneficiaries who are not enrolled in the Shared Savings Program.[283] Additionally, when calculating risk scores, we take all beneficiary data irrespective of the source, so diagnoses captured by MA organizations would still be reflected in the beneficiaries' risk scores for that year. When beneficiaries have 12 months of entitlement to Part A and less than 12 months of Part B enrollment during the data collection period, they do not receive the standard diagnosis-

[283] Details on CMS risk adjustment can be found at *https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/risk-adjustment.*

based risk adjustment. Instead, CMS assigns risk using new enrollee's demographic factors, such as age, sex, and original reason for Medicare Entitlement. CMS uses the same model for Medicare Advantage risk adjustment and other Medicare payment purposes. Because the CMS–HCC risk adjustment model already reflects cost variation across the full range of Medicare FFS beneficiaries, the model already accounts for enrollment history and beneficiary transitions. Using one model across Medicare Advantage, the Shared Savings Program, and other Medicare payment contexts allows CMS to risk-adjust based on the same national standard for all beneficiaries. Modifying the model, or applying a different one, solely for ACO-assigned beneficiaries could create inconsistency in how CMS measures expected costs across the Medicare program and may undermine the comparability that a single, nationally calibrated model provides.

Comment: Many commenters recommended that CMS delay implementation until further analysis and monitoring can be conducted to assess the impact of this policy, including distributions of the simulated policy impact by varying ACO characteristics such as revenue or population size.

Response: We acknowledge recommendations made in the comments to delay policy implementation until CMS has conducted further analysis on the expected impact. Additionally, we appreciate the commenters' recommendations for further monitoring to ensure that the implementation of the proposed policy has the intended effect without negatively impacting certain ACOs, providers, or beneficiary populations. CMS declines to delay implementation but will continue monitoring the impact of the policy on ACOs.

In addition to proposed rule simulations, further analysis was conducted to examine the CY 2027 PFS proposed rule's impact on ACOs using simulated data from PY 2025. We found that policy impacts on aggregate savings/losses were very minimal on average, decreasing ACO aggregate shared savings/shared losses by $1,574 (−0.02 percent). Impacts on per capita savings/losses were also relatively small, decreasing average ACO per capita savings/losses by −$14.02 (−2.78 percent). The number of assigned beneficiaries increased by an average of 1,182 (5.07 percent).

In these additional simulations using PY 2025 data, we compared the impact of the policy on financial performance of ACOs with higher average HCC scores. ACOs with higher HCC scores experienced a $54,116 increase in average aggregate gross savings/losses (0.41 percent), while other ACOs had a $20,138 decrease in average per capita gross savings/losses (−0.22 percent). This difference was not statistically significant and therefore does not provide evidence that the policy would have different effects on ACOs by average risk score.

For additional analysis on this proposed policy, CMS directs commenters to the Regulatory Impact Analysis in section VI of the CY 2027 PFS proposed rule (91 FR 44253 through 44258).

After consideration of public comments, we are finalizing revisions to the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status under § 425.401, and to apply the revised criteria in determining assignment for the PY starting on January 1, 2028, and subsequent PYs as proposed. We are also finalizing to revise and republish § 425.401, to specify the existing criteria for a beneficiary to be assigned to an ACO for a performance or benchmark year apply to PYs starting prior to January 1, 2028 (as applicable), and to specify the proposed criteria applicable for the performance year starting on January 1, 2028, and subsequent performance years as proposed. We are also finalizing as proposed a technical and conforming change to cross-references to provisions of § 425.401 within § 425.612(a)(1)(iv)(A)(*2*), which describes certain conditions under which we make payments for SNF services furnished to a beneficiary preliminarily prospectively assigned to an ACO for which a waiver of the SNF 3-day rule was approved.

(c) Simulations To Understand the Potential Effect of Changes

In the CY 2027 proposed rule we performed separate simulations to understand the potential effect for each of the changes to the assignment methodology.

Using PY 2024 data we simulated the impact of the proposed approach to excluding from assignment calculations allowed charges for primary care services billed through a non-ACO TIN by an ACO professional used in assignment (described in section III.G.2.a.(2)(a) of this final rule). The simulation was performed using data for all 476 ACOs reconciled for PY 2024. For purposes of the simulation, we made multiple simplifying assumptions. This included treating all ACOs as if they were under preliminary prospective assignment with retrospective reconciliation for purposes of identifying the impact on assignment and simplicity of simulating benchmark assignment. Since the change is to plurality competition, we would anticipate a comparable impact if we performed the simulation using the off-set assignment window. For simulating financial impacts, we assumed all ACOs to be starting their first agreement period on January 1, 2024, to have benchmark years of BY 2021, 2022 and 2023, and applied an equal weight to each BY in benchmark calculations. In approximating the benchmark calculations under the simulations, we applied the benchmarking methodology applicable for ACOs entering an agreement period beginning on January 1, 2024 under §§ 425.652 through 425.660, with several exceptions. In adjusting the benchmark to account for changes in severity and case mix of the assigned beneficiary between BY3 and PY 2024 under § 425.652(a)(10), we applied the approach to capping positive adjustments at 3 percent in accordance with §§ 425.605(a)(1)(i) and 425.610(a)(2)(i) rather than the demographic plus 3 percent cap specified under §§ 425.605(a)(1)(ii) and 425.610(a)(2)(ii). We also simulated the updated benchmark using a one-third weight for the ACPT component of the three-way blended update factor, although a one-sixth weight was applied in determining financial reconciliation for PY 2024, as described in section III.G.5.g of this final rule. In simulating the updated benchmark calculations we did not apply the existing guardrail policy specified in § 425.652(b)(5), which ensures that the use of the three-way blended update factor will not result in lower benchmarks than the two-way national-regional blended update factor in a way that poses higher financial risk for ACOs under two-sided models, or that could jeopardize an ACO's continued participation in the Shared Savings Program under the financial performance monitoring policy described in § 425.316(d), or both.[284]

Under these simulations, we observed that the change to the plurality competition would add over 97,800 assigned beneficiary person years to Shared Savings Program assignment (nearly 1 percent growth). In simulations, we found that 462 of 476 ACOs (or 97 percent) observed less than 1 percent growth, while the remaining 14 out of 476 ACOs (3 percent) experienced growth greater than 4

[284] See 87 FR 69885.

percent, including one ACO that observed growth as large as 12 percent.

Under simulations of the financial impacts, using PY 2024 data, we calculated ACOs' updated benchmark expenditures minus PY expenditures, to estimate impacts on gross savings/losses; with a resulting reduction in this amount indicating potentially lower shared savings, and greater liability for shared losses. We found that ACOs observed an average 3.90 percent decrease in per capita gross savings/losses ($14 per capita)[285] and an average 3.92 percent decrease in aggregate gross savings/losses. Average reductions in gross savings/losses were driven by two factors: (1) the simulated assignment method tended to add relatively more beneficiaries in the PY (2024) than they added in the benchmark years (2021, 2022, 2023); and (2) the added beneficiaries were substantially higher cost and had higher risk scores than beneficiaries assigned to ACOs under the existing assignment methodology. These two factors combined mean that ACOs' average benchmark expenditures increased by a relatively smaller degree than their PY expenditures increased, resulting in lower gross savings/losses.

Using PY 2024 data in the proposed rule analysis, we simulated the impact of the proposed approach to revising the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status (described in section III.G.2.a.(2)(b) of this final rule). For purposes of simulating the changes to the prospective assignment exclusion criteria based on Medicare enrollment status, it was important to recognize the ACO's selection of assignment methodology, to be able to accurately observe the impact of the change. Therefore, we performed separate simulations for ACOs based on their selection of assignment methodology. For ACOs under preliminary prospective assignment with retrospective reconciliation, we simulated the change to assignment eligibility criteria using a 12-month assignment window that aligned with PY 2024. For ACOs under prospective assignment, we simulated the change to assignment eligibility criteria using an offset assignment window from October 2022 through September 2023. In both cases, we identified beneficiaries with at least 1 month of Part A and Part B enrollment and no Medicare group health plan enrollment (including MA) during that same month during the applicable assignment window as being eligible for assignment. For ACOs under prospective assignment we further simulated application of the modified exclusion criteria applied at the end of PY 2024 based on CY 2024 data (making certain simplifying assumptions). To remain prospectively assigned under the simulated modified Medicare enrollment status criteria, the beneficiary had at least 1 month of Part A and Part B enrollment and no Medicare group health plan enrollment during the same month, during CY 2024. For simulating financial impacts, we made the same assumptions as previously described in this discussion used to simulate the impact of the proposed changes to plurality competition, with respect to identifying benchmark years and related weights for ACOs, as well as the benchmarking methodology that was applied including the approach to adjusting and updating the historical benchmark.

Based on our simulations, across all ACOs for PY 2024, we observe an increase of approximately 248,000 (2.45 percent) assigned beneficiary person years resulting from the proposed modifications to the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status. We observed differing impacts on the assigned population for ACOs under prospective assignment versus preliminary prospective assignment with retrospective reconciliation, with the assigned population (in terms of assigned beneficiary person years) increasing with final assignment by 2.25 percent versus 2.57 percent respectively. This difference is explained by the type of beneficiaries that are being added with use of modified assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status. We observed that a larger share of beneficiaries that are initially prospectively assigned were removed from final assignment because they transition to and remain in a Medicare group health plan during the PY.

Under simulations of the financial impacts of modifying assignment criteria based on Medicare enrollment status, using PY 2024 data, we calculated ACOs' updated benchmark expenditures minus PY expenditures, to estimate impacts on gross savings/losses; with a resulting reduction in this amount indicating potentially lower shared savings, and greater liability for shared losses. We found that on average ACOs' PY per capita expenditures increased slightly more (by 0.60 percent) than benchmark per capita expenditures increased (by 0.43 percent), resulting in $20 lower average per capita gross savings/losses (−6.62 percent). Overall impacts on aggregate gross savings/losses were also negative but relatively smaller, decreasing average ACO gross savings/losses and program-wide gross savings/losses by 3.20 percent.

We observed differences in average expenditures and risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) among the beneficiary population added with the simulated changes in assignment compared to the population already assigned. Related findings are summarized in Table B–G1. Within the ESRD enrollment type, we observed a disproportionately higher number of additional beneficiaries compared to the other enrollment types. The added population of ESRD beneficiaries had, on average, largely similar per capita expenditures and lower average risk scores than already assigned ESRD beneficiaries. Within the disabled and aged/dual eligible enrollment types, the added populations of beneficiaries had, on average, higher per capita expenditures and higher average risk scores than the corresponding populations of already assigned beneficiaries. Within the aged/non-dual eligible enrollment type, the added population of beneficiaries had, on average, slightly lower per capita expenditures and lower average risk scores than already assigned aged/non-dual eligible beneficiaries.

[285] The proposed rule cited an average per capita decrease of $355 under PY 2024 simulations. However, the correct average per capita decrease is $14. The value of $355 refers to the overall average per capita gross savings/losses under the simulated policy.

TABLE B-G1: SIMULATION OF PROPOSED CHANGES TO ASSIGNMENT ELIGIBILITY CRITERIA - NUMBER AND CHARACTERISTICS OF BENEFICIARIES ADDED FOR PY 2024

	Assigned Population under Existing Eligibility Criteria	Assigned Population Added with Proposed Medicare Enrollment Status Criteria	Percent Difference
Mean Assigned Person Years	**21,241.8**	**531.8**	**2.50%**
ESRD	75.6	6.1	8.03%
Disabled	1,448.2	85.9	5.93%
Aged/Dual	1,143.7	88.1	7.70%
Aged/Non-Dual	18,574.3	351.7	1.89%
Mean Per Capita Expenditures	**$13,256**	**$15,433**	**16.42%**
ESRD	$95,405	$92,714	-2.82%
Disabled	$12,657	$16,797	32.71%
Aged/Dual	$19,287	$23,435	21.51%
Aged/Non-Dual	$12,594	$12,570	-0.19%
Mean CMS-HCC Risk Score	**0.993**	**0.899**	**-9.47%**
ESRD	0.969	0.955	-1.38%
Disabled	0.966	1.122	16.15%
Aged/Dual	0.962	1.005	4.50%
Aged/Non-Dual	1.003	0.852	-15.08%

Note: The reported "Percent Difference" may slightly differ from manual recalculation using other values reported in the table due to rounding.

For additional analysis on estimated impacts, we also refer readers to the Regulatory Impact Analysis in section VI of this final rule. In the Regulatory Impact Analysis of this final rule, we describe the estimated financial impact of the change to exclude from assignment calculations for purposes of plurality competition, allowed charges for a beneficiary's primary care services billed through a non-ACO TIN by an ACO professional used in assignment if that beneficiary also had primary care services billed by an NPI under an ACO TIN (described in section III.G.2.a.(2)(a) of this final rule), and the changes to assignment eligibility criteria and prospective assignment exclusion criteria (described in section III.G.2.a.(2)(b) of this final rule). We explain that in combination the proposed changes to assignment would be estimated to result in higher net Federal savings, although the policies may also marginally decrease the number of ACOs participating in the Shared Savings Program as a result of assignment of higher cost beneficiaries to ACOs and reduced gross savings, while also increasing overall the number of beneficiaries assigned to Shared Savings Program ACOs. The collective proposed changes represent an opportunity to grow the number of Medicare FFS beneficiaries involved in accountable care relationships, and drive savings, which would advance us towards our goal to align spending and value in OM, and related strategic objectives (described in section III.G.1.a. of this final rule). The change to assignment calculations (described in section III.G.2.a.(2)(a) of this final rule) would reduce the potential for differences in billing patterns by ACO professionals (inside and outside the ACO), for care of the same beneficiaries, to result in differences in assignment outcomes that advantage the ACO's financial performance, in particular billing that results in non-assignment of higher cost and higher risk beneficiaries. The changes to assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status (described in section III.G.2.a.(2)(b) of this final rule), would allow for greater symmetry between the ACO assigned population and the assignable population, and help ensure consistency between Shared Savings Program calculations used in determining ACO financial performance. At this juncture, we believe the considerations outweigh the concern about the potential for attrition from the Shared Savings Program by ACOs unwilling to be held accountable for the quality and cost of care of this population of Medicare beneficiaries.

We also noted in the CY 2027 PFS proposed rule that we did not simulate the potential impact of the proposed changes to the assignment methodology on ACO quality performance. We refer readers to section III.G.3. of this final rule for a discussion of changes to the Shared Savings Program quality performance standard and other quality reporting requirements. Given the relatively small increases in ACOs' assigned populations that are likely to result under the proposed changes to the assignment methodology, we anticipate there would be minimal impact on ACOs' reporting of quality measures for the expanded population of beneficiaries.

We sought comment on the potential effects of the proposed changes to the assignment methodology on the composition of ACOs' assigned populations and ACOs' financial and quality performance. We also sought comment on the potential for these proposed changes to have unintended consequences for participation by ACOs, ACO participants, and ACO professionals, including with respect to their ability to meet Shared Savings Program goals for an expanded population of assigned beneficiaries which would result under the proposed changes to the Shared Savings Program assignment methodology. No comments were received related to quality performance or reporting and other relevant comments were summarized earlier in this section.

(d) Implementation of Revisions to the Beneficiary Assignment Methodology

As described in sections III.G.2.a.(2)(a) and (b) of the CY 2027 PFS proposed rule, we proposed changes to the Shared Savings Program beneficiary assignment methodology that would be applicable to all ACOs for the PY starting on January 1, 2028, and subsequent PYs. In this section of this final rule, we discuss impacts on certain program operations in additional detail, specifically: (1) the timing of applicability for the proposed approach in connection with the timing of the annual application cycle for ACOs to

enter a new agreement period under the Shared Savings Program; (2) applicability of the proposed approach to determining benchmark assignment and relatedly adjustments to historical benchmark calculations for ACOs participating in an existing agreement period; and (3) considerations specific to program reports and data which we make available to ACOs.

Consistent with how we have implemented previous changes to the Shared Savings Program assignment methodology, we would use the revised methodology each time assignment is determined for a given benchmark year or PY and, as applicable, to determine the eligibility of ACOs applying to enter into or renew participation in the Shared Savings Program. Regarding the latter, applicant eligibility for PY 2027 will be determined during CY 2026. As discussed in the proposed rule (91 FR 43855), we stated that we would not be able to review public comments and decide whether to finalize the proposed changes in sufficient time to apply the revised criteria for PY 2027 applications. We use estimates for the ACO's benchmark year assignment in multiple determinations during Phase 1 of the application cycle, which concludes in mid-October 2026, before the CY 2027 PFS final rule will likely be issued.[286] This includes, determining whether an ACO applicant meets the requirement for having at least 5,000 assigned beneficiaries (refer to § 425.110(a)(1) and (a)(3)), determining whether an ACO meets the definition of a low revenue ACO for purposes of eligibility for the Advance Investment Payment option (refer to § 425.630(b)(4)), and calculating the ACO's repayment mechanism amount (refer to § 425.204(f)). Additionally, we anticipate that the proposed revised approach to determining beneficiary assignment described in section III.G.2.a. of this final rule, would require significant operational changes to the Shared Savings Program assignment methodology, which would take time to prepare in advance of initial use of the approach during the application process. For these reasons, we would not be able to apply the revised beneficiary assignment methodology for the PY starting on January 1, 2027, and we proposed to apply this change beginning with the PY starting on January 1, 2028.

Additionally, we would apply the proposed revised approach to determining beneficiary assignment in establishing, adjusting, updating, and resetting historical benchmarks for ACOs entering new agreement periods beginning on January 1, 2028, and in subsequent years. Also consistent with how we have implemented previous changes to the assignment methodology, we would adjust benchmarks at the start of PY 2028 for all ACOs in agreement periods for which PY 2028 is a second or subsequent PY. Accordingly, the ACOs' benchmarks would reflect the use of the same assignment rules as would apply in the PY (refer to § 425.652(a)(9)).

In accordance with the Shared Savings Program regulations under subpart H, we provide ACOs with certain aggregate reports and beneficiary-identifiable claims data on the ACO's assigned beneficiary population, to conduct healthcare operations work. We are committed to maintaining transparency of Shared Savings Program by providing ACOs with data related to the determination of their assigned population, and providing ACOs with data on their assigned population to aid in their operations under the Shared Savings Program. Under § 425.704, we provide ACOs with monthly claim and claim line feed (CCLF) files with beneficiary-identifiable data, which include Parts A, B, and D data.[287] Further, in accordance with § 425.702, we provide ACOs with Shared Savings Program reports which include aggregate and beneficiary-identifiable information on their assigned population near the start of each PY, during each quarter, and in conjunction with annual financial reconciliation.[288] [289] We anticipate updating the Shared Savings Program's publicly available specification documents, programmatic resources, and program reports to include information that would help ACOs understand their assigned population and the population of beneficiaries eligible to be assigned under the revised assignment methodology.

We received no comments on our proposed implementation approach and are finalizing as proposed.

b. Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided by physicians in the ACO who are ACO professionals and, in the case of PYs beginning on or after January 1, 2019, services provided by a FQHC or RHC. However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212 and 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747 through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279; 87 FR 69821 through 69825; 88 FR 79163 through 79174; 89 FR 98087 through 98101; 90 FR 49794 through 49797) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program. For the PY starting on January 1, 2025, and subsequent PYs, we defined primary care services for purposes of assigning beneficiaries to ACOs under § 425.402 at § 425.400(c)(1)(ix).

(2) Revisions

Based on continued review of the HCPCS and CPT codes that are currently

[286] See Medicare Shared Savings Program, Key Application Actions and Deadlines For Agreement Periods Beginning on January 1, 2027, available at *https://www.cms.gov/files/document/key-application-actions-deadlines.pdf.*

[287] See for example, CMS, ''Accountable Care Organization—Operational System (ACO–OS), Claim and Claim Line Feed (CCLF) Information Packet (IP)'' (version 43.0, 5/13/2026), available at *https://www.cms.gov/files/document/cclf-information-packet.pdf.*

[288] See, for example, Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (Appendix F: Report Descriptions).

[289] CMS has made publicly available the PY 2026 Shared Savings Program Report templates through the ''Program Guidance & Specifications'' webpage of the Shared Savings Program website, at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations.*

used for payment under the PFS or that we proposed to use for payment under the PFS starting in CY 2027, we have determined it would be appropriate to propose to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes for the PY starting on January 1, 2027, and subsequent PYs, to remain consistent with billing and coding under the PFS.

We proposed (91 FR 44035 through 44036) to specify a revised definition of primary care services used for assignment for the PY starting on January 1, 2027, and subsequent PYs in a new provision of the Shared Savings Program at § 425.400(c)(1)(xi) to include the list of HCPCS and CPT codes specified at § 425.400(c)(1)(x), as well as the following additions: Screening, Brief Intervention, and Referral to Treatment (SBIRT) (HCPCS codes G2011, G0396, and G0397), Vaccine Adverse Effects Management (HCPCS code GADV1), Advance Care Planning (HCPCS codes GACP1 and GACP2), under OM payment policy.

We proposed to use the new provision at § 425.400(c)(1)(xi) for determining beneficiary assignment for the PY starting on January 1, 2027, and in subsequent PYs.

The following provides additional information about the CPT and HCPCS codes that we proposed to add to the definition of primary care services used for purposes of beneficiary assignment:

- *Screening, Brief Intervention, and Referral to Treatment (HCPCS G2011, G0396, and G0397):* The purpose of the SBIRT program is to implement the screening, brief intervention, and referral to treatment public health model for children, adolescents, and/or adults in primary care and community health settings (for example, health centers, hospital systems, health maintenance organizations (HMOs), preferred-provider organizations (PPOs) health plans, Federally Qualified Health Centers (FQHC), behavioral health centers, pediatric healthcare providers, children's hospitals, etc.) and schools with a focus on screening for underage drinking, opioid use, and other substance use.[290] SBIRT [291] has three major components:

(1) Screening: Screen or assess a patient for risky substance use behaviors with standardized assessment tools (known as Medicare Structured Assessment) to identify the appropriate level of care. Screening quickly assesses a patient's substance use severity and identifies the appropriate treatment level;

(2) Brief Intervention: Brief intervention increases substance use insight and awareness and motivates behavioral change. Engage the patient in a short conversation to increase their awareness of risky substance use behaviors and provide feedback, motivation, and advice; and

(3) Referral to Treatment: Refer patients whose assessment or screening shows a need for additional services to specialty care treatment using specific tools such as Alcohol Use Disorders Identification Test (AUDIT) Manual or Drug Abuse Screening Test (DAST).

These three codes include screening and counseling services similar to counseling and other evaluation and management services already included in the definition of primary care services used for purposes of assignment. In the CY 2019 PFS final rule (83 FR 59965 through 59969), we finalized the addition of HCPCS G0442 (*Annual alcohol misuse screening, 15 minutes*) and G0443 (*Alcohol misuse counseling*) to the definition of primary care services used for purposes of assignment. In the CY 2024 PFS final rule (88 FR 79163 through 79175) we finalized the addition of CPT codes 99406 and 99407 for smoking and tobacco-use cessation counseling services. We also finalized the inclusion of G2086, G2087, and G2088 for office-based opioid use disorder services in the definition of primary care services used for purposes of assignment. Since HCPCS codes G2011, G0396, and G0397 include screening and documentation related to alcohol misuse, similar to G0442 and G0443, we believe this supports the inclusion of these HCPCS codes in the definition of primary care services.

- *Vaccine Adverse Effects Management* (HCPCS code GADV1): In section II.E. of the CY 2027 PFS proposed rule (91 FR 43905 through 43906), we proposed an add-on payment for diagnosis and management of a suspected vaccine adverse reaction for services going above and beyond those captured in an E/M visit. These services entail listening to patient concerns, answering questions, and building trust; selecting diagnosis strategies and conveying information in a manner specific to the clinical situation and individual patient needs; providing patients with appropriate resources; and planning with patients the treatment of symptoms of vaccine adverse effects. We proposed that this add-on code, HCPCS code GADV1 (*Office or other outpatient evaluation and management service(s) for the diagnosis and treatment of vaccine adverse effects, new or established patient; each 15 minutes personally performed by the physician or qualified healthcare professional (list separately in addition to CPT codes 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350*)), would be payable when a physician or NPP: (1) establishes and documents a temporal relationship to vaccination, and (2) performs a medically appropriate assessment to rule out alternative causes. Since, as proposed, this service is an add-on payment for diagnosis and management of a suspected vaccine adverse reaction for services going above and beyond those captured in an evaluation and management (E/M) visit we believe these services will likely be provided by the clinician that is responsible for the overall care of the beneficiary and should, therefore, be included in the definition of primary care services used for purposes of assignment.

We have, over time, proposed separate payment and coding in instances where E/M codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries which were then incorporated into the definition of primary care services used for purposes of assignment (see, for example: Transitional Care Management (77 FR 68978 through 68994), Chronic Care Management (78 FR 43337 through 43343), Advance Care Planning (80 FR 70955 through 70959)). Similarly, we believe that the inclusion of GADV1 for the assessment and treatment of vaccine adverse effects represents services and resources supportive of the furnishing of comprehensive, coordinated care management that are not reflected in E/M codes and therefore should be included in the definition of primary care services used for purposes of assignment. Further, the valuation of this service is cross walked to HCPCS code G2212, which is included in the definition of primary care services used for purposes of assignment.

- *Advance Care Planning* (HCPCS codes GACP1 and GACP2): As discussed in section II.G. of the CY 2027 PFS proposed rule (91 FR 43947 through 43949), we proposed to create two new HCPCS codes to describe advance care planning services furnished by clinical staff under the direct supervision of the billing physician or other practitioner: HCPCS

[290] See Medicare Shared Savings Program, Key Application Actions and Deadlines For Agreement Periods Beginning on January 1, 2027, avaliable at *https://www.cms.gov/files/document/key-application-actions-deadlines.pdf.*

[291]

G-code GACP1 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), first 20 minutes of clinical staff time with the patient, family member(s), surrogate directed by a treating physician or other treating qualified health care professional*) and GACP2 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), each additional 20 minutes with the patient, family member(s), surrogate directed by a treating physician or other treating qualified health care professional (List separately in addition to code for primary procedure)*) and proposing that the existing CPT codes 99497 and 99498 would only be used to report time personally spent by the billing practitioner. We believe that this new coding would more accurately distinguish and value the work of the billing practitioners, from time that is spent by their clinical staff in the provision of advance care planning services. As discussed in section II.G of this final rule, CMS emphasizes that clinicians must not, under any circumstances, attempt to influence their patients' decisions with respect to ACP.

In the CY 2019 PFS final rule (83 FR 59965 through 59968), we finalized the inclusion of advance care planning CPT codes 99497 and 99498 in the definition of primary care services under the Shared Savings Program because the services provided as part of advance care planning include counseling and other E/M codes similar to the services included in Annual Wellness Visits and other E/M codes that are already included in the list of primary care services used for purposes of assignment. We continue to believe that the care billed under advance care planning CPT and HCPCS codes would be considered primary care, and as such, believe that the new HCPCS that represent clinical time provided under direct supervision should be included in the definition of primary care services used for purposes of assignment.

As part of this revised definition of primary care services used for assigning beneficiaries at § 425.402, we proposed to incorporate a provision at § 425.400(c)(1)(xi)(C), specifying that the primary care service codes for purposes of assigning beneficiaries include a CPT code identified by CMS that directly replaces a CPT code specified at § 425.400(c)(1)(xi)(A) or a HCPCS code specified at § 425.400(c)(1)(xi)(B), when the assignment window or expanded window for assignment (as defined at § 425.20) for a benchmark year or PY includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

We also proposed a technical modification to the introductory text in § 425.400(c)(1)(x), to limit the applicability of that provision to the PY starting on January 1, 2026. This change is necessary so that we can effectuate § 425.400(c)(1)(xi) as explained in this section of this final rule to apply for the PY starting on January 1, 2027, and subsequent PYs.

We sought comments on these proposed changes to the definition of primary care services used for assigning beneficiaries at § 425.400(c)(1)(xi) to Shared Savings Program ACOs for the PY starting on January 1, 2027, and subsequent PYs, and related technical change. We also sought comments on any other existing or new HCPCS or CPT codes proposed in the CY 2027 PFS proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported expanding the definition of primary care services used for beneficiary assignment. Commenters supported adding Screening, Brief Intervention, and Referral to Treatment (SBIRT) services, Advance Care Planning (ACP) services, and Vaccine Adverse Effects Management, with several commenters expressly supporting the proposed HCPCS codes and recommending finalization for PY 2027 where the underlying codes are finalized for payment. Commenters stated that these services reflect prevention, care planning, behavioral health, patient engagement, care coordination, chronic disease intervention, and other longitudinal, relationship-based activities that are fundamental to comprehensive primary care. Several commenters stated that including these services would more accurately align beneficiary assignment with the clinicians and ACO participants furnishing meaningful primary care and would keep the assignment methodology aligned with Medicare billing codes and PFS policy. Some commenters noted that the descriptors for the proposed services are similar to services already included in the assignment methodology.

Commenters offered service-specific rationales. Several commenters stated that ACP is a core component of longitudinal primary care, particularly for seriously ill and medically complex beneficiaries, and that primary care's longitudinal relationships make it well suited for discussions of goals of care, advance directives, end-of-life preferences, and surrogate decision-making. Commenters also noted the roles of nurses, APRNs, clinical staff, family members, and surrogates in ACP and stated that ACP can help ensure that patients' care preferences are honored. Commenters supporting SBIRT stated that screening, brief intervention, and referral are core primary care and population health activities and can promote earlier identification and treatment of substance use disorders before more serious consequences occur. A commenter supporting Vaccine Adverse Effects Management stated that primary care is often the first and most consistent point of contact for patients with suspected vaccine adverse events and may provide symptom management, counseling, risk-benefit discussions, follow-up, and guidance regarding future immunizations.

Response: We appreciate the comments in support of adding advance care planning; screening, brief intervention, and referral to treatment; and vaccine adverse effects management codes to the definition of primary care services used for Shared Savings Program beneficiary assignment beginning in 2027, and agree that these services reflect prevention, care planning, behavioral health, patient engagement, care coordination, chronic disease intervention, and other longitudinal, relationship-based activities that are fundamental to comprehensive primary care which would keep the assignment methodology aligned with Medicare billing codes and PFS policy. We also agree that the proposed codes are similar to many already included in the definition of primary care services used for purposes of assignment. We also appreciate the service-specific rationale provided by commenters to support the inclusion of these services in the definition of primary care services used for purposes of assignment.

Comment: A commenter generally supported the expanded definition but recommended delaying use of the Advanced Care Planning codes, GACP1 and GACP2, for assignment for at least one year to obtain claims experience and evaluate whether the codes strengthen assignment or inadvertently shift attribution away from established primary care relationships. Another

commenter urged CMS to review the assignment code set annually as coding and care delivery evolve, including consideration of remote therapeutic monitoring and advanced primary care management. Another commenter recommended monitoring the acuity and expenditure patterns of beneficiaries newly assigned through the added services and ensuring that benchmark and risk-adjustment methodologies reflect expected cost of care. Another commenter recommended monitoring whether the new service codes appropriately identify longitudinal primary care relationships and their effects on FQHCs and RHCs. A commenter supported the three proposed service categories but made clear that they recognize that CMS did not propose the addition of similar therapy evaluation codes because statutory practitioner classifications limit CMS's ability to add those services under current law. Another commenter supported G2011, G0396, GADV1, GACP1, and GACP2 but opposed adding G0397 stating that G0397 is more frequently associated with specialty care.

Response: We acknowledge feedback in the comments. It is important for the definition of primary care services used for purposes of beneficiary assignment to remain in sync with billing and coding updates and changes and include appropriate new CPT and HCPCS codes as they are implemented. We believe that delaying the inclusion of new assignment codes or conducting multi-year testing of codes could result in beneficiaries not being assigned to an ACO based on primary care services that are provided by their primary care provider as utilization of these services is implemented. Implementing billing and coding updates and changes as they are finalized under the PFS is important for purposes of assignment to ensure that beneficiaries are assigned appropriately as services billed shifts from already existing CPT/HCPCS codes to new CPT/HCPCS codes. If the Shared Savings Program is out of sync with coding changes and updates, assignment of beneficiaries could be inaccurate. We also note that the step-wise assignment methodology maintains the statutory requirement to conduct claims-based beneficiary assignment based on beneficiaries' utilization of physician primary care services, recognizing the necessary and appropriate role of certain specialists in providing primary care services so we are not persuaded to delay implementation of these services.

We acknowledge the concerns about potential impact of unknown utilization and the suggestion to delay the addition of GACP1 and GACP2. Advance care planning (ACP) is a voluntary, face-to-face discussion between a practitioner and patient or their family member, caregiver, or surrogate (as appropriate) to discuss the patient's healthcare wishes if they become unable to make their own medical decisions.[292] The ACP HCPCS codes being finalized in this rule (see section II.G) are used to describe ACP services furnished by clinical staff under the direct supervision of the billing physician or other practitioner (and incidental to their professional services) and the existing CPT codes 99497 and 99498 would only be used to report time personally spent by the billing practitioner. Additionally, as explained in section II.G of this final rule, ACP services are a voluntary component of the annual wellness visit and can be billed together with CPT codes 99497 and 99498, if time thresholds by the billing practitioner and clinical staff are each met. Because annual wellness visits and other ACP services are currently included in the definition of primary care services used for purposes of assignment, we believe including the proposed ACP services (finalized as HCPCS codes G0572 and G0573) is critical to maintain consistency in the regulatory definition of primary care services used for purposes of assignment under § 425.400 regardless of future utilization.

We agree that monitoring the billing and utilization of the primary care service codes used for purposes of beneficiary assignment, and other codes, to ensure that the Shared Savings Program considers appropriate billing codes for purposes of beneficiary assignment is an important step in maintaining an accurate and effective assignment methodology. As we described in the CY 2025 PFS final rule (89 FR 98095), we will monitor the billing and utilization of the current primary care service codes used for purposes of beneficiary assignment, and other codes, to ensure that the Shared Savings Program considers appropriate billing codes for purposes of beneficiary assignment. If monitoring shows that the inclusion of service codes in the definition of primary care services used for beneficiary assignment is not appropriate, we will address that issue as needed.

With regard to the comment on statutory practitioner classifications, we confirm that therapy services are not included in the definition of primary care services used in assignment because therapists are not providers upon which assignment can be determined.

Regarding G0397 being more frequently furnished by specialists, we are not persuaded that this is a reason not to include this code for purposes of assignment in the Shared Savings Program. As we have previously explained in rulemaking (see, for example, 76 FR 67853 through 67855; see also 80 FR 32748 and 32754 and 89 FR 98095), the step-wise assignment methodology maintains the statutory requirement to conduct claims-based beneficiary assignment based on beneficiaries' utilization of physician primary care services, recognizing the necessary and appropriate role of certain specialists in providing primary care services, such as in areas with primary care physician shortages. Additionally, we noted in the June 2015 final rule (80 FR 32750), that we expect that specialist physicians often take the role of primary care physicians in the overall treatment of beneficiaries with certain chronic conditions, and such patterns are captured in step 2 in the current assignment methodology. Further, if services billed under these codes are provided by specialists not considered for purposes of beneficiary assignment, then the services will not be considered in beneficiary assignment.

Comment: Another commenter supported CMS's proposed beneficiary assignment changes but stated that claims-based assignment alone has limitations in expanding accountable care relationships. The commenter recommended that Medicare beneficiaries also have a practical and accessible mechanism to affirmatively designate the clinician they trust to coordinate their care. The commenter viewed such a mechanism as complementary to CMS's efforts to expand beneficiary access to coordinated, accountable care in Original Medicare.

Response: We believe this comment is referring to voluntary alignment and agree it is complementary to CMS's efforts to expand beneficiary access to coordinated, accountable care in Original Medicare. Under § 425.402(e) beneficiaries may voluntarily align themselves to an ACO at any time by logging into Medicare.gov and designating a provider or supplier who they believe to be responsible for coordinating their overall care. We are currently researching additional ways CMS can support beneficiary education

[292] See for example, CMS, ''Accountable Care Organization—Operational System (ACO-OS), Claimaim and Claim Line Feed (CCLF) Information Packet (IP)'' (version 43.0 , 5/13/2026), available at *https://www.cms.gov/files/document/cclf-information-packet.pdf*.

and enhance the accessibility of voluntary alignment.

After consideration of public comments, we are finalizing as proposed the revised definition of primary care services used for assignment for the performance year starting on January 1, 2027, and subsequent performance years in a new provision of the Shared Savings Program at § 425.400(c)(1)(xi) to include the list of HCPCS and CPT codes specified at § 425.400(c)(1)(ix), as well as the following additions: Screening, Brief Intervention, and Referral to Treatment (SBIRT) (HCPCS codes G2011, G0396, and G0397), Vaccine Adverse Effects Management (HCPCS code GADV1, which is finalized as G0576), Advance Care Planning (HCPCS codes GACP1 and GACP2, which are finalized as G0572 and G0573, respectively), as finalized under OM payment policy.

Additionally, we received no comments on our proposal regarding the incorporation of a provision at § 425.400(c)(1)(xi)(C), specifying that primary care service codes used for purposes of assigning beneficiaries include a CPT code identified by CMS that directly replaces a CPT code specified at § 425.400(c)(1)(xi)(A) or a HCPCS code specified at § 425.400(c)(1)(xi)(B), when the assignment window or expanded window for assignment (as defined at § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under Medicare FFS and are finalizing as proposed.

Further, the text of the proposed regulations in the CY 2027 PFS CY 2027 PFS proposed rule (91 FR 44035) included a proposed technical modification to the introductory text in § 425.400(c)(1)(x), to limit the applicability of that provision to the performance year starting on January 1, 2026. This change is necessary so that we can effectuate § 425.400(c)(1)(xi) as explained in the CY 2027 PFS proposed rule and its regulatory text: to apply for the performance year starting on January 1, 2027, and subsequent performance years. We received no comments addressing the proposed technical modification to § 425.400(c)(1)(xi), and we are finalizing this change without modification.

3. Quality Performance Standard and Other Quality Reporting Requirements

a. Overview

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by Shared Savings Program ACOs and seek to improve the quality of care furnished by Shared Savings Program ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for Shared Savings Program ACOs has been to identify measures of success in the delivery of high-quality healthcare at the individual and population levels. In the November 2011 final rule, we established a quality measure set spanning four domains: patient experience of care, and wherever practicable, caregiver experience of care; care coordination/patient safety; preventative health; and at-risk population (76 FR 67872 through 67891). We have subsequently updated the measures that comprise the quality measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, 2019, 2021, 2023, 2024, 2025, and 2026 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71269, 81 FR 80484 through 80489, 83 FR 59708 through 59715, 85 FR 84733 through 84734, 87 FR 69860 through 69863, 88 FR 79112 through 79114, 89 FR 98124 through 98132, and 90 FR 49797 through 90 FR 49822, respectively).

b. Extending the Availability of the MIPS CQMs Collection Type and the MIPS CQM Reporting Incentive for Shared Savings Program ACOs

(1) Background

In the CY 2027 PFS proposed rule (91 FR 44036 and 44037), we stated that, in the CY 2025 PFS proposed rule, we proposed to streamline the collection types available for Shared Savings Program ACOs reporting the APM Performance Pathway (APP) Plus quality measure set to the eCQMs and Medicare CQMs collection types for PY 2025 and subsequent PYs (89 FR 61856 and 61857). We also stated that our proposal to establish the APP Plus quality measure set to align with the Adult Universal Foundation measure set should aim to prioritize the eCQMs collection type—the gold standard collection type that underlies the Digital Quality Measurement Strategic Roadmap (available at *https://ecqi.healthit.gov/sites/default/files/CMSdQMStrategicRoadmap_032822.pdf*)—and use Medicare CQMs as the transition step on our building-block approach for Shared Savings Program ACOs' progress to adopt digital quality measurement (89 FR 61838). As stated in the CY 2025 PFS final rule (89 FR 98107), many commenters expressed concern with the proposal to eliminate the MIPS CQMs collection type for Shared Savings Program ACOs beginning in PY 2025. These commenters stated that eliminating the MIPS CQMs collection type would cause administrative burden due to Shared Savings Program ACOs having disparate electronic health records (EHRs) and experiencing reporting challenges with the submission of the eCQMs collection type. Several commenters noted that their efforts and resources would need to focus on determining the best reporting approaches at the expense of innovations that support patients. Some commenters stressed the challenges related to prior investments made in MIPS CQM reporting infrastructure that would be wasted following the elimination of the MIPS CQM collection type. Several of these commenters stated that having limited notice from CMS that the MIPS CQMs collection type would not be available to Shared Savings Program ACOs reporting the APP Plus quality measure set provides Shared Savings Program ACOs with only a few months to pivot to another option if the proposal not to include MIPS CQMs in the APP Plus quality measure set was finalized. A commenter objected to the exclusion of the MIPS CQMs collection type from the APP Plus quality measure set and stated MIPS CQMs allow Shared Savings Program ACOs to leverage multiple data sources beyond just electronic medical record (EMR) data, including claims data, as an important component to ensuring the accuracy and completeness of data reported. Lastly, many commenters encouraged us to consider extending the availability of the MIPS CQMs collection type for Shared Savings Program ACOs and requested that the collection type remain available for an additional 1 to 3 years (89 FR 98107).

In response to these comments, we stated in the CY 2025 PFS final rule (89 FR 98107) that we acknowledged commenters' feedback regarding the challenges associated with not having MIPS CQM available to Shared Savings Program ACOs as a collection type for reporting the APP Plus quality measure set. We agreed with commenters that additional time was needed for Shared Savings Program ACOs that have invested in MIPS CQMs to transition to eCQMs and that having MIPS CQMs as a reporting option would allow Shared Savings Program ACOs to gain

experience with all payer quality measure data collection and reporting before MIPS CQMs are phased out as a collection type for Shared Savings Program ACOs. We also stated that we were aware that some Shared Savings Program ACOs had already contracted with vendors for the MIPS CQMs collection type at their own expense, and that for these Shared Savings Program ACOs, additional time to transition to the eCQMs collection type was desirable. In addition, we expressed our understanding that the MIPS CQMs collection type allows Shared Savings Program ACOs to leverage multiple data sources beyond just EMR data, thereby allowing for improved accuracy and completeness of data submitted with this collection type. For these reasons, we finalized in the CY 2025 PFS final rule that we would provide Shared Savings Program ACOs with the option to use the MIPS CQMs collection type for 2 additional PYs (that is, PYs 2025 and 2026) when reporting the APP Plus quality measure set. We stated that we believed making the MIPS CQMs collection type available for Shared Savings Program ACOs for 2 additional PYs would fairly balance investments Shared Savings Program ACOs have already made with the MIPS CQMs collection type and CMS' long-term goals of adopting digital quality measurement. As finalized in the CY 2025 PFS final rule, the collection types available to Shared Savings Program ACOs reporting the APP Plus quality measure set for PY 2025 and subsequent years recognized the need for some Shared Savings Program ACOs to build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient measures while incentivizing Shared Savings Program ACOs to transition to eCQMs (89 FR 98107). We also stated that MIPS CQMs would no longer be available starting in PY 2027 and that we would continue to monitor the uptake of collection types by Shared Savings Program ACOs in the coming years (89 FR 98107).

In the CY 2023 PFS final rule, we extended the incentive for reporting eCQMs/MIPS CQMs through PY 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow Shared Savings Program ACOs an additional year to gauge their performance on the eCQMs/MIPS CQMs before full reporting of the measures were required beginning in PY 2025 (87 FR 69836 through 69838 and 89 FR 98121). We originally adopted this incentive in the CY 2022 PFS final rule to encourage Shared Savings Program ACOs to begin the transition to eCQM/MIPS CQM reporting in PYs 2022 and 2023 (86 FR 65269).

To continue to align the reporting incentive with the MIPS CQMs collection type, in the CY 2025 PFS final rule (89 FR 98123 and 98124), we extended the reporting incentive to Shared Savings Program ACOs reporting MIPS CQMs in PYs 2025 and 2026 to further support Shared Savings Program ACOs in meeting the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track.

Specifically, we finalized that for PYs 2025 and 2026, a Shared Savings Program ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the Shared Savings Program ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a PY, meeting the data completeness requirement at § 414.1340 for all eCQMs/MIPS CQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set, and;
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

In the CY 2027 PFS proposed rule (91 FR 44037), we stated that over the past 2 years, we have developed a greater understanding of the challenges Shared Savings Program ACOs face in reporting eCQMs and transitioning to digital quality measurement. Comments stated in the CY 2025 PFS final rule (89 FR 98107), responses to the RFI on deregulation and other forums, and feedback from Shared Savings Program ACOs and other interested parties expressed concerns about increased administrative burden and Shared Savings ACO's prior investments in MIPS CQM reporting infrastructure that would be wasted if the MIPS CQMs collection type was eliminated and encouraged CMS to preserve the MIPS CQMs collection type and the corresponding MIPS CQM reporting incentive during the transition to digital quality measurement. By extending the MIPS CQMs collection type and the corresponding MIPS CQM reporting incentive, Shared Savings Program ACOs could continue to utilize investments already made in MIPS CQM reporting infrastructure while taking steps towards making the full transition to digital quality measurement. After considering the feedback we received, we believe that the widespread adoption of the all payer/all patient collection types will require further time and support.

In the CY 2025 PFS final rule, we stated that we intend to fully transition to digital quality measurement in CMS quality reporting and value-based purchasing programs (89 FR 98106). We also reiterated the numerous benefits to using eCQMs, including their use of electronic standards that reduce the burden of manual extraction and reporting for measured entities, their use of clinical data to assess the outcomes of treatment by measured entities, and their fostering of access to real-time data for point of care quality improvement and decision support (89 FR 98106).

In the CY 2027 PFS proposed rule (91 FR 44037), we referred readers to the Fast Healthcare Interoperability Resources® (FHIR®)-Based Digital Quality Measurement in the Quality Payment Program and other CMS Quality Programs—RFI in the CY 2027 PFS proposed rule (91 FR 44151). In that section, we stated that we are advancing quality measurement by transitioning existing quality measures and reporting processes to FHIR-based digital approaches and requesting public comment on the timeline for transitioning to FHIR-based quality measurement. We also stated that we requested input from interested parties, ahead of future policy decisions, on developing a phased transition to FHIR-based digital quality reporting for applicable measures (that is, the 5 eCQMs and Medicare eCQMs in the APP Plus quality measure set as proposed in the CY 2027 PFS proposed rule (91 FR 44152) under which we would introduce a 2-year transition period beginning with PY 2028. During the transition period, existing quality reporting options for Shared Savings Program ACOs (that is, eCQMs, MIPS CQMs, Medicare CQMs, and the proposed Medicare eCQMs), would continue to be available while FHIR-based digital quality measure (dQM) options are introduced for selected measures. For Shared Savings Program ACOs, the transition to FHIR-based dQMs builds upon the existing eCQM reporting infrastructure used for the APP Plus quality measure set (including APP/APP Plus measure alignment and current electronic reporting approaches) while introducing FHIR-based specifications for dQMs and related software tools, such as the Measure Authoring Development Integrated Environment (MADiE), so that Shared

Savings Program ACOs would have a feasible pathway to adopt FHIR-based quality measurement. Following this transition period, beginning with PY 2030, FHIR-based reporting would be required for those applicable measures that were available as FHIR-based dQM reporting options during the transition period. As discussed in the CY 2027 PFS proposed rule (91 FR 44152 and 44153), by PY 2030, Shared Savings Program ACOs would need to be prepared to report each applicable APP Plus measure via FHIR-based digital quality reporting where a FHIR-based dQM specification exists for that measure. For APP Plus measures that do not have FHIR-based dQM specifications following the transition period, Shared Savings Program ACOs would continue to use applicable existing reporting mechanisms (for example, MIPS CQMs, Medicare CQMs, eCQM reporting via QRDA files, and proposed Medicare eCQMs) until FHIR-based dQM options are developed and adopted through future rulemaking.

Table B–G2 of the CY 2027 PFS proposed rule (91 FR 44038) is the same as Table B–G2 in this section of this final rule (with the Medicare eCQMs collection type and flat benchmarks for Medicare CQMs and Medicare eCQMs no longer shown as ''proposed'') and illustrates the timeline for the transition to FHIR-based quality reporting for Shared Savings Program ACOs, as described in the CY 2027 PFS proposed rule (91 FR 44153), as well as potential future quality performance scoring considerations subject to future notice and comment rulemaking. We noted in the CY 2027 PFS proposed rule (91 FR 44038) that between January 21, 2026, and February 23, 2026, CMS posted and sought public comment on draft FHIR-based digital specifications for 49 eligible clinician dQMs. This posting of draft specifications included specifications for the 5 measures in the APP Plus quality measure set that currently are available under the eCQMs, MIPS CQMs, and Medicare CQMs collection types (*https://ecqi.healthit.gov/sites/default/files/FHIR-Public-Comment-Webinar-CMS-20260121.pdf*).

TABLE B-G2: IMPLEMENTATION TIMELINE AND MILESTONES FOR TRANSITION TO FHIR-BASED DIGITAL QUALITY MEASUREMENT FOR SHARED SAVINGS PROGRAM ACOS

Phase	Timeframe	Collection Types Available for Quality Reporting	Potential Future Scoring Considerations
Transition Period with FHIR-Based Reporting Options (Year 1)	PY 2028	**FHIR-based dQM reporting options:** • dQMs • Medicare dQMs **Non-FHIR-based reporting options:** • eCQMs • MIPS CQMs • Medicare CQMs • Medicare eCQMs	**FHIR-based dQM reporting options:** Benchmarking policies and reporting incentives would be established through future notice and comment rulemaking **Medicare CQMs and Medicare eCQMs:** Flat benchmarks **All other non-FHIR-based reporting options:** Consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii) Anticipate sunsetting the current MIPS CQM reporting incentives
Transition Period with FHIR-Based Reporting Options (Year 2)	PY 2029	**FHIR-based dQM reporting options:** • dQMs • Medicare dQMs **Non-FHIR-based reporting options:** • eCQMs • MIPS CQMs • Medicare CQMs Medicare eCQMs	**FHIR-based dQM reporting options:** Benchmarking policies and reporting incentives would be established through future notice and comment rulemaking **Medicare CQMs and Medicare eCQMs:** Flat benchmarks **All other non-FHIR-based reporting options:** Consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii)
Mandatory FHIR-Based Reporting	PY 2030 and subsequent PYs	**FHIR-based dQM reporting options:** • dQMs • Medicare dQMs	Benchmarking policies would be established through future notice and comment rulemaking

(2) Revisions

In the CY 2027 PFS proposed rule (91 FR 44038 and 44039), we stated that in light of the concerns raised by Shared Savings Program ACOs and other interested parties, and our commitment to supporting Shared Savings Program ACOs in the transition to dQM reporting, we proposed to extend the availability of the MIPS CQMs collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set for PY 2027 and subsequent PYs. We believe that the removal of the MIPS CQMs collection type for ACOs during this transition would be disruptive considering there was a significant increase in the number of Shared Savings Program ACOs that reported MIPS CQMs in PY 2025 compared to PYs 2023 and 2024. Based on initial PY 2025 MIPS quality submission data, Shared Savings Program ACOs are continuing to report the APP Plus quality measure set using the MIPS CQMs collection type, where 140 out of 472 financially reconciled ACOs reported at least one MIPS CQM; whereas 33 out of 453 financially reconciled Shared Savings Program ACOs in PY 2023 and 36 out of 476 financially reconciled Shared Savings Program ACOs in PY 2024 reported at least one MIPS CQM.

We stated in the CY 2027 PFS proposed rule (91 FR 44039) that maintaining the availability of the MIPS CQMs collection type for PY 2027 and subsequent PYs would eliminate the administrative burden associated with Shared Savings Program ACOs changing their current quality reporting collection type to another collection type after PY 2026 when the MIPS CQMs collection type would no longer be available under the policy finalized in the CY 2025 PFS final rule (89 FR 98123) and would also allow Shared Savings Program ACOs to focus their resources and efforts on the transition to dQM reporting instead.

In the CY 2027 PFS proposed rule (91 FR 44039), we stated that subject to future notice and comment rulemaking we anticipate sunsetting the MIPS CQMs collection type beginning in PY 2030, when FHIR-based reporting becomes mandatory for all the eCQMs and the proposed Medicare eCQMs in the APP Plus quality measure set, and we requested feedback on the phased timeline for FHIR-based reporting which starts with a 2-year transition period followed by required FHIR-based reporting for applicable measures.

In the CY 2027 PFS proposed rule (91 FR 44039), we stated that to continue to align the reporting incentive with the MIPS CQMs collection type, we proposed to extend the reporting

incentive to Shared Savings Program ACOs reporting MIPS CQMs for PY 2027 and subsequent PYs to further support Shared Savings Program ACOs in meeting the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track. Specifically, we proposed that for PY 2027 and subsequent PYs, a Shared Savings Program ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the Shared Savings Program ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a PY, meeting the data completeness requirement at § 414.1340 for all eCQMs/MIPS CQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile

of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set, and;

- Achieves a quality performance score equivalent to or higher than the 40th percentile

of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

In the CY 2027 PFS proposed rule (91 FR 44039), we stated that based on a CMS analysis of PY 2024 Shared Savings Program ACO quality results, 26 Shared Savings Program ACOs reported MIPS CQMs and met the Shared Savings Program quality performance standard by meeting the criteria for the MIPS CQM reporting incentive, through which they were eligible to receive maximum shared savings and avoid maximum shared losses (if applicable) for their track regardless of their quality score. These 26 Shared Savings Program ACOs did not achieve a quality score at or above the 40th percentile MIPS quality performance category score value, which is one of the pathways for meeting the quality performance standard, and therefore, would not have met the quality performance standard without the MIPS CQM reporting incentive.

We stated in the CY 2027 PFS proposed rule (91 FR 44039) that we would continue to assess the appropriateness of having the MIPS CQMs collection type being an available collection type for Shared Savings Program ACOs along with the associated MIPS CQM reporting incentive. Subject to future notice and comment rulemaking, we anticipate sunsetting the MIPS CQM reporting incentive when we introduce the 2-year transition period beginning with PY 2028 during which the existing quality reporting options for Shared Savings Program ACOs (that is, eCQMs, MIPS CQMs, Medicare CQMs, and the proposed Medicare eCQMs) would continue to be available while FHIR-based dQM reporting options are introduced for selected measures (that is, the 5 eCQMs and the proposed Medicare eCQMs in the APP Plus quality measure set as proposed in the CY 2027 PFS proposed (91 FR 44039)).

In the CY 2027 PFS proposed rule (91 FR 44039), we noted that we proposed to create the Medicare eCQMs collection type, which would be a new collection type for PY 2027 and subsequent PYs. In the CY 2027 PFS proposed rule (91 FR 44039), we stated that, as part of our proposal to extend the availability of the MIPS CQMs collection type and the MIPS CQM reporting incentive for PY 2027 and subsequent PYs, § 425.512(a) would contain the following information:

- Under paragraph (a)(2)(iv), we would specify that the paragraph applies to eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs.
- Under paragraph (a)(5)(i)(B), we would specify that the paragraph applies to PY 2025 and subsequent PYs.
- We would remove paragraph (a)(5)(i)(C).
- We would revise paragraph (a)(5)(iii)(C) to specify that it applies to eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs.

We sought public comments on our proposals to extend the availability of the MIPS CQMs collection type for Shared Savings Program ACOs and the MIPS CQM reporting incentive for PY 2027 and subsequent PYs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported our proposals to extend the availability of the MIPS CQMs collection type for Shared Savings Program ACOs and the MIPS CQM reporting incentive for PY 2027 and subsequent PYs. Many of these supportive commenters cited ongoing interoperability, health IT, data aggregation and digital reporting challenges, and the need to reduce administrative and technical burden during the transition to digital quality measurement and FHIR-based reporting as reasons to extend the MIPS CQMs collection type and associated reporting incentive. Many supportive commenters further cited the importance of maintaining flexibility, stability, predictability, and consistent reporting options throughout the transition to mandatory FHIR-based reporting.

Several of these commenters supported the proposal and noted that retaining the MIPS CQMs collection type reduces burden for ACOs that have invested significant resources in this collection type and helps organizations serving complex beneficiary populations address ongoing reporting challenges. Several supportive commenters noted that availability of the MIPS CQMs collection type supports continued participation in the Shared Savings Program. Several other supportive commenters noted that the extension of the MIPS CQMs collection type through PY 2029 provides a realistic transition period for adopting FHIR-based reporting.

A couple commenters supported the proposal and noted that extending the MIPS CQM reporting incentive through PY 2027 and subsequent years recognizes the scoring challenges when reporting on all payers and all patients, and when serving complex, homebound, and facility-based beneficiaries.

Response: We appreciate comments that support our proposals to extend the availability of the MIPS CQMs collection type for Shared Savings Program ACOs and the MIPS CQM reporting incentive for PY 2027 and subsequent PYs.

Comment: A commenter requested that CMS clarify whether the MIPS CQM reporting incentive would persist through the full duration of the availability of the MIPS CQMs collection type.

Response: We are finalizing as proposed to extend the reporting incentive to Shared Savings Program ACOs reporting MIPS CQMs for PY 2027 and subsequent PYs. The sunsetting of the MIPS CQM reporting incentive would be subject to future notice and comment rulemaking. In the CY 2027 PFS proposed rule (91 FR 44039), we stated that (subject to future rulemaking), we anticipate sunsetting the MIPS CQM reporting incentive when the 2-year FHIR-based reporting transition period begins in PY 2028 (which is before the anticipated sunsetting of the MIPS CQM collection type (PY 2030)).

Comment: A commenter recommended that CMS continue to extend the MIPS CQMs collection type and reporting incentives until organizations have demonstrated that adopting FHIR-based reporting is feasible within various EHRs and registry environments.

Response: The sunsetting of the MIPS CQMs collection type and MIPS CQM reporting incentive would be subject to future notice and comment rulemaking,

at which time feasibility and functionality of FHIR-based reporting may be considered.

After consideration of public comments, we are finalizing as proposed to extend the availability of the MIPS CQMs collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set for PY 2027 and subsequent PYs. We are also finalizing as proposed to extend the reporting incentive to Shared Savings Program ACOs reporting MIPS CQMs for PY 2027 and subsequent PYs to further support Shared Savings Program ACOs in meeting the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track. Specifically, we are finalizing that for PY 2027 and subsequent PYs, a Shared Savings Program ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the Shared Savings Program ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a PY, meeting the data completeness requirement at § 414.1340 for all eCQMs/MIPS CQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set, and;
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

We note that, in section III.G.3.d.(3) of this final rule, we are finalizing our proposal to create the Medicare eCQMs collection type, which will be a new collection type for PY 2027 and subsequent PYs. As part of our final policies to extend the availability of the MIPS CQMs collection type and the MIPS CQM reporting incentive for PY 2027 and subsequent PYs, § 425.512(a) would contain the following information:

- Under paragraph (a)(2)(iv), we are specifying that the paragraph applies to eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs.
- Under paragraph (a)(5)(i)(B), we are specifying that the paragraph applies to PY 2025 and subsequent PYs.
- We are removing paragraph (a)(5)(i)(C).
- We are revising paragraph (a)(5)(iii)(C) to specify that it applies to eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs.

c. Extending the Scoring of Shared Savings Program ACOs Reporting Medicare CQMs Using Flat Benchmarks

(1) Background

In the CY 2027 PFS proposed rule (91 FR 44039 and 44040), we stated that in the CY 2024 PFS final rule (88 FR 79110), we finalized our proposal to establish Medicare CQMs and new benchmarks for scoring Shared Savings Program ACOs on the Medicare CQMs under MIPS in alignment with MIPS benchmarking policies. Because historical Medicare CQM data would not be available, we finalized that for PYs 2024 and 2025, we would score Medicare CQMs using performance period benchmarks. We also finalized that, for PY 2026 and subsequent PYs, when baseline period data became available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii), we would score Medicare CQMs using historical benchmarks.

As stated in the CY 2024 PFS final rule (88 FR 79109 and 79110), a few commenters expressed concern about Shared Savings Program ACOs being compared only to other Shared Savings Program ACOs that report Medicare CQMs. As part of their concern, they referenced that Medicare CQMs would be available only to Shared Savings Program ACOs. A commenter stated their preference to have their quality performance compared to all other participants on these measures, while another commenter stated that CMS should stop measuring Shared Savings Program ACOs against each other and instead measure Shared Savings Program ACOs on a national standard so that all ACOs can pass and do not lose out on savings due to arbitrary quality decile cut points. In our response to these comments, we stated that given that benchmarks are specific to each collection type and that since we proposed to establish Medicare CQMs as a new collection type for only Shared Savings Program ACOs, only Shared Savings Program ACO data will be available to benchmark Medicare CQMs. For these reasons, we stated that it was appropriate to establish benchmarks for Medicare CQMs that were consistent with MIPS benchmarking policies (88 FR 79110). We also stated that Shared Savings Program ACOs that prefer to be compared to clinicians at large could do so by reporting eCQMs or MIPS CQMs, for which CMS calculates a benchmark using data reported by MIPS eligible clinicians reporting under the chosen collection type.

In the CY 2025 PFS final rule (89 FR 98117), we stated that in PY 2022, Shared Savings Program ACOs had a higher average performance on quality measures they were required to report to share in savings compared to other similarly sized clinician groups not in the Shared Savings Program. This included statistically significant higher performance for quality measures related to diabetes and blood pressure control; breast cancer and colorectal cancer screening; tobacco screening and smoking cessation; and depression screening and follow-up. We further stated that in shifting to Medicare CQMs, Shared Savings Program ACOs' quality performance would be benchmarked against other Shared Savings Program ACOs only reporting Medicare CQMs. We explained that since Shared Savings Program ACOs are high performers relative to comparably sized MIPS groups, benchmarking Medicare CQMs using only Shared Savings Program ACO data would lower some Shared Savings Program ACOs' MIPS measure achievement points on those measures. In other words, high-performing Shared Savings Program ACOs could earn lower measure achievement points relative to comparable MIPS groups because the Medicare CQM benchmarking pool is comprised of higher-than-average performance data. This would, in effect, create a ''tournament approach'' to scoring Medicare CQMs wherein Shared Savings Program ACOs must compete with other Shared Savings Program ACOs to earn measure achievement points.

In the CY 2025 PFS final rule, we finalized our proposal to add § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQMs collection type would be scored using flat benchmarks for their first 2 performance periods in MIPS (89 FR 98120). We further stated that the use of flat benchmarks would allow Shared Savings Program ACOs with high scores to earn maximum or near maximum achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years (89 FR 98118). Use of flat benchmarks also helps to ensure that Shared Savings Program ACOs with high quality performance on a measure are not penalized as low performers (89 FR 98118).

As stated in the CY 2025 PFS final rule, many commenters supported the proposal to score Shared Savings Program ACOs reporting Medicare CQMs using flat benchmarks (89 FR

98119). A commenter stated that it will be a difficult transition for ACOs to progress from the CMS Web Interface attestation method to CQM/eCQM reporting and that Medicare CQM flat benchmarking will remove uncertainty from Shared Savings Program ACO attestation to Medicare CQMs as they will no longer have to rely on benchmarking based upon the PY (89 FR 98119). Additionally, many commenters recommended that flat benchmarks for Medicare CQM be made permanent rather than for 2 years and noted that flat benchmarks make Medicare CQM scoring more predictable (89 FR 98120). A commenter recommended that CMS consider extending the flat benchmark scoring policies for Medicare CQMs beyond each measure's first 2 performance periods and some commenters recommended that CMS retroactively apply the flat benchmark policy for the 2024 performance period (89 FR 98120).

In response to comments on the proposals in the CY 2026 PFS final rule (90 FR 49812) related to removing the population and income adjustment applied to a Shared Savings Program ACO's quality score beginning in PY 2025, another commenter stated that flat benchmarks are temporary and are not a lasting offset to the unique challenges faced by Shared Savings Program ACOs that serve high Area Deprivation Index (ADI), Medicare Part D Low Income Subsidy (LIS), and dual eligible populations. We stated that should we consider extending flat benchmarks for Medicare CQMs, we would do so through notice and comment rulemaking (90 FR 49813).

(2) Revisions

In the CY 2027 PFS proposed rule (91 FR 44040 through 44044), we stated that through responses to the RFI on deregulation and other forums, Shared Savings Program ACOs and other interested parties expressed support for policies that promote continuity while Shared Savings Program ACOs transition to digital quality measurement. In response to ACOs' concerns and to support Shared Savings Program ACOs in the transition to dQM reporting, for PY 2027 and subsequent years, in the CY 2027 PFS proposed rule (91 FR 44040 through 44044, 44205), we proposed that all measures of the Medicare CQMs collection type would be scored using flat benchmarks. We also proposed that for PY 2026, the following measures reported via the Medicare CQMs collection type for PY 2026 are scored using flat benchmarks instead of using historical benchmarks as finalized in the CY 2025 PFS final rule (89 FR 98120): Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001), Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134), and Controlling High Blood Pressure (Quality ID: 236). These three Medicare CQMs, under the policy finalized in the CY 2025 PFS final rule (89 FR 98120), would have historical benchmarks for PY 2026, consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii), because these measures would be in their third performance period in MIPS. We proposed that Quality IDs: 001, 134, and 236, if reported via the Medicare CQMs collection type for PY 2026 (and subsequent years), would be scored using flat benchmarks (91 FR 44205). As discussed in the CY 2027 PFS proposed rule (91 FR 44042), failure to apply this change retroactively would be contrary to the public interest. We noted that Breast Cancer Screening (Quality ID: 112) and Colorectal Cancer Screening (Quality ID: 113) reported via the Medicare CQMs collection type would be scored using flat benchmarks for PY 2026 under the policy finalized in the CY 2025 PFS final rule (89 FR 98120), which is consistent with CMS' intent to score all measures reported via Medicare CQMs collection type using flat benchmarks.

We also stated in the CY 2027 PFS proposed rule (91 FR 44040 and 44041) that in response to commenters who requested that we make Medicare CQMs a permanent collection type in the CY 2025 PFS final rule (89 FR 98108), we stated that from the inception of the Medicare CQMs collection type beginning in PY 2024, that we intended for the Medicare CQMs collection type to serve as a transition collection type to help ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient measures (88 FR 79097 and 79098). In addition, as we stated in the CY 2025 PFS proposed rule, we believed that our policy to establish the APP Plus quality measure set to align with the Adult Universal Foundation measure set should also aim to prioritize the eCQMs collection type and the use of the Medicare CQMs collection type is a transition step on our building-block approach for ACOs to adopt digital quality measurement (89 FR 61838). We noted in the CY 2025 PFS final rule that the sunsetting of Medicare CQMs would take place no sooner than 5 years from the time the rule was written, when we anticipated there would be widespread uptake of FHIR API technology (89 FR 98108). While FHIR technology is employed in other components of digital health information, we noted that we would assess the uptake of FHIR API technology for quality reporting in alignment with the CMS Digital Quality Measurement Strategic Roadmap, specifically, Domain 3: Optimize Data Aggregation. In particular, we would assess whether Shared Savings Program ACOs broadly have developed capabilities to efficiently leverage FHIR API technology to aggregate quality reporting data and patient-centered measurement and are reporting eCQMs.

We stated in the CY 2027 PFS proposed rule (91 FR 44041) that, as of PY 2026, FHIR-based reporting of quality measures to CMS is not yet available to Shared Savings Program ACOs. As discussed in the CY 2027 PFS proposed rule (91 FR 44152), we intend to introduce a 2-year transition period to FHIR-based reporting beginning with PY 2028. During the transition period, existing quality reporting options for Shared Savings Program ACOs (that is, eCQMs, MIPS CQMs, Medicare CQMs, and the proposed Medicare eCQMs) would continue to be available while FHIR-based dQM options are introduced for selected measures (that is, the 5 eCQMs and the proposed Medicare eCQMs in the APP Plus quality measure set as proposed in the CY 2027 PFS proposed rule (91 FR 44150)). Following this transition period, beginning with PY 2030, FHIR-based reporting would be required for those applicable measures that were available as FHIR-based dQM reporting options during the transition period. The timing of this transition would influence our proposals related to the collection types available to Shared Savings Program ACOs and the associated scoring policies. We anticipate sunsetting the Medicare CQMs collection type and the use of flat benchmarks to score Medicare CQMs beginning in PY 2030, when FHIR-based reporting becomes mandatory for all the eCQMs and proposed Medicare eCQMs in the APP Plus quality measure set. As discussed in the CY 2027 PFS proposed rule (91 FR 44151 through 44154), we requested feedback on the phased timeline for FHIR-based reporting which starts with a 2-year transition period followed by required FHIR-based reporting for applicable measures. We noted that we expect the policies associated with this timeline would be proposed through future rulemaking.

In response to commenters who requested that we extend or make permanent flat benchmarks for Medicare CQMs, we stated in the CY 2025 PFS final rule (89 FR 98120) that we believed that the baseline period data,

which would be available to establish historical benchmarks is consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii). As we stated in the CY 2025 PFS proposed rule (89 FR 61860), the use of historical benchmarks, when data are available, allows Shared Savings Program ACOs to know benchmarks prior to start of the PY and create opportunities for improvement. Also, as discussed in the CY 2024 PFS final rule, since Medicare CQMs would be subject to MIPS scoring policies, the application of MIPS benchmarking policies to Medicare CQMs is both logical and necessary for implementation of the new collection type (88 FR 79180). We believe it is no longer logical to apply this benchmark methodology to Medicare CQMs due to Shared Savings Program ACOs' concerns that quality-related changes are disruptive to the transition to digital quality measurement as well as due to the sunsetting of the population and income adjustment as finalized in the CY 2026 PFS final rule, each described in further detail in the CY 2027 PFS proposed rule (91 FR 44041 and 44042).

We stated in the CY 2027 PFS proposed rule (91 FR 44041) that, in 2025, we conducted interviews with a sample of Shared Savings Program ACOs who reported Medicare CQMs for PY 2024, the first year of the Medicare CQMs collection type.[293] Interviewed Shared Savings Program ACOs reported continued challenges with the transition to digital quality measurement. Some Shared Savings Program ACOs shared that uncertainty regarding digital reporting standards have led them to restrict or pause adding new practices to their organization. These new restrictions limit practice access to the Shared Savings Program and beneficiary access to value-based care. To support the transition to digital quality measurement, Shared Savings Program ACOs and other interested parties that responded to the RFI on deregulation demonstrated support for policies that promote continuity and recommended against further alignment of Shared Savings Program quality reporting policies with MIPS. Given the challenges and concerns that Shared Savings Program ACOs have shared regarding navigating additional Shared Savings Program policy changes in a time of larger quality reporting transition, coupled with Shared Savings Program ACO patient data privacy concerns and lack of capability to report other measure collection types such as eCQMs, as discussed in the CY 2027 PFS proposed rule (91 FR 44039 through 44044), we proposed to extend the use of flat benchmarks to score all Medicare CQMs for PY 2027 and subsequent PYs, and for Quality IDs 001, 134, and 236 for PY 2026. This proposal would continue to support Shared Savings Program ACOs that choose to report via that collection type during the transition to reporting and would be consistent with the goals of the deregulatory RFI (90 FR 15481 and 15482).

We stated in the CY 2027 PFS proposed rule (91 FR 44041) that, under current policy, flat benchmarks for Medicare CQMs are only used in a measure's first two years in MIPS. Thus, the number of Medicare CQMs in the APP Plus quality measure set that will use flat benchmarks will decline over time. For PY 2025, all four Medicare CQMs (Quality IDs 001, 112, 134, and 236) in the APP Plus quality measure set were scored using flat benchmarks; however, this number decreased to two (Quality IDs 112 and 113) of five Medicare CQMs for PY 2026.

In the CY 2026 PFS final rule (90 FR 49807), we stated that we conducted an internal analysis of the PY 2024 Shared Savings Program ACO quality results to better understand the potential impact of the proposed removal of the population and income adjustment on 13 ACOs that earned the population and income adjustment bonus points and reported only Medicare CQMs. Specifically, we simulated the application of flat benchmarks for Medicare CQMs (as described at § 414.1380(b)(1)(ii)(F)), which was in effect starting in PY 2025. Had flat benchmarks been applied to the three Medicare CQMs in the APP quality measure set in PY 2024, the average MIPS quality performance category score earned by these 13 Shared Savings Program ACOs would have been on average 14 percentage points higher compared to an average increase of 4 percentage points that these Shared Savings Program ACOs earned from the population and income adjustment in PY 2024, a difference of 10 percentage points. This would thus increase the likelihood that these Shared Savings Program ACOs would meet the quality performance standard by achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring or the alternative quality performance standard. We also stated that, while we anticipate that Shared Savings Program ACOs that choose to report Medicare CQMs would not be eligible for the eCQM/MIPS CQM reporting incentive or the Complex Organization Adjustment, these Shared Savings Program ACOs would likely sufficiently benefit from our policy to score Medicare CQMs using flat benchmarks as described at § 414.1380(b)(1)(ii)(F). Specifically, we anticipated that these Shared Savings Program ACOs would receive a positive scoring impact under flat benchmarks for Medicare CQMs, that would be greater than the current positive scoring impact these Shared Savings Program ACOs received under the population and income adjustment. This analysis further reflected the substantial impact of flat benchmarks on Shared Savings Program ACOs' quality scores. Since the population and income adjustment is no longer applicable beginning in PY 2026, as finalized in the CY 2026 PFS final rule (90 FR 49815), using flat benchmarks to score Quality IDs 001, 134, and 236 if reported via the Medicare CQMs collection type for PY 2026, and scoring all Medicare CQMs using flat benchmarks in PY 2027 and subsequent PYs, would further support Shared Savings Program ACOs that will no longer have access to the population and income adjustment and help ensure that Shared Savings Program ACOs with high quality performance on a measure are not penalized as low performers. Additionally, Shared Savings Program ACOs that report quality measures using the eCQMs or MIPS CQMs collection type may qualify for the collection type's respective reporting incentive or may be eligible to receive the Complex Organization Adjustment (if reporting using the eCQMs collection type). This proposed policy would also support Shared Savings Program ACOs that do not yet report or cannot report eCQMs or MIPS CQMs.

In the CY 2027 PFS proposed rule (91 FR 44042), we stated that section 1871(e)(1)(A) of the Act prohibits the Secretary from applying substantive changes in regulations retroactively before the effective date of the change except where the Secretary determines, as relevant here, that failure to apply the change retroactively would be contrary to the public interest. It is in the public interest to apply our proposed change to score Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001), Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134), and Controlling High Blood Pressure (Quality ID: 236) when reported via the Medicare CQMs collection type for PY 2026 using flat benchmarks. The evaluation of Shared

[293] aimaim and Claim Line Feed (CCLF) Information Packet (IP)'' (version 43.0, 5/13/2026), available at *https://www.cms.gov/files/document/cclf-information-packet.pdf*.

Savings Program ACOs' PY 2026 quality performance, including the use of measure benchmarks to calculate quality scores, will occur in PY 2027. Retroactive application of flat benchmarks for Medicare CQMs for PY 2026 would enable the Shared Savings Program to better recognize the quality of care provided in PY 2026 and incentivize future improvements based on the evaluation of that care. We analyzed PY 2024 data on Shared Savings Program ACOs that reported all three Medicare CQMs in the APP quality measure set, which had performance-based benchmarks, and compared PY 2024 quality scores to simulated quality scores using flat benchmarks for the three Medicare CQMs. Flat benchmarks were estimated to increase average quality scores by 11 percentage points in this analysis.[294] Higher percentage points would increase the likelihood that these Shared Savings Program ACOs would meet the quality performance standard for sharing in savings at the maximum rate under its track by achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring or the alternative quality performance standard to be eligible to share in savings at a lower rate that is scaled based on the ACO's quality performance. The quality performance standard helps hold Shared Savings Program ACOs accountable for the quality of care their providers furnish to their beneficiaries and further encourages ACOs to demonstrate consistently that they are providing high quality of care to their beneficiary populations year over year (90 FR 49836). This analysis also illustrated that the use of performance-based benchmarks could lead to Shared Savings Program ACOs forgoing shared savings that might otherwise have been available for reinvestment. Based on the Shared Savings Program ACO public reporting requirements § 425.308(b)(4)(ii), Shared Savings Program ACOs that generate shared savings must publicly report the total proportion of shared savings invested in infrastructure, redesigned care processes, and other resources required to support the triple aim of better health for populations, better care for individuals, and lower growth in expenditures, including the proportion distributed among Share Savings Program ACO participants. As such, the proposed change would afford the Shared Savings Program ACOs with increased shared savings the opportunity to devote greater resources to providing better quality of care to Medicare beneficiaries over time and improving care coordination that benefits the Medicare beneficiaries served by the Shared Savings Program ACOs.

Additionally, Shared Savings Program ACOs that participated in the interviews discussed in the CY 2027 PFS proposed rule (91 FR 44042) also shared that some practices have closed due to financial challenges associated with the transition to digital quality measurement. Furthermore, some Shared Savings Program ACOs have begun to remove practices that cannot meet digital reporting requirements from their organization.[295] For practices experiencing financial and organizational instability, the loss of shared savings would compound these challenges and may cause them to close or negatively affect their ability to provide continuity of care, coordination of care, preventive care initiatives, and quality improvement initiatives for Medicare beneficiaries they serve. As a result, beneficiaries may experience challenges with accessing care, ineffective utilization of services, fragmented care, or duplicative tests or services, and ACOs may be slower to adopt digital quality measurement as a result.

As discussed in the CY 2027 PFS proposed rule (91 FR 44042 and 44043), our proposal to remove Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) and Adult Immunization Status (Quality ID: 493) from the APP Plus quality measure set beginning in PY 2027, would result in the APP Plus quality measure set to have five Medicare CQMs for PY 2027 and subsequent PYs. These are the same Medicare CQMs that are in the APP Plus quality measure set for PY 2026. Under the proposals described in the CY 2027 PFS proposed rule (91 FR 44040 through 44044), all Medicare CQMs in the APP Plus measure set (Quality IDs: 001, 112, 113, 134, and 236) would be scored using flat benchmarks for PY 2026 and subsequent PYs. The proposed APP Plus quality measure set for PY 2027 and subsequent PYs is displayed in Table B–G5 of the CY 2027 PFS proposed rule (91 FR 44055). The APP Plus quality measure set for PY 2026 is displayed in Table 40 of the CY 2025 PFS final rule (89 FR 98129).

As discussed in the CY 2025 PFS final rule, a quality performance benchmark is the performance rate a Shared Savings Program ACO must achieve to earn the corresponding quality points for each measure (89 FR 98118). Flat benchmarks assign a performance rate range to each decile. In flat benchmarks for non-inverse measures, any performance rate at or above 90 percent is treated as the top decile; any performance rate between 80 percent and 89.99 percent would be treated as the second highest decile, and so on. For inverse measures, this would be reversed—any performance rate at or below 10 percent would be treated as the top decile; any performance rate between 10.01 percent and 20 percent would be treated as the second highest decile, and so on. The number of measure achievement points received for each measure is determined based on where a Shared Savings Program ACO's performance rate is within the benchmark decile categories.

For non-inverse measures, better quality performance is indicated by a higher performance rate. For example, Controlling High Blood Pressure (Quality ID: 236) is a non-inverse measure that measures the percentage of patients 18 to 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period. Better quality performance on this measure is demonstrated by having a higher percentage of patients whose blood pressure was adequately controlled. Table B–G3 of the CY 2027 PFS proposed rule lists the flat benchmarks for a non-inverse Medicare CQM under our proposals in the CY 2027 PFS proposed rule (91 FR 44043). For example, if a Shared Savings Program ACO reports a non-inverse Medicare CQM in PY 2026 or a subsequent PY and earns a performance rate of 55.25 percent, then the Shared Savings Program ACO would score in the 6th decile on that measure.

For inverse measures, better quality performance is indicated by a lower performance rate. This is reflected in flat benchmark such that lower quality performance rates are found in higher deciles. For example, Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001) is an inverse quality measure that measures the percentage of patients 18–75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) greater than 9.0 percent

[294] See, for example, Medicare Share dd Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0.* (Appendix F: Report Descriptions).

[295]

during the measurement period. Better quality performance on this measure is demonstrated by having a lower percentage of patients whose glycemic status assessment was greater than 9.0 percent. Table B–G4 of the CY 2027 PFS proposed rule lists the flat benchmarks for an inverse Medicare CQM under our proposals discussed in the CY 2027 PFS proposed rule (91 FR 44044). For example, if a Shared Savings Program ACO reports an inverse Medicare CQM in PY 2026 or subsequent year and earns a performance rate of 12.25 percent, then the Shared Savings Program ACO would score in the 9th decile on that measure. Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001) is the only inverse Medicare CQM in the APP Plus quality measure set.

There are scoring scenarios in which Shared Savings Program ACOs would earn higher measure achievement points under flat benchmarks compared to those they would earn under performance period benchmarks. Most notable are scenarios in which Shared Savings Program ACOs have a tight distribution of performance rates on a measure. For example, a non-inverse measure for which a performance rate of 90.00 percent is in the 8th decile. In this example, a Shared Savings Program ACO that reported a performance rate of 90.00 percent would be scored in the 8th decile when the hypothetical performance period benchmark is applied. Using the flat benchmarks described in Table B–G3 of the CY 2027 PFS proposed rule (91 FR 44043), a Shared Savings Program ACO that reported a performance rate of 90.00 percent would be scored in the 10th decile, resulting in greater measure achievement points than under the hypothetical performance period benchmarks described in this example. For more details on the calculation of measure achievement points, we refer readers to the ''APM Performance Pathway (APP) Toolkit'' which is updated for each PY and posted in the QPP Resource Library.

As described in the CY 2027 PFS proposed rule (91 FR 44040 and 91 FR 44205) and in § 414.1380(b)(1)(ii)(F)(2), we proposed that beginning with the CY 2026 performance period/2028 MIPS payment year, measures of the Medicare CQMs collection type would use flat benchmarks.

We sought public comment on our proposals to score Shared Savings Program ACOs reporting Medicare CQMs using flat benchmarks for PY 2027 and subsequent years and to retroactively apply the flat benchmarks for Quality IDs: 001, 134, and 236 when reported via the Medicare CQMs collection type for PY 2026.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported our proposal to score Medicare CQMs using flat benchmarks for PY 2027 and subsequent years. Many commenters stated that extending the use of flat benchmarks to score Medicare CQMs provides increased predictability, transparency, and stability, and noted the advantage of consistency in a time of evolving quality reporting requirements and during the transition to digital quality measurement. A commenter supported the proposal and recommended that CMS maintain stable quality scoring methodologies during the transition to digital quality measurements. A commenter also noted that flat benchmarks appropriately reward high-quality performance while preserving opportunities for continued improvement.

Many commenters highlighted the limitations of performance-based or historical benchmarks for measures only used in the Shared Savings Program. Several commenters noted that performance-based or historical benchmarks can distort performance results when based only on Shared Savings Program ACOs. Another commenter stated that flat benchmarks prevent Shared Savings Program ACOs from being penalized due to comparisons to prior high performance and encourage participation from new ACOs. A commenter stated that flat benchmarks protect high performers from being scored against a moving target.

Several commenters stated that flat benchmarks enable ACOs to focus on improving quality of care and data infrastructure modernization rather than focusing on reporting infrastructure and its associated administrative burden. A commenter noted administrative burden when measures within the same measure set use different benchmark methodologies. A commenter stated that flat benchmarks better recognize long-term investments in care management, clinical integration, quality improvement programs, and population health capabilities.

Several comments noted that flat benchmarks can prevent scoring results that reflect methodology differences rather than actual changes in clinical performance. A commenter stated that flat benchmarks can address challenges that can arise when benchmark distributions produce counterintuitive results.

A few comments supported the proposal to extend the use of flat benchmarks and stated that, in the absence of flat benchmarks, Shared Savings Program ACOs that reported via the Medicare CQMs collection type would be evaluated using MIPS benchmarks.

Response: We appreciate comments that support our proposal to score Medicare CQMs using flat benchmarks for PY 2027 and subsequent PYs.

Comment: Some commenters supported our proposal to score Medicare CQMs using flat benchmarks and suggested that CMS should periodically reassess the appropriateness of flat benchmarks and evaluate whether observed performance changes reflect improvements in care or differences in data capture and reporting methods. A commenter encouraged CMS to monitor benchmark performance to ensure that benchmarks appropriately distinguish high performers while avoiding unintended consequences for organizations serving medically complex, rural, or socially at-risk populations.

Response: We appreciate the supportive comments. We will continue to monitor ACOs' uptake of Medicare CQMs, the appropriateness of the flat benchmarks and how to assess quality of care improvements and differences as a result of using flat benchmarks.

Comment: A commenter supported our proposals to score Medicare CQMs using flat benchmarks for PY 2027 and subsequent PYs and also retroactively for PY 2026 when Quality IDs 001, 134, and 236 are reported as Medicare CQMs, but requested that CMS ensure that high-performing organizations are not disadvantaged by changes in scoring methodology.

Response: We appreciate the supportive comment. We stated in the CY 2027 PFS proposed rule (91 FR 44042) that we analyzed PY 2024 data on Shared Savings Program ACOs that reported all three Medicare CQMs in the APP quality measure set, which had performance-based benchmarks, and compared PY 2024 quality scores to simulated quality scores using flat benchmarks for the three Medicare CQMs. Flat benchmarks were estimated to increase average quality scores by 11 percentage points in this analysis. Higher percentage points would increase the likelihood that these Shared Savings Program ACOs would meet the quality performance standard for sharing in savings at the maximum rate under its track by achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category

scores, excluding entities/providers eligible for facility-based scoring or the alternative quality performance standard to be eligible to share in savings at a lower rate that is scaled based on the ACO's quality performance. The quality performance standard helps hold Shared Savings Program ACOs accountable for the quality of care furnished by the ACO and further encourages ACOs to demonstrate consistently that they are providing high quality of care to their beneficiary populations year over year (90 FR 49836). This analysis also illustrated that the use of performance-based benchmarks could lead to Shared Savings Program ACOs forgoing shared savings that might otherwise have been available for reinvestment. We will continue evaluating the use of flat benchmarks.

Comment: A commenter supported the use of flat benchmarks to score Medicare CQMs and recommended that CMS maintain separate benchmarks for Medicare CQMs and Medicare eCQMs, stating that separate benchmarks better account for differences in data collection methodologies and support more appropriate performance assessment across collection types.

Response: We agree with the commenter's suggestion to maintain separate benchmarks for Medicare CQMs and Medicare eCQMs as performance distributions may differ between collection types and note that, as stated at § 414.1380(b)(1)(ii), benchmarks are specific to each collection type. As such, Medicare CQMs and Medicare eCQMs will have separate benchmarks. Table B–G3 and Table B–G4 in this section of the final rule list the flat benchmarks for a non-inverse and an inverse Medicare CQM, respectively, for PY 2026 and subsequent PYs. As discussed in section III.G.3.d.(3) of this final rule, we are finalizing our proposal to score Medicare eCQMs using flat benchmarks beginning in PY 2027, and we believe that it is appropriate to use the same scales for both Medicare CQMs and Medicare eCQMs while ACOs gain experience with reporting these collection types and because Medicare eCQMs are a new collection type. The scales for the flat benchmarks for Medicare eCQMs are the same scales that were established for the flat benchmarks for Medicare CQMs when they were established in the CY 2025 PFS final rule (89 FR 98118 and 98119). We will continue to evaluate the appropriateness of the scales used for the flat benchmarks for Medicare CQMs and Medicare eCQMs.

Comment: Most commenters supported our proposal to retroactively apply the flat benchmarks to score Quality IDs: 001, 134, and 236 when reported via the Medicare CQMs collection type for PY 2026. Several commenters stated that the retroactive application of flat benchmarks improves benchmarking transparency, reduces reporting uncertainty, and promotes scoring consistency. Many of these commenters also noted that use of flat benchmarks provides the same scoring benefit to Shared Savings Program ACOs when reporting Shared Savings Program-specific measures. A few of these comments also stated that the retroactive application of the policy will reduce burden for ACOs.

A few commenters reported that maintaining consistent benchmarks is particularly important during the transition to digital quality measurement and other quality reporting transitions. A commenter also stated that this change enables ACOs to focus resources on quality improvement and that flat benchmarks support predictability by preventing scoring changes due to benchmark fluctuations.

Response: We appreciate the support for our proposal to retroactively apply the flat benchmarks to score Quality IDs: 001, 134, and 236 when reported via the Medicare CQMs collection type for PY 2026.

Comment: A commenter suggested that CMS provide additional justification regarding the retroactive use of flat benchmarks rather than the planned historical benchmarks for PY 2026. A commenter, while supportive of the proposal to use flat benchmarks to score Medicare CQMs, opposed the retroactive application of flat benchmarks to PY 2026. The commenter stated that the retroactive provision creates unpredictability and that Shared Savings Program ACOs should know the measure benchmarks prior to the start of the PY so that they can incorporate those standards into quality improvement strategies and appropriately direct clinical and operational resources.

Response: We proposed that Quality IDs: 001, 134, and 236, if reported via the Medicare CQMs collection type for PY 2026 would be scored using flat benchmarks. We discussed in the CY 2027 PFS proposed rule (91 FR 44042) that failure to apply this change retroactively would be contrary to the public interest and provided a detailed rationale to support our proposal in the CY 2027 PFS proposed rule. We stated in the CY 2027 PFS proposed rule that the evaluation of Shared Savings Program ACOs' PY 2026 quality performance, including the use of measure benchmarks to calculate quality scores, will occur in PY 2027. Retroactive application of flat benchmarks for Medicare CQMs for PY 2026 would enable the Shared Savings Program to better recognize the quality of care provided in PY 2026 and incentivize future improvements based on the evaluation of that care. We described that our simulated analysis of PY 2024 data showed that flat benchmarks were estimated to increase average quality scores by 11 percentage points, thus increasing the likelihood that Shared Savings Program ACOs would meet the quality performance standard for sharing in savings at the maximum rate under its track. This analysis also illustrated that the use of performance-based benchmarks, if flat benchmarks are not used, could lead to Shared Savings Program ACOs forgoing shared savings that might otherwise have been available for reinvestment. As such, applying flat benchmarks would afford the Shared Savings Program ACOs with increased shared savings the opportunity to devote greater resources to providing better quality of care to Medicare beneficiaries over time and improving care coordination that benefits the Medicare beneficiaries served by the Shared Savings Program ACOs. Additionally, we stated in the CY 2027 PFS proposed rule (91 FR 44042) that for practices experiencing financial and organizational instability, such as due to financial challenges associated with the transition to digital quality measurement, the loss of shared savings would compound these challenges and may cause them to close or negatively affect their ability to provide continuity of care, coordination of care, preventive care initiatives, and quality improvement initiatives for Medicare beneficiaries they serve.

In response to the commenter's concern that the retroactive application of flat benchmarks to score the three Medicare CQMs in PY 2026 would create unpredictability and that Shared Savings Program ACOs should know the measure benchmarks prior to the start of the PY, we acknowledge the preference for Shared Savings Program ACOs to know the measure benchmarks prior to the start of the PY but note that the policy as finalized will ensure that Shared Savings Program ACOs know the measure benchmarks prior to the end of the PY 2026 and before the Shared Savings Program ACO is required to submit quality data for PY 2026. We also note that these benchmarks are the same as the flat benchmarks used to score Medicare CQMs for PY 2025.

Specifically, the PY 2026 flat benchmarks we are finalizing for Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001), Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134), and Controlling High Blood Pressure (Quality ID: 236) are the same flat benchmarks used to score these measures for PY 2025, as established in the CY 2025 PFS final rule (89 FR 98118 and 98119). We believe that this will enable Shared Savings Program ACOs to incorporate those standards into quality improvement strategies and appropriately direct clinical and operational resources.

As described in section IV.B.1.c.(1) of this final rule and in § 414.1380(b)(1)(ii)(F)(2), we are finalizing as proposed that beginning with the CY 2026 performance period/2028 MIPS payment year, measures of the Medicare CQMs collection type would use flat benchmarks. After consideration of the public comments, we are finalizing as proposed that, for PY 2027 and subsequent PYs, all measures of the Medicare CQMs collection type would be scored using flat benchmarks.

We are also finalizing as proposed that the following measures reported via the Medicare CQMs collection type for PY 2026 are scored using flat benchmarks: Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001), Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134), and Controlling High Blood Pressure (Quality ID: 236).

As discussed in section IV.A.4.b.(2) of this final rule, we are finalizing our proposal to remove Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) and Adult Immunization Status (Quality ID: 493) from the APP Plus quality measure set beginning in PY 2027, which will result in the APP Plus quality measure set having five Medicare CQMs for PY 2027 and subsequent PYs. These are the same Medicare CQMs that are in the APP Plus quality measure set for PY 2026. Under the policies we are finalizing in this section, all Medicare CQMs in the APP Plus measure set (Quality IDs: 001, 112, 113, 134, and 236) would be scored using flat benchmarks for PY 2026 and subsequent PYs. The final APP Plus quality measure set for PY 2027 and subsequent PYs is displayed in Table B–G7 of this final rule. The APP Plus quality measure set for PY 2026 is displayed in Table 40 of the CY 2025 PFS final rule (89 FR 98129).

Table B–G3 lists the flat benchmarks for a non-inverse Medicare CQM. This is the same as Table B–G3 of the CY 2027 PFS proposed rule (91 FR 44043).

TABLE B-G3: FLAT BENCHMARKS FOR A NON-INVERSE MEDICARE CQM IN PY 2026 AND SUBSEQUENT PYs

Decile	Performance Rate Range
1	< 10.00
2	10.00 – 19.99
3	20.00 – 29.99
4	30.00 – 39.99
5	40.00 – 49.99
6	50.00 – 59.99
7	60.00 – 69.99
8	70.00 – 79.99
9	80.00 – 89.99
10	>= 90.00

Table B–G4 lists the flat benchmarks for an inverse Medicare CQM. This is the same as Table B–G4 of the CY 2027 PFS proposed rule (91 FR 44044).

TABLE B-G4: FLAT BENCHMARKS FOR AN INVERSE MEDICARE CQM IN PY 2026 AND SUBSEQUENT PYs

Decile	Performance Rate Range
1	99.00 – 90.01
2	90.00 – 80.01
3	80.00 – 70.01
4	70.00 – 60.01
5	60.00 – 50.01
6	50.00 – 40.01
7	40.00 – 30.01
8	30.00 – 20.01
9	20.00 – 10.01
10	<= 10.00

d. Addressing Shared Savings Program ACOs' Challenges With Meeting the MIPS Data Completeness Requirement

(1) Background

In the CY 2027 PFS proposed rule (91 FR 44044) we stated that requirements for data completeness are essential to ensure that data submitted on quality measures are sufficiently complete to accurately assess each Shared Savings Program ACO's quality performance. The data completeness requirement means that a Shared Savings Program ACO participant submitting measure data on a quality measure must submit data on at least a specific percentage of their patients that meet the measure's denominator criteria. Meeting the data completeness requirement ensures that the measure represents an appropriate percentage of the patient population applicable for a given quality measure. Robust data completeness requirements ensure the most accurate assessment of the performance of Shared Savings Program ACO participants.

In the CY 2017 Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (81 FR 77125), we established a data completeness threshold to ensure that data submitted on quality measures are complete enough to accurately assess each MIPS eligible clinician's quality performance. Additionally, in the CY 2020 PFS final rule (84 FR 62568, 62953), we added a requirement at § 414.1340 that quality data would not be considered true, complete, or accurate if such data are submitted selectively such that the data are unrepresentative of a MIPS eligible clinician or group's performance. In the CY 2024 PFS final rule, we finalized that we would maintain the data completeness criteria threshold of 75 percent (88 FR 79337). Specifically, as finalized, the data completeness criteria for the quality performance category (§ 414.1340) state that MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities submitting quality measure data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, and APM Entity's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026 through 2030. In the CY 2024 PFS final rule, for APM Entities, specifically Shared Savings Program ACOs, we likewise established the data completeness criteria threshold of at least 75 percent for the Medicare CQMs aligned with the data completeness criteria threshold established for the eCQMs and MIPS CQMs collection types (88 FR 79337).

In the CY 2021 PFS final rule, we finalized modifications to the Shared Savings Program quality reporting requirements and quality performance standard for PY 2021 and subsequent PYs (85 FR 84720 through 84743) requiring Shared Savings Program ACOs to report quality data via the APP codified at § 414.1367. In the CY 2025 PFS final rule, we finalized that for PYs beginning on or after January 1, 2025, Shared Savings Program ACOs must submit quality data via the APP on the quality measures contained in the APP Plus quality measure set to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of a Shared Savings Program ACO participant for purposes of the MIPS quality performance category of the Quality Payment Program (89 FR 98568).

For data completeness criteria pertaining to the quality performance category, we finalized in the CY 2025 PFS final rule that an APM Entity, specifically a Shared Savings Program ACO that meets reporting requirements under the APP, must meet the data completeness requirements established at § 414.1340(d)(1). Shared Savings Program ACOs reporting quality data on the APP Plus quality measure set meet the quality performance standard if they achieve a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores. If a Shared Savings Program ACO fails to meet data completeness on a measure in the APP Plus quality measure set, it will receive a 0/10 for the affected quality measure(s), resulting in a lower quality score used to determine eligibility for shared savings. For a Shared Savings Program ACO in the first PY of the ACO's first agreement period, the Shared Savings Program ACO must meet the MIPS data completeness requirement on all eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and receive a MIPS quality performance category score. Shared Savings Program ACOs are eligible for the eCQM/MIPS CQM reporting incentive if they report all eCQMs/MIPS CQMs in the APP Plus quality measure set and meet data completeness requirements for all measures. Lastly, under the Complex Organization Adjustment, Shared Savings Program ACOs may receive one measure achievement point for each submitted eCQM that meets case minimum and data completeness requirements.

Shared Savings Program ACOs continue to express concerns related to the transition to dQM reporting including challenges with data aggregation, engagement of specialty practices, and patient matching. Shared Savings Program ACOs have shared with CMS that specialty electronic health record (EHR) systems are not designed to support the APP Plus quality measure set and that certain specialties may not be able to collect the needed data elements for quality reporting. Shared Savings Program ACOs noted that patients that are not managed by the Shared Savings Program ACO or do not have a primary care relationship with the Shared Savings Program ACO present data aggregation and patient deduplication challenges because specialists may not have quality reporting capabilities for the measures in the APP Plus quality measure set, which may not be part of specialists' clinical workflows. These challenges complicate a Shared Savings Program ACO's ability to meet the data completeness requirement. We have also received feedback that the MIPS data completeness requirement is a deterrent to specialist participation in Shared Savings Program ACOs. In the CY 2025 PFS final rule, some commenters stated that small independent practices and specialty practices are often unable to participate or continue to participate in the Shared Savings Program due to the technical and financial burden associated with the adoption of new technologies needed to meet reporting requirements (89 FR 98105). Several commenters requested that we consider adding exceptions or exclusions for small practices and certain specialties and/or altering data completeness requirements to address ongoing challenges and allow for Shared Savings Program ACOs to be successful in reporting eCQMs, MIPS CQMs, and Medicare CQMs (89 FR 98105).

With the sunset of the CMS Web Interface beginning in PY 2025 as finalized in the CY 2022 PFS final rule (86 FR 65440), Shared Savings Program ACOs are now required to report MIPS CQMs, eCQMs and/or Medicare CQMs and have reported difficulties with meeting the MIPS data completeness requirement. Shared Savings Program quality reporting data in PYs 2023 and 2024 indicates that Shared Savings Program ACOs have been slow to report eCQMs.

Since the CY 2021 PFS final rule was issued, Shared Savings Program ACOs and other interested parties have continued to express concerns about requiring Shared Savings Program ACOs to report all payer/all patient eCQMs/MIPS CQMs due to the cost of purchasing and implementing a system-wide infrastructure to aggregate data from multiple ACO participant taxpayer identification numbers (TINs) and varying electronic health record (EHR) systems (86 FR 65257). In the CY 2022 PFS final rule, commenters supported our acknowledgement of the complexity of the transition to all payer/all patient eCQMs/MIPS CQMs (86 FR 65259). In the CY 2023 PFS final rule, commenters expressed concerns regarding the requirement to report all payer/all patient eCQMs/MIPS CQMs beginning in PY 2025, such as issues related to meeting all payer data requirements, data completeness requirements, data aggregation and deduplication issues, and interoperability issues among different EHRs (87 FR 69837).

In light of these concerns, we proposed in the CY 2024 PFS proposed rule to establish the Medicare CQMs as a new collection type for Shared Savings Program ACOs to help ACOs build the infrastructure, skills, knowledge, and expertise necessary to aggregate patient data. We established the data completeness criteria threshold of at least 75 percent for the Medicare CQMs aligned with the data completeness criteria threshold established for eCQM and MIPS CQM collection types. We believed that the Medicare CQM collection type would address the concerns from ACOs regarding the capability of meeting the data completeness requirement for all payer data.

In the CY 2024 PFS final rule, many commenters also raised questions and concerns regarding how CMS will determine the appropriate Medicare CQM population for these measures (88 FR 79102). Some commenters noted that the proposed denominator eligibility criteria are similar to, but differ in timeline from, the current assignment methodology and this creates unnecessary complexity. Additionally, while the availability of the Medicare CQMs as a collection type assists with the transition from reporting eCQMs and/or MIPS CQMs to reporting dQMs, some commenters noted that reporting through the Medicare CQMs collection type will not inherently advance their capabilities to report on eCQMs. For instance, the commenters noted that the Medicare CQMs collection type does not address the adoption of CEHRT across Shared Savings Program ACO participants, processes to enable aggregation of quality measurement data across all Shared Savings Program ACO participants, the ability to assess data completeness, efficiently calculate quality measures outcomes, and the generation of a QRDA–III file (88 FR 79103 and 79104). To address these concerns, in the CY 2026 PFS final rule, we revised the definition of a ''beneficiary eligible for Medicare CQM'' to align with our modifications to the stepwise assignment methodology and the approach to identifying the beneficiaries assignable to a Shared Savings Program ACO. We intended for the revised definition to reduce Shared Savings Program ACOs' burden in the patient matching necessary to report Medicare CQMs because the list of ''beneficiaries eligible for Medicare CQMs'' would have greater overlap with the list of beneficiaries that are assignable to a Shared Savings Program ACO.

The Shared Savings Program continues to hear from Shared Savings Program ACOs and other interested parties about the challenges with reporting on all payer/all patient measures and meeting data management requirements given their muti-practice/multi EHR structure, the challenges to aggregate data with the health IT infrastructure in use by Shared Savings Program ACOs and current state of interoperability (89 FR 98122).

In the CY 2027 PFS proposed rule (91 FR 44044 through 44052), we described several proposals to address data completeness challenges for ACOs, in recognition of the heterogeneity in Shared Savings Program ACO composition, with many Shared Savings Program ACOs being made up of numerous TINs of varying specialties. The proposals were intended to support Shared Savings Program ACOs' success in meeting the MIPS data completeness requirement by allowing for flexibility on the universe of beneficiaries that the Shared Savings Program ACO would be required to report quality data on, while still requiring the Shared Savings Program ACOs to collect meaningful data on their quality performance (that is, allowing ACOs to exclude some clinicians from their quality reporting and/or alignment with the Shared Savings Program ACO's list of assigned beneficiaries).

(2) Revising the Shared Savings Program Quality Reporting Requirements Beginning in PY 2026

As we stated in the CY 2027 PFS proposed rule (91 FR 44046), current Shared Savings Program quality reporting requirements at § 425.508(c) require that, for PYs beginning on or after January 1, 2025, Shared Savings Program ACOs must submit quality data on the APP Plus quality measure set to satisfactorily report on behalf of the

eligible clinicians who bill under the TIN of a Shared Savings Program ACO participant for purposes of the MIPS quality performance category. Shared Savings Program ACOs have raised concerns about meeting reporting requirements in situations where they are unable to obtain data from a Shared Savings Program ACO participant TIN. This situation may occur due to unforeseen circumstances such as the retirement of a provider in a solo practice or a practice closure. Additionally, Shared Savings Program ACOs have noted that specialty EHRs are not designed to support the APP Plus quality measure set and that certain specialties (for example, ophthalmology) provide little or no usable data.

In light of the concerns raised by Shared Savings Program ACOs regarding challenges meeting the Shared Savings Program quality reporting requirements, we proposed to revise the quality reporting requirements at § 425.508(c), to include that for PYs beginning on or after January 1, 2026, Shared Savings Program ACOs may exclude one or more Shared Savings Program ACO participant TINs from a Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM (if finalized) data (as applicable) for each measure (91 FR 44046 through 44048). As discussed in the CY 2027 PFS proposed rule (91 FR 44048 through 44050), we proposed to create the Medicare eCQMs collection type, which would be a new collection type for PY 2027 and subsequent PYs. We proposed in § 425.508(c)(1)(i) through (iii) that a Shared Savings Program ACO may choose to exclude a Shared Savings Program ACO participant TIN from its submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure. Applicable exclusions may include: (i) unforeseen circumstance(s) that are outside of the control of the Shared Savings Program ACO such as the unexpected closure of a group or individual's practice that bills under the ACO participant TIN (for example, closure of the group or individual's practice in the middle of the PY due to an unforeseen reason (such as the retirement of a provider) and the Shared Savings Program ACO is unable to access quality data for the closed practice); (ii) the ACO participant TIN has a CEHRT that is intended for specialty use and does not support the measure(s) included in the APP Plus quality measure set (for example, an ophthalmology practice may provide little to no usable data because it utilizes a specialty-focused EHR that does not collect the necessary data elements for reporting on the primary care-focused APP Plus quality measure set; in this instance, the ACO would be unable to aggregate the ACO participant TIN's data); and (iii) other circumstances as determined by CMS. We further proposed in § 425.508(c)(2)(i) through (iii) that Shared Savings Program ACOs may not exclude a Shared Savings Program ACO participant TIN from the Shared Savings Program ACO's quality data submission for each measure based on the demographics or health status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN or based on the estimated impact of the ACO participant TIN on the ACO's quality performance.

In addition, we proposed in § 425.508(c)(3) that, after the exclusion of Shared Savings Program ACO participant TINs, the Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. Since a Shared Savings Program ACO may encounter an unforeseen circumstance that may be specific to reporting a clinical quality measure(s), the Shared Savings Program ACO may exclude one or more Shared Savings Program ACO participant TINs from the quality data submitted for only the impacted measure(s) for the applicable PY. As such, a Shared Savings Program ACO would be required to meet the 95 percent requirement for each measure at the measure level. This means that the quality data submitted by the Shared Savings Program ACO for each measure in the APP Plus quality measure set must meet this requirement independent of the other measures in the APP Plus quality measure set. We noted in the CY 2027 PFS proposed rule that, due to each measure's inclusion and exclusion criteria as specified in the measure specification, a Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure may not include 95 percent of the beneficiaries assigned to the Shared Savings Program ACO (91 FR 44046). However, under our proposal, the data submitted for each measure must include ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. This 95 percent requirement would allow Shared Savings Program ACOs to exclude one or more Shared Savings Program ACO participant TINs from a measure submission based on applicable circumstances defined by CMS under the regulation text at § 425.508(c)(1) and discussed later in this section, while ensuring CMS still receives sufficient data to assess Shared Savings Program ACO quality in the applicable PY and over time.

We noted in the CY 2027 PFS proposed rule that our proposal to require that the Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications is different than the MIPS data completeness requirement for the MIPS quality performance category described at § 414.1340(a) and (d) and proposed (e) (91 FR 44046). Under our proposal, Shared Savings Program ACOs would still be required to meet the MIPS data completeness requirement (that is, the Shared Savings Program ACO must report on at least 75 percent of the APM Entity's applicable beneficiaries who meet the measure's denominator criteria for PY 2027) for each eCQM/MIPS CQM/Medicare CQM/Medicare eCQM the Shared Savings Program ACO submits data for (91 FR 44046 through 44047). MIPS data completeness is calculated based on the quality data submitted by a Shared Savings Program ACO and is assessed at the Shared Savings Program ACO-level; whereas, our proposal to allow a Shared Savings Program ACO to exclude one or more Shared Savings Program ACO participant TINs from a Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure would be applied by the Shared Savings Program ACO prior to its submission of quality data to MIPS. Under our proposal, a Shared Savings Program ACO would determine the denominator for a measure by applying the measure specifications using data from the participant TINs included in its quality data submission. MIPS data completeness would then be calculated based on that reported denominator (91 FR 44047).

In the CY 2027 PFS proposed rule, we stated that to facilitate population-based

activities related to improving health or reducing growth in healthcare costs, protocol development, case management, and care coordination under the existing § 425.702(c)(1)(ii) and to support Shared Savings Program ACOs in aggregating data for the Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure under the proposed § 425.508(c)(3), we would provide Shared Savings Program ACOs with a new aggregate report that would contain the data necessary to determine how many beneficiaries would be represented by the TINs the ACO plans to report on (91 FR 44047). Specifically, the report would be at the beneficiary-TIN level and contain the number of beneficiaries that will be assigned to the ACO and demonstrate how the assigned beneficiaries are matched to the TIN(s). This report would be provided in Quarter 3 and Quarter 4 of each applicable performance year beginning with PY 2026. This would allow the Shared Savings Program ACO to have access to the data that is necessary to determine if the ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure includes Shared Savings Program ACO participant TINs sufficient to represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. This new aggregate report would be delivered to Shared Savings Program ACOs via the Data Hub in the Shared Savings Program ACO Management System (*https://acoms.cms.gov*). We noted in the CY 2027 PFS proposed rule that if this proposal is finalized, we would provide instructions to Shared Savings Program ACOs in future education and outreach materials on how to use the new aggregate report to determine the Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications as required by the proposed § 425.508(c)(3) for purposes of submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (91 FR 44047). The Quarter 3 report would be intended to provide Shared Savings Program ACOs with a preview of the necessary data, while the Quarter 4 report would be the definitive source for ACOs to determine whether the Shared Savings Program ACO meets the proposed Shared Savings Program requirement that the data submitted for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. We noted in the CY 2027 PFS proposed rule that if our proposal is finalized, we would begin to provide ACOs with this report for Quarter 3 of PY 2026. For PY 2026 and subsequent PYs, Shared Savings Program ACOs must use the new Quarter 4 aggregate report to make the determination under the proposed § 425.508(c)(3) (91 FR 44047). We further noted in the CY 2027 PFS proposed rule that if this proposal is not finalized, we would not share the new aggregate reports (91 FR 44047).

Since we cannot align a beneficiary to a Shared Savings Program ACO participant TIN without eligible primary care claims, an ACO should not count beneficiaries without eligible primary care claims during the performance year when calculating the 95 percent of beneficiaries needed to meet the requirement proposed at § 425.508(c)(3). Moreover, beneficiaries that do not have at least one eligible primary care encounter during the performance year would not be included on the list of beneficiaries shared with ACOs in Quarter 3 and Quarter 4 during that performance year as noted earlier in this section. For example, if a beneficiary is voluntarily aligned to the ACO but did not have an eligible primary care claim with a Shared Savings Program ACO participant during the performance year, that beneficiary would not be included on the list of beneficiaries shared with that ACO in Quarter 3 and Quarter 4 of the applicable performance year and the ACO would not include that beneficiary when calculating the numerator used to determine whether the ACO was compliant with the 95 percent requirement proposed at § 425.508(c)(3). For purposes of calculating the 95 percent requirement, the denominator would be the Shared Savings Program ACO's total number of assigned beneficiaries, inclusive of beneficiaries that did not have an eligible primary care claim during the reporting period with a Shared Savings Program ACO participant.

We noted in the CY 2027 PFS proposed rule that, under the current definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20, beneficiaries eligible for Medicare CQMs for PY 2026 are closely aligned with the Shared Savings Program ACO's assignable population rather than the ACO's assigned population (as proposed in section III.G.3.d.(4) of the CY 2027 PFS proposed rule for PY 2027 and subsequent PYs) (91 FR 44047). Shared Savings Program ACOs that choose to report Medicare CQMs for PY 2026 would have the option to exclude Shared Savings Program ACO participant TINs from their submission of Medicare CQM data provided that the remaining Shared Savings Program ACO participant TINs represent at least 95 percent of the beneficiaries assigned to the ACO prior to the application of the measure specifications.

In addition, in § 425.508(c)(4), we proposed that we would retain the right to audit and validate eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure reported by a Shared Savings Program ACO and may request documentation from the Shared Savings Program ACO related to the exclusion of Shared Savings Program ACO participant TINs from the Shared Savings Program ACO's quality data submission (91 FR 44047). We also proposed that failure to report quality measure data accurately, completely, and timely may result in compliance actions as described in §§ 425.216 and 425.218 (91 FR 44047).

Section 1871(e)(1)(A) of the Act prohibits the Secretary from applying substantive changes in regulations retroactively before the effective date of the change except where the Secretary determines, as relevant here, that failure to apply the change retroactively would be contrary to the public interest. It is in the public interest to apply our proposed changes to § 425.508 ''Incorporating quality reporting requirements related to the Quality Payment Program Beneficiary'' beginning in PY 2026 because, absent the proposed changes, Shared Savings Program ACOs that generated savings while maintaining or improving quality of care may have difficulty meeting the quality reporting requirements at § 425.508(c). Based on the Shared Savings Program ACO public reporting requirements at § 425.308(b)(4)(ii), Shared Savings Program ACOs that generate shared savings must publicly report the total proportion of shared savings invested in infrastructure, redesigned care processes, and other resources required to support the triple aim of better health for populations, better care for individuals, and lower growth in expenditures, including the proportion distributed among Shared Savings Program ACO participants. If a Shared Savings Program ACO does not meet the quality reporting requirements, then that Shared Savings Program ACO would not be eligible to share in savings that could be used for quality improvement initiatives for the Medicare beneficiaries.

The evaluation of Shared Savings Program ACOs' PY 2026 quality performance, including evaluation of MIPS data completeness, occurs in 2027. As such, retroactive application of the proposed reporting requirement for PY 2026 would be in the public interest and would afford Shared Savings Program ACOs that earn shared savings the opportunity to devote greater resources to providing better quality of care to Medicare beneficiaries over time and improving care coordination that benefits the Medicare beneficiaries served by Shared Savings Program ACOs, in accordance with ACO public reporting requirements at § 425.308(b)(4)(ii).

Additionally, Shared Savings Program ACOs that participated in the interviews discussed in section III.G.3.c of this final rule have also shared that some practices have closed due to financial challenges associated with the transition to digital quality measurement and have begun to remove practices that cannot meet digital reporting requirements from their organization. Practices that do not meet the quality reporting requirements and, therefore, do not earn shared savings, could experience financial instability. For these practices, the loss of shared savings would compound these challenges and may cause them to close or may negatively affect their ability to provide continuity of care, coordination of care, preventive care initiatives, and quality improvement initiatives for Medicare beneficiaries they serve. As a result, beneficiaries may experience challenges with accessing care, ineffective utilization of services, fragmented care, or duplicative tests or services, and ACOs may be slower to adopt digital quality measurement as a result. The proposed changes would allow Shared Savings Program ACOs to devote greater resources to improving care coordination so that they are better positioned to deliver the right care at the right time, all to the benefit of Medicare beneficiaries served by the Shared Savings Program ACO and Medicare Trust Funds.

We believe the proposed changes would have minimal impact on Shared Savings Program ACOs' existing processes because the Shared Savings Program ACO would continue to aggregate quality data and apply the measure specifications prior to the submission of quality data. Additionally, Shared Savings Program ACOs would benefit from the ability to meet the MIPS data completeness requirement, in the event they are unable to acquire data from a subset of their participant TINs, which may enable them to achieve a quality score equivalent to the 40th percentile MIPS quality performance category score to be eligible to earn maximum shared savings and, for ENHANCED track Shared Savings Program ACOs, avoid shared losses.

In alignment with the proposals described in this section, we proposed to revise the regulation text at § 425.508 as follows:

- Under new paragraph (c)(1), we would specify that, for PYs beginning on or after January 1, 2026, ACOs may exclude one or more TINs of ACO participants from an ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure. We would specify that applicable exclusions may include:
  - ++ Unforeseen circumstance(s) that are outside of the control of the ACO, such as the unexpected closure of a group or individual's practice that bills under the ACO participant TIN.
  - ++ An ACO participant TIN has a CEHRT that is intended for specialty use and does not support the measure(s) included in the APP Plus quality measure set.
  - ++ Other circumstances as determined by CMS.
- Under new paragraph (c)(2), we would specify that ACOs may not exclude an ACO participant TIN from the ACO's quality data submission for each measure based on the following:
  - ++ The demographics status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN.
  - ++ The health status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN.
  - ++ The estimated impact of the ACO participant TIN on the ACO's quality performance.
- Under new paragraph (c)(3), we would specify that the ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the ACO prior to the application of the measure specifications.
- Under new paragraph (c)(4), we would specify that CMS retains the right to audit and validate eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data reported by an ACO and may request documentation from the ACO related to the exclusion of ACO participant TINs under paragraph § 425.508(c)(1). We would further note that failure to report quality measure data accurately, completely, and timely may result in compliance actions as described at §§ 425.216 and 425.218.

We sought public comments on our proposals to revise the Shared Savings Program quality reporting requirements at § 425.508 beginning in PY 2026. We also sought comment on other circumstances we should consider that would allow ACOs to exclude one or more TINs of ACO participants from their submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for a measure.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our proposals to revise the Shared Savings Program quality reporting requirements beginning in PY 2026. Many of these commenters noted that the policies address significant challenges and operational realities faced by ACOs. A commenter noted the policies acknowledge difficulties of obtaining quality data from all participant TINs, particularly in multi-specialty, multi-EHR environments while another noted that they recognize the variability of quality reporting capabilities among heterogeneous healthcare providers. Many commenters stated the policies will reduce burden and provide necessary flexibility while maintaining a meaningful MIPS data completeness threshold and while preserving accountability and the integrity of ACO-level quality results. A couple of commenters noted that the policies will reduce unnecessary reporting failures and protect ACOs against adverse reporting outcomes. A couple of commenters noted the policies will prevent them from being penalized for any future reporting issues outside their control. A commenter noted that this policy ensures health system-led ACOs that integrate information across multiple EHR platforms, provider/supplier organizations, and care settings have reasonable flexibility. The commenter noted that, in combination with other quality proposals, the policies will allow for investments in infrastructure needed to transition to dQMs and allow ACOs who report on behalf of a wide variety of EHRs to be successful. A commenter noted the policies will support practitioner participation and decrease the likelihood of practices being excluded from accountable care arrangements solely because of technology or data limitations. This commenter also stated that the policies would allow them to work toward more interoperable reporting options such as the eCQMs collection type instead of manual

options like the Medicare CQMs collection types.

A few commenters noted the flexibilities of the policies are particularly helpful to small and rural ACOs, that have limited resources and fewer administrative staff, and the policies avoid penalizing and help secure continued participation of these providers and suppliers. A commenter also noted the policies are important for physician-led ACOs that include independent practices using different EHR systems and another stated they protect independent, low-revenue practices from being penalized or forced into premature consolidation due to vendor EHR incompatibility or unexpected practice closures. A commenter noted the policies will support participating health centers who do not always have control over whether individual practitioners can report specific measures.

A few commenters supported the proposed exclusion criteria, including prohibiting exclusions based on beneficiary demographics, health status or potential impact on quality performance. A commenter agreed with the application of these exclusions at the TIN and individual-measure level and noted that the proposed safeguards ensure that exclusions address legitimate data-access and reporting barriers rather than being used to improve performance results selectively. Another commenter noted the safeguards appropriately protect program integrity. A couple of commenters agreed that reported data should continue to reflect the vast majority of ACO's' assigned beneficiaries.

Several commenters also supported applying the policies retroactively for PY 2026 to reduce burden and confusion during the upcoming reporting cycle. Lastly, some commenters were in support of the proposed quarterly reports, stating these reports will provide transparent and definitive data to ACOs to support implementation of these new flexibilities. Several comments supported the threshold but recommended that CMS monitor to ensure the threshold remains sufficient as implementation progresses, especially when measures shift to a fully digital environment. A comment appreciated the flexibility and encouraged CMS to avoid increases to the threshold that in their belief could create additional reporting burden for participating providers and suppliers.

Response: We appreciate comments that support our proposal to revise the Shared Savings Program Quality reporting requirements beginning in PY 2026. We note that we will monitor the appropriateness of the 95 percent threshold throughout the implementation process.

Comment: A commenter opposed the proposals to revise the Shared Savings Program quality reporting requirements and shared their belief that it is a new restriction for ACOs that is redundant, burdensome, and harmful to the participating practices that most need protection and encouragement. The commenter noted that the proposals are more restrictive than the 75 percent MIPS data completeness requirement and will disadvantage ACOs.

Response: We believe the comment may be misinterpreting the proposed Shared Savings Program quality reporting requirement revision, and we wish to clarify our proposal. As stated in the CY 2027 PFS proposed rule (91 FR 44046), current Shared Savings Program quality reporting requirements at § 425.508(c) require that, for PYs beginning on or after January 1, 2025, Shared Savings Program ACOs must submit quality data on the APP Plus quality measure set to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of a Shared Savings Program ACO participant for purposes of the MIPS quality performance category. In other words, Shared Savings Program ACOs must submit quality reporting data on all of their eligible clinicians who bill under a TIN of an ACO participant. Our proposals to revise the Shared Savings Program quality reporting requirements are intended to address concerns raised by Shared Savings Program ACOs regarding challenges meeting these requirements in situations where they are unable to obtain data from a Shared Savings Program ACO participant TIN. The proposals would allow ACOs the flexibility to exclude ACO participant TINs from their quality submission data based on the proposed criteria and still meet Shared Savings Program quality reporting requirements, rather than impose additional restrictions or burden.

We stated in the CY 2027 PFS proposed rule (91 FR 44046) that our proposal to require that the Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications is different than the MIPS data completeness requirement for the MIPS quality performance category described at § 414.1340(a) and (d) and proposed (e) (91 FR 44046). To further clarify the sequence of how the proposed 95 percent threshold interacts with the MIPS data completeness requirement, we note that the TIN exclusion would be applied by Shared Savings Program ACOs prior to the evaluation of the MIPS data completeness requirement. Under our proposal, a Shared Savings Program ACO would be able to exclude one or more Shared Savings Program ACO participant TINs from a Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure prior to its submission of quality data to MIPS.

A Shared Savings Program ACO then would determine the denominator for a measure by applying the measure specifications using data from the remaining ACO participant TINs after the application of the TIN exclusion policy. MIPS data completeness would then be calculated based on that reported denominator. Additionally, Shared Savings Program ACOs would be required to meet the MIPS data completeness requirement (that is, the Shared Savings Program ACO must report on at least 75 percent of the APM Entity's applicable beneficiaries who meet the measure's denominator criteria for the respective PY) for each eCQM/MIPS CQM/Medicare CQM/Medicare eCQM for which the Shared Savings Program ACO submits data. MIPS data completeness is calculated based on the quality data submitted by a Shared Savings Program ACO and is assessed at the Shared Savings Program ACO-level.

Comment: Many commenters suggested that CMS broaden the proposed second exclusion, which permits the exclusion of an ACO participant TIN that has CEHRT that is intended for specialty use and does not support the measure(s) included in the APP Plus quality measure set. Commenters recommended expanding this criterion to include an ACO participant TIN that has a CEHRT that does not support the measure(s) included in the APP Plus quality measure set, regardless of whether the CEHRT is intended for specialty use. The comment recommended that CMS broaden the proposed exclusion beyond ''specialty-focused'' EHR vendors to include any EHR vendor that is unable or unwilling to support required measures. Another commenter encouraged CMS to recognize ongoing interoperability challenges and continue investing in technical assistance, standardized data exchange, and

certified health IT capabilities so providers and suppliers can fully participate in quality reporting without relying on exclusion policies over the long term.

Response: We appreciate the suggestions from comments but continue to believe the second exclusion should remain limited to the scenario described in the CY 2027 PFS proposed rule in which an ACO participant TIN has a CEHRT that is intended for specialty use and, because of that focus, does not capture the data elements needed to report the APP Plus quality measure set. In the CY 2027 PFS proposed rule, we provided an example of an ophthalmology practice using an ophthalmology-focused EHR (90 FR 44046). In this case, the Shared Savings Program ACO cannot aggregate that participant TIN's data because the technology was never designed to capture the data elements needed to report the APP Plus quality measure set.

The suggestion to broaden this exclusion criterion is different in that it would extend the exclusion to any CEHRT, specialty-focused or not, that currently does not support the APP Plus quality measure set, for any reason, including business choices that are within the ACO's control, not an inherent mismatch between a specialty tool and the measure set. We disagree with broadening the exclusion on this basis. As described in section III.G.4. of this final rule, Shared Savings Program ACOs are required to have and use EHR technology that meets the definition of CEHRT (as defined at § 425.20) in one of the ways we are finalizing in § 425.507. Shared Savings Program ACOs also have multiple collection types available from which to choose and should choose the collection type that matches their data collection and reporting capabilities. Expanding the exclusion to cover any instance of vendor's non-support of the APP Plus quality measure set would allow Shared Savings Program ACOs to exclude data based on business choices within a Shared Savings Program ACO's control rather than genuine technical limitations and could reduce the completeness and comparability of quality data across ACOs.

We recognize, as another comment noted, that interoperability challenges persist. We note that interoperability is outside of the scope of our proposal and, as such, we are not addressing the comment's recommendations in this response. We are, therefore, finalizing the second exclusion criterion as proposed.

Comment: Many commenters suggested revisions to the proposed third exclusion, which permits the exclusion of an ACO participant TIN based on other circumstances as determined by CMS. Several commenters requested that CMS clearly define the scope of this criterion and establish a transparent process for ACOs to request exclusions under this category. One of these commenters also recommended a defined review timeline. Another commenter recommended CMS expand the proposed third exclusion to include small practices whose EHR and/or billing vendors charge restrictive fees for data transmission. A couple of commenters recommended that CMS expand the third exclusion to allow CMS to change the 95 percent assigned beneficiary threshold on a case-by-case basis.

Response: We note that the use of the proposed third exclusion described as ''other circumstances as determined by CMS'' is intended to address unforeseen circumstances that emerge during the PY. We would monitor implementation for recurring or systemic issues that are not adequately addressed by the specified exclusions and use those trends to inform ACOs when additional circumstances may warrant recognition under this provision ahead of the ACOs' quality reporting period.

We did not propose to establish a process for ACOs to request exclusions (*i.e.,* via the ACO–MS helpdesk, CMS regional office, or other means) or a review timeline under which an ACO may inform CMS of additional circumstances that may warrant an exclusion. We further clarify that there is no expectation that Shared Savings Program ACOs would need to submit a request to CMS to consider exclusions under § 425.508(c)(1)(iii) or that CMS will review such requests. Rather, CMS would identify and determine qualifying circumstances and communicate those determinations to ACOs, as appropriate. We are finalizing in this section of this final rule that CMS retains the right to audit and validate quality data for each measure reported by a Shared Savings Program ACO and may request documentation from the Shared Savings Program ACO related to the exclusion of Shared Savings Program ACO participant TINs from the Shared Savings Program ACO's quality data submission. Shared Savings Program ACOs are required to maintain documentation on TIN exclusions for the purposes of auditing and validation. Shared Savings Program ACOs should review the descriptions of the applicable exclusions at § 425.508(c)(1) as finalized in this section of this final rule and are responsible for determining whether any of these exclusions apply and what documentation they need to maintain to substantiate an applicable exclusion.

We are also rejecting the recommendation to expand the third exclusion to include small practices whose EHR and/or billing vendors charge restrictive fees and note that ACOs can choose vendors that best meet their needs. We further note that we are not allowing ACOs to meet a threshold that is lower than the 95 percent threshold through this third exclusion as suggested in the comment since we are finalizing that the 95 percent threshold would apply to all ACOs. We refer readers to our responses later in this section of this final rule where we discuss our belief that the 95 percent beneficiary threshold remains appropriate as this policy is intended to address limited and unusual circumstances in which the ACO is unable to obtain data from an ACO participant TIN.

Comment: A couple of commenters incorrectly stated that our proposed revisions to the Shared Savings Program quality reporting requirements allow Shared Savings Program ACOs to exclude low-volume TINs or those incapable of producing a QRDA file. A commenter requested that CMS add an exclusion for special-status (small volume) ACOs to align with the exclusions of the CEHRT use metrics. Another commenter stated that CMS should consider adding Promoting Interoperability exclusions and hardship exemptions to the applicable exclusions, as challenges with CEHRT can impede a TIN's ability to produce the necessary files for CQM reporting.

Response: We appreciate suggestions on other circumstances that would allow ACOs to exclude one or more TINs of ACO participants from their submission of quality measure data. We clarify that the current criteria allow for the exclusion of these TINs if they meet applicable criteria. Specifically, in the CY 2027 PFS proposed rule (91 FR 44046), we stated that applicable exclusions may include the following: (i) unforeseen circumstance(s) that are outside of the control of the ACO, such as the unexpected closure of a group or individual's practice that bills under the ACO participant TIN; (ii) an ACO participant TIN has a CEHRT that is intended for specialty use and does not support the measure(s) included in the APP Plus quality measure set; and (iii) other circumstances as determined by CMS. We also stated that ACOs may not exclude an ACO participant TIN from the ACO's quality data submission for each measure based on the

demographics or health status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN or based on the estimated impact of the ACO participant TIN on the ACO's quality performance.

Regarding the comment that our proposed revisions to the Shared Savings Program quality reporting requirements allow Shared Savings Program ACOs to exclude low-volume TINs or those incapable of producing a QRDA file, we note that under the proposed exclusions as described at § 425.508(c)(1) we did not propose to permit ACO participant TINs to be excluded solely based on volume or inability to produce a QRDA file. Low volume does not satisfy the applicable exclusion criteria at § 425.508(c)(1) as ACOs are expected to report on participant TINs, regardless of size. We did not propose to align an applicable exclusion with the criteria for the MIPS low volume threshold (as described at 42 CFR 414.1310(b)(1)(iii)) and instead proposed to allow ACOs to exclude an ACO Participant TIN based on that TIN's contributions to the ACO's assigned beneficiary population. We believe that this approach more appropriately reflects the basis and scope of the Shared Savings Program quality reporting requirements. With respect to the suggestion that we allow Shared Savings Program ACOs to exclude TINs incapable of producing QRDA files, we encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure and note that QRDA files are not necessarily required for all reporting options. We are, therefore, not adding a new exclusion to permit ACOs participant TINs to be excluded solely based on volume or inability to produce a QRDA file.

Regarding the request that we add an exclusion for special-status (small volume) ACO to align with the exclusions of the CEHRT use metrics, we believe the comment may be referring to the MIPS Promoting Interoperability exclusion for small practices. We note that as discussed in paragraph (3) of the definition of ''Small practice'' at 42 CFR 414.1305, beginning with the 2021 MIPS payment year, a small practice means a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period. We did not propose to include an exclusion for small practice because a small practice, as defined by MIPS, may contribute meaningfully to an ACO's assigned beneficiary population and, as such, should be included in an ACO's quality data submission, unless the small practice meets one of the other applicable exclusions as finalized in this section of this final rule. We do not believe a small practice exclusion is appropriate as ACOs are expected to aggregate data across TINs regardless of their practice size unless there are other circumstances outside the ACO's control.

Regarding the suggestion that we should consider adding Promoting Interoperability exclusions and hardship exemptions to the applicable exclusions at § 425.508(c)(1), we note that as described in section III.G.4. of this final rule, Shared Savings Program ACOs are required to have and use EHR technology that meets the definition of CEHRT (as defined at § 425.20) in one of the ways we are finalizing at § 425.507. We did not propose and are not finalizing a small practice exemption for the Shared Savings Program ACO CEHRT use metrics.

Comment: Several commenters requested CMS to clarify how Shared Savings Program ACOs and vendors would determine whether the submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure includes Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. A commenter asked if ACOs can exclude different TINs for different measures. Another commenter asked if threshold determination made earlier in the PY is treated as final, or whether an ACO must reassess and potentially adjust its TIN exclusions if beneficiary assignment changes between Quarter 3 and Quarter 4. A commenter suggested that CMS provide a specific list of the types of TINs that qualify for the proposed exclusions, which would allow ACOs to determine eligibility prospectively and reduce uncertainty and administrative burden during implementation. A commenter requested detailed reports by TIN to assist in the beneficiary and participant inventory process. Another requested information on data sources which could be used to identify beneficiaries and guidance on aggregation.

Response: In the CY 2027 PFS proposed rule (91 FR 44047), we stated that, for Quarter 3 and Quarter 4 of each applicable PY beginning with PY 2026, we would provide Shared Savings Program ACOs with a new aggregate report that would contain the data necessary to determine how many beneficiaries would be represented by the TINs the ACO plans to report on. Specifically, the report would be at the beneficiary-TIN level and contain the number of beneficiaries that will be assigned to the ACO and demonstrate how the assigned beneficiaries are matched to the TIN(s). This would allow the Shared Savings Program ACO to have access to the data that is necessary to determine if the ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure includes Shared Savings Program ACO participant TINs sufficient to represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications.

We also stated that the Quarter 3 report would be intended to provide Shared Savings Program ACOs with a preview of the necessary data, while the Quarter 4 report would be the definitive source for ACOs to determine whether the Shared Savings Program ACO meets the requirement that the data submitted for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. Regarding the recommendation that CMS provide a specific list of the types of TINs that qualify for the proposed exclusions, we note that ACOs must evaluate the ACO participant TINs based on the applicable exclusions to determine if any ACO participant TINs can be excluded while meeting the quality reporting requirements of § 422.508(c).

We stated in the CY 2027 PFS proposed rule (91 FR 40446) that since a Shared Savings Program ACO may encounter an unforeseen circumstance that may be specific to reporting a clinical quality measure(s), the Shared Savings Program ACO may exclude one or more Shared Savings Program ACO participant TINs from the quality data submitted for only the impacted measure(s) for the applicable PY; specifically, if all requirements are met, Shared Savings Program ACOs could potentially exclude different ACO participant TINs for different impacted measures. A Shared Savings Program ACO would be required to meet the 95 percent requirement for each measure at the measure level. This means that the quality data submitted by the Shared Savings Program ACO for each measure in the APP Plus quality measure set must meet this requirement independent of the other measures in the APP Plus quality measure set.

As stated in this section of this final rule, we are finalizing our proposed revisions to the Shared Savings Program

quality reporting requirements beginning in PY 2026. After the release of this final rule, we will provide instructions to Shared Savings Program ACOs in future education and outreach materials on how to use the new aggregate report to determine the Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. These materials will also include examples of the 95 percent threshold calculations. We also encourage ACOs and their vendors to participate in our monthly QCDR and Qualified Registry support calls, Learning System Webinars and to submit questions to the QPP Service Center, as needed.

Comment: Several commenters requested that CMS provide Shared Savings Program ACOs with the new aggregate reports that would contain the data necessary to determine how many beneficiaries would be represented by the TINs the ACO plans to report on early enough for ACOs to make informed decisions. A commenter stated that large ACOs require sufficient time to identify data gaps, determine TIN exclusions, implement corrective actions, and validate compliance with completeness requirements. This commenter recommended at least 90 days between release of the final report and quality reporting deadlines.

Response: In the CY 2027 PFS proposed rule (91 FR 44047), we stated that we would provide ACOs with the new aggregate reports for Quarter 3 and Quarter 4 of each applicable PY beginning with PY 2026. We also stated that the Quarter 3 report would be intended to provide Shared Savings Program ACOs with a preview of the necessary data, while the Quarter 4 report would be the definitive source for ACOs to determine whether the Shared Savings Program ACO meets the requirement that the data submitted for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. We intend to provide this new information in the Quarter 3 and Quarter 4 reports package. For PY 2026, the Quarter 3 reports package is scheduled to be issued to ACOs in November 2026, and the Quarter 4 reports package is scheduled to be issued to ACOs in February 2027 after the conclusion of the applicable performance year. While the Quarter 4 report would not be issued within 90 days of the quality reporting deadline, we believe this timing is sufficient as this policy is intended to address limited and unusual circumstances in which the ACO is unable to obtain data from an ACO participant TIN. ACOs, regardless of size, should attempt to report data from all TINs, and this policy is intended to be a safeguard for situations outside an ACO's control.

Comment: A few commenters suggested that the 95 percent requirement be revised to other thresholds, such as 80 percent, 85 percent, and 90 percent. A couple of the commenters noted that the 95 percent threshold is too narrow to accommodate the range of data-access failures, specialty CEHRT limitations, and other circumstances. Another commenter noted the 95 percent threshold creates operational challenges and recommends a 90 percent threshold with an attestation-based approach where Shared Savings Program ACOs would attest to reporting the full APP Plus quality measure set, for the participant TINs included in the quality submission, that the submitted data satisfies requirements and that the excluded TINs have been identified and documented per CMS requirements. A commenter recommended CMS consider a lower threshold or phase in approach for ACOs below a defined size. Another commenter recommended that particularly in the context of large multispecialty TINs, where it may be challenging to meet the 95 percent threshold criteria based on TIN-level exclusions, that CMS allow practice-, specialty-, or NPI-level exclusions or exceptions if the 95 percent threshold is met at the applicable level.

Response: Regarding the proposed revisions to the Shared Savings Program quality reporting requirements, we believe that the 95 percent beneficiary threshold remains appropriate as this policy is intended to address limited and unusual circumstances in which the ACO is unable to obtain data from an ACO participant TIN. Additionally, the 95 percent threshold ensures CMS still receives sufficient data to assess Shared Savings Program ACO quality in the applicable PY and over time. For these reasons, we also believe the 95 percent threshold is appropriate for ACOs of all sizes and reject the commenter's suggestion to consider a lower threshold or phase-in approach for ACOs below a defined size. Regarding the suggestion for an attestation-based approach, we refer to the section of this final rule where we finalize requirements for documentation on TIN exclusions for the purposes of auditing and validation (§ 422.508(c)(4)), which we believe minimize administrative burden compared to an attestation process. We are therefore rejecting the suggestion to add an attestation process. Regarding the suggestion to allow practice-, specialty-, or NPI-level exclusions, we did not propose to apply exclusions at these levels as the Shared Savings Program is a whole TIN program. For these reasons, we reject the suggestion to add practice-, specialty- and NPI-level exclusions.

Comment: Several commenters expressed concern regarding the calculation of the 95 percent threshold for ACOs that select prospective beneficiary assignment and ACOs with more voluntarily aligned beneficiaries. Commenters stated the proposed approach would disadvantage ACOs under prospective assignment since the assignment window does not align with the PY. The commenters also shared their belief that the approach would also disadvantage ACOs with more voluntarily aligned beneficiaries who may not have a qualifying primary care encounter in the PY. These commenters noted ACOs could fall below the 95 percent threshold without excluding any TINs. These commenters recommended that CMS calculate the threshold by using the ACO's final assigned beneficiary population as the basis for both the numerator and denominator to acknowledge the beneficiaries ACOs are financially responsible for and create fairness across ACOs.

A commenter recommended calculating the threshold against the subset of assigned beneficiaries who have an eligible primary care encounter during the PY. Another commenter recommended proportional reductions to the assigned beneficiary percentage after TIN exclusions are applied. Another commenter noted that CMS should consider whether the 95 percent assigned-beneficiary threshold provides sufficient flexibility for large, multispecialty ACOs and suggested CMS should establish appropriate safe harbors for documented EHR and vendor limitations.

Response: We appreciate the concerns expressed in the comments about how the 95 percent threshold calculation affects ACOs under prospective assignment and ACOs with higher shares of voluntarily aligned beneficiaries. We note that it is possible that ACOs may fall below the threshold without excluding data from any participant TINs. This scenario may be more likely to occur for prospective ACOs who may not be seeing some of their assigned beneficiaries in an eligible primary care encounter during

the PY. We further clarify that the 95 percent threshold requirement is only applicable if Shared Savings Program ACOs choose to exclude participant TINs under one of the applicable exclusions finalized in this section of this final rule. Shared Savings Program ACOs that choose not to exclude TINs would still meet the existing quality reporting requirements at § 425.508(c). However, ACOs have the option to choose their assignment type and can take into consideration these options weighed against the various Shared Savings Program requirements and how they want to operate as an ACO. Additionally, Shared Savings Program ACOs are expected to be accountable for the quality of care they provide to their assigned beneficiaries, so we believe the 95 percent threshold provides important flexibility to exclude participant TINs in limited circumstances, while otherwise ensuring that ACOs report quality data that reflect the care they provide. For these reasons, we also believe the current calculation of the threshold is appropriate and reject suggestions for alternative calculation methods.

Comment: A few commenters requested clarity on the audit process such as timing and documentation needs. A commenter asked how the ACO is supposed to track, document and substantiate a TIN exclusion and whether CMS intends to review TIN exclusions prior to application and suggested that CMS provide a standard template or structured data fields for documenting each exclusion.

Response: In the CY 2027 PFS proposed rule (91 FR 44047), we proposed to retain the right to audit and validate eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure reported by a Shared Savings Program ACO. We further proposed that CMS may request documentation from the Shared Savings Program ACO related to the exclusion of Shared Savings Program ACO participant TINs from the Shared Savings Program ACO's quality data submission. We also proposed that failure to report quality measure data accurately, completely, and timely may result in compliance actions as described in §§ 425.216 and 425.218. We clarify that, to streamline implementation and minimize operational burden, we will not review TIN exclusions prior to their application and instead require the ACOs to maintain documentation on TIN exclusions for the purposes of auditing and validation. We clarify that we defer to Shared Savings Program ACOs to maintain the necessary documentation that would substantiate an applicable exclusion. Therefore, Shared Savings Program ACOs should review the descriptions of the applicable exclusions at § 425.508(c)(1) finalized in this section of this final rule and are responsible for determining whether any of these exclusions apply.

Comment: A commenter expressed concern that the TIN exclusion policy does not address the PY 2026 mismatch between the Medicare CQM reporting population and the ACO's assigned population.

Response: In the CY 2027 PFS proposed rule (91 FR 44047), we noted that, under the current definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20, beneficiaries eligible for Medicare CQMs for PY 2026 are closely aligned with the Shared Savings Program ACO's assignable population rather than the ACO's assigned population (as finalized in section III.G.3.d.(4) of this final rule for PY 2027 and subsequent PYs). Since the TIN exclusion policy can be used by ACOs reporting the Medicare CQMs collection type, we believe the policy remains appropriate. For example, an ACO that chooses to report Medicare CQMs for PY 2026 could exclude ACO participant TIN(s) from the ACO's quality reporting as discussed in section III.G.3.d.(4) of this final rule prior to the application of the applicable measure specifications. This approach may address concerns that some ACOs have expressed about data aggregation and patient deduplication challenges for beneficiaries that do not have a primary care relationship with the ACO (91 FR 44045). We direct readers to section III.G.3.d.(4) of this final rule for further discussion of the revised definition of a beneficiary eligible for Medicare CQM for PY 2027 and subsequent PYs.

In section II.G.3.d.(3) of this final rule, we are finalizing our proposal to create the Medicare eCQMs collection type, which would be a new collection type for PY 2027 and subsequent PYs. After consideration of public comments, we are finalizing as proposed the revisions to the Shared Savings Program quality reporting requirements at § 425.508(c), to include that for PYs beginning on or after January 1, 2026, Shared Savings Program ACOs may exclude one or more Shared Savings Program ACO participant TINs from a Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure.

We are also finalizing as proposed in § 425.508(c)(1)(i) through (iii) that applicable exclusions may include: (i) unforeseen circumstance(s) that are outside of the control of the Shared Savings Program ACO such as the unexpected closure of a group or individual's practice that bills under the ACO participant TIN; (ii) the ACO participant TIN has a CEHRT that is intended for specialty use and does not support the measure(s) included in the APP Plus quality measure set; and (iii) other circumstances as determined by CMS.

We are further finalizing as proposed in § 425.508(c)(2)(i) through (iii) that Shared Savings Program ACOs may not exclude a Shared Savings Program ACO participant TIN from the Shared Savings Program ACO's quality data submission for each measure based on the demographics or health status of the beneficiaries who had an encounter during the PY with an ACO participant TIN or based on the estimated impact of the ACO participant TIN on the ACO's quality performance.

In addition, we are finalizing as proposed in § 425.508(c)(3) that, after the exclusion of Shared Savings Program ACO participant TINs, the Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications.

Shared Savings Program ACOs would still be required to meet the MIPS data completeness requirement (that is, the Shared Savings Program ACO must report on at least 75 percent of the APM Entity's applicable beneficiaries who meet the measure's denominator criteria for the respective PY) for each eCQM/MIPSCQM/Medicare CQM/Medicare eCQM for which the Shared Savings Program ACO submits data.

We will provide Shared Savings Program ACOs with a new aggregate report that will contain the data necessary to determine how many beneficiaries will be represented by the TINs the ACO plans to report on. Specifically, the report will be at the beneficiary-TIN level and contain the number of beneficiaries that will be assigned to the ACO and demonstrate how the assigned beneficiaries are matched to the TIN(s). This report will be provided in Quarter 3 and Quarter 4 of each applicable PY beginning with PY 2026.

This new aggregate report will be delivered to Shared Savings Program ACOs via the Data Hub in the Shared Savings Program ACO Management System (*https://acoms.cms.gov*). We will provide instructions to Shared Savings Program ACOs in future

education and outreach materials on how to use the new aggregate report to determine the Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. These materials will also include examples of the 95 percent threshold calculations.

As discussed in the CY 2027 PFS proposed rule, the Quarter 3 report is intended to provide Shared Savings Program ACOs with a preview of the necessary data, while the Quarter 4 report is the definitive source for ACOs to determine whether the Shared Savings Program ACO meets requirement that the data submitted for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications (91 FR 44047). We stated in the CY 2027 proposed rule that for PY 2026 and subsequent PYs, Shared Savings Program ACOs must use the new Quarter 4 aggregate report to make the determination under the proposed § 425.508(c)(3) (91 FR 44047), and clarify that ACOs must use the Quarter 4 report discussed in this section of this final rule to calculate that the TINs included in the ACO's quality data submission reflect 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications.

In addition, we are finalizing our proposal at § 425.508(c)(4) that we would retain the right to audit and validate eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure reported by a Shared Savings Program ACO. CMS may request documentation from the Shared Savings Program ACO related to the exclusion of Shared Savings Program ACO participant TINs from the Shared Savings Program ACO's quality data submission. We are also finalizing our proposal that failure to report quality measure data accurately, completely, and timely may result in compliance actions as described in §§ 425.216 and 425.218.

In alignment with the proposals we are finalizing in this section, we are finalizing the revisions to the regulation text at § 425.508 as follows:

- Under new paragraph (c)(1), we are specifying that, for PYs beginning on or after January 1, 2026, ACOs may exclude one or more TINs of ACO participants from an ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure. We are specifying that applicable exclusions may include:

++ Unforeseen circumstance(s) that are outside of the control of the ACO, such as the unexpected closure of a group or individual's practice that bills under the ACO participant TIN.

++ An ACO participant TIN has a CEHRT that is intended for specialty use and does not support the measure(s) included in the APP Plus quality measure set.

++ Other circumstances as determined by CMS.

- Under new paragraph (c)(2), we are specifying that ACOs may not exclude an ACO participant TIN from the ACO's quality data submission for each measure based on the following:

++ The demographics status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN.

++ The health status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN.

++ The estimated impact of the ACO participant TIN on the ACO's quality performance.

- Under new paragraph (c)(3), we are specifying that the ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the ACO prior to the application of the measure specifications.

- Under new paragraph (c)(4), we are specifying that CMS retains the right to audit and validate eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data reported by an ACO and may request documentation from the ACO related to the exclusion of ACO participant TINs under paragraph § 425.508(c)(1). We are also finalizing that failure to report quality measure data accurately, completely, and timely may result in compliance actions as described at §§ 425.216 and 425.218.

(3) Shared Savings Program ACOs To Report Using the Medicare eCQMs Collection Type

In the CY 2027 PFS proposed rule (91 FR 44048), we stated that Shared Savings Program ACOs have expressed concerns regarding the difficulty for multi-TIN Shared Savings Program ACOs to aggregate and deduplicate patient-level data. Additional challenges persist with integration across multiple EHRs, and these challenges can be an impediment for some Shared Savings Program ACOs. In light of the concerns raised by Shared Savings Program ACOs and other interested parties related to reporting quality measures using the eCQMs collection type and our commitment to supporting Shared Savings Program ACOs in the transition to dQM reporting, for PY 2027 and subsequent PYs, we proposed to establish the Medicare eCQMs for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs) as a new collection type for Shared Savings Program ACOs reporting on the Medicare eCQMs (reporting quality data on beneficiaries eligible for Medicare eCQMs as proposed to be defined at § 425.20) within the APP Plus quality measure set. A Medicare eCQM is essentially an eCQM that is part of the APP Plus quality measure set and reported by a Shared Savings Program ACO on only the Shared Savings Program ACO's assigned beneficiaries, instead of its all payer/all patient population. That is, the Medicare eCQMs will generally follow the eCQM measure specifications; however, they will be reported on a different population and use a different identifier to distinguish that the submission is for a Medicare eCQM rather than for an eCQM.

In the CY 2025 PFS final rule, we noted the numerous benefits to using eCQMs, including their use of electronic standards that reduce reporting burden, and expressed intent to fully transition to digital quality measurement in CMS quality reporting and value-based purchasing programs (89 FR 98106). We stated in the CY 2027 PFS proposed rule (91 FR 44049) that we believe the addition of Medicare eCQMs would support our efforts to transition to dQMs by supporting Shared Savings Program ACOs that want to report eCQMs but are not able to operationally report on all patient/all payer data due to data aggregation challenges.

We stated in the CY 2027 PFS proposed rule (91 FR 44049) that Medicare eCQMs would serve to address concerns which are discussed in the CY 2027 PFS proposed rule (91 FR 44044 through 44046) by defining a population of beneficiaries that exists within the all payer/all patient eCQM specifications and tethering that population to a Shared Savings Program ACO's assigned beneficiary population. Shared Savings Program ACOs have expressed challenges with quality data reporting as their list of eligible beneficiaries has often contained beneficiaries for whom the Shared Savings Program ACO is unable to identify a primary care relationship. Specifically, Medicare eCQMs would address the concern raised by Shared

Savings Program ACOs that for Shared Savings Program ACOs with a higher proportion of specialty practices and/or multiple EHRs, the broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the Shared Savings Program ACO. We intend to allow Shared Savings Program ACOs to continue to report using the existing collection types to maintain stability of collection types during the transition to dQMs. If finalized, Medicare eCQMs would provide an additional optional collection type for reporting quality data for Shared Savings Program ACOs. Medicare eCQMs would provide ACOs the option to report electronically only on their assigned beneficiary population, easing the operational considerations as outlined in this section, and support those Shared Savings Program ACOs with the transition to dQMs. For these reasons, we believe that it is appropriate to establish Medicare eCQMs as a new collection type for Shared Savings Program ACOs only. We also anticipate that in the future, when FHIR-based reporting becomes mandatory, Shared Savings Program ACOs would be able to continue to use the FHIR-based digital specifications to report only on their assigned beneficiary population.

In the CY 2027 PFS proposed rule (91 FR 44049), we encouraged ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure. In addition to our proposal to allow ACOs the option to report quality data using the Medicare eCQMs collection type, for PY 2027 and subsequent PYs, ACOs would have the option to report quality data using the all payer/all patient eCQMs/MIPS CQMs, and/or the Medicare CQMs collection types. Our long-term goal continues to be to support ACOs in the adoption of dQMs. We would monitor the reporting of quality data using the Medicare eCQMs collection type. To facilitate the reporting of Medicare eCQMs, in the CY 2027 PFS proposed rule (91 FR 44155), we proposed to amend the definition of ''collection type'' in § 414.1305 to include Medicare eCQMs as an available collection type in MIPS for ACOs that participate in the Shared Savings Program. Additionally, in the CY 2027 PFS proposed rule (44049 and 44050), we proposed to establish MIPS data submission and data completeness criteria, in §§ 414.1335(a)(5) and 414.1340(e), respectively, pertaining to the Medicare eCQMs collection type for the MIPS quality performance category. We also proposed to define a ''beneficiary eligible for Medicare eCQMs'' at § 425.20 as a beneficiary identified for purposes of reporting Medicare eCQMs for Shared Savings Program ACOs participating in the Medicare Shared Savings Program (Medicare eCQMs), who is a beneficiary that is assigned to the Shared Savings Program ACO under subpart E, in the CY 2027 PFS proposed rule (91 FR 44049).

In the CY 2027 PFS proposed rule (91 FR 44049), we proposed to revise § 414.1340(e) to establish the MIPS data completeness criteria threshold for the Medicare eCQMs collection type, in which Shared Savings Program ACOs that meet reporting requirements under the APP submitting quality measure data on Medicare eCQMs must submit data on at least 75 percent of the ACO's applicable beneficiaries eligible for the Medicare eCQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria for MIPS payment year 2029 and future MIPS payment years (PY 2027 and subsequent PYs).

We stated in the CY 2027 PFS proposed rule that to facilitate population-based activities related to improving health under the existing § 425.702(c)(1)(ii) and to aid Shared Savings Program ACOs in the process of patient matching and data aggregation necessary to report Medicare eCQMs, we would provide Shared Savings Program ACOs with a list of beneficiaries that are assigned to the Shared Savings Program ACO and thus are eligible for Medicare eCQM reporting within the Shared Savings Program ACO (91 FR 44049). We anticipate that the list of beneficiaries eligible for Medicare eCQMs would be shared with Shared Savings Program ACOs on a quarterly basis, beginning with Quarter 1 of PY 2027. We anticipate that the list of beneficiaries eligible for Medicare eCQMs would be in the same format and delivery schedule as the list of beneficiaries eligible for Medicare CQMs that Shared Savings Program ACOs currently receive on a quarterly basis. The list of beneficiaries eligible for Medicare eCQMs would differ from the list of beneficiaries eligible for Medicare CQMs in that we would apply the eCQM specifications to generate the measure-specific indicators for the list of beneficiaries eligible for Medicare eCQMs (unlike the list of beneficiaries eligible for Medicare CQMs which uses the Medicare CQM specifications to generate the measure-specific indicators). This new report would be delivered to Shared Savings Program ACOs via the Data Hub in the Shared Savings Program ACO Management System (*https://acoms.cms.gov*), but would not be included in the Shared Savings Program ACO's Quarterly Reports Package. The Quarter 4 list would include all beneficiaries eligible for Medicare eCQMs based on available claims data for encounters with dates of service from January 1 through December 31 and may be used as the final list for quality reporting. Like eCQMs, Medicare eCQMs would be reported end-to-end electronically. As such, we recognize that Shared Savings Program ACOs may have other technologically feasible means to identify beneficiaries eligible for Medicare eCQMs within the Shared Savings Program ACO or Shared Savings Program ACO participant TIN CEHRT. For this reason, we did not propose to require that Shared Savings Program ACOs use the list of beneficiaries eligible for Medicare eCQMs to identify the universe of beneficiaries upon which the Shared Savings Program ACO would report Medicare eCQMs for an applicable PY; rather, the Quarter 4 list can be used as a resource to help Shared Savings Program ACOs identify beneficiaries eligible for Medicare eCQM reporting.

In the CY 2027 PFS proposed rule (91 FR 44054 through 44055), we proposed that there would be five eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs in the APP Plus quality measure set for Shared Savings Program ACOs for PY 2027 and subsequent PYs.

- Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001);
- Breast Cancer Screening (Quality ID: 112);
- Colorectal Cancer Screening (Quality ID: 113);
- Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Quality ID: 134); and
- Controlling High Blood Pressure (Quality ID: 236).

ACOs would have the option to report the five Medicare eCQMs, or a combination of eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs, to meet the Shared Savings Program quality reporting requirement at § 425.510(b) and the quality performance standard at § 425.512(a)(5).

To operationalize the reporting of the Medicare eCQMs collection type, if finalized, specifically to distinguish between the submission of data for a Medicare eCQM from the submission of data for an eCQM to CMS, we will create unique identifiers that are associated with each Medicare eCQM. These identifiers must be included in

the submission files when reporting Medicare eCQMs beginning in PY 2027. Additional information on reporting Medicare eCQMs, if finalized, will be provided after the release of the CY 2027 PFS final rule.

We did not propose to add Medicare eCQMs to the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(B)(2) for PY 2027 and subsequent PYs. The eCQM/MIPS CQM reporting incentive intends to provide an incentive to ACOs to report the all payer/all patient eCQMs/MIPS CQMs while allowing them time to gauge their performance on the all payer/all patient eCQMs/MIPS CQMs. We also did not propose to add Medicare eCQMs to the Complex Organization Adjustment described at § 414.1380(b)(1)(vii)(C) for PY 2027 and subsequent PYs. We reiterate that the Complex Organization Adjustment intends to account for the organizational complexities Shared Savings Program ACOs face when reporting all payer/all patient eCQMs (89 FR 98116).

In the CY 2027 PFS proposed rule (91 FR 44050) and in the regulations at § 414.1380(b)(1)(ii)(G)(*1*), we proposed that, beginning with the CY 2027 performance period/2029 MIPS payment year, measures of the Medicare eCQMs collection type use flat benchmarks. As stated in the CY 2025 PFS final rule (89 FR 98118), the use of flat benchmarks may allow Shared Savings Program ACOs with high scores to earn maximum or near maximum measure achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years. Use of flat benchmarks also helps to ensure that Shared Savings Program ACOs with high quality performance on a measure are not penalized as low performers.

As part of our proposals for Shared Savings Program ACOs to report the Medicare eCQMs collection type for PY 2027 and subsequent PYs, we proposed to revise the regulation text at §§ 425.20 and 425.512 as follows:

Under a new paragraph at § 425.20, we would define a beneficiary eligible for Medicare eCQMs as a beneficiary identified for purposes of reporting Medicare eCQMs for Shared Savings Program ACOs participating in the Medicare Shared Savings Program (Medicare eCQMs), who is a beneficiary that is assigned to the Shared Savings Program ACO under subpart E of part 425.

Under § 425.512(a)(2)(iv), we would incorporate Medicare eCQMs into the existing quality performance standard policies for new Shared Savings Program ACOs. Under paragraph (a)(5)(iii)(C), we would also incorporate Medicare eCQMs into the existing policies that describe when a Shared Savings Program ACO would not meet the quality performance standard or the alternative quality performance standard.

We sought public comments on our proposals for Shared Savings Program ACOs to report the Medicare eCQMs collection type for PY 2027 and subsequent PYs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to establish Medicare eCQMs as a new collection type for Shared Savings Program ACOs for PY 2027 and subsequent PYs.

Commenters stated that they appreciated CMS' responsiveness to the challenges of multi-TIN data aggregation and all-payer population reporting. Many comments supported the additional flexibility a new collection type would provide and the reduction of burden provided by focusing on the ACOs' assigned beneficiary populations. A couple of comments expressed that the creation of the Medicare eCQMs collection type is an important interim step toward the transition to digital quality measurement and future all-payer models. A comment supported the Medicare eCQMs collection type as an option for ACOs that cannot readily aggregate data and encouraged CMS to treat this collection type as a foundation for outcome-based measures going forward and not only as a data aggregation solution.

Response: We appreciate comments that support our proposal to establish Medicare eCQMs as a new collection type for Shared Savings Program ACOs for PY 2027 and subsequent PYs.

Comment: A few commenters opposed the proposed effective date of the Medicare eCQMs collection type. A couple commenters stated that CMS should retain the existing three collection types and not add Medicare eCQMs as a fourth collection type for PY 2027. The comments noted that future inclusion of Medicare eCQMs should be done with appropriate lead time for implementation within EHRs. Another comment recommended that CMS delay implementation of the Medicare eCQMs collection type until the CY 2028 performance period to align the introduction of the Medicare eCQMs collection type with the start of the dQM transition period, or alternatively, prioritize finalizing and publishing dQM specifications rather than introducing an additional short-lived collection type for a single PY. A comment suggested CMS implement the Medicare eCQMs collection type after the necessary electronic workflows have been developed, tested, and made available.

Response: We stated in the CY 2027 PFS proposed rule (91 FR 44048 and 44049) that the Medicare eCQMs collection type was created to address concerns raised by Shared Savings Program ACOs and other interested parties related to reporting quality measures using the eCQMs collection type. We also stated that we believe the addition of Medicare eCQMs would support our efforts to transition to dQMs by supporting Shared Savings Program ACOs that want to report eCQMs but are not able to operationally report on all patient/all payer data due to data aggregation challenges.

We stated that we intend to allow Shared Savings Program ACOs to continue to report using the existing collection types to maintain stability of collection types during the transition to dQMs. Therefore, in addition to allowing ACOs the option to report quality data using the Medicare eCQMs collection type, for PY 2027 and subsequent PYs, ACOs would have the option to report quality data using the all payer/all patient eCQMs/MIPS CQMs, and/or the Medicare CQMs collection types. Therefore, we believe that it is appropriate to establish the Medicare eCQMs collection type for Shared Savings Program ACOs beginning in PY 2027 for those ACOs that could be ready and choose to report their quality data using this new collection type. We recognize that the Medicare eCQMs collection type may not be a suitable collection type for some ACOs at this time. Therefore, we encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure.

Regarding the comment that the Medicare eCQMs collection type would exist for a single PY, we note that we stated in the CY 2027 PFS proposed rule (91 FR 44038) that all quality reporting options for Shared Savings Program ACOs (that is, eCQMs, MIPS CQMs, Medicare CQMs, and Medicare eCQMs) would continue to be available during the 2-year transition period with FHIR-based reporting options that would begin in PY 2028. Therefore, at minimum, the Medicare eCQMs collection type would be available through PY 2029. Any changes to the availability of collection type quality reporting options would go through notice and comment rulemaking.

Comment: A commenter suggested CMS should ensure that adoption of Medicare eCQMs remains voluntary until health IT infrastructure, interoperability and data exchange capabilities are sufficiently mature. A commenter stated CMS should maintain multiple reporting pathways until digital quality measurement and interoperability are demonstrably mature across practice environments. Another comment encouraged CMS to implement Medicare eCQMs in a manner that minimizes additional requirements and provides sufficient flexibility for ACOs to select the reporting pathway that best aligns with their existing infrastructure.

Response: We stated in the CY 2027 PFS proposed rule (91 FR 44049) that we intend to allow Shared Savings Program ACOs to continue to report using the existing collection types to maintain stability of collection types during the transition to dQMs. Therefore, in addition to allowing ACOs the option to report quality data using the Medicare eCQMs collection type, for PY 2027 and subsequent PYs, ACOs would have the flexibility and option to report quality data using the all payer/all patient eCQMs/MIPS CQMs, and/or the Medicare CQMs collection types.

Comment: A few commenters had concerns regarding the attribution methodology. A comment stated that attribution has been a source of some ambiguity for CMS quality measurement and that rules or standards that address attribution directly would be valuable. Another comment asked that CMS clarify whether the CMS-provided Quarter 4 beneficiary list will be considered the authoritative reporting population, whether CMS intends to publish specifications describing acceptable alternative methodologies, and how CMS will address discrepancies between ACO's derived beneficiary population and the CMS-provided list.

Response: In the CY 2027 PFS proposed rule (91 FR 44049), we stated that a Medicare eCQM is essentially an eCQM that is part of the APP Plus quality measure set and reported by a Shared Savings Program ACO on only the Shared Savings Program ACO's assigned beneficiaries, instead of its all payer/all patient population. That is, the Medicare eCQMs will follow the eCQM measure specifications; however, they will be reported on a different population and use a different identifier to distinguish that the submission is for a Medicare eCQM rather than for an eCQM. We proposed to define a ''beneficiary eligible for Medicare eCQMs'' at § 425.20 as a beneficiary identified for purposes of reporting Medicare eCQMs for Shared Savings Program ACOs participating in the Medicare Shared Savings Program (Medicare eCQMs), who is a beneficiary that is assigned to the Shared Savings Program ACO under subpart E of part 425.

We stated that the Quarter 4 list would include all beneficiaries eligible for Medicare eCQMs based on available claims data for encounters with dates of service from January 1 through December 31 and may be used as the final list for quality reporting. We also stated that we recognize that Shared Savings Program ACOs may have other technologically feasible means to identify beneficiaries eligible for Medicare eCQMs within the Shared Savings Program ACO or Shared Savings Program ACO participant TIN CEHRT, thus, we did not propose to require that Shared Savings Program ACOs use the list of beneficiaries eligible for Medicare eCQMs to identify the universe of beneficiaries upon which the Shared Savings Program ACO would report Medicare eCQMs. We clarify, however, that the Assignment List Report (ALR) which we already provide to ACOs quarterly is the source for assignment related-information. ACOs may choose whether to use the Quarter 4 ALR we provide or the Quarter 4 Medicare eCQM list which will contain the beneficiaries listed in the ALR along with the additional variables that CMS will provide ACOs to identify beneficiaries that are assigned to the ACO for the applicable PY for purposes of quality reporting.

Regarding the commenter's question about addressing any potential discrepancies between the ACO's derived beneficiary population and the CMS-provided list, per 42 CFR 414.1390(b), all ACOs that submit data and information to CMS for purposes of MIPS must certify to the best of their knowledge that the data submitted to CMS is true, accurate, and complete. As such, it is incumbent upon ACOs to confirm the accuracy of the data being submitted. CMS retains the right to audit. More information on that process can be found in the QPP Resource Library at *https://qpp.cms.gov/content-management/resources/document/b624d0b4-fc05-4ee6-89a4-00aebdbc0511/download/file.*

Comment: A commenter requested that CMS ensure that beneficiaries assigned to ACOs for Medicare eCQMs do not change throughout the year as this causes unnecessary administrative burden and workflow burden. A commenter suggested that CMS should provide ACOs with advance data identifying assigned beneficiaries so they can effectively plan care management and quality improvement activities.

Response: Under 42 CFR part 425, subpart E, for ACOs under prospective assignment, claims-based beneficiary assignment is determined prospectively at the beginning of each benchmark and performance year based on the beneficiary's use of primary care services during the specified 12-month assignment window or specified 24-month expanded window for assignment for which data are available. Near the start of the performance year, ACOs receive an assignment list that includes beneficiaries prospectively assigned via claims-based assignment and beneficiaries prospectively assigned as a result of voluntary alignment based on most recent available data. If a Shared Savings Program ACO wants to ensure that beneficiaries are not added to the ACO's assignment lists throughout the year, they have the option to elect prospective assignment during the application cycle. Note that prospectively assigned beneficiaries may be removed from an ACO's assignment list as a result of meeting select assignment exclusion criteria.

Regardless of the assignment methodology selected by an ACO, as stated in the CY 2027 PFS proposed rule (91 FR 44049), we would provide Shared Savings Program ACOs with a list of beneficiaries that are assigned to the Shared Savings Program ACO and thus are eligible for Medicare eCQM reporting within the Shared Savings Program ACO. We anticipate that the list of beneficiaries eligible for Medicare eCQMs would be shared with Shared Savings Program ACOs on a quarterly basis, beginning with Quarter 1 of PY 2027. The Quarter 4 list would include all beneficiaries eligible for Medicare eCQMs based on available claims data for encounters with dates of service from January 1 through December 31 and may be used as the final list for quality reporting. Regarding the commenter's request to provide data in advance, we note that for PY 2027, we anticipate providing the Quarter 1 list in May 2027, the Quarter 2 list in August 2027, the Quarter 3 list in November 2027, and the Quarter 4 list in February 2028. We also noted that, like eCQMs, Medicare eCQMs would be reported end-to-end electronically. As such, we recognize that Shared Savings Program ACOs may have other technologically feasible means to identify beneficiaries eligible for Medicare eCQMs within the Shared Savings Program ACO or Shared Savings Program ACO participant TIN CEHRT. The Quarter 4 list can be used

as a resource to help Shared Savings Program ACOs identify beneficiaries eligible for Medicare eCQM reporting.

Comment: A few commenters requested that CMS provide guidance in advance of when the Medicare eCQMs collection type becomes available. A commenter requested that CMS release updated QRDA III Implementation Guide specifications as early as possible to ensure vendors have sufficient development lead time. Another comment suggested CMS finalize quality specifications early enough for EHRs, registries, and ACOs to build and test before the PY. A commenter requested clarification regarding operational specifications for Medicare eCQMs, including whether they will differ from existing eCQM specifications, specifically regarding data extraction requirements, submission expectations, validation requirements, and audit processes.

Another commenter recommended that CMS identify, or commit to publishing, the specific technical specifications that will define the Medicare beneficiary-limited denominator for the Medicare eCQMs collection type. The commenter also asked for clarification on which entity is responsible for maintaining and updating the specifications. A commenter requested that CMS provide the mechanism and format by which the assigned-beneficiary roster reaches the calculation system and that CMS specify the calculation approach.

A couple of commenters noted concerns with QRDA I files and stated that without the ability to filter QRDA I files to a defined population, ACOs would need to extract large volumes of data and then filter down to an assigned beneficiary population. These commenters suggested that CMS work with the vendor community to ensure CEHRT products support Medicare eCQM reporting. A commenter encouraged CMS to ensure the new pathway has interoperability with specialty registries and other established infrastructure.

Response: We acknowledge concerns related to the technical limitations of reporting Medicare eCQMs and recognize ACOs will have to develop these capabilities either in-house or through vendors. The Medicare eCQMs will follow the eCQM measure specifications; however, they will be reported on a different population. We will not be providing separate Medicare eCQM measure specifications. ACOs should use the eCQM measure specifications and report data on their assigned beneficiaries. The eCQM measure specifications for PY 2027 are available on the eCQI Resource Center website at *https://ecqi.healthit.gov/.* We also refer readers to *https://ecqi.healthit.gov/ecqm-lifecycle* for an overview of the processes for measure use, continuing evaluation, and maintenance. The updated QRDA III Implementation Guide will be available after the release of this final rule.

ACOs will need to work in-house or with their vendors to determine the mechanism for identifying the beneficiary-limited denominator and any mechanism for which the CMS-provided beneficiary list is appropriately included in the ACO's application of the applicable measure specifications. If interoperability with specialty registries and infrastructure to filter QRDA I files is desired, ACOs will need to address this in-house or through vendors. Additional information on reporting Medicare eCQMs will be provided after the release of this final rule.

Comment: A commenter noted that if CMS finalizes its proposal to introduce a distinguishing identifier for Medicare eCQM submissions, then implementing that identifier may require some development effort on the part of health IT vendors. The commenter noted that while they do not consider this to be a substantial burden, it is not without operational cost.

Response: We appreciate the comment's concern. As stated in the CY 2027 PFS proposed rule (91 FR 44050), to operationalize the reporting of the Medicare eCQMs collection type, specifically to distinguish between the submission of data for a Medicare eCQM from the submission of data for an eCQM to CMS, we will create and provide unique identifiers that are associated with each Medicare eCQM. These identifiers must be included in the submission files when reporting Medicare eCQMs beginning in PY 2027. Additional information on reporting Medicare eCQMs will be provided after the release of this final rule. We recognize that the Medicare eCQMs collection type may not be a suitable collection type for some ACOs at this time, and ACOs will have to develop capabilities either in-house or through vendors to report using the Medicare eCQMs collection type. Therefore, we encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure.

Comment: A few comments recommended that CMS include Medicare eCQMs in the reporting incentive available for eCQMs and MIPS CQMs. A comment felt withholding the incentive from ACOs will slow uptake of the new collection type and the transition to digital quality measurement.

Response: As stated in the CY 2027 PFS proposed rule (91 FR 44050), we did not propose to add Medicare eCQMs to the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(B)(2) for PY 2027 and subsequent PYs. We stated that the eCQM/MIPS CQM reporting incentive intends to provide an incentive to ACOs to report all payer/all patient eCQMs/MIPS CQMs while allowing them time to gauge their performance on the all payer/all patient eCQMs/MIPS CQMs. A Medicare eCQM is essentially an eCQM that is reported by a Shared Savings Program ACO on only the ACO's assigned beneficiaries, instead of its all payer/all patient population. Since Medicare eCQMs would include only the ACO's assigned beneficiaries, Medicare eCQMs are not a form of all payer/all patient reporting. As such, they are not included in the eCQM/MIPS CQM reporting incentive. In the CY 2025 PFS final rule (88 FR 79105), we declined to extend the reporting incentive to Medicare CQMs for the same reasons. We note that the alternative quality performance standard, which we finalized in the CY 2023 PFS final rule (88 FR 69831), would be applicable to ACOs that report Medicare eCQMs when those ACOs are otherwise eligible for scaled savings/losses.

Comment: A commenter encouraged CMS to reconsider excluding Medicare eCQMs from the Complex Organization Adjustment noting that although Medicare eCQMs reduce the reporting population, they do not eliminate the complexity associated with electronic quality reporting, validation, submission, and ongoing quality improvement activities.

Response: In the CY 2027 PFS proposed rule (91 FR 44049 and 44050), we stated that the Complex Organization Adjustment intends to account for the organizational complexities Shared Savings Program ACOs face when reporting all payer/all patient eCQMs. A Medicare eCQM is essentially an eCQM that is reported by a Shared Savings Program ACO on only the ACO's assigned beneficiaries, instead of its all payer/all patient population. Therefore, we believe that it is appropriate to not add Medicare eCQMs to the Complex Organization Adjustment.

Comment: A couple of commenters encouraged CMS to maintain separate benchmarks for Medicare CQMs and Medicare eCQMs and noted that

separate benchmarks would better account for differences in data collections methodologies and support more appropriate performance assessment across reporting types. A commenter expressed concern that flat benchmarks would result in lower quality scores for Medicare eCQMs compared to Medicare CQMs and suggested that CMS use performance-period benchmarks for Medicare eCQMs until sufficient historical benchmark data are available to establish reliable historical benchmarks.

Response: In the CY 2025 PFS final rule (89 FR 98118) regarding the use of flat benchmarks to score Medicare CQMs, we stated that flat benchmarks would allow ACOs with high scores to earn maximum or near maximum achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years. Use of flat benchmarks also helps to ensure that ACOs with high-quality performance on a measure are not penalized as low performers. Like Medicare CQMs, the use of flat benchmarks to score Medicare eCQMs would also allow room for quality improvement while allowing ACOs with high scores to earn maximum or near maximum achievement points. Flat benchmarks would also mitigate the risk that MIPS would not be able to calculate performance period benchmarks for these measures in the APP Plus quality measure set, as MIPS benchmarking requires 20 submissions of at least 20 cases as the minimum standard for establishing a benchmark to reliably score measures (81 FR 77277). As stated at § 414.1380(b)(1)(ii), benchmarks are specific to each collection type. As such, Medicare CQMs and Medicare eCQMs will have separate flat benchmarks.

We are clarifying in this final rule that, for PY 2027 and subsequent PYs, Table B–G5 lists the flat benchmarks for a non-inverse Medicare eCQM and Table B–G6 lists the flat benchmarks for an inverse Medicare eCQM. We believe the scales we are finalizing for Medicare CQMs in section III.G.3.c. of this final rule would also be appropriate for Medicare eCQMs since Medicare eCQMs will be a new collection type available to Shared Savings Program ACOs beginning in PY 2027 and, therefore, would not have data available to establish historical benchmarks and may not have enough submissions to establish a performance period benchmark.

TABLE B-G5: FLAT BENCHMARKS FOR A NON-INVERSE MEDICARE eCQM IN PY 2027 AND SUBSEQUENT PYs

Decile	Performance Rate Range
1	< 10.00
2	10.00 – 19.99
3	20.00 – 29.99
4	30.00 – 39.99
5	40.00 – 49.99
6	50.00 – 59.99
7	60.00 – 69.99
8	70.00 – 79.99
9	80.00 – 89.99
10	>= 90.00

TABLE B-G6: FLAT BENCHMARKS FOR AN INVERSE MEDICARE eCQM IN PY 2027 AND SUBSEQUENT PYs

Decile	Performance Rate Range
1	99.00 – 90.01
2	90.00 – 80.01
3	80.00 – 70.01
4	70.00 – 60.01
5	60.00 – 50.01
6	50.00 – 40.01
7	40.00 – 30.01
8	30.00 – 20.01
9	20.00 – 10.01
10	<= 10.00

We note that section 1899(b)(3)(C) of the Act directs that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. Applying

flat benchmarks for a new collection type is consistent with our intent to improve quality of care furnished by ACOs over time. Medicare eCQMs are an optional collection type. Beginning in PY 2027, ACOs have the option to report quality data using multiple collection types, such as, eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs. We recognize that Medicare eCQMs may not be a suitable collection type for some ACOs. Therefore, we encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure. As stated in the CY 2027 PFS proposed rule (91 FR 44049), we will monitor the reporting of quality data using the Medicare eCQMs collection type.

Comment: A commenter recommended that CMS apply benchmark changes prospectively rather than retroactively.

Response: In the CY 2027 PFS proposed rule (91 FR 44048 through 44050), we proposed to establish the Medicare eCQMs as a new collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set for PY 2027 and subsequent PYs, and we also proposed that beginning with PY 2027, Medicare eCQMs would be scored using flat benchmarks. We are finalizing these policies as proposed, thus none of these policies will be applied retroactively.

Comment: A commenter requested that Medicare eCQMs include a MIPS data completeness provision and that ACOs be required to submit data on at least 75 percent of applicable beneficiaries eligible for the measures.

Response: In the CY 2027 PFS proposed rule (91 FR 44049), we proposed to revise § 414.1340(e) to establish the MIPS data completeness criteria threshold for the Medicare eCQMs collection type, in which Shared Savings Program ACOs that meet reporting requirements under the APP submitting quality measure data on Medicare eCQMs must submit data on at least 75 percent of the ACO's applicable beneficiaries eligible for the Medicare eCQM, as defined at § 425.20, who meet the measure's denominator criteria for MIPS payment year 2029 and future MIPS payment years (PY 2027 and subsequent PYs). We are finalizing the revisions to § 414.1340(e) as proposed in section IV.A.4.d.(1)(d)(ii) of this final rule.

After consideration of public comments, in section IV.A.4.d.(1)(b) of this final rule, we are finalizing our proposal to establish Medicare eCQMs as a new collection type for Shared Savings Program ACOs reporting on the Medicare eCQMs (reporting quality data on beneficiaries eligible for Medicare eCQMs as finalized to be defined at § 425.20) within the APP Plus quality measure set.

To facilitate the reporting of Medicare eCQMs, in section IV.A.4.d.(1)(b) of this final rule, we are finalizing our proposal to amend the definition of ''collection type'' in § 414.1305 to include Medicare eCQMs as an available collection type in MIPS for ACOs that participate in the Shared Savings Program.

Additionally, we are finalizing our proposal to establish MIPS data submission and data completeness criteria, in §§ 414.1335(a)(5) and 414.1340(e), respectively, pertaining to the Medicare eCQMs collection type for the MIPS quality performance category, as discussed in sections IV.A.4.d.(1)(c)(v) and IV.A.4.d.(1)(d)(ii), respectively, of this final rule.

We are also finalizing our proposal to define a ''beneficiary eligible for Medicare eCQMs'' at § 425.20 as a beneficiary identified for purposes of reporting Medicare eCQMs for Shared Savings Program ACOs participating in the Medicare Shared Savings Program (Medicare eCQMs), who is a beneficiary that is assigned to the Shared Savings Program ACO under subpart E, in part 425.

In section IV.A.4.d.(1)(d)(ii) of this final rule, we are finalizing our proposal to revise § 414.1340(e) to establish the MIPS data completeness criteria threshold for the Medicare eCQMs collection type, in which Shared Savings Program ACOs that meet reporting requirements under the APP submitting quality measure data on Medicare eCQMs must submit data on at least 75 percent of the ACO's applicable beneficiaries eligible for the Medicare eCQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria for MIPS payment year 2029 and future MIPS payment years (PY 2027 and subsequent PYs).

We are finalizing in III.G.3.f of this final rule that, as proposed, there would be five eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs in the APP Plus quality measure set for Shared Savings Program ACOs for PY 2027 and subsequent PYs.

- Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001);
- Breast Cancer Screening (Quality ID: 112);
- Colorectal Cancer Screening (Quality ID: 113);
- Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Quality ID: 134); and
- Controlling High Blood Pressure (Quality ID: 236).

ACOs would have the option to report the five Medicare eCQMs, or a combination of eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs, to meet the Shared Savings Program quality reporting requirement at § 425.510(b) and the quality performance standard at § 425.512(a)(5).

In section IV.B.1.c.(2) of this final rule and in the regulations at § 414.1380(b)(1)(ii)(G)(1), we are finalizing, as proposed, that beginning with the CY 2027 performance period/2029 MIPS payment year, measures of the Medicare eCQMs collection type use flat benchmarks.

As part of finalizing our proposals for Shared Savings Program ACOs to report the Medicare eCQMs collection type for PY 2027 and subsequent PYs, we are finalizing the proposed revisions to the regulation text at §§ 425.20 and 425.512 as follows:

Under a new paragraph at § 425.20, we are defining a beneficiary eligible for Medicare eCQMs as a beneficiary identified for purposes of reporting Medicare eCQMs for Shared Savings Program ACOs participating in the Medicare Shared Savings Program (Medicare eCQMs), who is a beneficiary that is assigned to the Shared Savings Program ACO under subpart E of this part.

Under § 425.512(a)(2)(iv), we are incorporating Medicare eCQMs into the existing quality performance standard policies for new Shared Savings Program ACOs. Under paragraph (a)(5)(iii)(C), we would also incorporate Medicare eCQMs into the existing policies that describe when a Shared Savings Program ACO would not meet the quality performance standard or the alternative quality performance standard.

After consideration of public comments, we are finalizing as proposed for Shared Savings Program ACOs to report the Medicare eCQMs collection type for PY 2027 and subsequent PYs.

(4) Revising the Definition of a ''Beneficiary Eligible for Medicare CQMs''

In the CY 2027 PFS proposed rule (91 FR 44050), we stated that in the CY 2026 PFS final rule (90 FR 49797 through 49803), we finalized the revisions to the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 effective January 1, 2025. Specifically, beginning with PY 2025 and subsequent PYs, we revised the definition to require, in (1)(ii)(B) of the definition, ''at least one primary care

service with a date of service during the applicable performance year from a Shared Savings Program ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.'' We stated that the revised definition of a ''beneficiary eligible for Medicare CQMs'' would reduce Shared Savings Program ACOs' burden in the patient matching necessary to report Medicare CQMs because the list of ''beneficiaries eligible for Medicare CQMs'' would have greater overlap with the list of beneficiaries that are assignable to a Shared Savings Program ACO. We stated that we believed our revised definition of a ''beneficiary eligible for Medicare CQMs'' would substantially address Shared Savings Program ACOs' and interested parties' concerns by better aligning the definitions and clarifying which beneficiaries' data to use for quality data reporting through Medicare CQMs. In the CY 2026 PFS final rule, some commenters suggested that CMS require Medicare CQMs be reported for ''attributed'' beneficiaries only (90 FR 49800). In response, CMS noted that Medicare CQMs are designed to help Shared Savings Program ACOs address challenges with aggregating patient data required to report the all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that is broader than the assigned population but exists within the all payer/all patient MIPS CQM specification.

We also stated in the CY 2027 PFS proposed rule (91 FR 44050) that since the publication of the CY 2026 PFS final rule and implementation of the revised definition aligning with assignable beneficiaries, we have heard from Shared Savings Program ACOs and other interested parties that the current definition of a ''beneficiary eligible for Medicare CQMs'' continues to cause confusion regarding which beneficiaries to use for quality data reporting. Specifically, Shared Savings Program ACOs have inquired about the differences between the current list of beneficiaries eligible for Medicare CQMs (which is broader than an ACO's assigned population) and the Shared Savings Program ACO's assigned and assignable populations. As discussed in the CY 2026 final rule, an analysis using PY 2024 data noted an average 85 percent overlap between a Shared Savings Program ACO's list of beneficiaries eligible for Medicare CQMs and the list of beneficiaries assignable to the Shared Savings Program ACO (90 FR 49799). Moreover, we have heard from Shared Savings Program ACOs that the current definition aligning with assignable beneficiaries continues to create burden in patient matching, data aggregation and quality reporting for Shared Savings Program ACOs that elect to report Medicare CQMs. Lastly, Shared Savings Program ACOs have expressed that the current definition of ''beneficiaries eligible for Medicare CQMs'' that aligns with assignable beneficiaries includes beneficiaries for whom the Shared Savings Program ACO does not readily have data.

Considering the concerns raised by Shared Savings Program ACOs and other interested parties with reporting Medicare CQMs, in the CY 2027 PFS proposed rule (91 FR 44051), we proposed to revise the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 for PY 2027 and subsequent PYs, to align with the population of beneficiaries assigned to the ACO.

We also stated that we implemented Medicare CQMs in PY 2024 to help some Shared Savings Program ACOs build the infrastructure, skills, knowledge and expertise necessary to report all payer/all patient MIPS CQMs and eCQMs (91 FR 44051). The confusion that Shared Savings Program ACOs have expressed about the differences between the list of beneficiaries eligible for Medicare CQMs and a Shared Savings Program ACO's assigned populations have complicated the process for Shared Savings Program ACOs to meaningfully implement Medicare CQMs for this purpose. Our proposed revision would build upon the revisions finalized in the CY 2026 PFS final rule and further refine and align the definition of a ''beneficiary eligible for Medicare CQMs'' to correspond to a Shared Savings Program ACO's assigned beneficiary list to continue to address Shared Savings Program ACOs' challenges with patient data aggregation. The proposed change to the definition of a ''beneficiary eligible for Medicare CQMs'' for PY 2027 and subsequent PYs intends to better support these Shared Savings Program ACOs in the transition to digital quality measurement and to eliminate an unintended barrier that Shared Savings Program ACOs have experienced in reporting Medicare CQMs, which have persisted after the revision of the definition in the CY 2026 PFS final rule to align with assignable beneficiaries.

In the CY 2027 PFS proposed rule (91 FR 44051), we stated that the Shared Savings Program relies on primary care-based assignment, and the APP Plus quality measure set is primary care-based. Our proposals to use the Shared Savings Program ACO's assigned beneficiary population for the Medicare CQMs collection type beginning in PY 2027 would hold Shared Savings Program ACOs accountable for the quality of care for only the beneficiaries assigned to them and align with the voluntary risk they have undertaken to coordinate beneficiaries' care. Also, focusing on care provided by primary care providers would be a reasonable approach that addresses concerns with data aggregation and specialist participation. Similarly, we have heard from Shared Savings Program ACOs that the current definition of a ''beneficiary eligible for Medicare CQMs'' is a detriment to Shared Savings Program ACOs meeting the MIPS data completeness requirement described at § 414.1340. As such, the proposed change aims to support Shared Savings Program ACOs in meeting the MIPS data completeness requirement by tethering the universe of beneficiaries that a Shared Savings Program ACO is required to report on for Medicare CQMs to the universe of beneficiaries that have a primary care relationship with the Shared Savings Program ACO as demonstrated through the beneficiaries' assignment to the Shared Savings Program ACO. We anticipate that Shared Savings Program ACOs that choose to report Medicare CQMs would experience fewer barriers in aggregating the applicable numerator and denominator data for beneficiaries that are assigned to the Shared Savings Program ACO and, as a result, would be better positioned to meet the MIPS data completeness requirement described at § 414.1340.

As stated in the CY 2027 PFS proposed rule (91 FR 44051), in the CY 2024 PFS final rule, we finalized a new paragraph at § 425.702(c)(1)(iii) to share aggregate reports with Shared Savings Program ACOs with the aim of facilitating population-based activities related to the improvement of health through quality measurement using Medicare CQMs and to aid Shared Savings Program ACOs in the process of patient matching and data aggregation necessary to report Medicare CQMs (88 FR 79099). It was necessary at that time to revise the regulation text at § 425.702 because the list of beneficiaries eligible for Medicare CQMs, as finalized for PY 2024, was broader than the universe of beneficiaries assigned to the Shared Savings Program ACO. As discussed in the CY 2027 PFS proposed rule (91 FR

44050 through 44052), we proposed to align the definition of a ''beneficiary eligible for Medicare CQMs'' with the universe of beneficiaries assigned to the Shared Savings Program ACO. The sharing of aggregate reports for beneficiaries assigned to the Shared Savings Program ACO is regulated at § 425.702(c)(1)(ii). As such, since the list of beneficiaries eligible for Medicare CQMs would align with the universe of beneficiaries assigned to the Shared Savings Program ACO under this proposal, it is appropriate to also propose to sunset the regulation at § 425.702(c)(1)(iii) beginning in PY 2027. As we noted in the CY 2027 PFS proposed rule (91 FR 44051), if finalized, we would provide Shared Savings Program ACOs with a quarterly list of beneficiaries eligible for Medicare CQMs, starting with PY 2027, that aligns with an ACO's list of assigned beneficiaries under the existing regulation at § 425.702(c)(1)(ii).

We stated in the CY 2027 PFS proposed rule (91 FR 44051) that as part of our proposal to revise the definition of a ''beneficiary eligible for Medicare CQMs'' for PY 2027 and subsequent PYs, we would revise and republish the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 to include the following:

We would note that a beneficiary *eligible for Medicare CQMs* means a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who meets the following requirements (as applicable):

• For performance years 2024 through 2026, the beneficiary is either of the following:

++ A Medicare fee-for-service beneficiary (as defined at § 425.20) who—

—Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

—For performance year 2024, had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

—For performance years 2025 and 2026, had at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

++ A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

• For performance years 2027 and subsequent performance years, a beneficiary that is assigned to the ACO under subpart E of this part.

We also stated in the CY 2027 PFS proposed rule (91 FR 44052) that we would also revise the regulation text at § 425.702 to specify that paragraph (c)(1)(iii) applies for performance years 2024 through 2026. We sought public comments on our proposal to revise the definition of a ''beneficiary Eligible for Medicare CQMs''.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters were supportive of our proposal to revise the definition of a ''beneficiary eligible for Medicare CQMs'' to align with the population of beneficiaries assigned to the ACO. A couple of commenters thanked CMS for being responsive to concerns from interested parties. A couple of commenters noted that the policy helps address ACOs' challenges with meeting the MIPS data completeness requirements by addressing long-standing quality reporting issues, alleviating the reporting burden, encouraging ACOs to remain in the program and addressing ACO concerns with data aggregation.

Some commenters noted that the policy focuses quality measurement on the population for whom the ACO is actually accountable which directly addresses previous concerns with assessing ACOs' quality based on patients not managed by the ACO for purposes of determining shared savings and losses and stated the policy aligns with the beneficiaries for whom ACOs are responsible under shared savings and shared loss calculations. Commenters noted that the revised definition would better reflect primary care relationships and is more clinically coherent. A commenter noted that the revised definition more accurately reflects ACO performance, strengthens the alignment between quality measurement and accountability, and reduces unnecessary reporting burden relative to measuring performance among beneficiaries outside of the ACO's attributed population which may introduce factors beyond the ACO's ability to influence. Another commenter noted that the requirement for all-patient, all-payer reporting penalizes specialist participants in ACOs who CMS holds accountable for primary care measures that are not clinically appropriate and artificially lowers quality scores for ACOs with a higher proportion of specialists and thanked CMS for incorporating their feedback in this policy. Another commenter noted the revised definition as important for academic medical centers where primary care TINs are embedded in broader systems with specialty and hospital populations not directly accountable under the ACO and that CMS should continue aligning quality accountability with the population for which the ACO is responsible.

A commenter noted the policy eliminates unnecessary burdens associated with identifying a separate population and ensures performance results more accurately reflect care delivered by ACO providers and suppliers. A couple of commenters also noted the revision would match the proposed patient population for the newly proposed Medicare eCQMs collection type. A commenter supported the proposal's burden reduction improvements, including refinements to Medicare CQM reporting and proposals to align the reporting population with assigned beneficiaries, which would reduce reporting complexity and help ACOs meet existing MIPS data completeness requirements. Further, another commenter noted that the technical change addresses problems with identifying which Medicare fee-for service beneficiaries must be included in Medicare CQM.

Response: We appreciate comments in support of the proposal to revise the definition of a ''beneficiary eligible for Medicare CQMs'' for PY 2027 and subsequent PYs.

Comment: Several commenters recommended that beneficiaries' address (street, city, state, and zip code) be added to the Medicare CQM quarterly lists to increase the accuracy of patient matching.

Response: We appreciate the comments and may take it into consideration for future updates to the Medicare CQM quarterly lists.

Comment: Several commenters were supportive of our proposal to revise the definition of a ''beneficiary eligible for Medicare CQMs'' and encouraged CMS to finalize the definition for PY 2026 instead of PY 2027. A commenter stated that retroactive implementation would add certainty and reduce reporting burden sooner.

Response: Section 1871(e)(1)(A)(ii) of the Act prohibits the Secretary from

applying substantive changes in regulations retroactively before the effective date of the change except where the Secretary determines that failure to apply the change retroactively would be contrary to the public interest. In the CY 2026 PFS final rule (90 FR 49797 through 49803)), we revised the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 for PY 2025 and subsequent PYs so that the population identified for reporting within the Medicare CQM collection type would have greater overlap with the beneficiaries that are assignable to an ACO. The benefits of revising the definition a second time for PY 2026 to align with assigned beneficiaries would be outweighed by the risk of changing the population when PY 2026 is underway. ACOs have already made decisions regarding which collection type they would report on for PY 2026 based on the definition of a ''beneficiary eligible for Medicare CQMs'' currently in effect for PY 2026, and the retroactive change of this definition would create unnecessary disruption and confusion, increase burden for existing ACOs' operations, and cause uncertainty for ACOs. Therefore, we decline to finalize the definition for PY 2026.

Comment: A commenter urged CMS to investigate whether CMS' Medicare CQM proposal would disadvantage ACOs that prospectively assign beneficiaries, preventing these ACOs from meeting the 95% voluntarily aligned beneficiaries' requirement.

Response: We refer the commenter to our discussion on the impact of the revised Shared Savings Program quality reporting requirements on ACOs using prospective assignment in section III.G.3.d.(2) in this final rule. Regarding the commenter's concern whether our proposal to revise the definition of a ''beneficiary eligible for Medicare CQMs'' would disadvantage ACOs with prospective assignment, we note that our proposed revised definition of a ''beneficiary eligible for Medicare CQMs'' is the same for ACOs under preliminary prospective assignment with retrospective reconciliation and ACOs under prospective assignment. As stated in the CY 2024 PFS final rule (88 FR 79098), a Medicare CQM is essentially a MIPS CQM reported by an ACO under the APP on only the ACO's Medicare FFS beneficiaries, instead of its all payer/all patient population. In a manner that is identical to the MIPS CQM specifications, the Medicare CQM specifications will be applied in the same way regardless of the ACO's assignment election. We encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure.

After consideration of public comments, we are finalizing our proposal to revise the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 for PY 2027 and subsequent PYs, to align with the population of beneficiaries assigned to the Shared Savings Program ACO. We are also finalizing that we would provide Shared Savings Program ACOs with a quarterly list of beneficiaries eligible for Medicare CQMs, starting with PY 2027, that aligns with an ACO's list of assigned beneficiaries under the existing regulation at § 425.702(c)(1)(ii).

As part of our finalized proposal to revise the definition of a ''beneficiary eligible for Medicare CQMs'' for PY 2027 and subsequent PYs, we are revising and republishing the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 to include the following:

We are noting that a *beneficiary eligible for Medicare CQMs* means a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who meets the following requirements (as applicable):

- For performance years 2024 through 2026, the beneficiary is either of the following:

++ A Medicare fee-for-service beneficiary (as defined at § 425.20) who—

—Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

—For performance year 2024, had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

—For performance years 2025 and 2026, had at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

++ A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

- For performance years 2027 and subsequent performance years, a beneficiary that is assigned to the ACO under subpart E of this part.

We are also revising the regulation text at § 425.702 to specify that paragraph (c)(1)(iii) applies for performance years 2024 through 2026.

e. Revising the Shared Savings Program Scoring Policy for Excluded APP Plus Measures and APP Plus Measures That Lack a Benchmark

(1) Background

In the CY 2027 PFS proposed rule (91 FR 44052 and 44053), we stated that in the CY 2024 PFS final rule given that the Shared Savings Program does not determine which quality measures are excluded and lack a benchmark and that Shared Savings Program ACOs do not have a choice of measures that they can report under the APP, we do not want to adversely impact shared savings determinations for events outside the Shared Savings Program ACOs' control, such as in the event a measure is excluded or does not have a benchmark (88 FR 79122 and 79123). Therefore, we finalized a scoring policy for excluded APP measures and APP measures that lack a benchmark at § 425.512(a)(7). Specifically, we finalized that, to determine whether the Shared Savings Program ACO meets the quality performance standard required to share in savings at the maximum rate under its track (or payment model within a track), for PY 2024 and subsequent PYs, if a Shared Savings Program ACO reports all of the required measures, meeting the MIPS data completeness requirement at § 414.1340 of this subchapter for each measure in the APP measure set and receiving a MIPS quality performance category score as described at § 414.1380(b)(1) of this subchapter, we will use the higher of the Shared Savings Program ACO's quality score or the equivalent of the 40th percentile MIPS quality performance category score across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year when the Shared Savings Program ACO meets either of the following:

- The ACO's total available measure achievement points used to calculate the ACO's MIPS quality performance category score is reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.
- At least one of the eCQMs/MIPS CQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A) of this subchapter.

Shared Savings Program ACOs that qualify for this existing policy at § 425.512(a)(7) can meet the quality performance standard if one measure in the APP Plus quality measure set is excluded or lacks a benchmark, and the Shared Savings Program ACO will not be evaluated on their quality performance on the remaining quality measures reported by the Shared Savings Program ACO.

(2) Revisions

In the CY 2027 PFS proposed rule (91 FR 44052 and 44053), we stated that when our scoring policy for excluded APP measures and APP measures that lack a benchmark was finalized in the CY 2024 PFS final rule, there were six total measures in the APP quality measure set, and Shared Savings Program ACOs were required to report only three eCQMs/MIPS CQMs (in addition to administering the CAHPS for MIPS survey) for PY 2024 and subsequent PYs (88 FR 79113). In the CY 2025 PFS final rule, we finalized that, for PY 2025 and subsequent PYs, Shared Savings Program ACOs will be required to report the APP Plus quality measure set (89 FR 98105). In the CY 2027 PFS proposed rule (91 FR 44052), we proposed that, for PY 2027 and subsequent PYs, Shared Savings Program ACOs would be required to report on eight measures in the APP Plus quality measure set: five eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs, the CAHPS for MIPS survey, and two administrative claims-based measures that would be calculated by CMS. We stated in the CY 2027 PFS proposed rule (91 FR 44052 and 44053) that when CMS established the policy in the CY 2024 PFS final rule, we noted that there were two eCQMs in the legacy APP quality measure set that were suppressed by MIPS in PY 2022 (88 FR 79122). Since these two eCQMs were excluded, the growth in the number of quality measures Shared Savings Program ACOs are required to report increases the likelihood that a Shared Savings Program ACO's quality score would be based on a broader range of quality performance metrics than it would have been in PY 2022. This reduces the impact of measure exclusion on a Shared Savings Program ACO's MIPS quality performance category score. Applying the existing scoring policy at § 425.512(a)(7) when a single measure is excluded from MIPS would allow a Shared Savings Program ACO to meet the quality performance standard without an evaluation of the Shared Savings Program ACO's quality performance on the remaining measures in the APP Plus quality measure set.

Additionally, we stated in the CY 2027 PFS proposed rule (91 FR 44052 and 44053) that section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by Shared Savings Program ACOs and shall seek to improve the quality of care furnished by Shared Savings Program ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. We believe that revising the scoring policy at § 425.512(a)(7) such that it would only be applied when there are four or more excluded measures in PY 2027 would ensure that Shared Savings Program ACOs are fairly assessed on their quality performance in our determination of whether they meet the quality performance standard to be eligible to share in savings at the maximum rate available for the Shared Savings Program ACO's track and, for ACOs participating in the ENHANCED track, to avoid maximum shared losses. Specifically, we proposed to revise the scoring policy at § 425.512(a)(7) for PY 2027 and subsequent PYs, such that it would apply only if the Shared Savings Program ACO's MIPS quality performance category score is calculated on less than five measures for a given PY. In other words, if there are four or more measures in the APP Plus quality measure set that are excluded from MIPS under § 414.1380(b)(1)(vii)(A) in PY 2027 or a subsequent PY, then the proposed scoring policy at § 425.512(a)(7)(iii) would apply.

We stated that we believe that our proposed revisions to § 425.512(a)(7) would result in a more accurate assessment of Shared Savings Program ACOs' quality performance, as each measure in the five-measure minimum threshold would contribute a reasonable weight (20 percent) to the Shared Savings Program ACO's MIPS quality performance category score. However, if there are fewer than five measures available in a given PY, Shared Savings Program ACOs would not risk losing the ability to meet the quality performance standard to be eligible to earn maximum shared savings, and for Shared Savings Program ACOs in the ENHANCED track, avoid maximum shared losses, due to issues with the measures outside of their control.

As discussed in the CY 2027 PFS proposed rule (91 FR 44053), we proposed that the current scoring policy at § 425.512(a)(7) would no longer apply when at least one of the required measures in the APP Plus quality measure set does not have a benchmark for PY 2027 and subsequent PYs. Excluded measures do not contribute to the calculation of a Shared Savings Program ACO's MIPS quality performance category score for that PY. In the CY 2027 PFS proposed rule, we proposed that the APP Plus quality measure set would have eight measures in total for PY 2027 and subsequent PYs. Thus, we would calculate a Shared Savings Program ACO's MIPS quality performance category score if there are five or more measures in the APP Plus quality measure set that have not been excluded from MIPS. We noted in the CY 2027 PFS proposed rule that this policy would only apply if a Shared Savings Program ACO's MIPS quality performance category score is impacted by measure exclusion under MIPS. We also clarify that the policy would not apply for other reasons based on which a measure may be unscored. Specifically, it would not apply if the Shared Savings Program ACO does not meet the MIPS case minimum requirement at § 414.1380 on any measure in the APP Plus quality measure set. Our proposal would allow us to better evaluate Shared Savings Program ACOs' quality performance and appropriately determine shared savings eligibility based on quality of care.

Therefore, we proposed that, for PY 2027 and subsequent PYs, if the Shared Savings Program ACO's MIPS quality performance category score is calculated on less than five measures due to measure exclusion under MIPS and the Shared Savings Program ACO meets the other quality reporting requirements as described in the proposed § 425.512(a)(7)(iii), then we would use the higher of the Shared Savings Program ACO's quality score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

In the CY 2027 PFS proposed rule (91 FR 44052 and 44053), we provided two hypothetical examples of the application of this proposed policy for illustrative purposes. Hypothetical example 1: for PY 2027, a Shared Savings Program ACO reports three eCQMs (Quality IDs: 001, 112, and 236), one Medicare CQM (Quality ID: 134), and one MIPS CQM (Quality ID: 113) in the APP Plus quality measure set, meets the MIPS data completeness requirement at § 414.1340 on all of these five measures, and receives a MIPS quality performance category score. The Shared Savings Program ACO also administers the CAHPS for MIPS survey and has the two administrative claims-based measures in the APP Plus quality measure set calculated by CMS.

Hypothetically, if Quality IDs 001, 112, 113, and 236 are excluded from MIPS under § 414.1380(b)(1)(vii)(A) for PY 2027, then the Shared Savings Program ACO's MIPS quality performance category score would be based on four measures: the two administrative claims-based measures, the CAHPS for MIPS survey, and Quality ID: 134. The proposed scoring policy at § 425.512(a)(7)(iii) would apply in this scenario since the Shared Savings Program ACO's MIPS quality performance category score would be based on less than five measures. Therefore, the Shared Savings Program ACO would receive the higher of the Shared Savings Program ACO's quality score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS quality performance category scores. This would allow the Shared Savings Program ACO to meet the quality performance standard and be eligible to share in savings at the maximum rate available for their track and, for ENHANCED track Shared Savings Program ACOs, to avoid maximum shared losses.

Hypothetical example 2: for PY 2027, a Shared Savings Program ACO reports all five eCQMs in the APP Plus quality measure set, meets the MIPS data completeness requirement at § 414.1340 on all five eCQMs (Quality IDs: 001, 112, 113, 134, and 236), administers the CAHPS for MIPS survey, receives a MIPS quality performance category score, and has the two administrative claims-based measures calculated by CMS. Under this scenario, the eCQM version of Quality ID: 001 was excluded from MIPS under § 414.1380(b)(1)(vii)(A). Our proposed scoring policy would not apply in this case since the Shared Savings Program ACO's MIPS quality performance category score would be based on more than five measures: the two administrative claims-based measures, the CAHPS for MIPS survey, and four eCQMs.

In the CY 2027 PFS proposed rule (91 FR 44052 and 44053), we referred to the CY 2024 PFS final rule which stated that given the Shared Savings Program does not determine which quality measures do not have a benchmark and that Shared Savings Program ACOs do not have a choice of measures they can report under the APP, we do not want to adversely impact shared savings determinations for events outside the Shared Savings Program ACOs' control, such as in the event a measure does not have a benchmark (88 FR 79123). Therefore, we finalized at § 425.512(a)(7) to include eCQMs, MIPS CQMs, and Medicare CQMs within the APP measure set that do not have a benchmark as described at § 414.1380(b)(1)(i)(A). In the CY 2025 PFS final rule (89 FR 98120), we finalized that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQMs collection type would be scored using flat benchmarks for their first two performance periods in MIPS. Also, in the CY 2027 PFS proposed rule (91 FR 40444 and 44050), we proposed that Medicare CQMs and Medicare eCQMs would be scored using flat benchmarks for PY 2027 and subsequent PYs. The use of flat benchmarks to score Medicare CQMs and Medicare eCQMs would mitigate the risk that MIPS would not be able to calculate benchmarks for these measures in the APP Plus quality measure set. Additionally, we note that none of the eCQMs, MIPS CQMs, or Medicare CQMs that Shared Savings Program ACOs have reported over the past four PYs lacked benchmarks. Therefore, we proposed that the scoring policy at § 425.512(a)(7) would no longer apply when at least one of the required measures in the APP Plus quality set does not have a benchmark for PY 2027 and subsequent PYs.

In the CY 2027 PFS proposed rule (91 FR 44052 and 44053), we proposed to revise the regulation text at § 425.512(a)(7) as follows:

- We are revising paragraph (a)(7)(ii) to specify that it applies for performance years 2025 and 2026.
- Under new paragraph (a)(7)(iii), we would specify that, for performance year 2027 and subsequent performance years, if an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1), for the relevant performance year, and the ACO meets the following-

++ The ACO's MIPS Quality performance category score is calculated on less than five measures; and

++ Any unscored measure(s) must meet all of the following-

—The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A).

—The ACO's total measure achievement points used to calculate the ACO's MIPS Quality performance category score are not reduced under § 414.1380(b)(1)(iii).

We sought public comments on our proposed revisions to the Shared Savings Program scoring policy at § 425.512(a)(7).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of comments supported our proposal to revise the scoring policy for excluded APP Plus measures and APP Plus measures that lack a benchmark. Specifically, comments supported our proposal to increase the number of measures from one measure to four or more measures that would need to be excluded from MIPS in a given performance year for the policy to apply. A comment noted how the revisions create a more balanced and predictable approach to quality scoring while reducing unnecessary complexity within the APP Plus quality measure set. The comment noted that these changes should improve consistency, reduce administrative burden, and allow ACOs to focus resources on quality improvement activities that directly benefit patients. A comment noted that the use of flat benchmarks to score Medicare CQMs and Medicare eCQMs mitigate the need for the scoring policy.

Response: We appreciate comments that support our proposed revisions to the Shared Savings Program scoring policy at § 425.512(a)(7) for PY 2027 and subsequent PYs, such that it would apply only if the Shared Savings Program ACO's MIPS quality performance category score is calculated on less than five measures for a given PY. We also appreciate comments that support our proposal that the current scoring policy at § 425.512(a)(7) would no longer apply when at least one of the required measures in the APP Plus quality measure set does not have a benchmark for PY 2027 and subsequent PYs.

In response to the comment that the use of flat benchmarks to score Medicare CQMs and Medicare eCQMs mitigates the need for the scoring policy, we note that there are still circumstances when a Medicare CQM or Medicare eCQM could be excluded, such as a measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline as described at § 414.1380(b)(1)(vii)(A).

Comment: A comment opposed the proposed revisions to the scoring policy for excluded APP Plus measures; specifically, the proposal to increase the measure threshold. The comment noted that reducing the APP Plus quality measure set to eight measures would increase the weight of each individual measure in an ACO's quality score.

Other comments conceptually agreed with the proposal but provided alternative suggestions for the measure threshold. Several comments expressed concerns that ACOs could lose scoring policy protections when one, two, or three ACO-reported measures are excluded, despite such exclusions being outside the ACO's control. The comments noted that, as proposed, a Shared Savings Program ACO could have three of five ACO-reported measures excluded and be scored based on the two administrative claims-based measures, CAHPS for MIPS survey, and the two remaining ACO-reported measures. A few comments further noted that ACO members have expressed challenges with the administrative claims' measures and the CAHPS for MIPS survey given ACOs do not receive performance data on them during the performance year to conduct improvement efforts in a timely fashion. The comments expressed it would not be appropriate to assess an ACO's quality score in this scenario.

Several comments suggested that CMS modify the proposal such that the measure exclusion component of the current policy would apply when three or more of the ACO-reported measures in the APP Plus quality measure set are excluded for a given performance year. A comment recommended CMS retain the existing one-measure trigger at § 425.512(a)(7) rather than raising it to four, citing that with a smaller measure set each measure carries proportionally more weight in an ACO's quality score.

Response: Regarding comments that express concerns with potentially having the two administrative claims-based measures (Quality ID: 479 Hospital-Wide, 30-day, All Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups, and Quality ID: 484 Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions) and Quality ID: 321 CAHPS for MIPS survey comprise additional weight in their quality scores and the challenges the comments expressed with these measures, we note that these measures are well-established aspects of assessing a Shared Savings Program ACO's quality performance. Specifically, in the CY 2021 PFS final rule (85 FR 84726), when establishing the APP quality measure set for Shared Savings Program ACOs, we explained that the measures included in the APP were selected because they align with the Meaningful Measures framework, focus on management of chronic health conditions that are high priority and highly prevalent among Medicare beneficiaries assigned to ACOs, and are broadly applicable to the primary care population and population health goals associated with the Shared Savings Program. We explained that the administrative claims-based measures promote effective communication and coordination of care and are appropriate measures of ACO quality performance (85 FR 84726). In addition, we stated that we continue to value the patient voice and believe it should play a significant role in quality scoring, and that inclusion of the CAHPS for MIPS survey measure preserves the relevance of patient experience in the assessment of ACO quality performance.

Accordingly, we continue to believe that the two administrative claims-based measures in the APP Plus quality measure set and the CAHPS for MIPS survey measure are well-established quality metrics that are appropriate to assess ACO's quality of care; therefore, these measures, along with the remaining two ACO-reported measures in the comments' scenario, would capture sufficient data to represent the ACO's quality performance. Furthermore, the scenarios described in the comments would be very rare and would necessitate that a large number of measures be excluded from MIPS in a given PY.

We stated in the CY 2027 PFS proposed rule (91 FR 44052) that we believe that our proposed revisions to § 425.512(a)(7) would result in a more accurate assessment of Shared Savings Program ACOs' quality performance, as each measure in the five-measure minimum threshold would contribute a reasonable weight (20 percent) to the Shared Savings Program ACO's MIPS quality performance category score. However, if there are fewer than five measures available in a given PY, Shared Savings Program ACOs would not risk losing the ability to meet the quality performance standard to be eligible to earn maximum shared savings, and for Shared Savings Program ACOs in the ENHANCED track, avoid maximum shared losses, due to issues with the measures outside of their control, while allowing CMS to better evaluate ACOs' quality performance and appropriately determine shared savings eligibility based on quality of care.

In response to the suggestion from the comments that the exclusion component of the current policy be applied when three or more of the ACO-reported measures in the APP Plus quality measure set are excluded for a given performance year, we note that—while there are eight measures included in the APP Plus quality measure set for PY 2027 and subsequent PYs (as finalized in section III.G.f. of this final rule), we continue to believe that the less than five measure threshold for the application of this policy remains appropriate since it ensures that the ACO is otherwise scored on a sufficient number of quality measures that accurately reflect the ACO's quality performance. We further note that our intent is for this policy to function as a relief mechanism to address rare circumstances when four or more measures are excluded from the APP Plus quality measure set by MIPS. We disagree with, and are rejecting, the comments' suggestions to lower the threshold for the application of this policy to three or more measures since we do not believe that this suggestion would result in a more accurate assessment of the Shared Savings Program ACOs' quality performance.

Comment: A comment incorrectly stated that the proposed regulatory text amendments for the policy are stricter than the preamble narrative suggests, citing how under proposed § 425.512(a)(7)(iii), the policy would be available ''only if all unscored measures are excluded under § 414.1380(b)(1)(vii)(A).''

Response: In the CY 2027 PFS proposed rule (91 FR 44053), we stated that we propose that, for PY 2027 and subsequent PYs, if the Shared Savings Program ACO's MIPS quality performance category score is calculated on less than five measures due to measure exclusion under MIPS and the Shared Savings Program ACO meets the other quality reporting requirements as described in the proposed § 425.512(a)(7)(iii), then we would use the higher of the Shared Savings Program ACO's quality score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. This proposal was correctly described under the proposed new paragraph (a)(7)(iii) at § 425.512(a)(7) (91 FR 44053).

Comment: A comment recommended that CMS retain the existing protection for measures that lack a benchmark or apply the same four-or-more threshold to be inclusive of both excluded measures and measures that lack a benchmark. The comment noted how if even a single required measure lacks a benchmark, the ACO loses the floor entirely, no matter how many other measures are excluded or how the ACO performs on the measures that remain.

Response: The MIPS benchmarks for eCQMs and MIPS CQMs that are based on historical data are available prior to the start of the PY. Additionally, we are finalizing our proposals that Medicare

CQMs and Medicare eCQMs would be scored using flat benchmarks for PY 2027 and subsequent PYs, in sections III.G.3.c. and III.G.3.d.(3) of this final rule, respectively. In the CY 2027 PFS proposed rule (91 FR 44053), we noted that none of the eCQMs or MIPS CQMs that Shared Savings Program ACOs have reported over the past four PYs lacked benchmarks, and that the use of flat benchmarks to score Medicare CQMs and Medicare eCQMs would mitigate the risk that MIPS would not be able to calculate benchmarks for these measures in the APP Plus quality measure set. Thus, we believe our proposal that the current scoring policy at § 425.512(a)(7) would no longer apply when at least one of the required measures in the APP Plus quality set does not have a benchmark for PY 2027 and subsequent PYs is appropriate. ACOs would have advance awareness of which measures in the APP Plus quality measure set have historical benchmarks and may choose which collection type to report accordingly.

After consideration of public comments, we are finalizing the proposed revisions to the scoring policy at § 425.512(a)(7) for PY 2027 and subsequent PYs, such that it would apply only if the Shared Savings Program ACO's MIPS quality performance category score is calculated on less than five measures for a given PY. In other words, if there are four or more measures in the APP Plus quality measure set that are excluded from MIPS under § 414.1380(b)(1)(vii)(A) in PY 2027 or a subsequent PY, then the proposed scoring policy at § 425.512(a)(7)(iii) would apply. In section IV.A.4.b.(2) of this final rule, we are finalizing that, for PY 2027 and subsequent PYs, Shared Savings Program ACOs will be required to report on eight measures in the APP Plus quality measure set: five eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs, the CAHPS for MIPS survey, and two administrative claims-based measures that would be calculated by CMS. Thus, we would calculate a Shared Savings Program ACO's MIPS quality performance category score if there are five or more measures in the APP Plus quality measure set that have not been excluded from MIPS.

Specifically, we are finalizing that, for PY 2027 and subsequent PYs, if the Shared Savings Program ACO's MIPS quality performance category score is calculated on less than five measures due to measure exclusion under MIPS and the Shared Savings Program ACO meets the other quality reporting requirements as described in the proposed § 425.512(a)(7)(iii), then we would use the higher of the Shared Savings Program ACO's quality score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. We are also finalizing that the current scoring policy at § 425.512(a)(7) would no longer apply when at least one of the required measures in the APP Plus quality set does not have a benchmark for PY 2027 and subsequent PYs.

We are finalizing the revisions to the regulation text at § 425.512(a)(7) as proposed and as follows:

- We are revising paragraph (a)(7)(ii) to specify that it applies for performance years 2025 and 2026.
- Under new paragraph (a)(7)(iii), we are specifying that, for performance year 2027 and subsequent performance years, if an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1), for the relevant performance year, and the ACO meets the following—

++ The ACO's MIPS Quality performance category score is calculated on less than five measures; and

++ Any unscored measure(s) must meet all of the following—

—The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A).

—The ACO's total measure achievement points used to calculate the ACO's MIPS Quality performance category score are not reduced under § 414.1380(b)(1)(iii).

f. Updating the APP Plus Quality Measure Set

(1) Background

In the CY 2027 PFS proposed rule (91 FR 44150 and 44151), we referred to the CY 2025 PFS final rule (89 FR 98104), which stated that for PY 2025 and subsequent PYs, Shared Savings Program ACOs will be required to report the APP Plus quality measure set. We also finalized that Shared Savings Program ACOs will be required to report and be scored on all applicable quality measures in the APP Plus quality measure set according to the phase-in schedule for incorporating measures into the APP Plus quality measure set (89 FR 98105). We also stated in the CY 2025 PFS final rule (89 FR 98116 and 98117) that the APP Plus quality measure set for Shared Savings Program ACOs will include 11 measures (eight eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with PY 2028 or the PY that is one year after the eCQM specifications become available for the Screening for Social Drivers of Health (Quality ID: 487) and Adult Immunization Status (Quality ID: 493) measures, whichever is later, and Shared Savings Program ACOs will be scored on the required 11 measures. The final APP Plus quality measure set for Shared Savings Program ACOs, for PY 2025 and subsequent PYs, was specified in Tables 39 through 42 of the CY 2025 PFS final rule (89 FR 98128 through 98132).

In the CY 2025 PFS final rule (89 FR 98130 through 98132), we finalized that Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001), Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134), and Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups (Quality ID: 479) would be incorporated into the APP Plus quality measure set for PY 2025. Additionally, we finalized that Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) will be incorporated into the APP Plus quality measure set for PY 2027 and Adult Immunization Status (Quality ID: 493) will be incorporated into the APP Plus quality measure set beginning with PY 2028 or the PY that is 1 year after the eCQM specification becomes available for Quality ID: 493, whichever is later.

In the CY 2026 PFS final rule (90 FR 49818), we finalized the removal of Screening for Social Drivers of Health (Quality ID: 487) from the APP Plus quality measure set (90 FR 49817 and 50311). With the removal of Quality ID: 487, the APP Plus quality measure set for Shared Savings Program ACOs will include ten measures (seven eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with PY 2028 or the PY that is 1 year after the eCQM specification becomes available for Adult Immunization Status (Quality ID: 493), whichever is later (90 FR 49817). We stated that Shared Savings Program ACOs will be scored on the required ten measures (90 FR 49817). The final APP Plus quality measure set for Shared Savings Program ACOs, for PY 2028 or the PY that is 1 year after the eCQM specification becomes available for Quality ID: 493,

whichever is later, was specified in Table B–G5 of the CY 2026 PFS final rule (90 FR 49818).

Shared Savings Program ACOs expressed concerns with increasing the number of measures in the APP Plus quality measure set each year. Shared Savings Program ACOs have suggested maintaining a stable measure set as they transition to digital quality reporting. In response to the CY 2026 PFS Digital Quality Measurement RFI, many commenters recommended that CMS maintain the APP Plus quality measure set as finalized without adding new measures to preserve resources for the transition to digital quality measurement and to consider challenges Shared Savings Program ACOs face in data aggregations for eCQM/MIPS CQM/Medicare CQM reporting (90 FR 49855 and 49856).

(2) Revisions

As discussed in the CY 2027 PFS proposed rule (91 FR 44150 and 44422), we proposed to adopt measure specification changes to the following measures that are included in the APP Plus quality measure set:

- *Diabetes:* Glycemic Status Assessment Greater Than 9% (Quality ID: 001) (eCQMs collection type only)
- *Preventive Care and Screening:* Screening for Depression and Follow-up Plan (Quality ID: 134)
- Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups (Quality ID: 479)

As discussed in section IV.A.4.b.(2) and Table Group D, in Appendix 1 of this final rule, we are finalizing the measure specification changes to these measures as proposed.

With the removal of Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) and Adult Immunization Status (Quality ID: 493) from the APP Plus quality measure set as described in section IV.A.4.b.(2) of this final rule, the APP Plus quality measure set for Shared Savings Program ACOs would include eight measures (five eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with PY 2027. Shared Savings Program ACOs would be scored on the required eight measures. We believe that these policies would lessen the burden associated with implementing new quality measures as Shared Savings Program ACOs move toward digital quality measurement. The final APP Plus quality measure set for Shared Savings Program ACOs, for PY 2027 and subsequent PYs is specified in Table B–G7. This table also reflects the creation of the new Medicare eCQMs collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set for PY 2027 and subsequent PYs, as discussed in section III.G.3.d.(3) and Table Groups D and DD, in Appendix 1, of this final rule. Table B–G7 of this final rule is the same as Table B–G5 of the CY 2027 PFS proposed rule (91 FR 44055).

TABLE B-G7: MEASURES INCLUDED IN THE APP PLUS QUALITY MEASURE SET FOR SHARED SAVINGS PROGRAM ACOS FOR PY 2027 AND SUBSEQUENT PYs

Quality #	Measure Title	Collection Type	Submitter Type	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient Engagement/ Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Outcome^
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Outcome^
001	Diabetes: Glycemic Status Assessment Greater Than 9%	eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs	APM Entity/Third Party Intermediary	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs	APM Entity/Third Party Intermediary	Process
236	Controlling High Blood Pressure	eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs	APM Entity/Third Party Intermediary	Intermediate Outcome^
112	Breast Cancer Screening	eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs	APM Entity/Third Party Intermediary	Process
113	Colorectal Cancer Screening	eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs	APM Entity/Third Party Intermediary	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM/MIPS CQM reporting incentive and the alternative quality performance standard.

g. Summary of Final Policies

In Table B–G8 of this final rule, we summarize the quality reporting requirements and quality performance standard policies for PY 2027 and subsequent PYs, including the policies we are finalizing in this final rule. This table also reflects the creation of the new Medicare eCQMs collection type and removal of Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) and Adult Immunization Status (Quality ID: 493) from the APP Plus quality measure set for Shared Savings Program ACOs, as discussed in sections III.G.3.d.(3) and III.G.3.f.(2), respectively, of this final rule. Table B–G8 of this final rule is the same as Table B–G6 of the CY 2027 PFS proposed rule (91 FR 44056). The quality reporting requirements and quality performance standard policies for PY 2026 were summarized in Table B–G6 of the CY 2026 PFS final rule (90 FR 49819 and 49820).

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TABLE B-G8: APP PLUS QUALITY MEASURE SET REPORTING REQUIREMENTS AND QUALITY PERFORMANCE STANDARD POLICIES FOR SHARED SAVINGS PROGRAM ACOS FOR PY 2027 AND SUBSEQUENT PYS

	PY 2027 and Subsequent PYs
Shared Savings Program ACO Quality Reporting Requirements	ACOs are required to report **5** eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey (except if the ACO does not meet the minimum beneficiary sampling requirements specified at § 414.1380(b)(1)(vii)(B)). CMS will calculate 2 administrative claims-based measures.
Shared Savings Program ACO Quality Performance Standard and Alternative Quality Performance Standard*	**ACOs that report the APP Plus quality measure set can meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses (if applicable) via one of the three pathways:** **1**. ***For all ACOs:*** Achieve a quality score that is equivalent to or higher than the **40th** percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, or **2.** ***For ACOs that report the 5 eCQMs/MIPS CQMs in the APP Plus quality measure set and meet the MIPS data completeness requirement at § 414.1340 for all 5 eCQMs/MIPS CQMs:*** Meet the eCQM/MIPS CQM reporting incentive by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining 7 measures in the APP Plus quality measure set. ***3. For ACOs in their first PY of their first agreement period under the Shared Savings Program***: Report the APP Plus quality measure set and meet the MIPS data completeness requirement at 414.1340 on the 5 eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs in the APP Plus quality measure set, administer the CAHPS for MIPS survey (except if the ACO does not meet the minimum beneficiary sampling requirements specified at § 414.1380(b)(1)(vii)(B)), and receive a MIPS quality performance category score. **Alternative quality performance standard used to determine shared savings using the sliding scale methodology:** ACOs that do not meet the quality performance standard based on the criteria noted previously can meet the alternative quality performance by reporting quality data on the APP Plus quality measure set and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality score. If an ACO (1) does not report any of the 5 eCQMs /MIPS CQMs/Medicare CQMs/Medicare eCQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, unless the ACO does not meet the minimum beneficiary sampling requirements specified at § 414.1380(b)(1)(vii)(B), the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible for shared savings and will owe maximum shared losses, if applicable.

*The quality performance standard policies described in this table apply to ACOs that are not subject to the extreme and uncontrollable circumstances policies at § 425.512(c).

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4. Shared Savings Program Certified Electronic Health Record Technology (CEHRT) Use Requirements

a. Background

Section 1899(b)(3)(D) of the Act authorizes the Secretary to incorporate reporting requirements and incentive payments from section 1848 of the Act into the Shared Savings Program, such as requirements and incentive payments related to electronic prescribing and electronic health records. The statute also authorizes the Secretary to use alternative criteria for determining whether to make such incentive payments.

Section 1833(z)(2)(C)(iii)(II)(bb) of the Act (as amended by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)) generally requires Advanced Alternative Payment Models (Advanced APMs) to require the use of CEHRT. Under this authority, we have codified Advanced APM CEHRT use criteria at 42 CFR 414.1415(a). We have incorporated requirements related to the adoption and use of CEHRT in the Shared Savings Program regulations. We have adopted a definition of CEHRT in § 425.20 that cross references the

Quality Payment Program's definition of CEHRT (§ 414.1305).

For the Shared Savings Program, CMS updated the CEHRT definition in the CY 2024 PFS final rule (88 FR 79309). Under paragraph (3) of the CEHRT definition in § 414.1305, CEHRT currently means EHR technology (which could include multiple technologies) certified by the Office of the National Coordinator for Health Information Technology (ONC) under the ONC Health IT Certification Program as meeting the 2015 Edition Base EHR definition, or subsequent Base EHR definition (set forth at 45 CFR 170.102), and a designated set of health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM.

In the context of health IT, the secure exchange, access, and use of electronic health information supports better informed decision making and a more efficient healthcare system.[296] Interoperability (as defined at 45 CFR 170.102) enables this secure exchange and access. To this end, CMS intends to utilize approaches based on the HL7® (Health Level 7) Fast Healthcare Interoperability Resources® (FHIR) [297] standard to support the exchange of quality information, consistent with CMS' digital quality measurement initiatives, as described in the FHIR RFI in the CY 2026 PFS proposed rule (90 FR 32710 through 32715). FHIR is a widely used application program interface (API)-focused standard used to represent and exchange health information maintained by the standards development organization HL7. ONC adopts the FHIR standard (currently FHIR R4) as well as FHIR implementation guides for different API use cases in 45 CFR 170.215, and incorporates these standards into certification criteria for health IT.

In the CY 2019 PFS final rule (83 FR 59982 through 59988), we adopted requirements related to ACOs' use of CEHRT, beginning with PY 2019, and in subsequent years. In that final rule, we revised the Shared Savings Program annual certification requirements at 42 CFR 425.302(a)(3)(iii) to require ACOs to certify at the end of each PY that the percentage of eligible clinicians participating in the ACO who used CEHRT to document and communicate clinical care to their patients or other healthcare providers met or exceeded the applicable percentage specified in the requirements established in § 425.506(f) (83 FR 60092). Specifically, we codified that beginning with PY 2019, and in subsequent years, for ACOs in a track that did not meet the financial risk standard to be an Advanced APM (for example, ACOs participating under BASIC track Levels A through D), the ACO was required to certify that 50 percent of the ACO's eligible clinicians used CEHRT to document and communicate clinical care to their patients or other healthcare providers. For ACOs in a track that met the financial risk standard to be an Advanced APM (for example, ACOs participating under BASIC track Level E or the ENHANCED track), the ACO was required to certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other healthcare providers met or exceeded the threshold established under the Quality Payment Program at § 414.1415(a)(1). Under this requirement (§ 425.506(f)(2)), for PY 2019 through PY 2024, 75 percent of eligible clinicians were required to use CEHRT to document and communicate clinical care to their patients or healthcare providers (§ 414.1415(a)(1)(i)). In the same final rule, we updated our regulations at § 425.20 to incorporate the definition of CEHRT at § 414.1305 that applies under the Quality Payment Program (83 FR 60092).

In the CY 2024 PFS proposed rule (88 FR 52435), we stated our belief that aligning Shared Savings Program CEHRT use requirements with Merit-Based Incentive Payment System (MIPS) Promoting Interoperability performance category requirements would reduce burden on ACOs, because they would no longer have to meet distinct Shared Savings Program attestation requirements and MIPS Promoting Interoperability requirements. We also referred back to our statements in the CY 2019 PFS rule where we conveyed our desire to continue to promote and encourage CEHRT use by ACOs and their ACO participants and ACO providers/suppliers, and our desire to better align with the goals of the Quality Payment Program and the criteria for participation in certain alternative payment models tested by the CMS Innovation Center. We expressed our belief that our proposal to end the CEHRT attestation requirements and align the Shared Savings Program with the MIPS Promoting Interoperability performance category requirements would allow ACOs to focus on a unified set of program requirements for the use of CEHRT and reduce the administrative burden of managing compliance with a different set of program requirements with the same aim (88 FR 52435).

In the CY 2024 PFS final rule (88 FR 79124 through 79132), we modified the Shared Savings Program CEHRT requirements to end the CEHRT attestation requirements and align the Shared Savings Program with MIPS' Promoting Interoperability performance category requirements. We modified § 425.302(a)(3)(iii) to make the Shared Savings Program Annual CEHRT Certification requirement applicable only for PYs 2019 through 2024. This effectively sunset the Shared Savings Program CEHRT requirement that ACOs certify that the percentage of eligible clinicians participating in the ACO that used CEHRT to document and communicate clinical care to their patients or other healthcare providers met or exceeded the applicable percentage specified at § 425.506(f). We also revised the CEHRT reporting policy at § 425.507(a) for PYs beginning on or after January 1, 2025, to require, unless otherwise excluded, that ACO participants, ACO provider/suppliers, and ACO professionals who are MIPS eligible clinicians, Qualifying APM Participants (QP), or Partial QPs (each as defined at § 414.1305), regardless of track, must (88 FR 79131):

- Report the MIPS Promoting Interoperability performance category measures and requirements to MIPS according to 42 CFR part 414, subpart O at the individual, group, virtual group, or APM entity level; and
- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

In the CY 2024 PFS final rule, we also finalized § 425.507(b), under which ACO participants, ACO providers/suppliers, or ACO professionals are excluded from the requirements specified in § 425.507(a) based on applicable policies that exclude or exempt eligible clinicians from reporting the MIPS Promoting Interoperability performance category as set forth in 42 CFR part 414, subpart O. We included in that provision the qualifier that an ACO participant, ACO provider/supplier, or ACO professional cannot be excluded from the requirements specified at § 425.507(a) solely on the basis of being a QP or

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297 CMS has made publicly available the PY 2026 Shared Savings Program Report templates through the ''Program Guidance & Specifications'' webpage of the Shared Savings Program website, at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations*.erit-based Incentive Payment Systems (MIPS) Promoting Interoperability Performance Category FAQ (*https://www.cms.gov/files/document/frequently-asked-questions-shared-savings-program-requirement-report-objectives-measures-mips.pdf*.)

Partial QP (88 FR 79131). We finalized that applicable exclusions may apply to ACO participants, ACO providers/suppliers, or ACO professionals that meet the low volume threshold as set forth at § 414.1310(b)(1)(iii), are non-MIPS eligible clinicians [eligible clinician as defined at § 414.1305; who is not a MIPS eligible clinician as set forth in § 414.1310(b)(2)], or have a reweighted MIPS Promoting Interoperability performance category to zero percent of the final score in accordance with applicable policies set forth at § 414.1380(c)(2).

In the CY 2024 PFS final rule, we updated public reporting requirements at § 425.308(b)(9) to reflect the MIPS Promoting Interoperability performance category measures and activities (88 FR 79132). We required ACOs to publicly report the number of MIPS eligible clinicians, QPs, and Partial QPs (each as defined at § 414.1305) participating in the ACO who earned a MIPS Promoting Interoperability performance category score at the individual, group, virtual group, or APM entity level, as set forth in § 425.507. This includes:

- The number of ACO participants, ACO providers/suppliers, and ACO professionals that meet the requirements of § 425.507(a) and are not excluded under § 425.507(b) for the applicable PY; and
- The number of ACO participants, ACO providers/suppliers, and ACO professionals that are excluded under § 425.507(b) that voluntarily reported and received a MIPS Promoting Interoperability performance category score for the applicable PY.

For PY 2025, we exercised enforcement discretion for the Shared Savings Program CEHRT requirements and will not take compliance actions under §§ 425.216 or 425.218 for PY 2025 if an ACO does not meet the requirements of §§ 425.507 and 425.308(b)(9). There will also be no impact on the ACO's ability to earn or receive shared savings for PY 2025.[298] In the Frequently Asked Questions document where we provided notice that we were exercising enforcement discretion for PY 2025, we also stated that we would release additional information regarding Shared Savings Program Promoting Interoperability requirements for PY 2026.

In the CY 2027 PFS proposed rule, we provided ACOs with notice that we have extended the enforcement discretion that applied for PY 2025 to PY 2026 (91 FR 44058). We will not take compliance actions under §§ 425.216 or 425.218 for PY 2026 if an ACO does not meet the requirements of §§ 425.507 and 425.308(b)(9). There will also be no impact on the ACO's ability to earn or receive shared savings for PYs 2025 or 2026.

As we stated in the CY 2027 PFS proposed rule, Shared Savings Program ACOs, professional associations, and vendors reporting quality on behalf of ACOs have expressed concern with the burden of the Shared Savings Program requirement that all Shared Savings Program ACO participants report all MIPS Promoting Interoperability performance category measures and activities. Most Shared Savings Program ACOs (74 percent) are in tracks that qualify as Advanced APMs (BASIC level E and ENHANCED) [299] (91 FR 44058). Qualifying APM participants in these ACOs are exempt from Promoting Interoperability performance category reporting for the purposes of MIPS under § 414.1310(b)(i). Therefore, they were only being required to report MIPS Promoting Interoperability performance category measures and activities by the Shared Savings Program. ACOs have expressed confusion about MIPS Promoting Interoperability performance category reporting requirements, exclusions, and exceptions. Specifically, ACOs have requested clarification about how to aggregate and report across their organizations, especially when their practices use different EHRs or when ACOs have some practices that qualify for applicable exclusions.

We also stated in the CY 2027 PFS proposed rule that we recognized that ACOs are often comprised of many ACO professionals who serve large patient populations and that such ACOs may need to aggregate data across multiple EHR systems (91 FR 44058). We noted that an internal CMS analysis described in the CY 2025 PFS final rule that analyzed PY 2022 data indicates that Shared Savings Program ACOs reported substantially higher numbers of denominator-eligible patients for certain eCQM measures than other MIPS reporters, including 33 times more denominator eligible patients for eCQM 001—Diabetes: Hemoglobin A1c (HbA1c) Poor Control (≤9%), 53 times more denominator eligible patients for eCQM 134—Preventative Care and Screening: Screening for Depression and Follow-Up Plan, and 25 times more denominator eligible patients for eCQM 236—Controlling High Blood Pressure. CMS data analysis also showed that ACOs provide a high volume of services, particularly those related to preventative screening measures; for example, in PY 2022, one ACO reported on over 700,000 denominator eligible beneficiaries for a single eCQM (89 FR 98436). Additionally, ACOs and related interested parties have shared that relatively few ACOs use one EHR, while a greater share use two to ten.[300] These data underscore the operational scale and complexity associated with this reporting (91 FR 44058).

We explained our belief that providing additional flexibility to ACOs would be helpful in light of the complex populations they serve, the high volume of data they process, and the necessity of aggregating data across multiple EHRs. We further noted that changes to simplify the Shared Savings Program requirement for ACOs to fulfill CEHRT use requirements would also be consistent with the Administration's interest, as expressed in the ''Request for Information: Deregulation'' (90 FR 15481 and15482), in identifying proposals to rescind or replace regulations that burden American businesses. In response to that RFI, several commenters asked that CMS reduce burdensome requirements for ACOs to report MIPS Promoting Interoperability performance category measures and activities, including a few specific suggestions that we reverse the Shared Savings Program's MIPS Promoting Interoperability performance category reporting requirement due to the increased burden on ACOs without adding any value. Others suggested that we revert to an attestation requirement, revise the definition of CEHRT, re-evaluate numerator and denominator requirements for CEHRT use reporting, or recognize CMS Innovation Center model participation, use of FHIR, or participation in health information exchanges as evidence of interoperability without the need for additional reporting or attestation.

In the CY 2027 PFS proposed rule, we explained that from commenters' responses to a CMS RFI on digital quality measurement included in the CY 2026 PFS proposed rule (90 FR 32710 through 32715), we learned that interested parties broadly supported CMS' efforts to move toward FHIR-based digital quality measurement. Commenters noted that the use of interoperable sources that are available at the point of care would ultimately increase efficiency, reduce administrative burden, and empower patients and healthcare providers to make informed care decisions. We noted that many commenters also stated that

[299] See Shared Savings Program Fast Facts as of January 1, 2026 (*https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf*).

[300] See *https://www.naacos.com/ecqms-for-acos-recommendations-from-the-naacos-digital-quality-measurement-task-force/*.

significant technical and operational work remains to be completed before implementation of FHIR-based digital quality measurement, to ensure there is sufficient infrastructure to support the migration to and execution of FHIR. We further noted that several commenters described that the phased adoption, technical assistance, and incentives for use of EHR data would promote a successful transition to FHIR-based digital quality measurement. Some commenters opposed movement to FHIR-based digital quality measurement, with noted concerns including the ability of small practices to transition, potential performance issues with technology, need for clarity around exclusions, and difficulty with aggregating across large organizations (91 FR 44058 and 59).

b. Simplifying Shared Savings Program CEHRT Use Requirements

As we stated in the CY 2027 PFS proposed rule, we believe that reducing burden for reporting CEHRT use will free ACO resources to focus on meaningful advancement toward digital exchange of health information, including digital quality measurement. As noted previously in this section, commenters on the Request for Information: Deregulation asked that we recognize ACO use of FHIR technologies and that we simplify Shared Savings Program CEHRT use requirements. We believe that these suggestions would advance FHIR-based digital quality reporting by giving credit for incremental advances toward digital quality reporting (91 FR 44059).

We explained in the CY 2027 PFS proposed rule that, in response to the concerns and suggestions detailed previously in this section and in line with CMS' priorities to reduce burden and promote FHIR-based digital quality reporting and exchange of health information, we were proposing to sunset, beginning with PY 2027, the requirements at § 425.507(a) for Shared Savings Program ACO participants, ACO provider/suppliers, and ACO professionals that are MIPS eligible clinicians, Qualifying APM Participants, or Partial Qualifying APM Participants to report all MIPS Promoting Interoperability performance category measures and requirements and to earn a performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level (91 FR 44059). Accordingly, we also proposed to sunset the associated exclusions that complement this requirement at § 425.507(b) (91 FR 44059). We proposed to replace the requirement in § 425.507(a) with different options for ACOs to meet CEHRT use requirements for the Shared Savings Program, described in further detail in the CY 2027 PFS proposed rule (91 FR 44059).

We stated in the CY 2027 PFS proposed rule that, as Shared Savings Program ACOs cover 12.6 million beneficiaries, served by over 700,000 participating clinicians and facilities,[301] we believe that a shift to FHIR-based digital quality reporting and exchange of health information at this scale would meaningfully advance care coordination and quality improvement. We expressed our further belief that reducing the burden of Shared Savings Program participation could lead to increased program participation from ACOs and ACO professionals, which would magnify the impact, moving even more clinicians toward meaningful use of EHR technology to improve care for beneficiaries (91 FR 44059).

We explained in the CY 2027 PFS proposed rule that, to encourage widespread adoption of FHIR-based transmission of clinical data, enable bi-directional exchange of clinical data across practices within ACOs, and support the capture of robust clinical quality information, we were proposing, in § 425.507(c), that for PY 2027 and subsequent PYs, to meet the Shared Savings Program CEHRT use requirement, ACOs would be required to perform at least one of three allowable activities (91 FR 44059). In summary, they are:

(1) Completely report at least one of the five ACO-reported measures in the APP Plus quality measure set through the eCQMs collection type or the proposed Medicare eCQMs collection type (discussed in section III.G.3.d.(3) of this final rule) using CEHRT; OR

(2) Attest to the ACO's use of FHIR capabilities to support reporting of at least one of the five ACO-reported measures in the APP Plus quality measure set using CEHRT (section IV.A.4.b.(2) of this final rule contains measures in the APP Plus quality measure set that are reportable by ACOs in PY 2027); OR

(3) Select and attest to one of the proposed Shared Savings Program CEHRT use metrics, which are based on a subset of MIPS Promoting Interoperability performance category measures, and which may be updated annually if there are changes.

We also proposed to sunset existing public reporting requirements at § 425.308(b)(9) and proposed to add a new section at § 425.308(b)(11), which would require ACOs to publicly report which of the allowable CEHRT use options proposed previously in this section they elected to perform to meet CEHRT use requirements for the Shared Savings Program for PY 2027 and subsequent PYs (91 FR 44059).

(1) Meeting Shared Savings Program CEHRT Use Requirement by Reporting at Least One ACO-Reported Measure Through the eCQMs or Medicare eCQMs Collection Types

As discussed earlier in this section, previous commenters have asked that CMS recognize efforts that ACOs are already undertaking to advance CEHRT use, without the need for additional reporting or attestation. Accordingly, we proposed to recognize ACO reporting of eCQMs without additional reporting requirements, for the purpose of satisfying the Shared Savings Program CEHRT use requirements (91 FR 44059). We explained that, because reporting of eCQMs or the proposed Medicare eCQMs would require the use of CEHRT and submission of CMS EHR Certification IDs (also referred to as CEHRT IDs) [302] to communicate care quality to CMS, we believe that an ACO's reporting of measures using the eCQM collection type or the proposed Medicare eCQM collection type (see section III.G.3.d.(3) of this final rule for discussion of the Medicare eCQM collection type) is a concrete example of ACO CEHRT use that supports improved patient care. Clinical quality measure reporting helps identify areas for potential care improvement, and use of CEHRT to report quality of care is a step toward bi-directional exchange of health information and digital quality measurement.

We proposed, in § 425.507(c)(1), that one option ACOs could select to meet the Shared Savings Program CEHRT use requirement would be to use EHR technology that meets the requirements in paragraph (3) of the CEHRT definition at § 414.1305 (91 FR 44059) and supports the recording, calculation, and reporting of clinical quality measures by being certified to the ONC Health IT Certification Program certification criteria at 45 CFR 170.315(c)(1) (included in the Base EHR definition in 45 CFR 170.102), (c)(2), and (c)(3)) to completely report at least one measure in the APP Plus quality measure set, through the eCQMs or the

[301] See Shared Savings Program Fast Facts as of January 1, 2026 (*https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf*).

[302] For more information, please find the MIPS Data Submission User Guide on the QPP Resource Library: *https://qpp.cms.gov/resources/resource-library*.

proposed Medicare eCQMs collection type. Paragraph (3) of the CEHRT definition at 42 CFR 414.1305 is the paragraph applicable to Advanced APMs. The requirement that Shared Savings program ACOs use CEHRT that is certified to the ONC Health IT Certification Program certification criteria at 45 CFR 170.315(c)(2) and (c)(3) would be consistent with CEHRT use requirements under MIPS, as specified in paragraph (2)(ii)(B) of the CEHRT definition at 42 CFR 414.1305, which includes a specific requirement for use of EHR technology certified to the ONC health IT certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3).

We explained that to ''completely report,'' as we use that phrase in the proposed regulatory text, for the purpose of using this option to satisfy Shared Savings Program CEHRT use requirements, would mean that the ACO meets the Shared Savings Program quality reporting requirements we proposed at 42 CFR 425.508(c)(1) to (c)(4) and as discussed in section III.G.4.b.(2) of this final rule as well as the MIPS data completeness requirements at § 414.1340 for the measure submission. The measure must be completely reported as part of annual quality reporting. Under this proposal, ACOs that completely report at least one quality measure through the eCQMs or the Medicare eCQMs collection type, which we are finalizing in section III.G.3.d.(3) of this final rule, as determined by MIPS, would not be required to complete an attestation to meet Shared Savings Program CEHRT use requirements. In section III.G.4.c of this final rule, we are finalizing changes to the Shared Savings Program quality reporting requirements at § 425.508, which may alter the universe of patients used to determine compliance with the MIPS data completeness requirements at § 414.1340 and would be applicable to the proposed changes for the Shared Savings Program CEHRT use requirement, in that completely reporting a measure in the APP Plus quality measure set through the eCQMs or Medicare eCQMs collection type means the ACO must meet the revised Shared Savings Program quality reporting requirements we are finalizing at § 425.508(c)(1) to (c)(4) and MIPS data completeness requirements at § 414.1340 for that eCQM or the proposed Medicare eCQM measure submission.

We understand that ACOs may still face challenges in aggregating data. As discussed more fully in section III.G.3.d. of this final rule, we believe that the proposed data completeness requirement changes would help to mitigate some of the issues ACOs face in aggregating data for eCQM or proposed Medicare eCQM reporting. We also note that eCQM or proposed Medicare eCQM reporting is just one of three proposed ways an ACO could meet the Shared Savings Program CEHRT use requirement. We received public comments on these proposals. We summarize and respond to comments related to Shared Savings Program CEHRT proposals in section III.G.4.c. of this final rule.

(2) Meeting Shared Savings Program CEHRT Use Requirements by Attesting to Using FHIR Capabilities in Certified Health IT To Support Reporting of At Least One of the Five ACO-Reported Measures in the APP Plus Measure Set

We proposed, in § 425.507(c)(2), that another option ACOs could select for PY 2027 and subsequent PYs, to meet the Shared Savings Program CEHRT use requirement, is to completely report at least one of five ACO-reported measures in the APP Plus quality measure set, meet the data completeness requirement under § 414.1340 (91 FR 44060), and attest that it used technology certified to ONC Certification Criteria for Health IT (45 CFR 170.315) supporting FHIR-based exchange to meet paragraph (3) of the CEHRT definition at § 414.1305 to support measure data collection. Specifically, we proposed that the ACO would be required to attest that it used a Health IT Module (as defined in 45 CFR 170.102) certified to an unexpired criterion or criteria in 45 CFR 170.315 to make information in the U.S. Core Data for Interoperability (USCDI) available through a FHIR-based API (currently USCDI version 3; 45 CFR 170.213(b)), to support the complete reporting of at least one measure in the APP Plus quality measure set. Data represented by the USCDI can be used to support meeting the data requirements for measures in the APP Plus quality measure set. By mapping data elements in USCDI to measure specifications, users could leverage this functionality in their CEHRT to obtain data needed to calculate measures in the APP plus measure set.

We noted that eligible clinicians and APM entities already have the flexibility to use data obtained via Health IT Modules certified to certification criteria in 45 CFR 170.315 to report MIPS CQMs and Medicare CQMs, as CMS does not specify how eligible clinicians and APM entities must collect data for MIPS CQMs and Medicare CQMs, and no further updates are needed to our quality reporting policies to permit use of this technology. Rather, we stated that our proposed policy aimed to encourage Shared Savings Program ACOs to use this approach to obtain data for quality measure reporting. Using standardized data from FHIR APIs can support more seamless aggregation of data across different EHR systems used by ACO participants. To meet the Promoting Interoperability requirement for the Shared Savings Program at the APM entity level as presently required in 42 CFR 425.507(a), ACOs are already required to demonstrate use of CEHRT through the MIPS requirement to use CEHRT at § 414.1375(b)(1). Specifically, current policy requires that ACOs use EHR technology that is certified to certification criteria in 45 CFR 170.315(g)(10), as it is a part of the ''Base EHR'' definition at 45 CFR 170.102. The Base EHR definition is included in paragraph (3) of the ''Certified Electronic Health Record Technology (CEHRT)'' definition at 42 CFR 414.1305 used by the Shared Savings Program. For the purpose of meeting this option, an ACO electing to attest would attest that it used data collected from a FHIR-based API to support data collection using a Health IT Module certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access, to support reporting a measure in the APP Plus measure set.

We proposed to require ACOs to attest because, for the MIPS CQMs or Medicare CQMs collection types we cannot ascertain (absent attestation) whether an ACO used FHIR technology to support collection of data used to report these measures (91 FR 44060). For the CEHRT use activity option in 42 CFR 425.507(c)(1), discussed previously in this section, we will be able to identify the ACOs that met that CEHRT use activity from quality reporting submission data; however, attestation would be required for an ACO electing to meet Shared Savings Program CEHRT use requirements by using standardized data from FHIR APIs to support collection of data for reporting at least one measure in the APP Plus measure set. We note that, while the option to meet Shared Savings Program CEHRT use requirements by attesting to use of a FHIR-based API to support complete reporting of at least one measure in the APP Plus measure set could conceivably be used for any available measure collection type, it would not be necessary for ACOs electing to report eCQMs or Medicare eCQMs collection types. This is because those ACOs electing to report eCQMs or Medicare eCQMs collection types would receive

automatic credit for reporting through those collection types, as CMS would be able to ascertain based on quality data submissions that ACOs completely reported a measure in the APP Plus measure set using the eCQMs or Medicare CQMs collection type, and that is one option that would satisfy the Shared Savings Program CEHRT use requirement. Accordingly, the discussion here focuses only on the MIPS CQMs and Medicare CQMs collection types. For ACOs electing to meet Shared Savings Program CEHRT use requirements by attesting to use of data collected from a FHIR-based API to support complete reporting using a Health IT Module certified to an unexpired criterion or criteria that supports standardized API access, for at least one measure through the MIPS CQMs or Medicare CQMs collection types, the measure must be completely reported as part of annual quality reporting. We proposed that ACOs would attest to meeting this requirement through ACO–MS, after the conclusion of annual quality reporting, which occurs in the first quarter of the year following the PY. For example, we anticipate that the attestation would be available in ACO–MS in the second quarter of 2028, after the conclusion of quality reporting for PY 2027. This proposed option for meeting Shared Savings Program CEHRT use requirements through the use of standardized data from FHIR APIs to report MIPS CQMs or Medicare CQMs would serve to recognize efforts underway by ACOs taking an interim step in the transition to FHIR-based digital quality reporting.

CMS described a parallel goal to implement FHIR reporting for eCQMs in an RFI posted in the CY 2026 proposed rule (90 FR 32710 through 32715), and requested comment on a timeline for transitioning to FHIR-based digital quality measurement in section IV.A.4.c. of the CY 2027 PFS proposed rule (91 FR 44152 through 44154). In the RFI regarding the timeline to transition to FHIR-based reporting in the CY 2027 PFS proposed rule, we indicated that following this transition period, FHIR-based reporting would be required for those applicable measures that were available as FHIR-based dQM reporting options during the transition period, beginning with the 2030 performance period (91 FR 44152 through 44154). These Shared Savings Program CEHRT use proposals aligned with our efforts to recognize ACO movement toward FHIR-based digital quality measurement and take into consideration comments received on the Request for Information: Deregulation, where a few commenters noted that leveraging FHIR technology supports multidisciplinary collaboration and efficient information sharing without additional attestations. While we disagree that use of FHIR technology alone obviates the need for an attestation, since we are presently not able to discern whether an ACO has utilized a certified Health IT Module (for example, a 45 CFR 170.315(g)(10)-certified Health IT Module) to obtain standardized data from a FHIR-based API to aggregate data for quality reporting without an attestation, we acknowledge the value in use of FHIR technology. In response to commenters' concerns about reporting burden, we stated in the CY 2027 PFS proposed rule that we believe that this attestation would represent a significantly reduced burden in comparison to the current requirement in 42 CFR 425.507(a) that all ACO participants report all MIPS Promoting Interoperability performance category measures and activities. Another commenter responded that CMS should incorporate FHIR-based capabilities as a fundamental requirement in the Shared Savings Program. We believe that an ACO's use of a Health IT Module certified to an unexpired criterion or criteria within 45 CFR 170.315 to obtain standardized data from FHIR APIs to support collecting data is a concrete step toward interoperability that will enable both digital quality reporting and bi-directional exchange of health information (91 FR 44061).

Under this proposed option for meeting the Shared Savings Program CEHRT use requirement, we proposed that ACOs choosing to attest that they used a Health IT Module certified to an unexpired criterion or criteria within 45 CFR 170.315 to obtain standardized data from a FHIR API to support collection of data for reporting at least one measure in the APP Plus measure set would also need to have completely reported that measure, according to data completeness requirements detailed earlier in the CY 2027 PFS proposed rule (91 FR 44061). We received public comments on these proposals. We summarize and respond to comments related to Shared Savings Program CEHRT proposals in section III.G.4.b. of this final rule.

(3) Meeting Shared Savings Program CEHRT Use Requirements by Attesting to One of the Three ACO CEHRT Use Metrics

We proposed, in 42 CFR 425.507(c)(3), that another option ACOs could select to meet the Shared Savings Program CEHRT use requirement would be to attest to at least one of the Shared Savings Program CEHRT use metrics from the list of metrics established for the applicable performance year (91 FR 44061). We proposed three Shared Savings Program ACO CEHRT use metrics for PY 2027, listed in Table B–G7 of the CY 2027 PFS proposed rule. Like similar measures that are included in the MIPS Promoting Interoperability performance category, these three Shared Savings Program ACO CEHRT use metrics represent meaningful ACO use of CEHRT for improved patient care (91 FR 44061). We proposed to allow ACOs to attest that the ACO meets one of these three metrics to satisfy the Shared Savings Program CEHRT use requirement (91 FR 44061). We noted this proposal was responsive to public comments on the deregulatory RFI (90 FR 15481 and 15482). Responses to the RFI included several comments asking that CMS permit attestation for meaningful use of CEHRT and exchange of health information, to ease reporting burdens and encourage small practices to participate in the Shared Savings Program. A commenter also suggested CMS incentivize organizations to utilize real-time data exchange. We stated our belief that allowing ACOs to attest to the use of bi-directional exchange of health information as one of the three options would promote ACOs engaging in this valuable activity while representing a significantly reduced burden as compared to our current Shared Savings Program CEHRT requirement that ACOs report on all MIPS Promoting Interoperability performance category measures and activities.

We stated that we would update the list of allowable metrics through notice and comment rulemaking if there are any changes for future years.

The ACO CEHRT use metrics we proposed (91 FR 44061) are based on the following parallel MIPS Promoting Interoperability performance category measures: Electronic Prescribing,[303] Health Information Exchange (HIE) Bi-Directional Exchange,[304] and Provide Patients Electronic Access to Their Health Information.[305] The parallel MIPS Promoting Interoperability performance category measures provide instructions on how MIPS eligible clinicians can report the measures, with

[303] *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2026-MIPS-Promoting-Interoperability-e-Prescribing-Measure.pdf.*

[304] *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2026-MIPS-Promoting-Interoperability-HIE-Bi-Directional-Exchange-Measure.pdf.*

[305] *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2026-MIPS-Promoting-Interoperability-Provide-Patients-E-Access-to-Their-Health-Info-Measure.pdf.*

instructions to aggregate across all MIPS eligible clinicians for group and APM-level reporting in each of the measure specification documents. We did not propose, however, that ACOs would be required to report Shared Savings Program ACO CEHRT use metrics for every ACO provider/supplier in the ACO, as is required under the MIPS measure specifications, because we understand that this level of information may be difficult or burdensome for ACOs to aggregate (91 FR 44061 and 44062). To recognize the varying capacities for ACO participants to report on CEHRT use and for ACOs to report on CEHRT use for all of their ACO participants, we proposed that ACOs would be allowed to attest ''Yes'' if at least one ACO provider or supplier in each of the ACO's participating TINs performed the action described in the Shared Savings Program ACO CEHRT use metric using EHR technology certified to the ONC Certification Criteria for Health IT (45 CFR 170.315) necessary to meet paragraph (3) of the CEHRT definition at 42 CFR 414.1305 to complete the action described in each metric (91 FR 44062).

As discussed in the CY 2027 PFS proposed rule (91 FR 44062), ACOs have faced challenges in reporting a high volume of participant data involving multiple EHRs for MIPS Promoting Interoperability measures and activities. We also noted that an additional source of confusion is the requirement to report on behalf of all participants when an ACO reports at the APM entity level, including participants who would have been excluded or have received special status for reporting purposes when reporting at the individual or group level. We explained that, similarly, because QPs do not receive MIPS scores or payment adjustments, the requirement that QPs report the MIPS Promoting Interoperability performance category and earn a performance category score is a burden unique to the Shared Savings Program Promoting Interoperability requirements. ACOs have also reported incidents of practices included on the ACO's Participant Agreement closing throughout the year, which requires the ACO to report on behalf of groups with whom contact may be difficult. We noted that given this identified challenge, we no longer believe it is reasonable to require ACOs to report on every ACO provider and supplier in the ACO. We stated that we recognize and have been reminded by interested parties that participation in an ACO itself represents a commitment to coordinating care. ACOs in the Advanced APM tracks of the Shared Savings Program (BASIC track Level E and ENHANCED track) whose qualifying participants are exempt from MIPS have taken on financial risk for providing coordinated, efficient care. We stated our belief that, in addition to that undertaking, our proposal to allow ACOs to attest that one ACO provider or supplier from each of the ACO's participating TINs has completed the action required under one of the ACO CEHRT use metrics we proposed would be sufficient to demonstrate CEHRT use. We noted that healthcare providers and suppliers who are MIPS eligible clinicians and who participate in ACOs in Shared Savings Program tracks that do not meet the definition of an Advanced APM (BASIC track levels A–D) and those in Advanced APM tracks who are not QPs will still be required to report MIPS Promoting Interoperability performance category measures (unless they are otherwise excluded under MIPS) to earn a score for the Promoting Interoperability performance category.

In the CY 2027 PFS proposed rule, we provided summary level information of the three proposed ACO CEHRT use metrics (91 FR 44062). These details generally align with the measure specifications for the respective MIPS Promoting Interoperability measures; however, they reflect ACO-level attestation. From these, ACOs would be allowed to select one metric to which the ACO would be able to attest ''Yes,'' to meet Shared Savings Program ACO CEHRT use requirements. Following the discussion of the three proposed metrics, we describe proposed allowable exclusions from ACO attestation. For each of these proposed activities, to attest ''Yes,'' the ACO's participant TINs must use EHR technology certified to the ONC Certification Criteria for Health IT (45 CFR 170.315) necessary to meet paragraph (3) of the CEHRT definition at § 414.1305. We further describe the specific certified Health IT Modules that must be used to complete the action in the measure, consistent with information provided by the MIPS program for corresponding measures. We stated that, if finalized, we would make public on our website more detailed information on each of these metrics.

(i) ACO Electronic Prescribing: An ACO could attest ''Yes,'' if, during the PY, at least one permissible prescription was written by at least one ACO provider or supplier in each of the ACO's participant TINs, and the prescription was transmitted electronically using CEHRT. In addition to the allowable exclusions from Shared Savings Program CEHRT use attestation discussed later in this section, ACOs choosing to attest to this metric would be permitted to exclude from their assessment any ACO participant TIN whose ACO providers and suppliers wrote fewer than 100 total permissible prescriptions during the PY. This exclusion would align with a similar exclusion in the parallel MIPS Promoting Interoperability e-Prescribing measure, which provides an exclusion for any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period. This would mean that an ACO could attest that it met this metric even if no electronic prescription was written by any ACO provider or supplier in one of the ACO's ACO participant TINs, where all of the ACO's participants TINs were composed of ACO providers and suppliers who wrote fewer than 100 total permissible prescriptions. Similar to the MIPS e-Prescribing measure, a prescription would be defined as the authorization by an ACO provider or supplier to a pharmacist to dispense a drug that the pharmacist wouldn't dispense to the patient without such authorization. A permissible prescription is a prescription, as described in the preceding sentence, including electronic prescription of controlled substances, where creation of an electronic prescription for the medication is feasible using CEHRT and where allowable by state and local law. An ACO electing to attest to this metric to meet the Shared Savings Program CEHRT use requirement would be required to attest that at least one ACO provider or supplier in each of its ACO participant TINs used CEHRT, including health IT certified to the ''electronic prescribing'' criterion in 45 CFR 170.315(b)(3) to complete the actions of this Shared Savings Program CEHRT use metric.

(ii) ACO Health Information Exchange (HIE) Bi-Directional Exchange: An ACO could attest ''Yes'' if, during the PY, at least one ACO provider or supplier from each of the ACO's participant TINs has, for at least one patient seen by the ACO provider or supplier used EHR technology certified to the ONC Certification Criteria for Health IT (45 CFR 170.315) necessary to meet paragraph (3) of the CEHRT definition at § 414.1305 to support bi-directional exchange with an HIE that: enables secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the ACO provider or supplier's EHR during the PY in accordance with applicable law and policy; and that the

HIE is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs and does not engage in exclusionary behavior when determining exchange partners. These elements of this Shared Savings Program ACO CEHRT use metric align with those in the parallel MIPS Promoting Interoperability measure. An ACO electing to attest to this metric to meet the Shared Savings Program CEHRT use requirement would not be required to attest that at least one ACO provider or supplier from each ACO participant TIN used CEHRT functionality to perform bi-directional exchange for every patient throughout the PY. Rather, attesting ''yes'' to the measure requires that at least one ACO provider or supplier from each of the ACO's participant TINs used CEHRT functionality to perform bi-directional exchange for at least one patient with an HIE that has the capability to enable secure, bi-directional exchange for all patients, without excluding exchange partners. We noted that we recognize that an ACO provider or supplier may have different options with respect to the certified health IT that it uses to connect to an HIE. Health IT certified to criteria including, but not limited to, the ''transitions of care'' criterion in 45 CFR 170.315(b)(1), the ''Clinical information reconciliation and incorporation'' criterion in 45 CFR 170.315(b)(2), and the ''Standardized API for patient and population services'' 45 CFR 170.315(g)(10), could be utilized to support bi-directional exchange through an HIE. An ACO attesting to this metric, for the purpose of meeting the Shared Savings Program CEHRT use requirement, would be required to attest that at least one ACO provider or supplier in each of its ACO participant TINs used CEHRT, including health IT certified to but not limited to the criteria previously discussed, to complete the actions of this Shared Savings Program CEHRT use metric.

We noted that the MIPS Promoting Interoperability performance category includes a corresponding measure under the HIE objective entitled ''Enabling Exchange Under TEFCA,'' which enables eligible clinicians to earn credit for the HIE Objective if they participate as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability) to enable secure, bi-directional exchange of information for every patient encounter, transition of care or referral, and record stored or maintained in the EHR during the performance period, using CEHRT. We expressed that, while we had not proposed this measure for the proposed ACO CEHRT use requirements, ACO providers or suppliers who are able to attest ''Yes'' to the ''Enabling Exchange Under TEFCA'' measure under the MIPS Promoting Interoperability performance category would meet the requirement to have used CEHRT to perform bi-directional exchange for at least one patient. Accordingly, an ACO choosing to attest to having met this metric could consider an ACO provider or supplier who could attest to the MIPS Promoting Interoperability measure, ''Enabling Exchange Under TEFCA'' for a particular performance year to count as having met the requirement for their ACO participant TIN when determining whether one ACO provider or supplier from each of its ACO participant TINs has met the requirement for the proposed ACO Health Information Exchange (HIE) Bi-Directional Exchange metric.

(iii) ACO Provider to Patient Exchange: An ACO could attest ''Yes'' to this metric if, during the PY, at least one ACO provider or supplier from each of the ACO's participant TINs has, for at least one patient seen by the ACO provider or supplier (or the patient-authorized representative): provided timely access to view online, download, and transmit his or her health information; and ensured the patient's health information is available for the patient (or the patient's personal representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the clinician's CEHRT. Similar to the MIPS Promoting Interoperability performance category measure, ''Provide Patients Electronic Access to Their Health Information,'' for the ACO to attest ''Yes,'' the patient would need to be able to access this information on demand, such as through a patient portal or personal health record (PHR) or by other online electronic means.

As detailed in the measure specifications for the parallel MIPS measure, specific rights and privacy protections apply to the provision of protected health information (PHI) to individuals. While a covered entity may be able to fully satisfy a patient's request to access the patient's information through view, download, or transmit functionality, the metric would not replace a covered entity's responsibilities to meet the right of access requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (45 CFR part 160 and subparts A and E of part 164) to provide an individual, upon request, with access to PHI in a designated record set. There may be patients who can't access their health information electronically because of a disability. In these cases, ACO providers or suppliers who are covered by civil rights laws are required to provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

An ACO electing to attest to this metric to meet the Shared Savings Program CEHRT use requirement would be required to attest that at least one ACO provider or supplier in each of its ACO participant TINs used health IT certified to the ''view, download, and transmit to 3rd party'' criterion in 45 CFR 170.315(e)(1) to provide view, download, or transmit capabilities to at least one patient. The ACO participant would also be required to use health IT certified to the ''application access—patient selection'' criterion in 45 CFR 170.315(g)(7), the ''application access—all data request'' criterion in 45 CFR 170.315(g)(9), and the ''standardized API for patient and population services'' criterion in 45 CFR 170.315(g)(10) to support information access through an API to their patients. We noted, however, ONC proposed to remove the criteria in 45 CFR 170.315(g)(7) and (g)(9) as of January 1, 2027 in the Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI–5) Proposed Rule (90 FR 60998). We stated in the CY 2027 PFS Proposed Rule that, if ONC finalized these proposals, we would no longer require ACOs to use health IT certified to the removed criteria to meet the measure and rather, the ACO would be required to attest to having used health IT certified to the ''view, download, and transmit to third party'' criterion in 45 CFR 170.315(e)(1) to provide view, download, or transmit capabilities to patients and to the ''standardized API for patient and population services'' criterion in 45 CFR 170.315(g)(10), to meet the requirements of this Shared Savings Program ACO CEHRT use metric. ACOs electing to attest to any one of the three ACO CEHRT use metrics, including this one, would also still be required to attest that their participating ACO providers and suppliers used EHR technology necessary to meet paragraph (3) of the CEHRT definition at 42 CFR 414.1305, as described previously. Patient health information would need to be made available to the patient to view,

download, or transmit within 4 business days of the information being available to the ACO provider or supplier for every time that information is generated. Also, in alignment with the MIPS Promoting Interoperability performance category measure, for ''view, download, or transmit'' functionality, the required content would be: an unexpired version of the USCDI adopted at 45 CFR 170.213; healthcare Provider's name and office contact information; Laboratory test report(s); Diagnostic image report(s), and for API functionality, the required data set is the USCDI.

(iv) Allowable ACO exclusions from Shared Savings Program CEHRT use metrics: Based on feedback we received from the RFIs discussed earlier in this section and questions we have received from ACOs on the existing Shared Savings Program CEHRT use requirements that we to sunset and replace, we understand that ACOs may face difficulties in determining whether an ACO provider or supplier from each of its ACO participant TINs has performed the required action for a given proposed Shared Savings Program ACO CEHRT use metric (91 FR 44064). We, therefore, proposed to allow certain exclusions for ACOs electing to meet the Shared Savings Program CEHRT use requirement by attesting to one of the available Shared Savings Program CEHRT use metrics (91 FR 44064). By ''exclusion,'' we mean that an ACO would be able to attest to having performed the activity required by the metric, even if one or more of the ACO's participant TINs did not have at least one ACO provider or supplier that performed the activity, if that TIN or TINs meets one of the exclusions described later in this section.

We proposed that ACOs would be permitted to apply exclusions for similar circumstances as the exclusions and exceptions under MIPS, when ACOs choose to report one of the three proposed Shared Savings Program ACO CEHRT use metrics for purposes of satisfying the Shared Savings Program CEHRT use requirement in PY 2027 and future years (91 FR 44064). In the CY 2027 PFS proposed rule, we mistakenly stated that, under MIPS, special statuses result in automatic reweighting of the Promoting Interoperability performance category to zero (91 FR 44064) which, as discussed further later is this section, is not true for the special statuses of ''rural'' or ''located in a health professional shortage area (HPSA).'' We explained in the CY 2027 PFS proposed rule that, for hardship circumstances, MIPS eligible clinicians or groups may be required to submit a hardship exception application that is subject to CMS approval. However, for the purposes of the Shared Savings Program CEHRT use requirement, we proposed that an ACO may exclude from their Shared Savings Program CEHRT attestation an ACO participant TIN that meets certain exclusion criteria outlined later in this section without requesting approval from CMS (91 FR 44064). This means that the ACO may still attest to having performed the action required by the metric, without consideration of whether at least one ACO provider or supplier from a TIN meeting these criteria performed the required action, when at least one ACO provider or supplier in each of the ACO's other participant TINs (that are not permitted to be excluded) performed the required action. The criteria under which an ACO would be permitted to exclude an ACO participant TIN are that the ACO determines the TIN is comprised solely of ACO providers and/or suppliers who:

- Would meet the definition of ''special status''; or
- Are facing hardship circumstances that would qualify for MIPS Promoting Interoperability hardship exception requests, had such requests been submitted by a MIPS eligible clinician.

For Shared Savings Program CEHRT use metric exception purposes, we proposed the following would be considered special statuses. We noted that the definitions of these special statuses would be similar to the MIPS definitions at § 414.1305 except that they would not be limited to MIPS ECs, for the purpose of Shared Savings Program CEHRT use metric exceptions. For Shared Savings Program CEHRT use metric exclusion purposes, ACOs would be permitted to exclude an ACO participant TIN if the ACO determines that the TIN is comprised solely of ACO providers and suppliers meeting the following special statuses:

- ASC-based-ACO providers or suppliers who furnish 75 percent or more of their covered professional services during the performance period in sites of service identified by the POS codes used in the HIPAA standard transaction [306] as an ambulatory surgical center setting based on claims.
- Facility-based-ACO providers or suppliers who:

++ Furnish 75 percent or more of their covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the performance period with a 30-day claims run out; and

++ Furnish at least 1 covered professional service in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, or emergency room setting; and

++ Can be assigned to a facility with a value-based purchasing score, determined under the methodology specified in § 414.1380(e)(5), for the applicable period.

- Hospital-based-ACO providers or suppliers who provide 75 percent or more of their covered professional services during the PY in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims.
- Non-patient facing-ACO providers or suppliers who billed 100 or fewer patient-facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act) during the performance year. A patient-facing encounter is an instance in which the ACO provider/supplier bills for items and services furnished such as general office visits, outpatient visits, and procedure codes under the PFS, as specified by CMS.
- Located in a health professional shortage area (HPSA)-ACO providers and suppliers are located in areas as designated under section 332(a)(1)(A) of the Public Health Service Act.
- Rural area-ACO providers or suppliers that are in a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available as described in the definition of ''Rural area'' at § 414.1305.

As noted earlier in this section, the special status definition for the Shared Savings Program CEHRT use metric exclusions would be similar to the one used for MIPS eligible clinicians at § 414.1305. We noted that in contrast to the MIPS special status definition, however, small practices would not be considered a special status for the purpose of exclusion from ACO CEHRT use metric attestation because we believe that joining an ACO should be a way for small practices to receive assistance with care coordination and quality improvement efforts such as use of CEHRT.

[306] For more information on HIPAA transactions, please see the CMS HIPAA and Administrative Simplification webpage: *https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification/hipaa.*

The hardship circumstances that would qualify an ACO participant TIN for exclusion from Shared Savings Program CEHRT use metric attestation would parallel those described in § 414.1380(c)(2)(i)(C), except that neither the ACO nor the ACO provider or supplier would need to submit an application to CMS. An ACO could exclude, for purposes of determining whether the ACO can attest ''yes'' to a Shared Savings Program CEHRT use metric, ACO participant TINs comprised solely of ACO providers/suppliers meeting any of the following conditions:

- The ACO providers or suppliers lacked sufficient internet access during the performance period, and insurmountable barriers prevented them from obtaining sufficient internet access.
- The ACO providers or suppliers were subject to extreme and uncontrollable circumstances that caused their CEHRT to be unavailable.
- The ACO providers or suppliers were located in an area affected by extreme and uncontrollable circumstances as identified by CMS.
- 50 percent or more of the ACO providers' or suppliers' outpatient encounters occurred in practice locations where they had no control over the availability of CEHRT.
- The ACO providers' or suppliers' CEHRT was decertified under the Office of the National Coordinator for Health IT (ONC) Health IT Certification Program) either during the PY, or decertified during the calendar year preceding the performance year and the ACO providers or suppliers made a good faith effort to adopt and implement another CEHRT in advance of the performance year.

We proposed that an ACO may exclude ACO participant TINs composed entirely of ACO providers or suppliers who meet these criteria from their determination as to whether at least one ACO provider or supplier from each of its ACO participant TINs has completed the action required by the ACO CEHRT use metric and still attest that the metric is met. We explained our rationale was that ACO participant TINs comprised solely of MIPS eligible clinicians meeting the definition of ''special status'' under MIPS would be exempt from reporting MIPS Promoting interoperability and those facing circumstances that would qualify for a MIPS Promoting Interoperability hardship may be granted an exception under MIPS (91 FR 44065). As noted previously in this section and discussed more fully later in this section, we want to clarify that not all of the MIPS special statuses defined at § 414.1305 would actually result in automatic reweighting of the Promoting Interoperability performance category under MIPS; the special statuses of ''rural'' and ''located in an HPSA'' would not. We expressed that we recognize ACO providers and suppliers in Shared Savings Program ACO participant TINs would face challenges in these situations. We proposed that ACOs be allowed to determine whether any of their ACO participant TINs meet the criteria without requesting an exception from CMS because those ACO providers or suppliers who are QPs in an ACO that is in an Advanced APM track are exempt from MIPS and therefore cannot request MIPS hardship exceptions (91 FR 44065). They also cannot qualify for automatic reweighting due to special status. We expressed that we therefore believe it would be appropriate to allow ACOs to exclude such ACO participant TINs from the ACO's assessment of whether at least one ACO provider or supplier from each of the ACO's participant TINs met the requirement of the Shared Savings Program CEHRT use metric and still attest that the metric has been met. For example, similar to the non-patient facing exclusion, an ACO participant whose ACO providers or suppliers have fewer than 100 patient-facing encounters in a PY may not have engaged in e-Prescribing, exchange of health information, or provider to patient exchange of health information, so the ACO can make the determination to exclude the ACO participant for the purposes of attesting to one of the proposed metrics. In another example, an ACO may not be able to ascertain whether at least one ACO provider or supplier in an ACO participant TIN comprised of hospital-based physicians who are employed at a hospital that does not participate in the ACO have participated in an HIE. This ACO participant and its suppliers would be exempt from MIPS Promoting Interoperability reporting, so we believe it would be appropriate to recognize and account for these situations under the Shared Savings Program.

In the CY 2027 PFS proposed rule (91 FR 44065), we proposed that ACOs would be required to maintain documentation of excluded ACO participant TINs, including evidence that the TINs met one of the criteria for exclusion from the ACO's attestation to Shared Savings Program CEHRT use metrics, in the event of a CMS audit. We stated that ACOs that fail to maintain adequate documentation may be subject to compliance actions, as discussed in further detail in the Compliance with Shared Savings Program CEHRT Use Requirements paragraph of this final rule. We received public comments on these proposals. We summarize and respond to comments related to Shared Savings Program CEHRT proposals in section III.G.4.b. of this final rule.

(4) New Public Reporting Requirements

In the CY 2027 PFS proposed rule, we proposed to sunset the requirement at § 425.308(b)(9) that ACOs must publicly report the total number of ACO participants, ACO providers/suppliers, and ACO professionals that are MIPS eligible clinicians, QPs, or Partial QPs (each as defined at § 414.1305) that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category beginning with PY 2027 (91 FR 44065). We proposed to revise § 425.308(b)(9) by sunsetting its applicability after PY 2026 (91 FR 44065). We proposed to replace this reporting requirement, beginning with PY 2027, with a new requirement in proposed § 425.308(b)(11) that ACOs must publicly report which of the allowable CEHRT use activities in proposed § 425.507(c) the ACO has selected to perform to meet CEHRT use requirements for the Shared Savings Program (91 FR 44065). We stated our belief that one important aspect of patient-centered care is patient engagement and transparency, which can be achieved by the public reporting of ACO quality and cost performance. Public reporting helps to hold ACOs accountable and may improve a beneficiary's ability to make informed healthcare choices as well as facilitate an ACO's ability to improve the quality and efficiency of its care. We received public comments on these proposals. We summarize and respond to them in section III.G.4.b. of this final rule.

(5) Compliance With Shared Savings Program CEHRT Use Requirements

In the CY 2027 PFS proposed rule, we stated that we reserve the right to audit an ACO's compliance with the Shared Savings Program CEHRT use requirements proposed at § 425.507(c). Our audit, under § 425.314(a), could include, for example, requesting documentation from an ACO regarding its attestation to having used a Health IT Module certified to a criterion or criteria in 45 CFR 170.315 to obtain standardized data from a FHIR-based API to support collection of measure data to completely report at least one measure in the APP Plus quality measure set, as proposed at 42 CFR 425.507(c)(2), for ACOs electing that option to satisfy Shared Savings Program CEHRT use requirements. As a further example, an audit could also

include requesting documentation from an ACO regarding any ACO participant TINs excluded for purposes of the ACO attesting to any of the CEHRT use metrics, for ACOs electing the option proposed at § 425.507(c)(3) to report one of three allowable ACO Shared Savings Program CEHRT use metrics for the purpose of meeting Shared Savings Program CEHRT use requirements. We noted that as part of an audit, CMS may also require that ACOs produce the CEHRT IDs [307] for the EHRs used by ACOs to meet ACO CEHRT use requirements. For ACOs reporting via the eCQMs or Medicare eCQMs collection types, they would be required to produce this information at the time of submission when using that collection type, but for ACOs electing one of the other two Shared Savings Program CEHRT use options, the ACO would be required to maintain documentation of the CEHRT ID from the Certified Health IT Product List (CHPL). This would mean ACOs attesting they used a Health IT Module certified to an unexpired criterion or criteria within 45 CFR 170.315 to obtain standardized data from a FHIR-based API to support collection of data for reporting at least one measure in the APP Plus measure set would need to provide, on request, the CEHRT ID for the certified technology used. Similarly, for ACOs electing to attest to one of the three proposed ACO CEHRT use metrics, ACOs would need to provide, on request, the CEHRT ID for each of its participant TINs from which it attested at least one ACO provider or supplier utilized CEHRT to meet the requirements of the metric. ACOs are required under 42 CFR 425.314(b)(1) to maintain and give CMS, DHHS, the Comptroller General, the Federal Government or their designees access to records sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements. Furthermore, we proposed that, if ACOs fail to meet Shared Savings Program CEHRT use requirements, lack adequate documentation to demonstrate that TIN exclusions applied for an ACO's Shared Savings Program CEHRT use metric were appropriate, or fail to provide such adequate documentation upon request, we may apply compliance actions under §§ 425.216 or 425.218 (91 FR 44066). Such actions could include providing a warning notice, requesting a corrective action plan from the ACO, or placing the ACO on a special monitoring plan (91 FR 44065).

(6) No Impact on Current Shared Savings Program Quality or MIPS Scoring Policies or Process

In the CY 2027 PFS proposed rule, we stated that the proposed options for Shared Savings Program ACOs to meet the Shared Savings Program CEHRT use requirement will not change the existing scoring methodology for the MIPS Promoting Interoperability performance category. This means that, regardless of which of the three activities (or which option within their selected activity) ACOs choose to meet the Shared Savings Program CEHRT requirement, the MIPS Promoting Interoperability performance category reporting requirements for MIPS eligible clinicians participating in an ACO will remain unaffected. Additionally, an ACO performing any of the three CEHRT use requirement activities will not impact an ACO's quality score for purposes of determining the quality performance standard. For example, an ACO may choose to report an eCQM to meet the Shared Savings Program's ACO CEHRT use requirement; however, the eCQM will not necessarily be included in the MIPS quality performance category score as determined under § 414.1380. If an ACO reports multiple collection types for a given measure, including eCQMs, scoring is based on the highest scoring collection type which may not be eCQMs. Therefore, reporting the eCQM to meet the CEHRT use requirement may or may not contribute to the final quality performance score. In this example, even if the eCQM submission was not included in the ACO's MIPS quality performance category score as determined under § 414.1380, the ACO's complete reporting of the measure using the eCQMs collection type would satisfy the Shared Savings Program's CEHRT use requirement. Similarly, if an ACO uses FHIR technology to completely report a measure in the APP Plus measure set and attests to having done so, for the purpose of meeting the Shared Savings Program CEHRT use requirement, the requirement will be met, regardless of whether that measure submission is used to calculate the ACO's MIPS quality performance category score under § 414.1380. By extension, in this example, an ACO's quality score for the purposes of determining shared savings as calculated under § 425.512 would be unaffected. The ACO's MIPS quality performance category score is an aggregate of the highest measure-level scores submitted by the ACO. However, submissions that do not contribute to an ACO's final MIPS quality performance category score are still eligible for purposes of meeting the Shared Savings Program CEHRT use requirement (91 FR 44066).

(7) Regulatory Changes

We proposed the following revisions to the regulatory text at § 425.308(b) (91 FR 44066):

- Revising paragraph (b)(9) to remove the introductory phrase that made the subsequent requirements applicable to performance year 2025 and subsequent performance years, and limiting them to performance years 2025 and 2026.
- Adding new paragraph (b)(11) to specify that for performance year 2027 and subsequent PYs, the ACO must publicly report the CEHRT use activity selected by the ACO for the purpose of meeting the ACO CEHRT use requirement at § 425.507(c).

We proposed the following revisions to the regulation text at § 425.507 (91 FR 44066):

- Revising paragraph (a) to remove the introductory phrase that made the paragraph applicable to performance years beginning on or after January 1, 2025 and adding in its place an introductory phrase that would limit its applicability to performance years 2025 and 2026.
- Revising paragraph (b) by adding an introductory phrase that would limit its applicability to performance years 2025 and 2026,
- Adding new paragraph (c) to specify that, for PYs beginning on or after January 1, 2027, an ACO would be required to demonstrate the use of CEHRT as defined at § 425.20 in one of the following manners—

++ Use CEHRT (as defined in paragraph (3) of the CEHRT definition at § 414.1305) that also supports the calculation and reporting of clinical quality measures by being certified to the ONC health IT certification criteria at 45 CFR 170.315(c)(2) and (c)(3) to completely report at least one of the measures in the APP Plus quality measure set using the eCQMs or Medicare eCQMs collection types and meets the data completeness requirement at § 414.1340 of this chapter for the applicable PY; or

++ Completely report at least one measure in the APP Plus quality measure set and meet the data completeness requirement at 42 CFR 414.1340 of this chapter for the applicable performance year using EHR technology that meets paragraph (3) of the CEHRT definition at § 414.1305 and attests that it used data collected from

[307] The Office of the National Coordinator of Technology (ONC) maintains a searchable database of Certified Electronic Health Record Technology (CEHRT) IDs at CHPL Search (*https://chpl.healthit.gov/#/search*).

an HL7® Fast Healthcare Interoperability Resources (FHIR®)-based API to support quality measurement using a Health IT Module (as defined in 45 CFR 170.102) that has been certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access.

++ Attest to at least one of the Shared Savings Program CEHRT use metrics from the list of metrics established for the applicable PY.

We requested public comment on these proposed changes to the policy at 42 CFR 425.308(b) and 425.507.

c. Request for Information on Applying Electronic Prior Authorization Measures to Shared Savings Program ACOs

In section IV.A.4.d.(4) of the CY 2027 PFS proposed rule, we included proposals on the use of electronic prior authorization measures in the MIPS Promoting Interoperability performance category. Specifically, in that section of the CY 2027 PFS proposed rule, for the MIPS Promoting Interoperability performance category, we proposed to (1) change the Electronic Prior Authorization measure from a required measure to a bonus measure for the CY 2027 performance period/2029 MIPS payment year and a required measure beginning with the CY 2028 performance period/2030 MIPS payment year and (2) require a new measure, Electronic Prior Authorization for Prescription Drugs, that requires requesting prior authorization for at least one prescription drug electronically using CEHRT (91 FR 44066). This measure would be required for the MIPS Promoting Interoperability performance category beginning with the CY 2028 performance period/2030 MIPS payment year.

We sought feedback on the use of electronic prior authorization by ACOs that participate in the Shared Savings Program. Specifically, we sought comment on the following potential future changes:

- Requiring the use of specific FHIR-enabled Health IT Modules within CEHRT to complete at least one prior authorization request and determination for at least one medical item or service during the performance period or allowing it to be an option for meeting Shared Savings Program CEHRT use requirements beginning with the CY 2028 performance year.
- Creating a new, ACO-specific electronic prior authorization measure to require use of specific FHIR-enabled health IT modules within CEHRT to complete at least one prior authorization request and determination for at least one prescription drug during the performance period, beginning with the CY 2028 performance year.
- Considerations CMS should take into account, in developing electronic prior authorization measures to apply to Shared Savings Program ACOs.

We received public comments in response to our request for comment related to potential future policies for ACO use of electronic prior authorization and will take them into consideration for potential future rulemaking on this topic.

The following is a summary of the comments we received on our proposals related to Shared Savings Program CEHRT use and our responses.

Comment: Most commenters expressed support for the three proposed new options for ACOs to meet CEHRT use requirements, and several of these commenters expressed strong support. Commenters stated that the proposals would simplify CEHRT requirements, provide ACOs with greater flexibility to meet those requirements, and reduce unnecessary burden on ACOs and their healthcare providers. Of the commenters who stated the proposals would reduce burden, several noted that the proposals account for operational complexities such as those related to having multiple participating health centers, diverse EHR environments, multiple TINs, or large clinically integrated networks. One of those commenters indicated that the proposed CEHRT requirements would reduce burden without weakening accountability, and several added that the simplified requirements would account for these complexities while maintaining an expectation for electronic health information exchange or meaningful connection to electronic quality measurement. A commenter praised the proposals as a meaningful step away from development of EHRs for measurement and reporting rather than clinician and patient needs, and several supported the proposed Shared Savings Program CEHRT use options' alignment with quality measurement initiatives and progress toward digital quality measurement.

A few commenters supported that two of the proposed policies allow ACO-level attestation instead of requiring ACOs to satisfy requirements they stated were designed primarily for individual clinicians or groups.

Some commenters specifically supported the proposed availability of multiple options to meet the Shared Savings Program CEHRT use requirements, citing their belief that these varied pathways would accommodate different types of organizations or those with differing levels of technical readiness. Several commenters also expressed support for specific proposed options within those we proposed for ACOs to meet Shared Savings Program CEHRT use requirements. Several of these supported the option to leverage quality reporting through eCQMs or Medicare eCQMs collection types to also satisfy Shared Savings Program CEHRT use requirements, and some commenters specifically expressed support for the FHIR attestation option.

A commenter supported the proposed CEHRT use metrics, stating their belief that bi-directional exchange across the practices and systems responsible for a population can improve coordination while reducing duplicative reporting. A commenter supported the inclusion of the Health Information Exchange attestation option as one of the three ACO CEHRT use metrics.

Several commenters also supported the proposed exclusions for Shared Savings Program ACO CEHRT use metrics, which would allow qualifying participant TINs to be excluded under applicable special-status or hardship criteria without requiring advance CMS approval.

Several commenters specifically expressed support for the proposal to retire the current requirement that ACOs report the full set of MIPS Promoting Interoperability measures and activities, citing that they are burdensome, pose challenges for ACOs with differing compositions, systems, or capabilities, or that they served as a barrier to Shared Savings Program participation. Some of these commenters specifically expressed support for CMS' efforts to ensure that small, independent, or rural practices can participate in the Shared Savings Program, with one stating that the proposals restore trust, and another expressing appreciation for proposed movement away from requiring all Shared Savings Program ACO providers and suppliers to report MIPS promoting interoperability, including those in advanced APM tracks who would be otherwise exempt from MIPS.

Response: We appreciate the statements in support of our proposals. We agree with commenters that the proposed options recognize operational complexities and the various compositions of ACOs and would reduce burden for ACO providers and suppliers and ACOs, align with the movement toward digital quality measurement, and promote better use of EHRs to meet provider and patient needs. We appreciate comments that the proposals remove an administrative obstacle for small practices to join ACOs.

Comment: Several commenters who supported the proposals added recommendations about future implementation. Several of these commenters suggested that we align future CEHRT use requirements with other federal programs, including Innovation Center models such as ACO REACH, with one of these suggesting that ONC be the enforcement authority. The commenter suggested that alignment across programs would benefit organizations transitioning between value-based care models. A couple of commenters requested that CMS retain multiple pathways as proposed rather than narrowing them in the future or requiring ACOs to perform all three of the proposed pathways. These commenters suggested narrowing options or creating a cumulative requirement would preclude some organizations that exchange information interoperably from being able to meet the requirements or would recreate burden similar to our existing requirements.

A commenter suggested that future expansion of FHIR-based requirements should depend on demonstrated real-world readiness and reasonable implementation cost, and another recommended that CMS continue developing standards that integrate necessary data with appropriate safeguards. A couple of commenters addressed the future of the proposed FHIR attestation pathway, with one expressing hope that the FHIR attestation pathway would be ''genuinely available'' in practice and another encouraging CMS to keep the FHIR attestation pathway available on an ongoing basis.

A couple of commenters requested that CMS make the option for ACOs to attest that one ACO provider or supplier per participant TIN completed the activity required by the proposed CEHRT use metrics an initial requirement, rather than the endpoint.

Response: We appreciate comments regarding future implementation of Shared Savings Program CEHRT use policies. With regard to the suggestion that we align future Shared Savings Program CEHRT use requirements with other federal reporting programs or Innovation Center models, with ONC serving as the enforcement authority, we agree with the value in alignment and note that we coordinate with ONC, which oversees the ONC Health IT Certification Program. We note that ONC directly regulates certified health IT and health IT developers as part of the ONC Health IT Certification Program rather than healthcare providers (unless the healthcare provider is also a developer of certified health IT). The Shared Savings Program currently aligns quality reporting requirements with MIPS, and we intend to maintain that alignment to the extent it is practicable. As we explained the CY 2021 PFS proposed rule, using a single methodology to measure quality performance under both the Shared Savings Program and MIPS would allow ACOs to better focus on increasing the value of healthcare, improving care, and engaging patients (85 FR 50231). We acknowledge that our proposed CEHRT use requirements do not fully align with MIPS. This is intentional and is based on our experience with ACO challenges in ensuring that all of their applicable ACO participants reported MIPS Promoting Interoperability performance category requirements. The proposed ACO CEHRT use metric attestation option includes three metrics that align with three of the MIPS Promoting Interoperability performance category measures. We do not believe that aligning with Innovation Center models' CEHRT use requirements is necessarily appropriate for the Shared Savings Program, as these models are testing innovative approaches to reducing costs and improving or maintaining quality for a time-limited period. We proposed CEHRT use options that we believe reflect concrete steps toward broader FHIR-based digital quality measurement and health information exchange. We believe that our proposals will meaningfully advance FHIR based exchange of health information with minimal burden to ACOs.

With regard to comments suggesting we retain multiple pathways for ACOs to meet CEHRT use requirements, we proposed three options to give ACOs more opportunities and flexibility to meet CEHRT requirements. Should we consider changes to this approach in the future, we would make any potential future changes to Shared Savings Program CEHRT use policies through notice and comment rulemaking.

We will continue to consider opportunities to align Shared Savings Program CEHRT use requirements with other CMS programs and implementation timelines and consider how best to preserve flexibility in implementation. With regard to the suggestions that future expansion of CEHRT use requirements be dependent on real world readiness and that we continue to integrate necessary data with safeguards, we appreciate the comments and will continue to monitor CEHRT use uptake and advancements to progress ACO CEHRT use along with broader CMS efforts.

With regard to the comments on the FHIR attestation option, as discussed in more detail later in this section, we are finalizing this option as proposed. The option will be available to ACOs in PY 2027. As we advance efforts and requirements for digital quality reporting via FHIR, we would propose any changes to available CEHRT use options through future notice and comment rulemaking to ensure these options align with other requirements for the Shared Savings Program. We will provide additional instructions for ACOs that choose to utilize that option in advance of the CEHRT use reporting period, which we stated we anticipate would follow the quality reporting window in the first quarter after the performance year (91 FR 44061). We will continue to consider opportunities to align Shared Savings Program CEHRT use requirements with other CMS programs and implementation timelines and consider how best to preserve flexibility in implementation.

With regard to the recommendation that the option for ACOs to attest that at least one ACO provider or supplier billing under each ACO participant TIN completed the action required by the proposed CEHRT use metrics serve as an initial threshold rather than the endpoint, we believe the requirements we are finalizing establish an appropriate standard for demonstrating ACO use of CEHRT at this time, while maintaining flexibility and limiting additional reporting and implementation burden. We are not adopting additional exchange or participation thresholds at this time.

Comment: A commenter encouraged CMS to remove the Promoting Interoperability requirement altogether, stating that it creates administrative burden without added value, particularly for small practices that may choose to leave the program, and is unnecessary given ACOs' ongoing efforts to modernize and integrate EHR technology into their workflows.

Response: We believe the commenter is referring to Shared Savings Program CEHRT use requirement. We disagree with the commenter's assertion that CEHRT use requirements are unnecessary for the Shared Savings Program. As stated in the CY 2027 PFS proposed rule, section 1833(z)(2)(C)(iii)(II)(bb) of the Act (as amended by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)) generally requires Advanced Alternative Payment Models (Advanced APMs) to require the use of CEHRT (91 FR 44056). In order for certain participation tracks of the Shared Savings Program (that is, BASIC Level E

and ENHANCED) to be Advanced APMs, they must require CEHRT use, and eliminating the CEHRT use requirement for the remainder of the Shared Savings Program would result in inconsistent CEHRT use requirements across Shared Savings Program participation tracks. We believe maintaining consistent CEHRT use requirements across tracks supports the program's goals of improving the quality and coordination of care for Medicare beneficiaries. Further, we believe that removing CEHRT use requirements from any track of the Shared Savings Program would not be consistent with our belief in the value of advancing interoperability to improve patient care. We believe, as we noted in the CY 2027 PFS proposed rule (91 FR 44056), the secure exchange, access, and use of electronic health information supports better informed decision making and a more efficient healthcare system and that interoperability enables this secure exchange and access. For these reasons, we believe it is appropriate to retain CEHRT use requirements.

We recognize the commenter's concern regarding administrative burden associated with the existing requirements, particularly for small practices. We believe that the Shared Savings Program CEHRT use requirements we are finalizing will reduce burden for ACOs, including those with small practices. We proposed multiple options for ACO-level reporting or attestation to meet Shared Savings Program CEHRT use requirements. Additionally, for ACOs electing to attest to Shared Savings Program ACO CEHRT use metrics, the allowable exceptions for TINs comprised of ACO providers and suppliers with Shared Savings Program special statuses or those facing hardships are intended to provide greater flexibility for ACOs to meet the CEHRT use requirements. We believe these options appropriately balance the importance of CEHRT use in supporting coordinated, high-quality care with the need to reduce unnecessary reporting burden.

Comment: Several commenters expressed concern regarding ACOs' ability to comply with new Shared Savings Program CEHRT use requirements. A commenter recommended that CMS minimize documentation and audit burdens associated with CEHRT attestations. Another commenter recommended that minor documentation errors not threaten an ACO's shared savings eligibility if the ACO can otherwise demonstrate ''substantive compliance.'' Additionally, a commenter requested that we provide opportunities for CMS to cure isolated deficiencies of TINs that may impact an entire ACO's ability to meet the CEHRT use requirements. Some commenters requested that ACOs not be held accountable for ACO operational occurrences that may cause them to be out of compliance with the proposed changes. Similarly, a commenter recommended CMS ensure ACOs are not held accountable for technology infrastructure failure beyond their control.

Response: We appreciate commenters' concerns regarding documentation burden and isolated deficiencies or circumstances outside an ACO's control that may affect its ability to comply with the Shared Savings Program CEHRT use requirements. We agree that compliance expectations should be clear and that ACOs should not be subject to unnecessary administrative burden. However, we are not establishing a separate cure process for individual TINs or adopting a blanket exception for minor documentation errors or operational circumstances. We do not believe such policies are necessary in light of the policies we are finalizing. We proposed multiple CEHRT use options for ACOs to meet Shared Savings Program requirements and included TIN-specific exclusions of which ACOs electing the ACO CEHRT use attestation option could avail themselves as appropriate. We would address any instances of noncompliance through the existing compliance framework at §§ 425.216 and 425.218 as appropriate. With regard to ACOs being found out of compliance due to circumstances beyond their control, we note that ACOs may elect the CEHRT use option among the three choices that best meets their ACO's needs to satisfy Shared Savings Program requirements. Further, for those electing to attest to one of three proposed ACO CEHRT use metrics, they may exclude certain participant TINs that meet specified special status criteria or experience circumstances that would allow them to request a MIPS Promoting Interoperability hardship exception (91 FR 44064). We believe these exclusions, together with the multiple options for meeting the CEHRT use requirements, provide appropriate flexibility for ACOs while maintaining accountability for meeting Shared Savings Program CEHRT use requirements and mitigating the negative impact of circumstances outside of an ACO's control on Shared Savings Program CEHRT use compliance.

Comment: Many commenters requested guidance, additional information, technical assistance, or clarification from CMS. Several commenters requested that CMS confirm the documentation expectations clearly and in advance. Of these, a couple commenters expressed their belief that ACOs need to use this guidance to determine the best path for them. A commenter suggested CMS clarify in the final rule that the attestation is related to ACO CEHRT use and not a separate certification requirement for ACOs or their ACO participants. A commenter requested clear guidance on acceptable evidence of FHIR-enabled data exchange and quality reporting to promote consistent implementation across ACOs. A couple of commenters suggested CMS couple this proposal with ACO-level technical assistance, shared services models, and financial support, and a couple of commenters recommended that CMS clearly define the circumstances that qualify for exclusion. One of these commenters requested details about the documentation ACOs should maintain to support exclusion determinations, while the other stated that exclusion processes should be clear, objective, and administratively simple.

Response: We appreciate the commenters' recommendations regarding clear implementation expectations, documentation, technical assistance and financial support. We believe that the requirements described in this final rule provide ACOs with sufficient information to understand the available Shared Savings Program CEHRT use options, including applicable exclusions for ACOs electing the CEHRT use metric attestation option under § 425.507(c)(3), as discussed in the CY 2027 PFS proposed rule (91 FR 44064 and 44065). We fully described exclusions available to ACOs electing to attest to one of the three Shared Savings Program ACO CEHRT use metrics in the CY 2027 PFS proposed rule (91 FR 44064 and 44065). In response to comments, we have also provided a summary table of certification criterion requirements for these Shared Savings Program CEHRT use metrics (Table B–G10). We intend to provide additional instructions for completing Shared Savings Program CEHRT use attestations in the ACO–MS system, for ACOs electing to attest that they used a Health IT Module certified to an unexpired criterion or criteria within 45 CFR 170.315 to obtain standardized data from a FHIR-based API to support their complete reporting of at least one measure in the APP Plus and ACOs electing to attest to one of the three proposed ACO CEHRT use metrics. We intend to provide summary or

illustrative materials to assist ACOs in complying with Shared Savings Program CEHRT use requirements and will continue to provide ACOs with technical assistance through existing channels.

With respect to documentation, we disagree that additional guidance is required related to documentation requirements. Existing policy at § 425.314(b)(1) includes the requirement that ACOs retain evidence sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements. As discussed in the CY 2027 PFS proposed rule, ACOs electing to attest that they used a Health IT Module certified to an unexpired criterion or criteria within 45 CFR 170.315 to obtain standardized data from a FHIR-based API to support their complete reporting of at least one measure in the APP Plus measure set would need to provide, on request, the CEHRT ID for the certified technology used, and ACOs electing to attest to one of the three proposed ACO CEHRT use metrics would need to provide, on request, the CEHRT ID for each of its participant TINs from which it attested that at least one ACO provider or supplier utilized CEHRT to meet the requirements of the metric. If ACOs electing to attest to one of the three Shared Savings Program ACO CEHRT use metrics exclude a TIN based on the TIN meeting Shared Savings Program definition of ''special status'' or hardship, the ACO would be required maintain and provide on request adequate documentation to demonstrate that any TIN exclusions applied were appropriate (91 FR 44065 and 66). We believe these existing documentation requirements, together with the requirements and clarifications provided in this final rule, sufficiently establish CMS's expectations for demonstrating compliance.

We do not intend to provide financial support or establish shared services models for ACOs to implement the new Shared Savings Program CEHRT use options because the options are significantly less burdensome than our current CEHRT use policies. We confirm that the proposed CEHRT use option at § 425.507(c)(2), for ACOs to attest using FHIR to support reporting of a quality measure described in detail in section III.G.4.b.(2) of this final rule, is one option an ACO could select in order to meet Shared Savings Program CEHRT use requirements and is not an additional certification requirement for ACOs or their ACO participants. We agree that the processes should be clear and as simple as possible.

Comment: A commenter stated that ACOs should be free to select the pathway best suited to their circumstances and to change pathways between performance years without penalty.

Response: We agree that ACOs should have the flexibility to select the pathway that best suits their circumstances and to change pathways between performance years. We did not propose limiting an ACO's ability to change its selected pathway between performance years to meet the CEHRT use requirements, nor are we finalizing any such limitation at this time.

Comment: A couple of commenters requested clarification related to documentation of CEHRT identifiers. One of these commenters requested clarification in the final rule that the proposed Shared Savings Program CEHRT use options are an alternative, rather than an addition, to what they stated was the current practice of ACOs documenting that their practices are using CEHRT and another commenter requested that CMS confirm that, in addition to the three proposed CEHRT use options, direct verification using the CHPL would be considered to satisfy technology use verification requirements.

Response: We appreciate comments requesting clarification. We wish to clarify that an ACO documenting that its practices use CEHRT would not meet or have met current Shared Saving Program CEHRT use requirements in § 425.507(a) and (b) or the proposed requirements in (c). The proposed Shared Savings Program CEHRT use requirements described at section III.G.4.b. and that we are finalizing at section III.G.4.c. in this rule will replace existing Shared Savings Program CEHRT use requirements, beginning with PY 2027.

Regarding the comment asking for confirmation that verification of CEHRT using the CHPL would satisfy Shared Savings Program CEHRT use requirements, it would not. We are unsure whether the commenter may have been referring to existing MIPS requirements for documenting a CMS EHR Certification ID (also referred to as a CEHRT ID) obtained from the CHPL as part of MIPS Promoting Interoperability performance category reporting. As we stated in the CY 2027 PFS proposed rule, our proposed options for Shared Savings Program ACOs to meet the Shared Savings Program CEHRT use requirement will not change the existing scoring methodology for the MIPS Promoting Interoperability performance category (91 FR 44066). The Shared Savings Program CEHRT use requirements are separate from and in addition to any MIPS requirements for documentation of CEHRT IDs.

We did not propose that verification or documentation of a CEHRT ID using the CHPL alone would satisfy Shared Savings Program CEHRT use requirements, as it would not. ACOs may continue to use the CHPL to verify the certification status of health IT used by their ACO participant TINs. ACOs electing the option to attest to having used a Health IT Module certified to an unexpired criterion or criteria within 45 CFR 170.315 to obtain standardized data from a FHIR-based API to support the complete reporting of at least one measure in the APP Plus quality measure set (§ 425.507(c)(2)), or to attest to one of the three ACO CEHRT use metrics (§ 425.507(c)(3)) (that at least one ACO provider or supplier in each of the ACO's participating TINs performed the action described in the metric using EHR technology certified to the ONC Certification Criteria for Health IT (45 CFR 170.315) necessary to meet paragraph (3) of the CEHRT definition at 42 CFR 414.1305) would be required to maintain documentation that the EHR technology meets the requirements of the CEHRT definition and other requirements in § 425.507(c)(1)–(3) as applicable and provide such documentation to CMS upon request. Likewise, ACOs that use CEHRT (as defined in paragraph (3) of the CEHRT definition at § 414.1305) that also supports the calculation and reporting of clinical quality measures by being certified to the ONC health IT certification criteria at 45 CFR 170.315(c)(2) and (c)(3), to completely report at least one of the measures in the APP Plus quality measure set using the eCQMs or Medicare eCQMs collection types and meets the data completeness requirement at 42 CFR 414.1340 of this chapter for the applicable performance year (§ 425.507(c)(1)) would also be required to maintain documentation that the EHR technology meets the requirements of the CEHRT definition and other requirements in § 425.507(c)(1)–(3) as applicable and provide such documentation to CMS upon request.

Comment: A commenter stated that they supported our proposal to eliminate the Promoting Interoperability measure category for ACOs.

Response: We wish to clarify that we did not propose to eliminate the Promoting Interoperability Performance category, which is a part of MIPS. Rather, we proposed to sunset the *Shared Savings Program* requirement (§ 425.507(a)) that ACO providers and suppliers report all MIPS Promoting

Interoperability measures and requirements and publicly report on the number of MIPS eligible clinicians, QPs, and Partial QPs in the ACO who earned a MIPS Promoting Interoperability performance category score (§ 425.308(b)(9)). As we stated in the CY 2027 PFS proposed rule, regardless of which of the three proposed activities (or which option within their selected activity) ACOs choose to meet the Shared Savings Program CEHRT use requirement, the MIPS Promoting Interoperability performance category reporting requirements for MIPS eligible clinicians participating in an ACO would remain unaffected (91 FR 44066).

Comment: A couple of commenters requested clarification regarding the proposed option for ACOs to meet Shared Savings Program CEHRT use requirements through attesting to having used a FHIR-based API available in CEHRT to support measure data collection for complete reporting of a measure in the APP plus measure set. A commenter asked that CMS clarify that the FHIR-based attestation option is intended to become viable only once FHIR-based quality reporting capabilities are more broadly available and consider whether it is necessary to include this option for the CY 2027 performance period specifically, given that it is not currently operational for any ACO. Another commenter recommended we enumerate in the final rule which certification criteria other than 45 CFR 170.315(g)(10) satisfy the attestation pathway at § 425.507(c)(2) and state what an ACO must be able to demonstrate for a Health IT Module to qualify as ''supporting standardized API access.''

Response: We wish to clarify commenters' potential misunderstanding of our proposal at § 425.507(c)(2). Under that provision, one option an ACO could elect in order to meet the Shared Savings Program's CEHRT use requirements would be for the ACO to completely report at least one measure in the APP Plus quality measure set and meet the data completeness requirement at § 414.1340 of this chapter for the applicable performance year using EHR technology that meets paragraph (3) of the CEHRT definition at § 414.1305 and attest that it used data collected from a FHIR-based API to support quality measurement using a Health IT module certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access. Meeting these requirements is separate from any future reporting of FHIR-based digital quality measures and so could be implemented by ACOs electing that option for PY 2027. ACOs would attest to meeting this requirement through ACO–MS, after the conclusion of annual quality reporting (91 FR 44060 and 44061). We appreciate the request for clarification on which criteria other than 45 CFR 170.315(g)(10) would satisfy the requirement that the health IT module be certified to an unexpired criterion supporting standardized API access. At this time, 45 CFR 170.315(g)(10) is the only unexpired criterion that would meet this requirement. The language was intended to preserve flexibility for ACOs to utilize any future ONC Health IT certification criteria that may support standardized API access or a potential future situation where 45 CFR 170.315(g)(10) becomes expired and is replaced by a different criterion.

Comment: A commenter requested clarification as to whether ACOs with a significant share of small-practice participants may satisfy the requirement at the ACO level rather than requiring uniform compliance across every participant TIN.

Response: We appreciate the request for clarification. We believe the commenter may have been referring to the option for ACOs to attest that at least one ACO provider or supplier in each of its participant TINs completed a certain action. For ACOs electing this attestation option for the purpose of meeting Shared Savings Program CEHRT use requirements, in order to attest ''Yes,'' those with a large proportion of small practices would still be required to ensure that at least one ACO provider or supplier in each of the ACO's participating TINs performed the action described in the Shared Savings Program ACO CEHRT use metric using EHR technology certified to the ONC Certification Criteria for Health IT (45 CFR 170.315) necessary to meet paragraph (3) of the CEHRT definition at § 414.1305 to complete the action described in each metric.

Comment: Many commenters recommended that CMS provide a transition period to ACOs or hold them harmless from compliance actions based on their not meeting the proposed CEHRT use requirements. Of these, several requested an extension of the enforcement discretion for at least one additional performance year, with most expressing concern that the timing for our proposal to replace existing Shared Savings Program CEHRT use requirements in PY 2027 does not allow ACOs sufficient development and/or implementation time. A couple of commenters requested CMS to treat every ACO as compliant in the first year, while another commenter requested a minimum 1–2-year transition for compliance.

Response: We acknowledge the recommendations regarding a transition period. As discussed in section III.G.4.b. of this final rule, we are providing multiple options for ACOs to meet the CEHRT use requirements, allowing ACOs to select the option that best accommodates their organizational structure and technical capabilities. We believe these options significantly reduce burden on ACOs compared to our current CEHRT use requirements, while advancing ACOs toward digital quality measurement and health information exchange. We do not believe that an additional transition period is warranted because the proposed Shared Savings Program CEHRT use options at 42 CFR 425.507(c) overlap with activities the ACO will already be doing to participate in the Shared Savings Program in PY 2027, including quality reporting. We are also finalizing an option for ACOs to attest to one of three Shared Savings Program ACO CEHRT use metrics that are a subset of the MIPS Promoting Interoperability measures that ACOs are required to report for every ACO participant, ACO provider/supplier, and ACO professional under the current Shared Savings Program regulations at § 425.507(a). This subset of currently required MIPS Promoting Interoperability measures have also been simplified so that ACOs will only be required to attest that one ACO provider or supplier from each of the ACO's participant TINs has completed the action required by the metric. As the options under 425.507(c) allow ACOs to choose from multiple activities, including attesting to one of three simplified and lower-burden version of existing MIPS Promoting Interoperability measures, on which Shared Savings Program ACOs are currently required to report at 425.507(a), any ACO meeting the existing requirements should be able to attest that it met at least one of the proposed Shared Savings Program CEHRT use metrics.

We disagree with comments that we should utilize our enforcement discretion for an additional year or guarantee compliance in the first year, in light of finalizing new options through which ACOs can meet CEHRT use requirements for PY 2027. We note that we finalized existing CEHRT use requirements in the CY 2024 PFS final rule (88 FR 79124 through 79132), issued on November 2, 2023. Under the current policies, unless otherwise excluded, ACO participants, ACO provider/suppliers, and ACO

professionals who are MIPS eligible clinicians, Qualifying APM Participants (QP), or Partial QPs regardless of track, must report the MIPS Promoting Interoperability performance category measures and requirements to MIPS. We have exercised enforcement discretion for this requirement, for PY 2025 and PY 2026, due to challenges faced by ACOs including understanding the CEHRT requirements, determining which of their participants are excluded from the requirement, and aggregating data across providers. In contrast to the proposed policy at § 425.507(c), ACO providers/suppliers were required, under existing regulations at § 425.507(a), to report the full set of MIPS Promoting Interoperability measures and activities in PY 2025 and PY 2026. We believe the CEHRT use policies proposed to begin in PY 2027 allow for significantly greater flexibility, including for ACOs to choose to report one of three metrics that are parallel to three measures from the larger MIPS Promoting Interoperability performance category activities currently required under existing Shared Savings Program CEHRT use requirements at § 425.507(a). ACOs electing to attest to one of these metrics would complete ACO-level attestations as finalized in section III.G.4.c. of this final rule. In addition, we proposed to allow ACOs electing to attest to one of the proposed metrics to exclude from their determination of whether one ACO provider or supplier from each of their participating TINs completed the action under a list of circumstances. Due to the simplification of the proposed CEHRT requirements, the multiple options for ACOs to meet CEHRT requirement for the Shared Savings Program, and the overlap between the proposed CEHRT use requirements and quality reporting, we believe that the need for enforcement discretion in PY 2027 is diminished. Accordingly, after consideration of the comments, we are not extending the period of enforcement discretion, nor delaying the effective date for retiring the existing CEHRT use requirements or for implementing the ones we are finalizing at section III.G.4.c. of this final rule beginning with PY 2027.

Comment: Several commenters requested that CMS recognize standards and pathways outside of those we proposed. A commenter provided additional suggestions for CMS to include as options for ACOs to meet Shared Savings Program CEHRT use requirements, including recognition of standards-based health information exchange of health information with post-acute care, long-term care, or community partners, including for those that do not have CEHRT or that operate outside of a qualified health information network, making allowances for any technical failures these partners might experience. Another commenter recommended that we clarify that a contracted healthcare provider's technology status would not preclude an ACO from selecting any proposed CEHRT-use pathway, and another requested we add an option for meeting CEHRT requirements for the Shared Savings Program by reporting objective results for FHIR API performance for ACOs electing to report the Medicare eCQM pathway. A commenter also requested that CMS allow ACOs to meet Shared Savings Program CEHRT use requirements by documenting efforts to exchange with partners that lack needed technology or connectivity.

Response: We acknowledge the recommendations regarding additional options for meeting the Shared Savings Program CEHRT use requirements. We recognize the importance of supporting interoperability across the care continuum, including with post-acute care, long-term care, community-based and contracted healthcare providers that may face challenges adopting or using CEHRT. However, we believe the multiple options for meeting the CEHRT use requirements as finalized in section III.G.4.c. of this final rule provide ACOs with flexibility to accommodate differences in their organizational structures, existing health IT infrastructure and technical capabilities. Accordingly, we are not adopting additional options for meeting Shared Savings Program CEHRT use requirements at this time.

In response to commenters' concerns regarding exchange of health information with partners that may lack CEHRT, we believe that our Shared Savings Program CEHRT use options provide choices that do not require all of the healthcare providers with whom ACOs or ACO providers and suppliers exchange health information to have CEHRT. For example, for ACOs electing the option at § 425.507(c)(1), to use CEHRT meeting the requirements described in that section to completely report at least one of the measures in the APP Plus quality measure set using the eCQMs or Medicare eCQMs collection types and meet the data completeness requirement at § 414.1340 of this chapter for the applicable PY, it is the submitting EHR system that must be certified to ONC's regulations by the time eCQM data is generated for submission.[308] For ACOs electing the option at § 425.507(c)(2), to use EHR technology that meets paragraph (3) of the CEHRT definition at § 414.1305 and attest that they used data collected from FHIR-based API to support quality measurement using a Health IT module that has been certified to an unexpired criterion or criteria in 45 CFR 170.315 to support complete reporting of at least one of the five ACO-reported measures in the APP Plus quality measure set, there is also not a requirement that every system or organization with which the ACO exchanges health information must use CEHRT. Similarly, for ACOs electing the option in § 425.507(c)(3) to select and attest to the bi-directional HIE Shared Savings Program CEHRT use metric, attesting to that metric does not require that every system or organization with which the ACO provider or supplier exchanges information use certified health IT. Long-term and post-acute care settings can connect to a wide range of health information exchange entities that use a variety of methods to exchange information with ACO providers and suppliers in ACO participant TINs. As we explained in the CY 2027 PFS proposed rule, an ACO electing to attest to one of the three proposed CEHRT use metrics could consider an ACO provider or supplier in its participant TIN to have met the bi-directional HIE ACO CEHRT use metric's requirement if the ACO provider or supplier has, for at least one patient seen by the ACO provider or supplier, used EHR technology certified to the ONC Certification Criteria for Health IT (45 CFR 170.315) necessary to meet paragraph (3) of the CEHRT definition at § 414.1305 to support bi-directional exchange with an HIE that has the required functionality (91 FR 44062).

With regard to the suggestion that ACO documentation of efforts to exchange information with partners with limited technological capacity should be considered to meet Shared Savings Program CEHRT use requirements, we disagree. We note that CMS does not require that every system or organization with which the ACO provider or supplier exchanges information must use certified health IT. We believe the options we are finalizing in section III.G.4.c. of this final rule appropriately balance these considerations by providing ACOs with options to satisfy the CEHRT use requirement, which allow ACOs to select the option that best reflects their health IT infrastructure and capabilities.

[308] Please see *https://qpp.cms.gov/data-management/ehr.*

We also note that, while we did not propose to allow ACOs to meet Shared Savings Program CEHRT use requirements by documenting or reporting FHIR API performance, we did propose in 42 CFR 425.507(c)(2) that ACOs could elect to meet Shared Savings Program CEHRT use requirements by completely reporting at least one of the five ACO-reported measures in the APP Plus quality measure set and attesting to using CEHRT to support quality reporting using data collected from a FHIR-based API using a certified Health IT Module. While we do not believe that documentation of the FHIR-based API's performance should suffice as a demonstration of ACO CEHRT use, this option would allow an ACO that used a FHIR-based API to support complete reporting of an APP Plus quality measure using a Health IT Module that has been certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access to attest that it did so, in order to meet Shared Savings Program CEHRT use requirements.

Comment: A couple of commenters requested that CMS retain a public health data exchange option—for example, Immunization Registry Reporting or Electronic Case Reporting attestation, as one of the qualifying CEHRT-use activities under the revised Shared Savings Program requirement. These commenters noted this would align with the existing MIPS framework and support essential public health data exchange infrastructure.

Response: We appreciate the recommendation to include public health data exchange, such as Immunization Registry Reporting or Electronic Case Reporting, as one of the ACO CEHRT use metrics that ACOs can use to meet the requirement under § 425.507(c)(3). While we agree that electronic public health data exchange supports broader interoperability goals and recognize the role of CEHRT in facilitating the electronic exchange of public health data, we believe that the multiple options we are finalizing provide ACOs sufficient flexibility to demonstrate CEHRT use while advancing interoperability. For example, consider an ACO provider or supplier that is a signatory to a Framework Agreement under the Trusted Exchange Framework and Common Agreement (TEFCA),[309] and exchanges immunization data with public health agencies for patients using TEFCA. That ACO could count that activity as part of meeting the requirement for that ACO provider or supplier's ACO participant TIN when determining whether one ACO provider or supplier from each of its ACO participant TINs has met the requirement for the proposed ACO Health Information Exchange (HIE) Bi-Directional Exchange metric. We discussed how a TEFCA Framework Agreement can help ACOs meet the requirement for the HIE metric in the CY 2027 PFS proposed rule (91 FR 44063). Additionally, we note that public health agencies are potential participants in HIEs.[310] Accordingly, we are not adopting the recommendation to include public health data exchange as an additional qualifying CEHRT use activity at this time. However, we will consider including public health data exchanged as part of bidirectional exchange via a health information network as an example, in future instructions, of an activity that could contribute to satisfying the requirements of the bi-directional HIE metric, for ACOs that elect to attest to it, to meet the Shared Savings Program CEHRT use requirement in 42 CFR 425.507(c)(3).

Comment: A commenter recommended we add the MIPS Electronic Prior Authorization measure to the list of available metrics for Shared Savings Program CEHRT Use attestation for PY 2028 because omitting electronic prior authorization from the ACO CEHRT use metric list risks creating misalignment between payer obligations that take effect in 2027 and the incentives for ACOs to adopt ePA.

Response: We appreciate the recommendation to add an ACO CEHRT use metric related to the MIPS Promoting Interoperability performance category Electronic Prior Authorization measure to the list of metrics available for CEHRT use attestation for PY 2028. We disagree that not proposing or finalizing an electronic prior authorization CEHRT use metric for Shared Savings Program ACOs for PY 2028 creates misalignment with MIPS. In section IV.B.1.d. of this final rule, MIPS is finalizing, as proposed, modifications to the Electronic Prior Authorization measure that make the measure optional for the CY 2027 performance period and required starting with the CY 2028 performance period. Additionally, in section IV.A.4.d.(4) of this final rule, MIPS is finalizing, as proposed, the adoption of the new Electronic Prior Authorization for Prescription Drug measure, which will be a required measure starting with the CY2028 performance period. Further, the three Shared Savings Program ACO CEHRT use metrics, of which ACOs could choose to attest to one in order to meet Shared Savings Program CEHRT use requirements for PY 2027, align conceptually with the MIPS Promoting Interoperability performance category measures but have been revised to apply to ACOs. We proposed that we would make any future changes to the ACO CEHRT use metrics through notice and comment rulemaking. As we did not propose to include a metric around electronic prior authorization beginning with PY 2027, we are not accepting this suggestion but will consider it for potential future rulemaking.

Comment: A couple of commenters requested that CMS monitor the uptake and results of these proposed requirements. Of these, a commenter requested monitoring of the FHIR attestation pathway specifically, and the other requested monitoring of whether the one provider or supplier participant TIN requirement in the CEHRT use metrics leads to meaningful exchange at scale.

Response: We appreciate the suggestions and agree that there would be value in monitoring use of the FHIR attestation pathway as proposed in 42 CFR 425.507(c)(2). We intend to monitor ACOs' use of the available Shared Savings Program CEHRT use options including the FHIR attestation pathway. We appreciate the value in analyzing what activities lead to meaningful exchange of health information at scale, though we note that this option within the Shared Savings Program is only one factor in promoting increase in meaningful exchange of health information at scale. We do, however, believe that allowing ACOs to meet Shared Savings Program CEHRT use requirements through our recognition of ACOs' concrete steps toward FHIR-based digital quality measurement and health information exchange, such as through the proposed attestation to using FHIR-based exchange to support quality measure data collection, provides a low-burden incentive for ACOs to invest in infrastructure and redesigned care processes to improve care for the beneficiaries they serve.

Comment: We received several comments regarding movement toward interoperability in general, including ensuring our policies are meaningful and support ACOs' needs. Several

[309] TEFCA is a national framework for health information sharing created to remove barriers to sharing health records electronically among healthcare providers, patients, public health agencies, and payers. For more information on TEFCA and the Framework Agreement, please see *https://healthit.gov/policy/tefca/*.

[310] Please see *https://publichealth.jmir.org/2024/1/e64969.*

commenters recommended that CMS make sure our proposed Shared Savings Program CEHRT use requirements support interoperability specific to the operations and needs of ACOs and their partners, including nursing facilities.

A few commenters addressed the proposed policies' specific requirements that ACOs use CEHRT, expressing concern about potential CEHRT cost and reliance on a particular vendor or other proprietary input.

A few commenters requested that CMS ensure that the CEHRT use requirements meaningfully lead to increased interoperability, with a commenter expressing their belief that the increased flexibility alone would not create interoperability and another recommending we ensure that the HIE CEHRT use metric assesses meaningful capability to exchange actionable data.

Several commenters addressed advancement of interoperability and digital reporting requirements across CMS programs and models, with one supporting CMS's efforts to advance interoperability, FHIR-based exchange, and digital quality measurement and reduce reporting burden but cautioning against creating a lower interoperability standard for value-based care programs that could conflict with Medicare's long-term interoperability goals.

Response: We appreciate recommendations regarding meaningfulness and feasibility of the options for meeting Shared Savings Program CEHRT use requirements. We agree that the policies should support ACOs' ability to coordinate care and improve care quality for their assigned beneficiaries, including through interoperability, and address ACOs' needs, and we believe that the additional flexibilities and exclusions we proposed address a redesign of care processes for high quality and efficient service delivery across the wide variety of ACO compositions and capabilities. With regard to supporting interoperability with partners including nursing facilities, we agree and believe that the flexibilities and the clarification, as discussed previously in this section, that the proposals do not require that every system or organization with which the ACO provider or supplier exchanges information must use certified health IT, in order to meet Shared Savings Program CEHRT use requirements.

The proposed options do not require an ACO to use a specific EHR vendor or other proprietary input, and we believe that providing multiple options affords greater flexibility for ACOs and ACO participants with differing levels of health IT capabilities and resources. With regard to the comments suggesting we ensure the CEHRT use requirements are meaningful and that a lower bar is not set for interoperability in value-based care, we agree. We believe that the proposed options allow ACOs to demonstrate activities they have undertaken to use CEHRT to improve quality of care and service efficiency. We will continue to work to ensure advancement of interoperability within the Shared Savings Program, as interoperability advances in the larger Medicare program.

Comment: Many commenters requested that CMS add or modify an exception for certain types of healthcare providers. Of these, many requested a small practice exception, a few suggested exceptions or additional support for rural practices or expansion of the types of facility-based providers eligible for exclusion, and a commenter suggested an exclusion for specialists. Several commenters noted that the CY 2027 PFS proposed rule will be finalized after ACOs will have had to make participation decisions for PY 2027, which some stated would limit ACOs' ability to comply, based on their inclusion of small practices. A commenter noted that small practices build capacity over time and should receive additional support from CMS, and several expressed their belief that a small practice exception would better align with our intent to increase small and independent practice participation in ACOs. Several commenters expressed their belief that a small practice exclusion would be more in line with the MIPS framework, with one stating our proposed policy would create a new CEHRT reporting requirement for practices that are currently excluded from MIPS Promoting Interoperability performance category reporting.

Another commenter suggested that we add a time-limited exception for CEHRT use requirements for rural, small, or long-term/post-acute care when organizations demonstrate lack of access to technology or connectivity, and some commenters requested a rural health exemption, noting that adopting CEHRT for the first time may be prohibitive for them.

A few commenters expressed concern with ACOs' ability to influence facility-based practices' EHRs, and some of these requested we exclude additional types of facility-based practices from CEHRT use requirements, including for clinicians providing services in nursing facilities and assisted living facilities, who face similar challenges to those currently applicable for the exclusion.

Response: We acknowledge the recommendations to add additional exclusions for Shared Savings Program CEHRT use requirements. We wish to clarify that the exceptions we proposed are applicable to the option for ACOs to elect to attest to one of the Shared Savings Program ACO CEHRT use metrics as proposed for 42 CFR 425.507(c)(3). We believe an additional small practice exclusion is unnecessary because ACO participation enables participating practices to leverage shared infrastructure, technology, data and care management capabilities that may be difficult for individual practices to develop or maintain on their own. Accordingly, small practices participating in an ACO should generally be positioned to meet the revised, less burdensome options for the Shared Savings Program CEHRT use requirement through the ACO's broader infrastructure and support.

The proposed policy also provides multiple options for ACOs to demonstrate CEHRT use, including the option at § 425.507(c)(2) to completely report at least one measure in the APP Plus quality measure set and meet the data completeness requirement at § 414.1340 for the applicable performance year using EHR technology that meets paragraph (3) of the CEHRT definition at § 414.1305 and attests that it used data collected from a FHIR-based API to support quality measurement using a Health IT Module certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access, if an ACO would prefer that option over attesting that each of its participating practices performed a certain CEHRT use activity. We recognize that small practices may face resource and implementation challenges and that some may currently qualify for flexibility under MIPS. We do not believe, however, that practice size alone warrants exclusion from the Shared Savings Program CEHRT use requirements. Unlike the MIPS' Promoting Interoperability performance category, the CEHRT use policies proposed for the Shared Savings Program would not require practice-level reporting of Promoting Interoperability measures and activities (or the equivalent Shared Savings Program ACO CEHRT use metrics). ACOs could alternatively elect to: (1) Use CEHRT (as defined in paragraph (3) of the CEHRT definition at § 414.1305) that also supports the calculation and reporting of clinical quality measures by being certified to the ONC health IT certification criteria at 45 CFR 170.315(c)(2) and (c)(3) to completely report at least one of the measures in the APP Plus quality measure set using the

eCQMs or Medicare eCQMs collection types and meet the data completeness requirement at § 414.1340 of this chapter for the applicable PY; or (2) Completely report at least one measure in the APP Plus quality measure set and meet the data completeness requirement at § 414.1340 of this chapter for the applicable performance year using EHR technology that meets paragraph (3) of the CEHRT definition at § 414.1305 and attests that it used data collected from FHIR-based API to support quality measurement using a Health IT Module certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access, to satisfy the proposed Shared Savings Program CEHRT use requirements in § 425.507(c). We have also proposed to allow ACOs electing to attest to one of the three ACO-level CEHRT use metrics to exclude, from their assessment as to whether one ACO provider or supplier from each of their participating TINs met the metric, TINs comprised of ACO providers and suppliers meeting certain special statuses as well as hardships. ACO participant TINs that are small practices comprised of ACO providers and suppliers who meet the proposed hardship circumstances could be excluded by ACOs electing to attest to one of these metrics. We note that we have proposed multiple options for ACOs to satisfy Shared Savings Program CEHRT use requirements and have proposed exceptions to facilitate the ability of ACOs to meet them. Overall, the proposed requirements in § 425.507(c) result in a decreased burden for ACOs to meet the Shared Savings Program CEHRT use requirements compared to existing requirements under § 425.507(a). After consideration of these comments, we are not finalizing an exception for small practices.

We acknowledge the concerns regarding the timing of these requirements and their potential effect on ACO participation decisions and the inclusion of small and independent practices. However, we believe the options for demonstrating CEHRT use finalized in this rule provide ACOs flexibility in meeting the requirement while maintaining an appropriate minimum expectation for CEHRT use among ACO participants. We also believe that they represent a significant decrease in burden for ACOs as compared to the existing CEHRT use requirements.

With regard to the suggestion that specialists be excluded from the requirements, we disagree because we believe that specialists are an integral part of ACOs and that excluding them would decrease ACOs' ability to exchange health information to coordinate and improve care for the beneficiaries they serve.

Regarding the recommendation to expand CEHRT use exclusions to additional facility-based provider types, we did not propose to expand exclusions for ACOs electing to attest to one of three ACO CEHRT use metrics beyond those described in the CY 2027 PFS proposed rule (91 FR 44062), which align with those available under MIPS. We will consider this suggestion for future rulemaking.

Regarding the suggestion that we add an additional exception for rural ACOs or practices, we believe ACOs that include participant TINs serving rural populations can meet the proposed CEHRT use requirements given the multiple options available and the exclusions for ACO participant TINs comprised solely of ACO providers and suppliers in rural and/or Health Professional Shortage Area (HPSA) circumstances available for ACOs electing to attest to one of the CEHRT use metrics. Specifically, in the CY 2027 PFS proposed rule, we discussed that ACOs would be permitted to apply exclusions for similar circumstances as the exclusions and exceptions under MIPS (91 FR 44064). We noted that an ACO would be permitted to exclude an ACO participant TIN that the ACO determines is comprised solely of ACO providers and/or suppliers who meet the Shared Savings Program definition of ''special status'' (91 FR 44064). We explained that the Shared Savings Program definitions of special statuses would be similar to the MIPS definitions at § 414.1305 except that they would not be limited to MIPS ECs, for the purpose of Shared Savings Program CEHRT use metric exceptions. We proposed to include as special statuses being located in a HPSA, defined as areas designated under section 332(a)(1)(A) of the Public Health Service Act or being located in a rural area, defined as ZIP codes designated as rural by the Federal Office of Rural Health Policy (FORHP) using the most recent FORHP Eligible ZIP Code file available as described in the definition of ''Rural area'' at § 414.1305.

Additionally, we want to clarify that, while most of the special statuses defined at § 414.1305 are aligned with the MIPS Promoting Interoperability performance category framework, this is not true for the statuses of ''Located in a health professional shortage area (HPSA)'' or ''Rural area.'' While these two statuses convey differential scoring under MIPS for the Improvement Activities domain, they do not have an impact on scoring for or qualify for reweighting of the MIPS Promoting Interoperability performance category.[311] We proposed to allow ACOs electing to attest to one of the proposed metrics to exclude from their determination of whether one ACO provider or supplier from each of their participating TINs completed the action if the TIN is comprised entirely of ACO providers and suppliers meeting certain special statuses, including being located in a HPSA or rural area (as we further defined those in the CY 2027 PFS proposed rule). Because we have not received comments opposing the HPSA and rural areas as special statuses as they relate to the Shared Savings Program CEHRT use metric attestation exclusions, and these exclusions are consistent with commenters' request that we offer special consideration for small or rural practices, we are finalizing these exclusions as proposed.

Overall, we believe the new proposed requirements and exclusions represent a decrease in burden for ACOs to meet the Shared Savings Program CEHRT use requirements, and we will not be finalizing additional exclusions for § 425.507(c) at this time.

Comment: Several commenters mentioned exceptions to Shared Savings Program CEHRT use requirements related to hardships or other situations. A commenter recommended that we maintain reasonable exclusions for variables outside the ACO's control, including technology limitations, vendor issues, cybersecurity incidents, and other circumstances. A commenter suggested hardship exclusions be aligned with MIPS, and another recommended that hardship and special-status exclusions should be simple and, wherever feasible, automatic.

Response: We acknowledge the request for additional exclusions. We agree that providing certain exclusions is important, but we believe that additional exclusions are not necessary because the proposed policy provides multiple pathways for ACOs to demonstrate CEHRT use, enabling flexibility for a variety of ACOs to meet CEHRT requirements for the Shared Savings Program.

Regarding the suggestion that exceptions should be simple and automatic, we proposed that ACOs electing the option to attest to a Shared Savings Program CEHRT use metric would not be required to request

[311] Please refer to the PY 2026 Traditional MIPS Scoring Guide: *https://qpp.cms.gov/content-management/resources/document/6051c5a1-fb0b-463c-a863-00fb769629e8/download/file.*

hardship exceptions for Shared Savings Program CEHRT use requirements but would be required to maintain documentation substantiating them to provide to CMS in the event of an audit. Similarly, ACOs would determine whether a participant TIN is comprised solely of ACO providers and suppliers meeting special status.

Regarding the suggestion that hardship exclusions align with MIPS, we note that we proposed to allow ACOs to exclude from CEHRT use metric attestation any TIN comprised solely of ACO providers and suppliers meeting hardship circumstances that parallel those available by request from MIPS (91 FR 44064 and 44065). We did not propose that ACOs or their ACO providers and suppliers would be required to request a hardship approval but rather, that they would need to maintain documentation to provide to CMS in the event of an audit.

Comment: A commenter suggested we allow an ACO-level exclusion if a threshold proportion of its participating providers or suppliers meet an existing exclusion or reweighting criteria for the MIPS Promoting Interoperability performance category.

Response: We appreciate the recommendation regarding additional exclusions, but we do not agree that an ACO should be excluded from Shared Savings Program CEHRT use requirements if some proportion of its ACO providers or suppliers meet an existing exclusion or reweighting criteria. Unlike MIPS, which requires individual or group practice-level Promoting Interoperability performance category reporting, the proposed Shared Savings Program CEHRT use options would leverage eCQM or Medicare eCQM quality measure reporting or permit ACO-level attestation. Under our proposed policy, ACOs electing to attest to CEHRT use metrics would only need to attest that a single ACO provider or supplier in each ACO participant TIN performed the activity required by the metric.

Comment: A couple of commenters expressed concerns about what they perceive to be unnecessary administrative burden and duplicative reporting.

Response: We appreciate the input. We disagree that the proposed Shared Savings Program CEHRT use options would create duplicative reporting requirements. We proposed that Shared Savings Program CEHRT use requirements would be applicable at the ACO level. ACOs are not required to report Promoting Interoperability at the ACO level to MIPS, and the proposed Shared Savings Program CEHRT requirements do not require practice-level reporting. Therefore, we do not believe the Shared Savings Program CEHRT use requirements impose a duplicate reporting requirement as compared to MIPS. We also wish to clarify that, for ACOs electing the option at § 425.507(c)(1), to meet Shared Savings Program CEHRT use requirements by using CEHRT that meets the requirements described in that section to completely report at least one of the measures in the APP Plus quality measure set using the eCQMs or Medicare eCQMs collection types and meet the data completeness requirement at § 414.1340 of this chapter for the applicable PY, would simultaneously contribute to the ACO's compliance with the CEHRT use requirement and the ACO's compliance with the requirements under §§ 425.508 and 425.510 to report quality data on the APP Plus quality measure set established under § 414.1367. This is intended to reduce administrative burden.

Comment: A commenter requested that we ensure that the proposed CEHRT use changes would not adversely affect or weaken the data quality used for quality reporting requirements.

Response: We appreciate the comment and agree that the new CEHRT use requirements should not diminish quality measurement data. The Shared Savings Program CEHRT use options we proposed would not impact quality measure reporting requirements. ACOs would still be required to capture data required to meet Shared Savings Program quality measure reporting requirements, regardless of which of the proposed Shared Savings Program CEHRT use options they elect.

Comment: A commenter requested that CMS simplify the CEHRT use framework where possible, expressing their belief that multiple options create complexity.

Response: We acknowledge the feedback. The multiple options are intended to give ACOs flexibility in being able to demonstrate use of CEHRT, and that may help them choose an option that takes into account their organizational structure, how they aggregate information across their ACOs and other ACO characteristics. Because we believe we have appropriately balanced any added complexity with the flexibility we believe to be beneficial to ACOs, we are not considering narrowing the proposed options at this time because this would limit flexibility for ACOs to demonstrate CEHRT use.

Comment: Several commenters agreed with the proposed public reporting requirements and suggest finalizing as proposed. Some commenters specifically expressed support for sunsetting the current public reporting requirements and replacing them with reporting on the allowable CEHRT use activities attested to or performed. A commenter supported the straightforward public reporting requirement as proposed because it does not impose unnecessary reporting friction.

Response: We appreciate the support. We agree that the proposed public reporting requirements (91 FR 44065 and 44066) are intended to simplify ACOs reporting to publicly demonstrate CEHRT use.

Comment: A few commenters requested additional clarification regarding public reporting expectations, and one of these also suggested we evaluate whether CEHRT utilization data would provide meaningful information to beneficiaries.

Response: We appreciate the recommendations. We agree that clear documentation and public reporting expectations are important and direct commenters to the proposed requirement in section III.G.4.b.(4) of this final rule, where we state our proposal for § 425.308 to require ACOs to publicly report which allowable CEHRT use activity in proposed § 425.507(c) the ACO has selected to perform to meet CEHRT use requirements for the Shared Savings Program. The Shared Savings Program will continue to provide public reporting guidance, including a template for ACOs to provide information they are required to report with ACOs, to facilitate their compliance with this public reporting requirement. We note that while one purpose for publicly reported information is to inform beneficiary choice and understanding, we also believe such information can be helpful to potential ACO participants. Beneficiaries and potential ACO participants may have an interest in how an ACO is advancing FHIR-based digital quality measurement and health information exchange. We also believe that public reporting can support program transparency and oversight by making information about how the program is executed in practice available to beneficiaries, participants, and other interested parties. We will continue to consider the benefit of public reporting of Shared Savings Program CEHRT use.

After considering public comments, we are finalizing the Shared Savings Program CEHRT use requirements as proposed and are finalizing the public

reporting requirement as proposed. Specifically, we are finalizing as proposed our requirements for meeting Medicare Shared Savings Program CEHRT use requirements at § 425.507 as follows:

- Revise paragraph (a) to remove the introductory phrase that made the paragraph applicable to performance years beginning on or after January 1, 2025 and adding in its place an introductory phrase that would limit its applicability to performance years 2025 and 2026.
- Revise paragraph (b) by adding an introductory phrase that would limit its applicability to performance years 2025 and 2026.
- Add new paragraph (c) to specify that, for PYs beginning on or after January 1, 2027, an ACO would be required to demonstrate the use of CEHRT as defined at paragraph (3) of the CEHRT definition at § 414.1305 in one of the following manners:

++ Use CEHRT (as defined in paragraph (3) of the CEHRT definition at § 414.1305) that also supports the calculation and reporting of clinical quality measures by being certified to the ONC health IT certification criteria at 45 CFR 170.315(c)(2) and (c)(3) to completely report at least one of the measures in the APP Plus quality measure set using the eCQMs or Medicare eCQMs collection types and meets the data completeness requirement at § 414.1340 of this chapter for the applicable PY.

++ Completely report at least one measure in the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this chapter for the applicable performance year using EHR technology that meets paragraph (3) of the CEHRT definition at § 414.1305 and attests that it used data collected from an HL7® Fast Healthcare Interoperability Resources (FHIR®)-based API to support quality measurement using a Health IT module (as defined in 45 CFR 170.102) that has been certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access.

++ Attest to at least one of the Shared Savings Program CEHRT use metrics from the list of metrics established for the applicable PY.

We are also finalizing as proposed our policy to revise the public reporting requirements, at § 425.308(b) as follows:

- Revise paragraph (b)(9) to remove the introductory phrase that made the subsequent requirements applicable to performance year 2025 and subsequent performance years, and limiting them to performance years 2025 and 2026.
- Add new paragraph (b)(11) to specify that for performance year 2027 and subsequent PYs, the ACO must publicly report the CEHRT use activity selected by the ACO for the purpose of meeting the ACO CEHRT use requirement at § 425.507(c).

We are finalizing the following three CEHRT use metrics which would be available for PY 2027, for ACOs electing to attest to at least one of the Shared Savings Program CEHRT use metrics from the list of metrics established for the applicable performance year:

TABLE B-G9: PY 2027 AVAILABLE METRICS FOR SHARED SAVINGS PROGRAM ACO CEHRT USE ATTESTATION

MIPS Promoting Interoperability Performance Category Objective	Shared Savings Program ACO CEHRT Use Metric and Description
A. Electronic Prescribing	ACO Electronic Prescribing: At least one permissible prescription was written by an ACO provider or supplier in each of the ACO's participating TINs (except any TIN that had fewer than 100 permissible prescriptions in the performance period) and the prescription was transmitted electronically using CEHRT.
B. Health Information Exchange	ACO Health Information Exchange Bi-Directional Exchange: At least one ACO provider or supplier from each of the ACO's participating TINs participated in HIE bi-directional exchange for at least one patient with an HIE that has the capability to enable secure, bi-directional exchange for all patients, without excluding exchange partners, using CEHRT.
C. Provider to Patient Exchange	ACO Provider to Patient Exchange: At least one ACO provider or supplier from each of the ACO's participant TINs provided at least one patient electronic access to their health information using CEHRT.

As mentioned previously in this section, ONC proposed in the HTI–5 Proposed Rule (90 FR 60998), to remove the criteria in 45 CFR 170.315(g)(7) and (g)(9) as of January 1, 2027. We stated in the CY 2027 PFS proposed rule that if ONC finalized these proposals, we would no longer require ACOs to use health IT certified to the removed criteria to meet the measure (91 FR 44063). We note that ONC did finalize the removal of the criteria in 45 CFR 170.315(g)(7) and (g)(9) as of January 1, 2027, in their HTI–5 final rule (91 FR 67963 through 67965). Accordingly, we are not finalizing that ACOs electing to attest to the ACO Provider to Patient Exchange metric would need to attest to having used health IT certified to the removed criteria to meet the measure. As we stated we would, in the event that the criteria at 45 CFR 170.315(g)(7) and (g)(9) were finalized for removal, we are finalizing instead that an ACO electing to attest to the ACO Provider to Patient Exchange metric will be required to attest to having used health IT certified to the ''view, download, and transmit to third party'' criterion in 45 CFR 170.315(e)(1) to provide view, download, or transmit capabilities to patients and to the ''standardized API for patient and population services'' criterion in 45 CFR 170.315(g)(10), to meet the requirements of this Shared Savings Program ACO CEHRT use metric. We summarize the required certification criteria to complete the actions of each Shared Savings Program CEHRT use metric in Table B–G10: For ACOs electing to attest to one of the three available ACO CEHRT use metrics,

they would be required to attest that they used CEHRT that meets the requirements in paragraph (3) of the CEHRT definition at § 414.1305 (which includes the 45 CFR 170.102 *Base EHR* definition that includes 45 CFR 170.315 (g)(10)—*Standardized API for patient and population services*), in addition to the following criteria:

TABLE B-G10: CEHRT CERTIFICATION CRITERIA FOR SHARED SAVINGS PROGRAM ACO CEHRT USE METRICS

Metric	Certification Criteria
ACO Electronic Prescribing	"Electronic prescribing" criterion in 45 CFR 170.315(b)(3)
ACO Provider-to-Patient Exchange	"View, download, and transmit to third party" criterion in 45 CFR 170.315(e)(1)
ACO HIE Bi-Directional Exchange	Criterion supporting connection to an HIE, which could include but is not limited to: - "Transitions of care" criterion in 45 CFR 170.315(b)(1) (part of Base EHR definition); - "Clinical information reconciliation and incorporation" criterion in 45 CFR 170.315(b)(2); or - "Standardized API for patient and population services" criterion at 45 CFR 170.315(g)(10) (part of Base EHR definition).

5. Financial Methodology

a. Overview

As explained in the CY 2027 PFS proposed rule, the Shared Savings Program has demonstrated a strong track record of generating savings for Medicare while achieving high quality care for beneficiaries assigned to ACOs (91 FR 44067). For example, the Shared Savings Program has had eight consecutive years of generating savings for Medicare relative to benchmarks, with over $12 billion in total savings and a trend of increasing savings year-over-year between 2017 and 2024. As described in the CY 2026 PFS final rule Regulatory Impact Analysis (90 FR 49975 through 49976) and in the regulatory impact section of the CY 2027 PFS proposed rule, the Shared Savings Program has maintained a net savings percentage on total FFS spending of 0.5 percent (91 FR 44067). At the same time, ACOs in the Shared Savings Program have demonstrated higher quality relative to other physician groups, indicating that the Shared Savings Program is achieving savings while improving quality of care. For example, in PY 2024, Shared Savings Program ACOs helped more patients improve markers of good health, such as controlled blood pressure, hemoglobin A1c control (an indicator for diabetes), and depression screening with a follow-up plan, compared to 2023.[312] In PY 2024, nearly all ACOs outperformed similar types of physician groups on quality measures. As described in the CY 2027 PFS proposed rule, based on an internal CMS analysis of 87 ACOs that participated continuously in the Shared Savings Program between 2014 and 2023, Shared Savings Program ACOs showed statistically significant and substantial improvement across 7 comparable CMS Web Interface quality measures used during that period where quality performance improved across a wide range of clinical practice areas including screening and preventive measures, control of health conditions such as hypertension and diabetes (91 FR 44067). ACOs have performed consistently better than comparable physician groups on the patient experience survey measure, Getting Timely Care, Appointments, and Information, for every year that the survey has been fielded since 2019 (91 FR 44067).

Based on the experience of the Shared Savings Program and as part of our effort to align spending and value in OM, we are focused on developing policies that would grow the number of healthcare providers and beneficiaries in accountable care relationships and grow savings to the Medicare Trust Funds while improving the quality of care for beneficiaries. To achieve these goals, in the CY 2027 PFS proposed rule, we proposed several complementary modifications to the benchmarking and financial methodology under the Shared Savings Program to encourage new and sustained participation by ACOs in the program (91 FR 44067). Specifically, we proposed to: (1) increase the sharing rate under BASIC track Level E (91 FR 44068 through 44072), (2) reduce the weight on the regional adjustment for ACOs in the ENHANCED track (91 FR 44072 through 44076), (3) modify the prior savings adjustment to increase the scaling factor (91 FR 44076 through 44082), (4) risk adjust the 5 percent cap on upward adjustments to the historical benchmark (91 FR 44082 through 44087), (5) incentivize new participation through a growth adjustment (91 FR 44091 through 44103), and (6) reform the Accountable Care Prospective Trend (ACPT) component of the benchmark update factor to address projection error and allow for greater consistency in the calculations across agreement periods (91 FR 44103 through 44114).

Across the financial methodology proposals described in the CY 2027 PFS proposed rule, 91 FR 44068 through 44072 (proposal to increase the sharing rate under BASIC track Level E), 91 FR 44072 through 44076 (proposal to reduce the weight on the regional adjustment for ENHANCED track ACOs), and 91 FR 44076 through 44082 (proposal to modify the prior savings adjustment scaling factor), we described our observations of recurring patterns, that ENHANCED track ACOs receive larger positive regional adjustments than BASIC track ACOs, which inflate benchmarks and increases the probability of generating gross savings independent of operational efficiencies. At the same time, as discussed in the CY 2027 PFS proposed rule (91 FR 44068 through 44072), BASIC track Level E ACOs generate higher net savings for the Trust Funds despite lower gross savings, as the 75 percent shared savings rate under the ENHANCED track requires

[312] Medicare Shared Savings Program Performance Year 2024 Financial and Quality Results Fact Sheet, *https://www.cms.gov/files/document/fact-sheet-ssp-py24-financial-quality-results.pdf.*

disproportionately higher gross savings to achieve equivalent net outcomes for the Trust Funds. Combined analyses described in the CY 2027 PFS proposed rule (91 FR 44072 through 44076; 91 FR 44076 through 44082) further show that the interaction of regional adjustment weighting, prior savings scaling, and track—specific sharing rates may incentivize ACOs to progress into the ENHANCED track based on benchmark generosity rather than demonstrated capacity to reduce expenditures. Together, these overlapping findings support the recalibration of incentives reflected in our proposals discussed in these sections—namely increasing the BASIC track Level E sharing rate, lowering the positive regional adjustment weight applied to ENHANCED track ACOs, and strengthening the prior savings adjustment methodology—to better align benchmark dynamics with underlying efficiency, reduce distortions driven by regional cost variation, and reinforce long—term net savings objectives for the Shared Savings Program.

b. Summary of Statutory and Regulatory Background on Adjusting the Historical Benchmark

As discussed in the CY 2027 PFS proposed rule, section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established, updated, and reset at the start of each agreement period under the Shared Savings Program (91 FR 44067). This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for OM beneficiaries assigned to the ACO. The benchmark shall be reset at the start of each agreement period. Section 1899(d)(1)(B)(ii) of the Act also provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Under this authority, over time we have adopted a variety of methods to adjust the historical benchmark to meet certain policy goals.

Benchmarking policies applicable to all ACOs in agreement periods beginning on January 1, 2024, and in subsequent years, are specified at § 425.652. We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (see November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991; December 2018 final rule, 83 FR 68005 through 68030; CY 2023 PFS final rule, 87 FR 69875 through 69928; CY 2024 PFS final rule, 88 FR 79174 through 79208; CY 2025 PFS final rule, 89 FR 98155 through 98203; and CY 2026 PFS final rule, 90 FR 49831 through 49835).

In the CY 2023 PFS final rule, we adopted policies to modify the regional adjustment under § 425.656 (87 FR 69915 through 69923) and to reinstate a prior savings adjustment under § 425.658 (87 FR 69898 through 69915). The modifications to the regional adjustment were designed to limit the impact of negative regional adjustments on ACO historical benchmarks and further incentivize program participation among ACOs serving high-cost beneficiaries (87 FR 69916). We also reinstated the prior savings adjustment policy, such that a renewing or re-entering ACO may be eligible to receive an adjustment to its benchmark to account for savings generated in performance years that correspond to the benchmark years of its new agreement period (87 FR 69898 through 69915).

In the CY 2024 PFS final rule (88 FR 79185 through 79196), we modified the regional adjustment policy further to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment. We modified the prior savings adjustment policy further to account for the following: a change in savings earned by the ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries or a change in the amount of savings or losses for a benchmark year as a result of a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315 (88 FR 79196 through 79200).

In the CY 2025 PFS final rule (89 FR 98155 through 98167), we finalized a health equity benchmark adjustment (HEBA) (revised to the ''population adjustment'' in the CY 2026 PFS final rule (90 FR 49831 through 49835)) that adjusts upward some ACOs' historical benchmarks based on the number of beneficiaries the ACO serves who are dually eligible or enrolled in the Medicare Part D and receive the Low-Income Subsidy (LIS).

c. Changes to the Shared Savings Program Financial Methodology To Encourage Additional Savings in Two-Sided Risk

(1) Increase the Sharing Rate Under Level E of the BASIC Track

(a) Background

As finalized in the December 2018 final rule (83 FR 67831 through 67841), for agreement periods beginning on July 1, 2019, and in subsequent years, eligible ACOs enter into an agreement period of not less than 5 years under one of two tracks of the Shared Savings Program, either the BASIC track (see §§ 425.600(a)(4) and 425.605) or the ENHANCED track (see §§ 425.600(a)(3) and 425.610).

As finalized in the December 2018 final rule (83 FR 67841 through 67857), the BASIC track includes a glide path from one-sided model Levels A and B to incrementally higher levels of performance-based risk under Levels C, D, and E. The ENHANCED track offers the highest level of risk and potential reward under the Shared Savings Program. Level E of the BASIC track and the ENHANCED track each qualify as an Advanced APM under the Quality Payment Program. In rulemaking following the December 2018 final rule, we modified the approach for determining an ACO's eligibility for participation options in the BASIC track and ENHANCED track, along with the number of performance years an ACO may remain under a one-sided model of the BASIC track's glide path.[313] In the CY 2027 PFS proposed rule we discussed that we provide select regulatory background on our establishment of the BASIC track's glide path, and relatedly the level of risk and potential reward under the glide path, as well as our considerations for ACOs' progression from participation in BASIC track Level E to the ENHANCED track (91 FR 44068).

With the December 2018 final rule (83 FR 67863 through 67922), we established an approach for determining an ACO's eligibility for participation options in the BASIC track and ENHANCED track, based on a combination of factors: ACO participants' Medicare FFS revenue (low revenue ACOs versus high revenue

[313] We refer readers to discussions in earlier rulemaking, including: December 2018 final rule (83 FR 67863 through 67922); May 8, 2020 COVID–19 IFC (85 FR 27575 and 27576) and CY 2021 PFS final rule (85 FR 84767 through 84769); Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule (86 FR 45502 through 45506); CY 2023 PFS final rule (87 FR 69805 through 69821); and CY 2026 PFS final rule (90 FR 49760 through 49775).

ACOs) and the experience of the ACO legal entity and its ACO participants with performance-based risk Medicare ACO initiatives. We finalized an approach under § 425.600(d) where ACOs eligible for the BASIC track's glide path that are inexperienced with performance-based risk Medicare ACO initiatives would have the flexibility to enter the glide path at any one of the five levels, with a limited exception under § 425.600(a)(4)(i)(B)(*1*) (see, for example, 83 FR 67904 through 67905). With the December 2018 final rule, we finalized provisions on the progression of ACOs along the BASIC track's glide path under § 425.600(a)(4)(i)(B), and finalized an approach to allow ACOs in the BASIC track's glide path to take on higher risk and potential reward within their current agreement period by more rapidly progressing along the glide path (see 83 FR 67844, and 67858 through 67859; and § 425.226(a)(2)). We also finalized that the BASIC track's highest Level of risk and potential reward (Level E) may be elected for any performance year by ACOs that enter the BASIC track's glide path, but it will be required no later than the ACO's fifth performance year of the glide path (83 FR 67844; 67850).[314]

To provide incentives for ACOs to move towards higher levels of performance-based risk, we limited the amount of potential shared savings under the one-sided model of the BASIC track (Levels A and B), while offering higher potential reward in relation to each level of higher risk as ACOs under the two-sided model levels of the BASIC track (Levels C, D and E) (see, for example, 83 FR 67848 and 67849). We explained in the December 2018 final rule that ACOs have reduced incentives to enter or remain in a one-sided model of the BASIC track's glide path if they are prepared to take on risk, and we anticipated that ACOs would seek to accept greater performance-based risk in exchange for the chance to earn greater reward (see 83 FR 67844).

In the December 2018 final rule, we stated that the approach to determining the maximum amount of shared losses under BASIC track Level E strikes a balance between (1) placing ACOs under a higher Level of risk to recognize the greater potential reward under this financial model and the additional tools and flexibilities available to BASIC track ACOs under performance-based risk and (2) establishing an approach to help ensure the maximum Level of risk under the BASIC track remains moderate (83 FR 67845). Further, this approach recognizes that eligible ACOs in Level E have the opportunity to earn the greatest share of savings under the BASIC track, and should therefore be accountable for a higher share of losses, particularly in light of their access to tools for care coordination and beneficiary engagement. We finalized higher maximum sharing rates for ACOs participating in two-sided levels of the BASIC track as a means of encouraging participation in the program and potentially providing greater resources to ACOs to support their transition to performance-based risk (87 FR 69951).

In the CY 2023 PFS final rule (87 FR 69819 through 69821), we removed the cap on the number of performance years an ACO was allowed to participate in BASIC track Level E, allowing ACOs to continue to participate in BASIC track Level E in future agreement periods and not requiring ACOs to advance to the ENHANCED track. We explained that, in our implementation of the Shared Savings Program, we intend to achieve larger programmatic goals by encouraging ACO participation and thereby promoting high quality, value-based care for OM beneficiaries (87 FR 69819). We continuously seek to balance creating sufficient incentives for participation in a voluntary program with ensuring that our policies achieve program goals to increase quality of care for Medicare beneficiaries and reduce expenditure growth to protect the Trust Funds. Accordingly, we discussed our belief that it would be in the best interest of the program and OM beneficiaries to permit eligible ACOs to continue participating under BASIC track Level E, rather than risk significant numbers of experienced, successful ACOs terminating their participation in the program instead of progressing to the higher level of risk and potential reward under the ENHANCED track (87 FR 69819). Our experience as of the CY 2023 PFS final rule showed that ACOs in BASIC track Level E and ACOs in the ENHANCED track had similar performance results (we have since gained additional experience as discussed later in this section, that shows ACOs in BASIC track Level E produce greater net savings for CMS compared to ACOs in the ENHANCED track). We noted our belief that it is important to offer the option to remain in BASIC track Level E, to encourage ACOs that may be ready to take on the higher level of risk and potential reward under the ENHANCED track to progress to that participation option, secure in the knowledge that the more moderate level of risk and potential reward under BASIC track Level E would be available to the ACO in the future if the ACO concludes based on experience that that participation option is more appropriate for the ACO than the ENHANCED track (87 FR 69819).

We refer readers to the provisions of BASIC track under § 425.605, and the ENHANCED track under § 425.610, for policies on the calculation of shared savings and losses under each track/level (as applicable). With the CY 2026 PFS final rule (90 FR 49782 through 49783), we provided a summary of the level of risk and potential reward under Levels A through E of the BASIC track and ENHANCED track. In the following discussion we provide a consolidated summary.

In general, an ACO that meets or exceeds its minimum savings rate (MSR), and otherwise qualifies for a shared savings payment, shares in savings at a sharing rate specified by the ACO's participation track (and level, if applicable), not to exceed a performance payment limit (a percentage of the ACO's updated historical benchmark).[315] [316] An ACO under a two-sided model that meets or exceeds its minimum loss rate (MLR) shares in losses at a shared loss rate [317] specified by the ACO's participation track (and level, if applicable), not to exceed a loss recoupment limit (a percentage of the ACO's updated historical benchmark).

Under Levels A and B of the BASIC track (§ 425.605(d)(1)(i) and (ii)), ACOs may share in savings at a sharing rate of up to 40 percent, not to exceed 10 percent of the updated benchmark. Levels C, D, and E of the BASIC track (§ 425.605(d)(1)(iii), (iv) and (v)) each offer a sharing rate of up to 50 percent capped at 10 percent of the updated benchmark, with a fixed 30 percent loss sharing rate in each level's two-sided model. The loss recoupment limits increase across these levels. Under Level C (§ 425.605(d)(1)(iii)(D)), an ACO's shared losses may not exceed 2 percent of total Medicare Parts A and B

[314] In in the December 2018 Final Rule (83 FR 67844 through 67846) we also described advancing to Level E would be required for ACOs in their fourth performance year if they previously participated in Track 1, or new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO.

[315] We note that provisions of §§ 425.605(d)(1) and 425.610(d) refer to the applicable ''final sharing rate'', which we sometimes refer to as the ''sharing rate'' (for brevity), or alternatively the ''shared savings rate''. We consider these terms synonymous.

[316] There is a limited exception for eligible low revenue ACOs participating under the BASIC track, under which an ACO that does not meet the MSR requirement but meets other criteria may qualify for a shared savings payment, at a lower sharing rate, in accordance with § 425.605(h).

[317] We note that the ''shared loss rate'' is also referred to as the ''loss sharing rate''.

FFS revenue of the ACO participants in the ACO capped at 1 percent of updated benchmark. Under Level D (§ 425.605(d)(1)(iv)(D)), an ACO's shared losses may not exceed 4 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 2 percent of updated benchmark. Under Level E (§ 425.605(d)(1)(v)(D)), an ACO's shared losses may not exceed 8 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 4 percent of updated benchmark. Under Level E, the loss recoupment limit is the percentage of revenue specified in the revenue-based nominal amount standard under the Quality Payment Program (QPP) (42 CFR 414.1415(c)(3)(i)(A)) capped at 1 percentage point higher than the expenditure-based nominal risk amount (§ 414.1415(c)(3)(i)(B)). Under the ENHANCED track (§ 425.610), ACOs may share in savings at up to 75 percent (§ 425.610(d)), not to exceed 20 percent of the updated benchmark (§ 425.610(e)), and share in losses at a rate of 40 to 75 percent (§ 425.610(f)), capped at 15 percent of the updated benchmark (§ 425.610(g)). Since the establishment of the ENHANCED track (formerly named Track 3) with the June 2015 final rule (see 80 FR 32778 through 32779), and the BASIC track's glide path with the December 2018 final rule (as previously described in this section), we have not modified the maximum upside potential reward with the final sharing rates or downside potential risk with the loss sharing rates under each track/level (as applicable).

(b) Revisions

In the CY 2027 PFS proposed rule we stated that in 2020, the first full performance year under the glide path, 13.5 percent of ACOs in the Medicare Shared Savings Program participated under BASIC track Level E (91 FR 44069). As ACOs became more experienced and progressed through the glide path, participation in BASIC track Level E experienced modest increases, which peaked in PY 2023 at 27.2 percent. As of PY 2026, participation in BASIC track Level E decreased to 16 percent.

We discussed in the CY 2027 PFS proposed rule that the disparity in sharing rates between the highest risk option under the BASIC track (BASIC track Level E) and the next highest risk option (ENHANCED track) has potentially disproportionately driven ACOs to take on the maximum risk allowed (91 FR 44069). For PY 2026, 58 percent of ACOs are participating in the ENHANCED track. This in part is likely a result of the 40 percent sharing rate in Levels A and B of the BASIC track and 50 percent sharing rate in Levels C, D, and E of the BASIC track, compared to the 75 percent sharing rate in the ENHANCED track. We noted that, based on current participation trends across the various risk tracks, we anticipate that the participation in BASIC track Level E may continue a downward trend as a percentage of total participation unless some action is taken (91 FR 44070). We stated that we believe that some ACOs cease longer term program participation in BASIC track Level E before they otherwise would because they transition to the ENHANCED track based on the incentives of the higher sharing rate, and this transition occurs before they're ready for the increased demands associated with the higher risk track (91 FR 44070). We added that decreased Shared Savings Program retention rates of ACOs that transition too quickly to the ENHANCED track, in combination with the decreased net savings rates associated with the ENHANCED track, ultimately result in decreased savings for the Medicare Trust Fund (91 FR 44070). Table B–G11 summarizes the distribution of ACO participation across the various risk tracks for PY 2022 through CY 2026.

TABLE B-G11: COUNT OF ACOS PARTICIPATING IN BASIC TRACK LEVELS AND ENHANCED TRACK FOR PYS 2022 THROUGH 2026

Performance Year	Total	BASIC Track			ENHANCED Track
		Levels A and B	Levels C and D	Level E	
PY 2022	483	199 (41%)	40 (8%)	98 (21%)	146 (30%)
PY 2023	456	151 (33%)	19 (4%)	125 (28%)	161 (35%)
PY 2024	480	159 (33%)	10 (2%)	104 (22%)	207 (43%)
PY 2025	476	137 (29%)	5 (1%)	81 (17%)	253 (53%)
PY 2026	511	121 (24%)	12 (2%)	82 (16%)	296 (58%)

As discussed in the CY 2027 PFS proposed rule, while we still have the goal of ACOs transitioning to performance-based risk, we want to be conscious of long-term impacts to the Shared Savings Program related to participation, success, and growth (91 FR 44070). We stated that participation in the ENHANCED track is a positive, but we believe that some ACOs may be taking on additional risk more quickly than they otherwise would because the ENHANCED track offers a 50 percent increase in savings compared to BASIC track Level E, while both tracks include two-sided risk (91 FR 44070). We noted that, if ACOs progress to higher levels of risk before they are adequately prepared, they may take on too much risk with higher shared losses rates in the ENHANCED track, potentially resulting in program termination and a subsequent reduction in both program participation and care coordination for beneficiaries (91 FR 44070). We stated our belief that by reducing the savings percentage gap between BASIC track Level E and the ENHANCED track, we may increase participation in BASIC track Level E as well as the Shared Savings Program and increase long-term success of ACOs, particularly those with less experience, with unique patient or provider populations, and low revenue ACOs (which tend to be small, rural and physician-only ACOs) (91 FR 44070).

Additionally, in the CY 2027 PFS proposed rule we shared a data analysis from the CMS Office of the Actuary of benchmark performance for cohorts of ACOs that participated in both PY 2022 and PY 2023 indicates that ACOs participating in the BASIC track generated 42 percent higher net savings for CMS as a percentage of their benchmark than ACOs transitioning to or continuing participation in the ENHANCED track, despite favorable regional adjustments likely inflating gross savings for ACOs under the ENHANCED track (91 FR 44070). We noted that an analysis of PY 2024 financial performance also indicated that net savings for the Trust Funds

remained higher on average for BASIC track ACOs (91 FR 44070). We stated that this is also largely due to the 50 percent differential in sharing rate currently present between BASIC track Level E and the ENHANCED track, which resulted in ENHANCED track ACOs needing to generate twice the gross savings to equal the same net savings for the Trust Funds as ACOs participating under BASIC track Level E (91 FR 44070). We stated, for example, if an ACO participated in BASIC track Level E and generated $2,000,000 in gross savings, and the ACO received the maximum sharing rate of 50 percent, the ACO would receive a $1,000,000 shared savings payment and net savings for the Trust Funds would be $1,000,000 (91 FR 44070). We noted that if this same ACO participated in the ENHANCED track and generated $2,000,000 in gross savings, and the ACO received the maximum sharing rate of 75 percent, the ACO would receive a $1,500,000 shared savings payment and net savings for the Trust Funds would be $500,000 (91 FR 44070). We concluded that to generate the same net savings for the Trust Funds, the ENHANCED track ACO would need to have generated twice the gross savings, $4,000,000, to have generated $1,000,000 ($4,000,000 × 25 percent) net savings for the Trust Funds (91 FR 44070). We stated that, for PY 2024, gross savings was higher for the ENHANCED track ACOs, but net savings as a percentage of gross savings and per capita net savings are higher for ACOs participating in BASIC track Level E, as shown in Table B–G12 (91 FR 44070).

TABLE B-G12: PY 2024 GROSS AND NET SAVINGS FOR BASIC TRACK LEVEL E AND ENHANCED TRACK

Risk Track	Aggregate Gross Savings/Losses	Aggregate Net Savings/Losses	Per Capita Net Savings/Losses	Net Savings as a percent of Gross Savings
BASIC Track Level E	$1,114,104,073	$555,399,727	$286	50%
ENHANCED Track	$4,224,728,667	$1,129,061,411	$206	27%

We stated in the CY 2027 PFS proposed rule that, as we seek to increase the percentage of Medicare beneficiaries in accountable care arrangements, we are balancing incentives and participation options to serve the dual purposes of sustaining participation by existing ACOs and increasing program growth, recognizing that ACOs vary in their composition of providers/suppliers, the needs of the populations they serve, and have varying degrees of efficiency relative to their region and experience with accountable care initiatives (91 FR 44071). We also reiterated our intention to achieve larger programmatic goals by encouraging ACO participation and thereby promoting high quality, value-based care for OM beneficiaries (91 FR 44071). We stated that we continuously seek to balance creating sufficient incentives for participation in a voluntary program while ensuring that our policies achieve program goals to increase quality of care for Medicare beneficiaries and reduce expenditure growth to protect the Trust Funds (91 FR 44071).

In the CY 2027 PFS proposed rule, we stated that trends in recent performance years indicate ACOs participating in BASIC track Level E have roughly one-third fewer assigned beneficiaries and participating providers than ACOs participating in the ENHANCED track (91 FR 44071). Understanding that ACOs participating in BASIC track Level E face additional obstacles to success given their different compositions and experience, we stated our belief that narrowing the gap in sharing rates between these two tracks will encourage long-term participation and growth in the Shared Savings Program by encouraging less experienced ACOs to only progress to the ENHANCED track when they're adequately prepared to do so (91 FR 44071).

In the CY 2027 PFS proposed rule, we stated that increasing the sharing rate for BASIC track Level E presents an opportunity to reverse the decreased participation in the BASIC track, increase net savings opportunities for the Trust Funds, and increase program participation (91 FR 44071). We noted, however, that before considering whether to propose changes, we analyzed what change to the sharing rate was needed to ensure our goals were met without unintended consequences (91 FR 44071).

We noted, as we did when we established the BASIC track in the December 2018 final rule, we considered many sharing rates before arriving at our proposal (91 FR 44071). With the current sharing rate for BASIC track Level E set at 50 percent and ENHANCED track set at 75 percent, we analyzed in the CY 2027 PFS proposed rule alternative sharing rates for BASIC track Level E between 55 percent and 65 percent (41 FR 44071).

In the CY 2027 PFS proposed rule we noted that, for the 104 ACOs entering an agreement period beginning on January 1, 2024 that participated in BASIC track Level E, we found that if all else is equal, the increase in shared savings payments under the alternative sharing rates we considered for BASIC track Level E ranged between 9.1 percent and 22.8 percent (91 FR 44071). After considering other policy changes proposed in the CY 2027 PFS proposed rule , such as the proposal to reduce the weight on regional adjustment for ACOs under the ENHANCED track (91 FR 44072 through 44076) and the proposal to modify the prior savings adjustment to increase the scaling factor (91 FR 44076 through 44082), we determined a 65 percent sharing rate was too high to maintain a sufficient gap in incentives between the two tracks and a 55 percent sharing rate was an inadequate incentive to achieve our goals of increasing participation in the program and increasing savings to the Trust Funds (91 FR 44071).

In the CY 2027 PFS proposed rule, we stated that we believe that increasing the sharing rate to 60 percent for BASIC track Level E appropriately balances creating sufficient incentive to increase program participation and savings to the Trust Funds (91 FR 44071). We also stated that we believe that there would still be sufficient benefits for ACOs to take on the higher risk and reward offered under the ENHANCED track, so that ACOs would continue to progress the ENHANCED track when they're ready to take on those higher levels of risk and reward (91 FR 44071).

We proposed to increase the savings rate for BASIC track Level E from 50

percent to 60 percent for agreement periods beginning on or after January 1, 2027 (91 FR 44071). The proposal to apply a modified sharing rate for agreement periods beginning on or after January 1, 2027 would ensure we maintain a consistent sharing rate for Level E throughout the duration of an ACO's an agreement period under the BASIC track, in accordance with § 425.212(a).[318] We stated in the CY 2027 PFS proposed rule that closing the gap in the sharing rates between BASIC track Level E and the ENHANCED track would likely increase savings for the Trust Funds, while striking a better balance among incentivizing robust participation in the Shared Savings Program, incentivizing ACOs' move to two-sided risk, and offering a lower risk option than is offered under the ENHANCED track (91 FR 44071).

We shared in the CY 2027 PFS proposed rule an analysis of the PY 2024 financial results which indicates that the average impact of increasing the sharing rate for BASIC track Level E from 50 percent to 60 percent was an increase in shared savings payments of $1,348,867 and a total increase of $110,607,059 in shared savings payments for the 104 ACOs that participated in BASIC track Level E (91 FR 44071). We stated that, while the total shared savings payments for BASIC track Level E would increase under this proposal, we anticipate net savings to the Trust Funds to increase because of increased participation in the Shared Savings Program, higher retention of ACOs, and some ACOs opting to delay transition into the ENHANCED track (91 FR 44071).

We stated that under our approach, the current maximum 50 percent sharing rate under BASIC track Level E specified in § 425.605(d)(1)(v)(A)(*4*) (which is applicable for PYs beginning on or after January 1, 2024) would continue to apply to ACOs completing existing agreement periods in the BASIC track (91 FR 44071). Specifically, the maximum 50 percent sharing rate would apply in determining financial performance for a BASIC track ACO participating in an agreement period beginning on January 1, 2022, 2023, 2024, 2025, and 2026, that is participating in Level E for PY 2025 or any subsequent PY of the ACO's existing agreement period.

[318] In accordance with § 425.212(a), an ACO is subject to all regulatory changes that become effective during the agreement period, with the exception of the following program areas, unless required by statute: (1) eligibility requirements concerning the structure and governance of ACOs, and (2) calculation of the sharing rate.

We proposed to specify in a new paragraph (d)(1)(v)(A)(*5*) added to § 425.605 the sharing rate for BASIC track Level E, applicable for agreement periods beginning on or after January 1, 2027, for performance years beginning on or after January 1, 2027 (91 FR 44071 through 44072). Accordingly, we stated that this new paragraph would specify that an ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in § 425.605(d)(1)(v)(B)) (91 FR 44072). Except as provided in § 425.605(h) (which specifies an additional opportunity for an eligible low revenue BASIC track ACO to share in savings even if it does not meet the MSR requirement), the percentage would be as follows:

(1) 60 percent for an ACO that that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(2) 60 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

We also proposed technical and conforming changes to other provisions of § 425.605 (91 FR 44072). We proposed to revise the heading text in the first sentence of § 425.605(d)(1)(v)(A)(*4*) introductory text, to specify the provisions are applicable for ACOs in agreement periods beginning July 1, 2019, through January 1, 2026, for performance years beginning on or after January 1, 2024 (91 FR 44072). For completeness and clarity, we stated that this proposed heading text would be inclusive of ACOs participating in agreement periods beginning on July 1, 2019 and January 1, 2020, which were previously reconciled for participation in BASIC track Level E for the performance year beginning on January 1, 2024 (91 FR 44072). We noted that agreement periods of 5 years and 6 months beginning on July 1, 2019, and 5-year agreement periods beginning on January 1, 2020, concluded on December 31, 2024 (91 FR 44072). As we explained previously in this section of this final rule, the final sharing rate provisions specified under § 425.605(d)(1)(v)(A)(*4*) would continue to apply to ACOs participating in agreement periods beginning on January 1, 2022, 2023, 2024, 2025 and January 1, 2026, that would be reconciled for participation in BASIC track Level E for PY 2025 and any remaining PY of their agreement period (91 FR 44072). We also proposed to amend § 425.605(h)(2), describing calculation of the sharing rate applied to a low revenue BASIC track ACO eligible for the expanded opportunity to share in savings if it does not meet the MSR, to revise the existing list of cross-references to include a reference to new paragraph § 425.605(d)(1)(v)(A)(*5*) (91 FR 44072).

We also proposed several technical corrections to the regulations in § 425.605 (91 FR 44072). With the CY 2026 PFS final rule (see 90 FR 49816 through 49817, and 50018), we finalized amendments to phrasing in § 425.605, including in paragraphs (d)(1)(v)(A)(*3*)(*ii*) and (d)(1)(v)(A)(*4*)(*ii*) (describing the sharing rate applied under BASIC track Level E, by PY, for an ACO that meets the alternative quality performance standard). There were technical errors in the implementation of these finalized changes in the Code of Federal Regulations (CFR). We proposed the following technical corrections (91 FR 44072):

- To revise § 425.605(d)(1)(v)(A)(*3*)(*ii*) to read, 50 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).
- To revise § 425.605(d)(1)(v)(A)(*4*)(*ii*) to read, 50 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

We solicited comment on the proposal to increase the sharing rate under BASIC track Level E from 50 percent to 60 percent, applicable for ACOs in agreement periods beginning on or after January 1, 2027, for performance years beginning on or after January 1, 2027, and the proposal to specify related provisions in the Shared Savings Program regulations under new § 425.605(d)(1)(v)(A)(*5*), as well as proposed technical and conforming changes to § 425.605(d)(1)(v)(A)(*4*) introductory text and § 425.605(h)(2). We also sought comment on our proposed technical corrections to § 425.605(d)(1)(v)(A)(*3*)(*ii*) and (d)(1)(v)(A)(*4*)(*ii*). The following is a summary of the comments we received and our responses.

Comment: Most commenters supported our proposal to increase the BASIC track Level E shared savings rate from 50 percent to 60 percent. A commenter conditionally supported the proposal, provided that the increase

meaningfully helps organizations, particularly those serving rural and low-resourced communities, sustain the substantial investments required for accountable care, including care coordination, workforce capacity, health information technology, data analytics, quality improvement, and population health management. Many supportive commenters shared their beliefs that the higher sharing rate would better align rewards with the accountability required under value-based payment arrangements, narrow the incentive gap between BASIC track Level E and the ENHANCED track, and improve returns on the substantial infrastructure and operational investments needed to accept two-sided risk. Several commenters also stated that the proposal would make BASIC track Level E a more viable participation option for rural, low-revenue, and other ACOs that need additional time to build capacity before assuming the higher level of risk associated with the ENHANCED track, thereby supporting retention and continued participation. A few commenters further observed that smaller and physician-led ACOs can generate Medicare savings that increase over time, while another commenter stated that attracting high-cost ACOs to BASIC track Level E would preserve greater opportunities for Medicare to share in savings.

Response: We appreciate the support. We agree that increasing the shared savings rate for BASIC track Level E may better align financial rewards with the accountability associated with two-sided risk, narrow the incentive gap between BASIC track Level E and the ENHANCED track, and strengthen incentives for continued participation in the Shared Savings Program. We appreciate comments regarding the potential benefits for rural, low-revenue, and other ACOs, as well as the opportunity for ACOs to reinvest additional shared savings in care management, health equity, data and digital infrastructure, patient outreach, and clinician engagement. We recognize that ACOs may make substantial infrastructure and operational investments to participate in two-sided risk arrangements and that the increased sharing rate may strengthen the potential return on those investments.

Comment: A couple of commenters opposed increasing the BASIC track Level E shared savings rate, arguing that larger shared savings payments based on potentially flawed benchmarks could increase participation and payouts without increasing gross savings, thereby reducing or reversing net Medicare savings.

Response: We appreciate the comments regarding the potential effects of increasing the BASIC track Level E shared savings rate on the distinction between BASIC track Level E and the ENHANCED track. We agree that the Shared Savings Program should maintain incentives for ACOs to progress to higher levels of downside risk. We believe that increasing the maximum shared savings rate for BASIC track Level E from 50 percent to 60 percent appropriately strengthens incentives for ACOs participating under two-sided risk while preserving a meaningful distinction from the ENHANCED track, which retains a higher shared savings rate and requires a greater level of downside risk.

Comment: Many supportive commenters encouraged CMS to implement the proposed increase in the sharing rate alongside related benchmark reforms, stating that the combined changes would improve the financial return on the substantial infrastructure and organizational investments needed to accept two-sided risk. A commenter stated that the sharing rate increase and related changes could attract higher-cost ACOs to BASIC track Level E and preserve greater opportunities for Medicare to share in savings. Another commenter cautioned that CMS should preserve a meaningful financial advantage for ACOs that progress to the ENHANCED track and accept the highest level of downside risk, while maintaining incentives for organizations beginning the transition to value-based care.

Separately, a commenter remained neutral on the proposed changes to the BASIC track and regional adjustment, stating that the changes may meaningfully affect decisions between BASIC track Level E and the ENHANCED track for lower-spending, community-based ACOs but would have limited effect on higher-spending ACOs whose per-beneficiary costs exceed their benchmarks. Another commenter requested that CMS finalize benchmark rebasing changes and balance the incentives between the BASIC Level E and ENHANCED tracks to avoid penalizing ACOs serving higher-risk populations.

Response: We appreciate the recommendations regarding the interaction between the proposed increase in the BASIC track Level E shared savings rate and related benchmarking and track incentive policies. We agree that these policies should work together to provide appropriate incentives for ACOs to participate in two-sided risk arrangements while accounting for differences in organizational capacity and the populations they serve. As discussed elsewhere in section III.G. of this final rule, we are finalizing all proposed benchmarking policies after considering the comments received. We believe that the benchmarking policies we are finalizing are designed to ensure that shared savings payments reflect measurable performance against applicable benchmarks, and we will continue to monitor these benchmarking policies' effects on net Medicare savings. We also believe that increasing the maximum shared savings rate for BASIC track Level E from 50 percent to 60 percent improves the balance of incentives between BASIC track Level E and the ENHANCED track, while preserving the ENHANCED track's higher shared savings rate for ACOs that assume greater downside risk.

Comment: Several supportive commenters requested flexibility for ACOs applying for a January 1, 2027 start date to revise their BASIC Level E or ENHANCED track selection after publication of the final rule. Collectively, the commenters explained that proposed changes to benchmarking, risk adjustment, and shared savings policies could invalidate actuarial analyses completed before the final rule and materially affect participation decisions. They offered several recommendations to support informed decision-making, including that CMS communicate the flexibility period promptly, provide at least 60 days for ACOs to reevaluate their track selections, incorporate complete 2025 reconciliation data, allow sufficient time for updated forecasting, avoid penalizing ACOs that need additional evaluation time, and provide technical guidance, data files, and modeling assumptions as early as possible. Another supportive commenter encouraged CMS to provide sufficient implementation timelines, information, and policy stability to allow ACOs to effectively plan for and implement the proposals. Rural ACOs in particular may face a disproportionate burden from needing to conduct additional actuarial analysis after key contracting activities have begun, according to a commenter, who argued that ACOs should not be expected to make significant risk-bearing decisions before the policies governing those decisions are finalized.

Response: We appreciate comments regarding concerns around the timing of the final rule and the potential need for ACOs applying for a January 1, 2027 start date to update their actuarial analyses and reassess their track selections in light of finalized benchmarking, risk adjustment, and

shared savings policies. We recognize the importance of providing ACOs with timely information and sufficient opportunity to make informed participation decisions, particularly when those decisions involve assuming downside risk. CMS intends to offer ACOs an additional opportunity to update their risk track selection during the Phase 2 RFI period (November 12, 2026–November 17, 2026 at 12:00 p.m. Eastern Time). CMS will communicate applicable procedures for revising track selections through established program guidance and application processes. We are unable to provide additional time for ACOs to reevaluate their track selection that would otherwise extend the Shared Savings Program application cycle and delay downstream program operations but will continue to provide relevant technical guidance, data, and modeling information, as appropriate, to support ACO decision-making. These operational considerations do not alter our determination that increasing the maximum shared savings rate for BASIC track Level E from 50 percent to 60 percent is appropriate.

Comment: A few supportive commenters offered additional implementation considerations. A commenter requested that the 60 percent shared savings rate apply to all ACOs already in BASIC Level E agreements. Ongoing CMS transparency and monitoring of effects on participation, net savings, and the Medicare Trust Fund were also recommended. Commenters further encouraged us to continue evaluating whether rewards appropriately reflect the level of financial risk assumed. Regarding other participation options, a commenter recommended strengthening incentives in one-sided BASIC track Levels A and B to encourage ACO entry. Another supportive commenter requested that the increased rate apply to participation agreements beginning on or after January 1, 2024, suggesting that early renewal would force rebasing and loss of accumulated savings history for these ACOs.

Response: We appreciate comments with recommendations regarding the scope and implementation of the policy. Section 1871(e)(1)(A) of the Act prohibits substantive regulatory changes from being applied retroactively unless the Secretary determines that failing to apply the changes retroactively would be contrary to the public interest. For purposes of the BASIC track Level E sharing rate policy, we do not believe that the policy rises to a level to satisfy the requirements for retroactive application of the rule. Maintaining that rate does not create comparable unanticipated harm or program disruption and therefore does not satisfy the public interest standard for retroactive application. Accordingly, the 60 percent maximum shared savings rate will apply only to ACOs participating in BASIC track Level E for agreement periods beginning on or after January 1, 2027. We agree that continued monitoring and transparency are important and will assess the policy's effects on program participation, net savings, and the Medicare Trust Fund as additional performance data become available. We will also continue to evaluate whether the Shared Savings Program appropriately aligns potential rewards with the level of financial risk assumed across participation options.

After consideration of public comments, we are finalizing our proposal to increase the sharing rate under BASIC track Level E from 50 percent to 60 percent, applicable for ACOs in agreement periods beginning on or after January 1, 2027, for performance years beginning on or after January 1, 2027, and the proposal to specify related provisions in the Shared Savings Program regulations under new § 425.605(d)(1)(v)(A)(*5*), as well as proposed technical and conforming changes to § 425.605(d)(1)(v)(A)(*4*) introductory text and § 425.605(h)(2).

We received no public comments on our proposed technical corrections at § 425.605. Specifically, with the CY 2026 PFS final rule (see 90 FR 49816 through 49817, and 50018), we finalized amendments to phrasing in § 425.605, including in paragraphs (d)(1)(v)(A)(*3*)(*ii*) and (d)(1)(v)(A)(*4*)(*ii*) (describing the sharing rate applied under BASIC track Level E, by PY, for an ACO that meets the alternative quality performance standard). There were technical errors in the implementation of these finalized changes in the Code of Federal Regulations (CFR). As such, we are finalizing as proposed the following technical corrections at § 425.605:

- § 425.605(d)(1)(v)(A)(3)(ii) to read, 50 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).
- § 425.605(d)(1)(v)(A)(4)(ii) to read, 50 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(2) Reduce the Maximum Weight on the Regional Adjustment for ACOs Under the ENHANCED Track

(a) Background

In the June 2016 final rule (81 FR 37962 through 37974), we introduced a regional adjustment to ACOs' historical benchmarks to increase participation in the Shared Savings Program and recognize efficiency of providers/suppliers in their regional service area. To implement the regional adjustment, we also established a methodology for defining regional Medicare spending. We defined an ACO's ''regional service area'' at § 425.20 as the counties in which its assigned beneficiaries reside and calculated regional costs using county-Level Medicare fee-for-service expenditures for assignable beneficiaries in those counties (81 FR 37958). These county expenditures were then aggregated to estimate average per-capita spending in the ACO's region, which served as the basis for the regional adjustment applied when benchmarks were rebased (81 FR 37957 and 37958).

In the June 2016 final rule (81 FR 37954 through 37991), we finalized a Shared Savings Program benchmark rebasing methodology to include a regional adjustment to the historical benchmark. More specifically, we finalized that the regional adjustment would be calculated as a percentage of the difference between risk-adjusted average per capita expenditures in the ACO's regional service area and the ACO's rebased historical expenditures (81 FR 37966). We finalized that the regional adjustment would be applied for second or subsequent agreement periods, while benchmarks for an ACO's first agreement period would continue to be based solely on the ACO's historical spending and were not adjusted for regional expenditures (81 FR 37973).

To provide time for ACOs to anticipate and adapt to the regional adjustment being applied to historical benchmarks, we implemented a phased approach that gradually increased the weight applied to regional spending. The first time an ACO's benchmark was rebased using the regional adjustment, we applied 35 percent of the difference between regional spending and the ACO's rebased historical benchmark if the ACO's spending was below the regional average, and 25 percent if the ACO's spending was above the regional average. The second time the benchmark was rebased, CMS increased the weight to 70 percent for ACOs with spending below their regional average and 50 percent for those with spending

above the regional average. Beginning with the third rebasing and in subsequent agreement periods, the adjustment was set at 70 percent of the difference between regional and ACO spending for all ACOs, unless CMS established a different weight through future rulemaking (81 FR 37971 through 37973).

In the 2016 final rule, we also finalized that if we adjust an ACO's benchmark during the term of the agreement period due to changes in participating providers/suppliers, the agency would reassess whether the ACO's spending was above or below the regional average to determine the appropriate adjustment percentage (81 FR 37964). Together, these provisions increased the role of regional spending in benchmark calculations while providing a transition period intended to limit abrupt benchmark reductions for higher-spending ACOs.

In the December 2018 final rule (83 FR 68018), we revised the methodology to address concerns that the 2016 regional adjustment could inadvertently inflate benchmarks for low-spending ACOs while discouraging participation by high-spending ACOs relative to their region. Under the revised rule, we also applied the regional adjustment starting with the first agreement period. By design, the regional adjustment results in more generous benchmarks for ACOs that spend below their regions. In the December 2018 final rule (83 FR 68018), we noted that our initial experience with the regional adjustment found that 80 percent of ACOs that renewed for a second agreement period starting in 2017 received a positive adjustment. These ACOs saw their benchmarks increase by 1.8 percent, on average, when the adjustment was applied with the 35 percent weight, with several ACOs seeing increases of over 5 percent, and one over 7 percent. We also noted that for ACOs that renewed for a second agreement period starting in 2018, they showed a similar share of ACOs receiving a positive adjustment and one ACO seeing an adjustment of over 10 percent. We noted our concern that as the weight applied to the regional adjustment increases, benchmarks for the ACOs with the lowest spending relative to their region would become overly inflated to the point where they would need to do little to change their care practices to generate savings, which could reduce incentives for these ACOs to improve the efficiency of care provided to beneficiaries. To limit the influence of regional cost disparities, we reduced the maximum weight that could be applied to the regional adjustment in any agreement period from 70 percent to 50 percent. Additionally, we capped the total dollar impact of the regional adjustment at ±5 percent of national OM per capita expenditures for each beneficiary category (83 FR 68017 through 68024, and 42 CFR 425.603).

In the CY 2023 PFS final rule (87 FR 69915 through 69923), we finalized additional policies to modify the regional adjustment to further support participation by high-cost or high-risk ACOs. We implemented a set of policies designed to mitigate the impact of negative regional adjustments on ACOs' benchmarks. First, we reduced the maximum negative adjustment from −5 percent to −1.5 percent of national OM per capita expenditures for Parts A and B services (based on benchmark year 3 for assignable beneficiaries). Second, we established an approach that gradually decreased the size of the negative regional adjustment for ACOs that have a higher proportion of dually eligible Medicare and Medicaid beneficiaries or a higher weighted—average prospective Hierarchical Condition Category (HCC) risk score (87 FR 69923). In the CY 2023 PFS final rule (87 FR 69919), we expressed our belief that by reducing the impact of negative regional adjustments, these policies would incentivize ACOs that serve high-cost beneficiaries to join or continue to participate in the Shared Savings Program.

Most recently, in the CY 2024 PFS final rule (88 FR 79185 through 79196), we modified the regional adjustment policy further to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment.

In the CY 2027 PFS proposed rule we stated, as part of CMS's effort to align spending and value in OM, we are focused on developing policies that would accelerate accountable care service delivery across a spectrum of risk-bearing options (91 FR 44073). To achieve this vision, we stated that our proposed change to the regional adjustment is informed by strategic objectives focused on strengthening financial incentives for ACOs to participate in the Shared Savings Program and driving savings for ACOs and the Trust Funds (91 FR 44073).

(b) Revisions

For the reasons discussed in the CY 2027 PFS proposed rule, we proposed to reduce the maximum weight used in calculating the positive regional adjustment for lower-spending ACOs participating in agreement periods under the ENHANCED track from 50 percent to 35 percent, while leaving the weights for ACOs with a higher spending than the regional average unchanged (91 FR 44073).

In the CY 2027 PFS proposed rule, we discussed that under the Shared Savings Program, an ACO's historical benchmark is adjusted to reflect differences between its own historical spending and average spending in its region—the regional adjustment (91 FR 44073). For ACOs with expenditures below their regional average, this adjustment is positive, increasing the ACO's benchmark and expanding savings opportunities available to the ACO. In the CY 2027 PFS proposed rule we shared an analysis of PY 2024 financial reconciliation data which indicates that ACOs in the ENHANCED track receive substantially larger positive regional adjustments on average than ACOs in BASIC track Level E ($304 versus $166 per beneficiary) (91 FR 44073). We stated that, taken together with observed differences in gross savings—where ENHANCED track ACOs achieve higher gross savings [319] per beneficiary than BASIC track Level E ACOs ($961 versus $714 in CY 2024)—this pattern suggests that more favorable benchmark adjustments may be contributing to the higher levels of observed gross savings for ENHANCED track ACOs (91 FR 44073). To assess whether the magnitude of the regional adjustment is associated with ACO performance, we calculated Pearson's correlations [320] between regional adjustment size and gross savings for ACOs reconciled in PY 2024.[321] Within the ENHANCED track, we noted that the larger regional adjustments are strongly associated with higher gross savings performance (r=0.691, n=59), a relationship that is not observed among BASIC track Level E ACOs (r=0.09, n=17) (91 FR 44073). We stated that the contrast between tracks raises the possibility that the scale of positive regional adjustments to the benchmark are partly driving performance rather than genuine efficiency gains (91 FR 44073). We noted that, while this is a descriptive finding, it is consistent with

[319] Gross savings were calculated as the ACO's total savings amount divided by the total assigned beneficiary person years.

[320] Pearson's correlation coefficient is a statistical measure that summarizes the strength and direction of the linear relationship between two variables, taking values from −1 (perfect negative relationship) to +1 (perfect positive relationship), with 0 indicating no linear relationship.

[321] Internal analysis of financial performance according to track/level of participation of Medicare Shared Savings Program ACOs that participated in PY2024, including assessment of whether the magnitude of regional adjustment is associated with ACO performance.

our concern motivating the proposed reduction in the positive regional adjustment weight from 50 percent to 35 percent (91 FR 44073). Moreover, the average size of the adjustment has gone up—from $206 in PY 2020 to $344 in PY 2025, while the share of ACOs receiving a positive regional adjustment has remained mostly stable within a range between 70 and 86 percent over the same time period. We stated that this pattern suggests that, while the prevalence of regional adjustments has remained broadly unchanged, the financial impact of those adjustments has increased over time, amplifying the influence of regional adjustments on ACO benchmark calculations (91 FR 44073).

As discussed in the CY 2027 PFS proposed rule, there is limited evidence suggesting that the ENHANCED track is generating additional Trust Funds savings relative to the BASIC track (91 FR 44073). First, the size of the regional adjustment may be contributing to higher gross savings performance in the ENHANCED track, which causes us to question whether those savings reflect genuine cost reduction. Second, lower spending ACOs (defined as those with historical expenditures below their regional average) in the ENHANCED track currently benefit from both a higher shared savings rate and larger regional adjustments on average. We stated that together these advantages may incentivize selection into the ENHANCED track independent of an ACO's capacity to achieve genuine cost savings to Medicare (91 FR 44074). We proposed to reduce the positive regional adjustment weight for these ACOs, paired with an increase in the shared savings rate for BASIC track Level E, which is designed to rebalance financial incentives across tracks and encourage ACOs to select their tracks based on their actual capacity to reduce costs rather than differences in financial advantages embedded in track design, thereby potentially improving Trust Funds net savings (91 FR 44074). We referred readers to the discussion in the CY 2027 PFS proposed rule (91 FR 44067) and the data analysis described in the CY 2027 PFS proposed rule (91 FR 44068 through 44072) for additional details.

We stated that we believe that a 35 percent positive regional adjustment would maintain consistency with the current schedule of weights used to calculate the regional adjustment, a structure with which ACOs are already familiar (91 FR 44074). We also stated that we believe this approach would minimize complexity by maintaining a single weight for lower-spending ENHANCED track ACOs for all participation years (91 FR 44074). We noted that, at the same time, it would preserve an appropriate balance between rewarding regional efficiencies demonstrated at the start of the agreement period and rewarding improvement relative to an ACO's past historical performance over time (91 FR 44074).

TABLE B-G13: PROPOSED PERCENTAGE WEIGHT APPLIED IN CALCULATING THE REGIONAL ADJUSTMENT

Agreement Period When ACO is Subject to Regional Adjustment	Weight Used to Calculate Regional Adjustment for BASIC Track ACOs that are Lower Spending Compared to Their Region	Weight Used to Calculate Regional Adjustment for ENHANCED Track ACOs that are Lower Spending Compared to Their Region	Weight Used to Calculate Regional Adjustment for ACOs that are Higher Spending Compared to Their Region
First	35%	35%	15%
Second	50%		25%
Third			35%
Fourth and subsequent			50%

NOTE: Refer to § 425.601(e)(2)(ii) and (f), and § 425.656(e) and (f). Refer to the December 2018 final rule (83 FR 67908–67909) Table 6 for examples of existing phase-in of regional adjustment weights based on agreement start date and applicant type.

We proposed this change to be effective for agreement periods beginning on January 1, 2027, and in subsequent years (91 FR 44074). We stated that reducing the weight used in calculating the regional adjustment applied to ACOs considering participation in the ENHANCED track would reduce the contribution of baseline regional efficiency on historical benchmark calculations (91 FR 44074). And we stated that, as a result, it would put a stronger emphasis on rewarding improvement in the provision of coordinated care and lowering costs rather than baseline efficiency at entry to the agreement period (91 FR 44074). We stated that the focus on improvement is accentuated when paired with the proposed higher prior savings adjustment weighting, discussed in the CY 2027 PFS proposed rule (91 FR 44076 through 44082). We stated that one goal of this proposal—reducing the regional adjustment weight—is to encourage ACOs to select a diverse cross-section of participants so that ACOs' success is driven by operational efficiencies and clinical performance rather than passive capture of ACO participants with pre-existing regional efficiencies (91 FR 44074). We added that more modest regional adjustment amounts could also result in ACOs opting for participation in BASIC track Level E instead of the ENHANCED track, and therefore result in the Trust Funds retaining a greater share of savings while still offering ACOs a long-term incentive for creating savings because of the proposed higher prior savings adjustments in future agreement periods (91 FR 44074).

In the CY 2027 PFS proposed rule, we stated that under this proposal, the phase-in of weights used in the regional adjustment calculation for agreement periods beginning on January 1, 2027, and in subsequent years, as determined by an ACO's expenditures relative to their region, would change for ENHANCED track ACOs (91 FR 44074). We did not propose to modify the negative regional adjustment weights, so the negative regional adjustment would remain unchanged (91 FR 44074). We proposed that the maximum weight used to calculate the regional adjustment for ENHANCED track ACOs that are lower spending relative to their region would be set at 35 percent for all agreement periods, replacing the current

phase-in schedule (91 FR 44074). We noted that the weights used for ACOs that are higher spending relative to their region, and for BASIC track ACOs that are lower spending would remain unchanged (91 FR 44074).

As discussed in the CY 2027 PFS proposed rule, to assess the impact of the proposed policy change, we conducted a simulation [322] using PY 2024 historical benchmarks, in which the maximum positive regional adjustment weight was reduced from 50 percent to 35 percent for lower spending ACOs,[323] all other parameters, including the prior savings adjustment, were held constant. ACOs with an agreement start date prior to January 1, 2024 (n=53) experience larger percentage reductions in historical benchmarks (-0.87 percent) than ACOs with agreement start dates of January 1, 2024 (n=48, -0.69 percent) (91 FR 44074). The difference reflects the benchmark methodology applicable to ACOs with agreement period start dates of January 1, 2024, under which ACOs are eligible for multiple upward adjustments and CMS applies the highest for which an ACO qualifies. In this simulation, we noted that ACOs that transition from receiving a regional adjustment to receiving the prior savings adjustment (because the regional adjustment has decreased to below the prior savings adjustment) experience smaller decreases in historical benchmarks than ACOs that remain subject to the regional adjustment (91 FR 44074 through 44075). We stated that for lower spending ACOs, the prior savings adjustment can partially offset reductions to the benchmark when the weight of the regional adjustment is reduced (91 FR 44075). ACOs with agreement period start dates prior to January 1, 2024, do not have prior savings adjustments included in historical benchmark calculations, so they would be more impacted by our proposal to reduce the maximum weight of the regional adjustment.

Our proposal to reduce the maximum weight used in calculating the positive regional adjustment for lower-spending ACOs participating in agreement periods under the ENHANCED track is consistent with our authority under section 1899(d)(1)(B)(ii) of the Act, which we have consistently relied on to make regional adjustments to the historical benchmark (81 FR 37962). In the CY 2027 PFS proposed rule, we stated that under this framework, ACO benchmarks are adjusted for beneficiary characteristics and other factors deemed appropriate by the Secretary, updated to reflect the projected absolute growth in national per capita expenditures for the original Medicare fee-for-service program, and reset at the commencement of each agreement period (91 FR 44075).

We proposed to amend § 425.656 to specify the phase-in of weights used in calculating the regional adjustment as applicable by agreement period start date (91 FR 44075). We proposed to amend the introductory text of paragraph (e) of § 425.656 to specify the paragraph includes the phase-in of weights used in the regional adjustment calculation for agreement periods beginning on or after January 1, 2024 and before January 1, 2027 (91 FR 44075). We proposed to redesignate paragraph (f) of § 425.656 as paragraph (g) (91 FR 44075). We proposed to add a new paragraph (f) to specify the phase-in of weights used in the regional adjustment calculation for agreement periods beginning on January 1, 2027, and in subsequent years (91 FR 44075). Accordingly, in the CY 2027 PFS proposed rule (91 FR 44075) we proposed to specify the following under new proposed § 425.656(f)(1) through (4):

- Under new paragraph (f)(1) we would specify that the first time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, we would calculate the regional adjustment as follows:

++ Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area.

++ Using 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

- Under new paragraph (f)(2) we would specify that the second time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, we would calculate the regional adjustment as follows:

++ For an ACO participating under the BASIC track—

—Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

—Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

++ For an ACO participating under the ENHANCED track—

—Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

—Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

- Under new paragraph (f)(3) we would specify that the third time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, we would calculate the regional adjustment as follows:

++ For an ACO participating under the BASIC track—

—Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

—Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

++ For an ACO participating under the ENHANCED track—

—Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

[322] Internal simulation analysis using PY2024 historical benchmarks, in which the positive regional adjustment weight was reduced from 50 percent to 35 percent for lower spending ACOs to assess the impact of the proposed policy change. This analysis did not stratify by agreement period; all ACOs with the same start date (before or after January 1, 2024) were treated as a single cohort.

[323] Defined as ACOs with historical expenditures below their regional service area average.

—Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

• Under new paragraph (f)(4) we would specify that the fourth or subsequent time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, we would calculate the regional adjustment as follows:

++ For an ACO participating under the BASIC track, using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark.

++ For an ACO participating under the ENHANCED track—

—Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

—Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

We proposed to specify under new § 425.656(f)(5) the approach we would use to determine if an ACO has lower or higher spending compared to the ACO's regional service area, which would be identical to the existing approach for making this determination as specified under § 425.656(e)(5), except to include updated cross-references to provisions within the proposed new paragraphs (f)(1) through (4) rather than paragraphs (e)(1) through (3) (91 FR 44075 through 44076).

In the CY 2027 PFS proposed rule (91 FR 44076), we also proposed the following technical and conforming changes to the Shared Savings Program regulations, for completeness and clarity:

• In § 425.656(a), describing (generally) the purpose of the section on calculating the regional adjustment to the historical benchmark and the timing of applicability, we proposed to revise the last sentence to denote the section ''applies to regional adjustment calculations for agreement periods beginning on January 1, 2024, and in subsequent years, *except as specified otherwise*'' (emphasis added to reflect revised text).

• In § 425.656(c)(2), describing percentage weight applied in the calculation of the regional adjustment, we proposed to amend the existing cross-reference to § 425.656(e) to include cross-references to both § 425.656(e) and the proposed new § 425.656(f).

• Redesignating § 425.656(f) as § 425.656(g), and in redesignated § 425.656(g) introductory text, describing special rules for determining the weights used in the regional adjustment calculation for a re-entering ACO, we proposed to replace the existing cross-references to § 425.656(b) through (e) with cross-references to § 425.656(b) through (f), to include proposed new § 425.656(f) in the cross-references.

• In § 425.600(f)(4)(ii), describing the program requirements that phase in over multiple agreement periods, and specifically the weight used in calculating the regional adjustment to the ACO's historical benchmark, we proposed replacing the existing cross-references to §§ 425.601(f) and 425.656(e), with cross-references §§ 425.601(f), § 425.656(e), and § 425.656(f), to include proposed new § 425.656(f) in the cross-references.

We sought comment on the proposal to reduce the maximum weight on the regional adjustment for lower-spending ACOs under the ENHANCED track to a weight of 35 percent for agreement periods beginning on January 1, 2027, and in subsequent years. We stated that under this proposal, the weight for higher-spending ACOs, and for BASIC track ACOs that are lower spending would remain unchanged (91 FR 44076). We also sought comment on proposed technical and conforming changes to other provisions of § 425.656, and § 425.600.

The following is a summary of the comments we received and our responses.

Comment: Some commenters supported the proposal to reduce the maximum weight of the positive regional adjustment. A commenter stated that increasing the shared savings rate under BASIC track Level E while reducing the weight of the positive regional adjustment in the ENHANCED track may help attract more high-cost ACOs to the BASIC track, where Medicare has greater opportunities to share in savings. A commenter supported both the regional adjustment and prior savings adjustment proposals and recommended that the policies be considered in tandem rather than approved separately. Another commenter supported the changes if it helps community health centers (CHCs) enter, remain in, and succeed under the Shared Savings Program.

Response: We appreciate the support of our proposal to reduce the maximum weight used in calculating the positive regional adjustment for lower-spending ACOs participating under the ENHANCED track from 50 percent to 35 percent. The policy we are finalizing is limited in scope. It only applies to ENHANCED track ACOs that have lower spending than their regional service area, beginning with the second agreement period, where the ACO's benchmark is adjusted based on regional service area expenditures. It does not change the weights used for the regional adjustment for BASIC track ACOs, for ENHANCED track ACOs in their first agreement period (which weight remains at 35 percent), or for ACOs with higher spending than their region. It also does not change the negative regional adjustment or the cap on the regional adjustment. We agree with commenters that the interaction of benchmark policies and shared savings opportunities can influence ACO participation decisions. As a commenter observed, increasing the shared savings rate under BASIC track Level E while reducing the maximum weight of the positive regional adjustment for lower-spending ACOs under the ENHANCED track may improve the relative appeal of BASIC track Level E for certain ACOs. We believe these changes, when considered together, will better balance participation incentives across tracks and more closely align the financial opportunities available under each track with an ACO's capacity to reduce expenditures and assume performance-based risk. We also agree that moderating the magnitude of the positive regional adjustment under the ENHANCED track advances our goal of reducing differences in benchmark advantages that may influence ACO participation and track selection. While we agree with the commenter that described the revisions to the regional adjustment and the prior savings adjustment as complementing one another, we do not believe they are inextricably linked or that they must be adopted together. Each independently furthers program goals: the reduced maximum weight applied to the positive regional adjustment moderates benchmark advantages for lower-spending ENHANCED track ACOs, and the increased prior savings adjustment scaling factor mitigates the effects of rebasing for ACOs that have generated savings.

We appreciate comments in support of the proposal on the basis that it may support the participation of community health centers in the Shared Savings Program. We also appreciate comments supporting the proposal on the basis that it would improve the alignment of financial incentives within the Shared Savings Program and moderate benchmark advantages that may result from differences in spending relative to an ACO's regional service area. We continue to believe that regional expenditures are an important component of benchmarking methodology while recognizing the need to ensure that the magnitude of the regional adjustment does not create unintended participation incentives.

Comment: A couple of commenters supported the proposal because it is consistent with their prior-year recommendations to mitigate selection effects and improve benchmark calculation but urged CMS to phase out the regional adjustment entirely to more fully address the effects of selective participation, noting this would also remove its influence on the prior savings adjustment and reduce program complexity. Some commenters further urged CMS to continue monitoring the selection effects of the regional adjustment, including its impact on the prior shared savings adjustment, as part of a broader effort to understand how the Shared Savings Program affects Medicare spending prior to applying risk adjustment and upward benchmark adjustments. Similarly, a commenter stated that regional benchmarks can reward preexisting efficiency without inducing additional savings and can attract already low-spending providers, and recommended that CMS reduce reliance on regional adjustments and evaluate changes in ACO composition as a program cost rather than as savings.

A couple of commenters supported the proposed reduction in the maximum weight of the positive regional adjustment for ENHANCED track ACOs but urged CMS to eliminate the regional adjustment across all tracks rather than reducing its weight for the ENHANCED track alone, stating the adjustment is asymmetrical because the benchmark increase for low-cost providers exceeds the reduction for high-cost providers and therefore rewards recruiting low-cost providers and beneficiaries over improving care. One of these commenters cited that 382 of 476 ACOs participating in 2024 received a positive regional adjustment and that the adjustment alone accounted for 2.1 percent of benchmark growth for ACOs beginning in 2024, and stated that higher benchmarks did not produce meaningful program growth. The commenter recommended that if CMS concludes additional support is needed to sustain rural and safety-net participation, it should provide that support directly rather than through a benchmark mechanism that rewards the exclusion of high-cost providers.

A commenter supported the proposed modifications, recognizing CMS's effort to place greater emphasis on an ACO's own performance and value-creation activities. The commenter recommended, however, that CMS consider a phased transition to the new methodology rather than an immediate change. The commenter stated that a gradual reduction of the regional adjustment factor would give organizations a predictable pathway to adapt their financial planning and care management strategies; and that a transition period would help maintain confidence in long-term program participation.

Response: We thank commenters for their support and recommendations. Several commenters recommended that we go beyond the proposed reduction and phase out or eliminate the regional adjustment, either for the ENHANCED track or across all tracks. The positive regional adjustment accounts for regional cost variation by making an ACO's benchmark less dependent on its own historical expenditures and more reflective of spending in its regional service area, which reduces disincentives for ACOs that are already efficient relative to their region to participate and continue lowering spending (91 FR 44081). Based on our experience with the program, we believe it is appropriate to rebalance rather than eliminate the adjustment by moderating the extent to which regional efficiency is reflected in benchmarks for lower-spending ENHANCED track ACOs.

Specifically, as discussed in the CY 2027 PFS proposed rule (91 FR 44073 through 44074), ENHANCED track ACOs on average receive larger positive regional adjustments than BASIC track ACOs while also benefiting from a higher shared savings rate. We noted that the proposed reduction in the positive regional adjustment weight for these ACOs, paired with an increase in the shared savings rate for BASIC track Level E, is intended to rebalance financial incentives across tracks and encourage ACOs to select their tracks based on their actual capacity to reduce costs rather than differences in financial advantages embedded in track design, thereby potentially improving Trust Funds net savings (91 FR 44074). We believe that reducing the maximum weight used in calculating the positive regional adjustment from 50 percent to 35 percent for lower-spending ENHANCED track ACOs, beginning in the second agreement period, meets the needs of the program by continuing to account for regional cost variation for these ACOs while better balancing financial incentives across tracks. We will monitor the impact of this change.

We appreciate the considerations commenters raised in support of a broader change, including the observation that the adjustment may influence the prior savings adjustment, that reliance on regional comparisons adds complexity to the benchmarking methodology, and that a substantial majority of ACOs participating in 2024 received a positive regional adjustment. We also acknowledge the concern that a regional comparison may recognize spending levels established before an ACO's participation in the program. As we explained in the December 2018 final rule, ''by design, the regional adjustment results in more generous benchmarks for ACOs that spend below their regions,'' and we stated at that time that we had concerns that the regional adjustment could have unintended consequences and adverse effects on ACO incentives and we would continue to monitor the regional adjustment for changes that may be needed in the future (83 FR 68018). The reduction we are finalizing moderates the magnitude of the positive regional adjustment for lower-spending ACOs in the track where it is largest, and it does not rest on the conclusion that the adjustment lacks continuing value. Additionally, we are not in this rule substituting a direct form of support for rural or safety net ACOs in place of the regional adjustment.

We agree with commenters who urged us to continue monitoring the selection effects of the regional adjustment, including its interaction with the prior savings adjustment. Consistent with the commitments we made when the adjustment was established and refined (81 FR 37962; 83 FR 68023), we will continue to monitor the effects of the regional adjustment on ACO participation, benchmark calculations, and expenditures, and will address any necessary refinements through future rulemaking. As part of that monitoring, we will consider the recommendation that we account for changes in ACO composition in assessing program savings. A commenter recommended that we phase in the reduced weight rather than apply it immediately. We address this recommendation together with other comments on implementation timing under section III.G.5.c.(2) of this final rule.

Comment: Most commenters opposed the proposal to reduce the maximum weight of the positive regional adjustment from 50 percent to 35 percent, stating it would reduce the recognition provided to ACOs that maintain expenditures below those of their regional service areas. These commenters stated that reducing the maximum weight would weaken incentives for ACOs to enter or remain in the ENHANCED track, accept greater levels of performance-based risk, and continue investing in activities intended to improve quality and reduce expenditures. Several commenters stated that the proposal is inconsistent with the Shared Savings Program's objective of encouraging ACOs to assume greater risk and could discourage efficient, high-performing ACOs from continuing their participation under the ENHANCED track.

A few of these commenters also stated that reducing the adjustment could reduce resources available for reinvestment in care coordination, population health infrastructure, analytics, workforce, information technology, and other activities that support quality improvement and expenditure reductions. Among commenters who opposed this proposal, some expressed particular concern about the effects on smaller ACOs, including those with benchmarks that are more heavily weighted toward regional expenditure trends. A couple of commenters added that the change could undermine the longer-term transition toward regional, sustainable benchmarking.

Some commenters stated that reducing the maximum weight in the Shared Savings Program while the CMS Innovation Center's Long-term Enhanced ACO Design (LEAD) Model retains a 50 percent positive regional adjustment would create inconsistent incentives across CMS accountable care programs and that efficient ENHANCED track ACOs might move to LEAD rather than remain in the Shared Savings Program. Some other commenters raised concerns about inconsistency across models, or about effects on continued participation, without predicting movement between programs. Commenters raising these concerns noted that CMS adopted the 50 percent positive regional adjustment in LEAD based on its application in the Shared Savings Program, that changing the adjustment is not a feature LEAD was intended to test, and that LEAD eliminates periodic rebasing during its 10-year performance period to provide a predictable opportunity to sustain savings and investment.

Response: We appreciate comments expressing concerns that reducing the maximum weight of the positive regional adjustment could diminish the incentive provided to ACOs that maintain expenditures below those of their regional service areas, weaken incentives to accept greater levels of performance-based risk, or discourage participation in the ENHANCED track. We continue to believe that regional expenditures are an important component of the benchmarking methodology. The policy we are finalizing does not eliminate the positive regional adjustment or alter its fundamental role. Instead, it moderates the maximum weight applied to the positive regional adjustment for lower-spending ENHANCED track ACOs, beginning in the second agreement period when the ACO's benchmark is adjusted based on regional service area expenditures. ACOs with higher spending than their region, and all BASIC track ACOs, are unaffected by this policy change. Lower-spending ENHANCED track ACOs will continue to be eligible to receive a positive regional adjustment.

We recognize commenters' concerns that a reduced regional adjustment may lessen the financial benefit available to certain ACOs and could affect participation decisions, particularly for ACOs considering whether to participate under the ENHANCED track. We also recognize commenters' concerns that shared savings payments support continued investments in care coordination, population health management, analytics, workforce, and other activities intended to improve quality and reduce expenditures. In evaluating this proposal, we considered the importance of maintaining incentives for participation and performance while also ensuring that the financial opportunities available under the Shared Savings Program remain appropriately balanced across participation options. We believe that under the finalized policy, affected ACOs will continue to have ample opportunities to generate shared savings and to use these resources to continue to improve quality and reduce expenditures in future years.

As discussed elsewhere in sections III.G.5.c.(1) and III.G.5.d of this final rule, we are simultaneously increasing the shared savings rate under BASIC track Level E and increasing the prior savings adjustment scaling factor. Considered together, these policies will better align the financial opportunities available under the program with an ACO's capacity to reduce expenditures and assume performance-based risk. These changes will support continued participation in the Shared Savings Program while preserving greater potential rewards for ACOs that accept the higher levels of risk associated with participation under the ENHANCED track.

Using PY 2025 simulation data, we estimate that 144 of 249 ENHANCED-track ACOs (58 percent) would be impacted by the proposed reduction in the maximum positive regional adjustment weight (0.50 to 0.35). Of those, 141 experienced a benchmark reduction, with an average decrease of approximately $96 per beneficiary per year (0.82 percent of the historical benchmark). Individual benchmark reductions ranged from about $0.26 to $193 (0 percent to 1.79 percent of the historical benchmark). Three ACOs benefitted from this proposed reduction as it reduced the negative impact of enrollment groups that were higher spending than their region while the positive impact of other enrollment groups was subject to the cap under both weightings (0.50 and 0.35). We note, however, that these estimated benchmark reductions should be considered in the context of the rule as a whole, including other financial provisions that are expected to offset or mitigate these impacts for many ACOs.

We acknowledge commenters' concerns regarding the possible effects of the policy on smaller ACOs and other ACOs whose benchmarks may be more affected by regional expenditures. The revised maximum weight applies prospectively to agreement periods beginning on or after January 1, 2027, and does not alter the weights applicable to agreement periods already underway. As discussed in the CY 2027 PFS proposed rule, we are not modifying the negative regional adjustment weights, which will remain unchanged (91 FR 44074). In addition, the revised maximum positive regional adjustment weight applies only to lower-spending ENHANCED track ACOs beginning the second agreement period and no impact on BASIC track ACOs, ENHANCED track ACOs with higher spending than their region, or ENHANCED track ACOs in their first agreement period. We will continue to monitor participation, track selection, and program outcomes following implementation, including among smaller ACOs and ACOs currently participating under the ENHANCED track, and may consider refinements through future rulemaking.

We recognize the commenters' concerns that different maximum

weights for the positive regional adjustment in the Shared Savings Program and the LEAD Model could affect how ACOs consider participation in each. The Shared Savings Program and LEAD are distinct initiatives with different structures, participation requirements and purposes, financial calculations, and methods to assess financial and quality performance and we do not believe that every benchmarking parameter should be identical across them. The Shared Savings Program is a permanent program established under section 1899 of the Act, and the LEAD Model is being tested under separate authority with a distinct design, including a longer performance period and different rebasing provisions. The adoption of a program parameter in an Innovation Center model does not preclude CMS from reconsidering that parameter for the Shared Savings Program and potentially implementing it through notice-and-comment rulemaking. The weights we are finalizing continue to provide a meaningful positive regional adjustment for lower-spending ENHANCED track ACOs, alongside the higher shared savings rate. We believe that ACOs choosing among accountable care options consider many factors, including the full set of benchmark and financial features. We nonetheless take seriously the concern that differences across our accountable care initiatives may create incentives that participants find difficult to navigate, and we will consider the interaction between the Shared Savings Program benchmarking methodology and our accountable care models as we continue to evaluate both. We will monitor participation in the program and the ENHANCED track and movement between the Shared Savings Program and other accountable care initiatives.

Comment: Some commenters who opposed this proposal stated that CMS has not provided sufficient analysis to support reducing the maximum weight of the positive regional adjustment from 50 percent to 35 percent. These commenters stated that CMS relied primarily on descriptive observations rather than rigorous analysis and asserted that the receipt of positive regional adjustment by efficient, long-standing ACOs reflected the intended operation of the policy rather than a problem with the existing weight. A commenter specifically recommended that CMS conduct and publish additional modeling of the effects of the proposal and obtain additional public input before making the change.

Some commenters recommended that CMS conduct further analysis before reversing a longstanding policy central to Shared Savings Program benchmark design, including causal analysis and simulation testing of current and higher caps accounting for ACO longevity across CMS ACO programs, size, rurality, physician versus hospital or health-system leadership, and patient complexity, and an examination of whether ACO participation generates market-level spillover effects that reduce spending among non-ACO-attributed beneficiaries and create an additional ratchet effect for successful ACOs.

Response: We appreciate comments with concerns regarding the analytic basis for the proposal. We disagree that this policy reverses a longstanding policy. The positive regional adjustment remains in place for all eligible ACOs, and the 35 percent weight we are finalizing for lower-spending ENHANCED track ACOs is the same weight that applies for ACOs in the first agreement period. The policy applies only to lower-spending ENHANCED track ACOs, beginning in the second agreement period, and ACOs with higher spending than their region and all BASIC track ACOs are unaffected. In developing this policy, we considered both program experience and quantitative analyses, including the size and distribution of the positive regional adjustment, changes in the average size of the adjustment over time, gross and net savings across participation options and the experience of ACOs participating in BASIC track Level E and the ENHANCED track. To further inform this final rule, we also examined performance under alternative benchmark scenarios, as described in our response to the following comment.

We appreciate comments suggesting a need for additional analysis, including causal and simulation analyses accounting for ACO longevity, size, rurality, leadership structure, and patient complexity, and an examination of market-level spillover effects. We will continue to evaluate these and other analytic approaches as we continue to monitor the program and consider future modifications to the program's financial methodology through notice-and-comment rulemaking.

Comment: A commenter stated that CMS's comparison of ACOs that moved from BASIC track Level E to the ENHANCED track with ACOs that remained in BASIC track Level E did not adequately account for benchmark rebasing. This commenter further stated that the 38 ACOs identified by CMS in the CY 2027 PFS proposed rule were, by its calculations, twice as likely to have undergone rebasing as BASIC track ACOs, and that the observed reduction in their net savings rate from 2.5 percent to 1.7 percent reflects the effects of rebasing more than any change in ACO performance. This commenter also stated that CMS measured savings relative to administratively established benchmarks rather than a counterfactual estimate of expenditures in the absence of ACO participation.

A commenter also stated that the observed correlation between the positive regional adjustment and gross savings partly reflects the inclusion of the adjustment in the benchmark used to calculate gross savings. The commenter reported that an alternative calculation intended to remove the adjustment from gross savings produced a substantially lower association, which the commenter cited as evidence that the result is sensitive to the savings measure used.

Response: In response to the comment that CMS measured savings relative to administratively established benchmarks rather than a counterfactual estimate, we agree that benchmark-measured savings are not, by themselves, causal estimates of expenditure reductions. However, the benchmark establishes a basis to determine shared savings payments, and the size of the regional adjustment directly affects shared savings payments and Trust Fund net savings. We also considered commenters' concerns that reducing the maximum regional-adjustment weight could weaken incentives to generate additional savings or affect the allocation of measured savings between Medicare and ACOs. A positive regional adjustment increases an ACO's benchmark and may increase the shared savings payment. The shared savings associated with that adjustment are measured relative to the adjusted benchmark and do not, by themselves, establish the amount by which Medicare expenditures were reduced relative to what expenditures would have been in the absence of ACO participation. We therefore considered both the role of benchmark adjustments in supporting continued participation and expenditure-reduction efforts and their effects on the calculation of gross savings, net savings, and shared savings payments. The analyses presented in our response to comments in section III.G.5.c.(2) of this final rule are comparisons under alternative benchmark scenarios and should not be interpreted as causal estimates of Medicare expenditure reductions relative to a counterfactual without ACO participation.

To further inform this final rule and respond to commenters' concerns

regarding the effects of rebasing and benchmark adjustments on comparisons across participation options, we examined performance for PY 2024 and PY 2025 under alternative benchmark scenarios in which benchmark adjustments (including the regional adjustment, prior savings adjustment, and population adjustment) were removed from the historical benchmark calculation. For PY 2024, BASIC track Level E ACOs generated $576 and $293 in gross and net per capita savings, respectively, compared with $767 and $205 for lower-spending ENHANCED track ACOs. When benchmark adjustments were removed, gross and net per capita savings were $418 and $205 for BASIC track Level E ACOs and $423 and $107 for lower-spending ENHANCED track ACOs. For PY 2025, BASIC track Level E ACOs generated $491 and $249 in gross and net per capita savings, respectively, compared with $756 and $203 for lower-spending ENHANCED track ACOs.[324] When benchmark adjustments were removed, gross and net per capita savings were $294 and $144 for BASIC track Level E ACOs and $361 and $98 for lower-spending ENHANCED track ACOs.

These analyses provide additional information regarding the contribution of benchmark adjustments to measured savings under the two participation options. The percentages and dollar amounts in this paragraph represent the reduction in gross per capita savings when all benchmark adjustments are removed from the historical benchmark; they do not represent estimated changes in shared savings payments under the finalized policy. Although lower-spending ENHANCED track ACOs generated higher gross per capita savings in both performance years, they also generated lower net per capita savings. As these scenarios remove all benchmark adjustments together, they do not isolate the effect of the regional adjustment. Removing benchmark adjustments reduced measured gross savings for both groups, with a larger reduction for lower-spending ENHANCED track ACOs (45 percent (-$344) in PY 2024 and 52 percent (-$395 in PY 2025)) compared to BASIC track Level E ACOs (-27 percent (-$158) and 40 percent (-$197)), respectively). In other words, roughly half of the measured gross savings for lower-spending ENHANCED track ACOs was attributable to benchmark adjustments, compared with roughly one-quarter to two-fifths for BASIC track Level E ACOs. Although these findings are descriptive and should not be interpreted as establishing a causal relationship, they do provide context for concerns that the observed relationship between positive regional adjustments and gross savings may partly reflect the effect of benchmark adjustments on the calculation of savings. They also suggest that lower-spending ENHANCED Track ACOs are more dependent on their benchmark adjustments, most often the regional adjustment, to generate their higher measured gross savings. As these ACOs also share in savings at a higher rate, a larger portion of their shared savings payments may reflect pre-existing efficiency relative to their region rather than reductions in expenditures during the performance year. At the same time, both groups continued to generate positive gross savings after benchmark adjustments were removed, indicating that ACOs in both tracks are achieving savings beyond what benchmark adjustments alone would produce. For these reasons, we believe moderating, rather than eliminating, the maximum positive regional adjustment weight for lower-spending ENHANCED track ACOs will better protect Trust Fund net savings while continuing to account for regional cost variation.

We also examined how the positive regional adjustment changed over time, further exploring the topic we described in the CY 2027 PFS proposed rule (91 FR 44073) that the financial impact of the regional adjustment has increased over time and may influence ACO track participation decisions. We analyzed historical benchmark data for all ACOs from PY 2022 through PY 2025 and identified 213 ACOs across all tracks that received a positive regional adjustment in every performance year of that period. Of those 213 ACOs, 92 entered a new agreement period in which their maximum positive regional adjustment weight increased from 35 percent to 50 percent, 28 entered a new agreement period in which the maximum weight was already 50 percent, and 93 did not enter a new agreement period, of which 51 ACOs were subject to a maximum weight of 35% and 42 ACOs were subject to a maximum weight of 50%. For the 92 ACOs whose maximum weight increased, the regional adjustment rose from an average of 2.2 percent to 3.7 percent of the historical benchmark; for the 28 ACOs whose maximum weight was already 50 percent, the regional adjustment rose from an average of 3.1 percent to 3.9 percent of the historical benchmark; for the 93 ACOs that did not enter a new agreement period, the regional adjustment remained relatively stable (2.8 percent to 2.6 percent of the historical benchmark). For both groups that entered a new agreement period, the difference between the ACO's historical spending and risk-adjusted regional spending also widened, from approximately 6 percent to approximately 8 percent of regional spending, indicating that the increases in the regional adjustment were accompanied by increases in the underlying differences in regional spending and did not reflect the higher weight alone.[325] This matters because the increase occurs regardless of whether an ACO is actually ready to generate the additional gross savings needed to offset the ENHANCED track's higher sharing rate. This indicates the agreement-period transition, and the accompanying weight increase may influence track participation decisions, separate from any change in the ACO's own performance in continuing to improve quality and decrease costs. Reducing the maximum positive regional adjustment weight to 35 percent for lower-spending ENHANCED track ACOs, beginning with the second agreement period, limits CMS's exposure to this effect, and better ensures the adjustment reflects an ACO's demonstrated readiness to generate the savings needed to preserve net savings under ENHANCED's higher sharing rate.

We conducted these additional analyses in response to comments and to consider all important aspects of the issue. Our proposal rested on the analyses described in the CY 2027 PFS proposed rule, including the larger average positive regional adjustment for ENHANCED track ACOs than ACOs in BASIC track Level E ($304 versus $166 per beneficiary), the association between regional adjustment size and gross savings (r=0.691 versus r=0.09), and the growth in the average adjustment from $206 to $344 while the share of ACOs receiving a positive adjustment remained between 70 and 86

[324] Please note, at the time of this final rule publishing, performance year 2025 financial reconciliation results have not yet been released to ACOs. We anticipate embargoed and unembargoed performance year 2025 financial reconciliation results to be shared with ACOs shortly after the finalization of this final rule.

[325] These analyses are descriptive, limited to a selected subset of ACOs with consistently positive regional adjustments. The analyses do not identify the causes of the observed changes in regional adjustment amounts or the underlying differences between ACO and regional spending, and they do not isolate the effects of renewal, benchmark rebasing, participant composition, or other concurrent factors. Accordingly, these results should not be interpreted as estimates of the effect of the policy finalized in this rule, and should not be interpreted as estimates of this rule's policy effects.

percent (91 FR 44073). These additional findings are consistent with, and further support, our conclusion to finalize the policy and should be interpreted as descriptive rather than causal evidence.

We also considered the comment that the observed reduction in net savings among ACOs that moved from BASIC track Level E to the ENHANCED track may reflect the effects of rebasing more than differences in underlying performance. We agree that savings measured relative to an ACO's benchmark are affected by the timing of rebasing and are not, by themselves, estimates of the reduction in expenditures relative to what would have occurred without ACO participation, although benchmarks are designed to approximate expected expenditures for the ACO's assigned population. Our decision therefore does not rest on that comparison alone. Rather, we considered that comparison together with the analyses described in the CY 2027 PFS proposed rule, the analyses described previously in this section, and the size and distribution of positive regional adjustments over time. Differences in net savings across participation options may also reflect differences in the applicable shared savings rates. We discuss the comparison of gross and net savings across tracks, including our consideration of rebasing among ACOs that changed tracks, in the Regulatory Impact Analysis in section VI.F.7. of this final rule. That section includes additional analytical evidence including the observation that per capita spending growth was similar for PY 2022 ACOs remaining in BASIC through PY 2024 versus the BASIC ACOs that migrated to ENHANCED by PY 2024, yet gross savings grew by a larger margin for the latter group and net savings fell sharply notwithstanding the favorable effect of regional adjustments on rebased benchmarks. That observation that ACO participation in the ENHANCED track has sharply increased both the average gross savings and average payment to ACOs migrating from the BASIC track without demonstrating lower average underlying spending growth relative to ACOs that remained in the BASIC track lends additional support to the finalized policy to marginally reduce the maximum weighting on the regional adjustment for lower-spending ENHANCED track ACOs.

Comment: Some commenters stated that the proposal appears to respond to a subset of organizations that may selectively recruit already efficient providers or passively capture efficient populations, and that a broad reduction in the maximum weight would reduce rewards for all lower-spending ENHANCED track ACOs, including those that achieved lower spending through sustained investment. These commenters recommended that CMS instead develop targeted policies addressing selective provider aggregation. A commenter acknowledged that participant selection may contribute to an ACO's observed regional efficiency at baseline in some cases but stated that it is not the only explanation: observed efficiency may also reflect efforts made before participation in the Shared Savings Program, such as performance improvements achieved in ACO REACH, for which no prior savings adjustment is available under the Shared Savings Program. Another commenter recommended that, if CMS's concern relates to newly formed ACOs or newly participating TINs receiving favorable regional adjustments before demonstrating performance, CMS should develop a more targeted policy, such as one based on length of participation in the program.

Response: We recognize that an ACO's composition, including the recruitment of ACO providers and suppliers whose assigned beneficiaries have relatively low spending, may contribute to the ACO's measured spending relative to its region. Because the positive regional adjustment is based on an ACO's spending position relative to its regional service area when the benchmark is established, changes in ACO composition can affect the size of the adjustment regardless of whether expenditures are subsequently reduced.

We also considered commenters' recommendation that we develop targeted policies to address selective provider aggregation or passive capture of efficient populations, rather than applying the reduced maximum weight to all lower-spending ENHANCED track ACOs. We are concerned that a policy targeted to a subset of ACOs could be difficult to administer consistently and could be avoided through changes to ACO structure or participant lists. Applying the reduced maximum weight to all lower-spending ENHANCED track ACOs, beginning with the second agreement period, addresses the magnitude of the positive regional adjustment regardless of the source of an ACO's regional efficiency. We will continue to monitor changes in ACO composition and their relationship to the regional adjustment and may consider additional refinements through future rulemaking.

We agree with commenters that participant selection is not the only explanation for an ACO's regional efficiency. Many ACOs have achieved lower spending through sustained efforts to improve care and manage expenditures, including efforts undertaken before entering the Shared Savings Program or through participation in other accountable care initiatives. The regional adjustment does not distinguish among the different factors that may contribute to an ACO's spending relative to its region. We also considered commenters' recommendations to adopt more targeted approaches, such as policies based on the length of program participation or the tenure of participating TINs. However, such approaches would introduce additional complexity and operational considerations into the benchmarking methodology that would likely outweigh the benefits. For example, a tenure-based approach would require us to determine how tenure is measured as ACO participant lists, legal entities, and TIN composition change, and to consider cross participation in other initiatives. It could also create incentives to restructure ACOs or ACO participant lists to qualify. These approaches were also not proposed, so other interested parties have not had an opportunity to comment on them. Rather than attempting to distinguish among the various sources of regional efficiency, we believe that reducing the maximum weight of the positive regional adjustment for lower-spending ENHANCED track ACOs, in the second agreement periods, provides a more straightforward approach to moderating the magnitude of the adjustment while continuing to account for regional cost variation in the benchmark.

Comment: Several commenters stated that the regional adjustment is a longstanding component of the Shared Savings Program benchmarking methodology and that ACOs have made participation, investment, and track-selection decisions in reliance on the current weights. Commenters requested additional transition time or other accommodations to account for those reliance interests. Some commenters asked CMS to allow ACOs to select their track after the final rule is published for ACOs applying for a January 1, 2027 start to allow them to review the changes and act in the best interests of their organization. These commenters also recommended that CMS phase-in the change, or delay implementation until 2028. Another commenter stated that the proposal was issued after the application cycle for PY 2027 had closed and would be finalized shortly before agreement periods beginning

January 1, 2027. The commenter added that ACOs entering a second agreement period on that date may have incurred considerable expenses in order to reach and make that decision based on the increase in the maximum weight from 35 percent to 50 percent between the first and subsequent agreement periods under the current policy and that ACOs made early renewal and application decisions during the PY 2027 application cycle, before the proposal was issued.

Response: We recognize that ACOs consider benchmarking policies when making participation and investment decisions, and that stability and predictability of our policies are important. We have repeatedly updated the benchmarking methodology in past rulemaking cycles. It is not a static, longstanding methodology, and when we propose updates to the benchmarking methodology, we consider the impacts those proposed policies would have on the full range of ACOs participating in the program, including transition times ACOs could need under the proposed policies and associated participation planning efforts ACOs may need to undertake should we finalize proposals. Regarding the comment recommending CMS delay the application of the policy, we do not agree that a delay to 2028 is warranted. We recognize that some ACOs incurred costs in making participation decisions for a January 1, 2027 start date. However, we do not believe these costs warrant delay. First, for lower-spending ACOs entering a second agreement period, the finalized 35 percent weight is the same weight that applied the first time their benchmark was adjusted; the policy forgoes an anticipated increase rather than reducing an existing adjustment. Second, ACOs entering agreement periods beginning January 1, 2027, may benefit from the increased prior savings adjustment scaling factor, the risk-adjusted 5 percent benchmark cap, and the growth adjustment finalized in this rule, and these policy changes may mitigate or outweigh a reduction in the regional adjustment. Finally, because weights are established at the start of an agreement period, delaying until 2028 would apply the 50 percent weight for the full duration of agreement periods beginning in 2027, prolonging the benchmark effects described in this section.

We agree, however, that applicants should have an opportunity to consider the final policy in making their track selection, including lower-spending ACOs entering a second agreement period under the ENHANCED track that may have anticipated the maximum weight available under current policy. Given the timing of CY 2027 PFS rulemaking and the Shared Savings Program application cycle for the January 1, 2027 start date, we are providing additional flexibility to applicants in making their final selection of track and level of participation. Following issuance of this final rule, ACOs applying for an agreement period start date of January 1, 2027 will have a time-limited opportunity to change their final selection between the BASIC track and the ENHANCED track, if eligible. This will be available during the Phase 2 RFI period, which will run November 12, 2026 to November 17, 2026 at 12:00 p.m. Eastern Time. We will communicate the applicable process through program guidance. We believe these approaches balance commenters' reliance interests with the policy objectives supporting this change.

Comment: Several commenters including a commenter that otherwise supported the proposal, disagreed with the characterization that ACOs may passively earn shared savings based solely on baseline regional efficiency. Some commenters stated that maintaining expenditures below those of the regional service area requires continuing investments in care coordination, population health management, analytics, workforce, information technology, beneficiary engagement, and other infrastructure, much of which is not separately billable. A few other commenters stated that these efforts must be sustained as assigned beneficiaries change over time. A commenter similarly stated that an ACO must continue managing utilization and expenditures to remain efficient relative to its region.

Many commenters stated that successful ACOs already face benchmark-ratchet effects because expenditure reductions achieved during one agreement period may be reflected in the benchmark established for a subsequent agreement period. These commenters stated that reducing the maximum weight of the positive regional adjustment could intensify the effects of rebasing and weaken incentives for ACOs to generate additional savings. Some commenters separately noted that CMS previously described the regional adjustment as making an ACO's benchmark more independent of its historical expenditures and more reflective of fee-for-service spending in its region.

Some commenters also stated that the regional adjustment and the prior savings adjustment serve distinct purposes and therefore are not interchangeable. These commenters stated that increasing the prior savings adjustment scaling factor would not fully offset a reduction in the regional adjustment because the prior savings adjustment recognizes savings generated during a prior agreement period, whereas the regional adjustment recognizes an ACO's sustained spending position relative to its regional service area. Some of these commenters stated that the net effect for many long-term participants would be limited or negative, citing CMS's own analysis showing continued net benchmark reductions for some ACOs and the fact that the prior savings adjustment considers only the final three years of an agreement period. Another commenter stated, however, that the proposed increase in the prior savings adjustment scaling factor would offset the effect of the reduced regional-adjustment weight for its ACOs. Some of these commenters stated that ACO activities may reduce expenditures for beneficiaries who are not assigned to the ACO and that these market-level spillover effects could create an additional benchmark-ratchet effect.

Response: We appreciate the comments expressing concerns, and we acknowledge the continuing effort required for many ACOs to maintain expenditures below those of an ACO's regional service area, and concerns that many ACOs are not passively benefitting from baseline regional efficiency. We recognize that maintaining expenditures below regional levels may require sustained investments in care coordination, population health management, analytics, information technology, workforce, beneficiary engagement, and other infrastructure, much of which may not be separately billable. We also recognize that these efforts must continue as an ACO's assigned beneficiary population changes over time.

We acknowledge maintaining spending below regional expenditures requires continuing effort and investment, and the amount of the positive regional adjustment is determined by the ACO's spending position relative to its regional service. Additionally, for some ACOs there is an opportunity to favorably select regionally efficient ACO participants that may be one factor contributing to the larger positive regional adjustments observed among some ENHANCED track ACOs. As the positive regional adjustment weight increases, it comprises a larger portion of an ACO's historical benchmark and of any resulting shared savings payment. For

some ACOs, the current maximum weight may therefore increase benchmarks and result in increased shared savings payments that can be driven in part based on selection of participants with regional efficiencies, which can be known and acted on by ACOs prior to the start of the performance year. This scenario is one consideration supporting our conclusion that the regional adjustment can be influenced by ACOs and the current maximum weight under the ENHANCED track is higher than warranted, balanced with a continued incentive of actual improvements that are made by many ACOs to sustain and increase regional efficiency.

We also acknowledge commenters' concerns regarding the benchmark ratchet effect and its potential effect on incentives to generate additional savings. When an ACO begins a new agreement period, its historical benchmark is rebased using more recent expenditure experience, including expenditure reductions achieved in earlier periods. As a result, savings generated by an ACO in a prior agreement period may lower the benchmark against which its performance is measured in a subsequent agreement period. The prior savings adjustment and the regional adjustment are among the policies intended to mitigate this effect; the regional adjustment does so in part by making an ACO's benchmark less dependent on its own historical expenditures and more reflective of expenditures in its regional service area. We agree that rebasing may lower benchmarks for successful ACOs, but we do not believe the finalized policy materially undermines the mitigation of that effect. Lower-spending ENHANCED track ACOs continue to receive a positive regional adjustment, and the increased prior savings adjustment scaling factor returns a larger share of prior savings to the rebased benchmark. The ACPT also continues to insulate a portion of the annual benchmark update from savings generated by ACOs (87 FR 69882).

We also acknowledge that the regional adjustment and the prior savings adjustment address related, but distinct, features of the benchmarking methodology. The regional adjustment reflects the relationship between an ACO's spending and spending in its regional service area, and it reduces the benchmark's dependence on the ACO's historical expenditures. Whereas the regional adjustment depends on the ACO's spending relative to its region regardless of whether the ACO generated savings, the prior savings adjustment is tied directly to savings the ACO generated against its benchmark during a prior agreement period. We therefore do not view the prior savings adjustment and the regional adjustment as interchangeable, and we did not propose to increase the prior savings adjustment scaling factor as a substitute for a higher regional adjustment weight or expect that it would offset the revised weight for every ACO. In our simulations, the increase offset or mitigated the reduced weight for some ACOs (9 of 37 in the 2024 cohort and 42 of 107 in the 2025 cohort) but not for others (91 FR 44078). Rather, we intentionally preserved the regional adjustment, albeit at a lower weight, and are increasing the scaling factor to the prior savings adjustment to continue both types of incentives for ACOs across the program while providing an additional incentive to generate savings, because a larger share of savings generated during the current agreement period will be reflected in the ACO's benchmark for its next agreement period. As discussed in sections III.G.5.c.(2) of this final rule, we considered the interaction across the program between the maximum regional-adjustment weight and the increase in the prior savings adjustment scaling factor policies in developing the final provisions. We recognize that their combined effect will vary across ACOs based on their historical expenditures, regional spending position, prior savings, agreement-period timing, and other features of the benchmark calculation.

Finally, we acknowledge commenters' concerns that ACO activities may affect expenditures for beneficiaries who are not assigned to the ACO and these spillover effects may therefore contribute to changes in regional expenditures. Such spillover effects could influence regional expenditure comparisons, and we will continue to monitor the related interaction among ACO performance, regional expenditure trends, rebasing, and benchmark adjustments.

Comment: A couple of commenters urged CMS to ensure that reducing the ENHANCED track positive regional adjustment weight does not inadvertently disadvantage ACOs whose market characteristics shape their measured performance, stating that both rural and higher-cost-market ACOs may be affected differently than the proposal contemplates. One of these commenters stated that its ACO has demonstrated strong performance relative to its region but that a lower weight would make it more difficult for ACOs in higher-cost markets to demonstrate savings when compared with lower-cost regions and encouraged CMS to carefully consider geographic variation in spending when finalizing the proposal.

A few commenters suggested that CMS consider applying different benchmark policies based on an ACO's tenure in the program or the length of time participating TINs have been engaged in accountable care models. These commenters stated that such an approach would address CMS's stated concerns without reducing incentives for ACOs that have demonstrated long-term success. A commenter also recommended that CMS retain the 50 percent maximum weight and make it available to ACOs returning to the Shared Savings Program in their second or subsequent agreement period, regardless of whether they previously received a regional adjustment.

A commenter recommended that CMS retain the 50 percent maximum weight for the positive regional adjustment under the ENHANCED track and also raise the 5 percent cap on upward benchmark adjustments (currently 5 percent of national per capita expenditures for assignable beneficiaries) which is distinct from the maximum weight. The commenter stated that the 5 percent cap limits the extent to which these adjustments mitigate the effects of rebasing and constrains the long-term savings opportunity available to ACOs.

Response: We appreciate the comments expressing concerns and making recommendations and have considered each of the alternatives suggested.

We appreciate comments with concern that market characteristics shape measured performance. The policy we are finalizing is limited in scope: it applies only to the maximum weight used in calculating the positive regional adjustment for ACOs participating under the ENHANCED track. It does not change the weights applicable to the BASIC track, the calculation of the negative regional adjustment, or the cap on the adjustment. An ACO that spends more than its region is unaffected by this change, as is an ACO participating at any level of the BASIC track. The reduction also does not eliminate the incentive of regional efficiency; it moderates the maximum weight at which that efficiency is reflected in the benchmark for the track in which the adjustment has been largest. We will monitor participation among rural ACOs and among ACOs in higher-cost markets following implementation.

Commenters suggested that we differentiate benchmark policies based

on an ACO's tenure in the program, the length of time participating TINs have been engaged in accountable care initiatives, or the risk profile of an ACO's assigned population. We disagree with commenters who advocated that we adopt different benchmark policies as described in this section of this final rule. These suggestions go beyond the scope of our proposal, and other commenters have not had an opportunity to review and comment on such potential policies. Additionally, a differentiated structure of the kind a commenter suggested would introduce additional complexity into the benchmarking methodology. For example, such a structure would require us to determine how tenure would be measured across changes in ACO composition, legal entity, and participation across initiatives. The recommendation to make the 50 percent maximum weight available to returning ACOs that have not previously received a regional adjustment would increase, rather than moderate, the magnitude of the positive regional adjustment under the ENHANCED track and is therefore inconsistent with the policy we are finalizing.

We also considered the recommendation to raise the 5 percent cap applicable to positive benchmark adjustments. Because this recommendation concerns the level and calculation of the cap, we address it in section III.G.5.e of this final rule.

Accordingly, we are finalizing the amendments to § 425.656 as proposed, including the addition of new § 425.656(f) specifying the phase-in of weights used in the regional adjustment calculation for agreement periods beginning on January 1, 2027, and in subsequent years, together with the conforming changes to § 425.656(a), § 425.656(c)(2), redesignated § 425.656(g), and § 425.600(f)(4)(ii). We are also providing the additional flexibility for applicants described in this section.

After consideration of public comments, we are finalizing our proposal as follows: we are finalizing, without modification, our proposal at § 425.656 to reduce the maximum weight used to calculate the positive regional adjustment for ENHANCED track ACOs from 50 percent to 35 percent. We are also finalizing, without modification, our proposed revisions at § 425.600(f)(4)(ii) to replace the existing cross-references to §§ 425.601(f) and 425.656(e), with cross-references to §§ 425.601(f), § 425.656(e), and § 425.656(f), to include new § 425.656(f) in the cross-references. This change rebalances the role of regional and historical expenditures in establishing benchmarks, while continuing to recognize ACOs that spend less than their region. Together with the increase to the BASIC track Level E shared savings rate and the revisions to the prior savings adjustment finalized in sections III.G.5.c.(1) and III.G.5.d of this final rule, this policy better aligns each track's financial opportunity with an ACO's capacity to reduce expenditures. Consistent with our prior commitments (81 FR 37962; 83 FR 68018), we will monitor how this policy affects ACO participation, track selection, and program savings, and will address any needed changes through future rulemaking.

d. Increase the Prior Savings Adjustment by Increasing the Scaling Factor

(1) Background

As discussed in the CY 2027 PFS proposed rule, under section 1899(d)(1)(B)(ii) of the Act, an ACO's benchmark must be reset at the start of each agreement period (91 FR 44076). Section 1899(d)(1)(B)(ii) of the Act provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Under this authority, as described in the June 2015 final rule (80 FR 32785 through 32791), we established a prior savings adjustment [326] that applied when establishing the benchmark for ACOs entering a second agreement period beginning on January 1, 2016, to account for the average per capita amount of savings generated during the ACO's prior agreement period (79 FR 72838). The prior savings adjustment was originally designed to adjust an ACO's benchmark for its second agreement period to account for the average per capita amount of savings generated by the ACO across the 3 performance years of its first agreement period. This average per capita amount also accounted for the ACO's quality performance in each performance year under its first agreement period. We limited the adjustment to the benchmark for the second agreement period to the average number of assigned beneficiaries in the prior agreement period (80 FR 32789).

We removed the prior savings adjustment introduced as part of the June 2015 final rule and replaced it with the existing regional adjustment as part of the June 2016 final rule (81 FR 37954 through 37992). We reintroduced the prior savings adjustment as an ongoing component of the Shared Savings Program as part of the CY 2023 PFS final rule (87 FR 69898 through 69915).

In the CY 2023 PFS final rule, we established the methodology, codified at § 425.658 of the regulations, for the prior savings adjustment that applied in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years. We describe the steps for calculating the prior savings adjustment in the CY 2023 PFS final rule (87 FR 69898). We finalized revisions to § 425.656 that specify how we express the regional adjustment as a single value and use this value in determining whether a regional adjustment or prior savings adjustment will be applied to the ACO's benchmark.

In the CY 2024 PFS final rule (88 FR 79185 through 79196), in response to concerns that negative regional adjustments may make it more difficult for ACOs to succeed in the Shared Savings Program financially, we finalized revisions to § 425.652 to specify that if the regional adjustment, when expressed as a single value, is negative then no regional adjustment will be applied to an ACO's historical benchmark. We also finalized revisions to § 425.658 to specify that we will calculate the per capita prior savings adjustment as the lesser of 50 percent of the prorated average per capita savings amount (computed as described in § 425.658(b)(3)(ii)) and the cap equal to 5 percent of national per capita OM expenditures for assignable beneficiaries for BY3, expressed as a single value.

In the CY 2024 PFS final rule we also finalized modifications to the approach to calculate and apply the regional adjustment, or the regional adjustment in combination with the prior savings adjustment, if applicable, for ACOs in agreement periods starting on January 1, 2024, or the regional adjustment, prior savings adjustment, or population adjustment, if applicable, for ACOs in agreement periods starting on January 1, 2025, and in subsequent years. Specifically, we finalized revisions to § 425.652 that specify how we will determine and apply the adjustment to an ACO's benchmark depending on whether the ACO is eligible for a prior savings adjustment, whether the ACO is eligible for the population adjustment, and whether the ACO's regional adjustment, expressed as a single value, is positive or negative. An ACO will receive the most favorable of the adjustments, as applicable, with each

[326] In the June 2015 final rule (80 FR 32788), we referred to this policy as accounting for shared savings payments when resetting the benchmark, after which we refer to it as the prior savings adjustment.

adjustment capped at 5 percent of BY3 national assignable expenditures.

In the CY 2024 PFS proposed rule (88 FR 52494 through 52495), we requested information on potential changes to the 50 percent scaling factor used in determining the prior savings adjustment. Most commenters supported increasing the prior savings adjustment, with several commenters recommending using the maximum shared savings rate the ACO was eligible to receive during the benchmark years. For the full summary of comments, refer to the CY 2024 PFS final rule (88 FR 79228).

(2) Revisions

In the CY 2023 PFS final rule (87 FR 69910), we stated that we believed that a 50 percent scaling factor used to calculate the prior savings adjustment would be appropriate because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track. In the CY 2027 PFS proposed rule, we stated that, after further analysis of this policy and gaining additional years of experience with the current policy, we believe changing the prior savings adjustment scaling factor from 50 percent to 75 percent is warranted because the current methodology may not provide sufficiently strong or consistent incentives for ACOs to generate and sustain savings (91 FR 44076 through 44077). We likewise stated that we believe that the current methodology may not provide sufficient incentives for ACOs to continue participation in future agreement periods when the ACOs are compared against benchmarks that include their own previous success in reducing expenditures (91 FR 44077). As noted in the CY 2023 PFS final rule (87 FR 69909), in an analysis estimating how the prior savings adjustment may impact ACOs participating in the Shared Savings Program if the prior savings adjustment would have been in place at that time, among 123 ACOs entering a new agreement period in PY 2020 and reconciled in one or more benchmark years, only 27 (22 percent) would have received a final adjustment that included prior savings. Among 153 ACOs entering a new agreement period in PY 2022 and reconciled in one or more benchmark years, only 43 (28.1 percent) would have received such an adjustment. These findings suggested that relatively few ACOs would benefit from the prior savings adjustment under the methodology that included the 50 percent scaling factor. Furthermore, we stated in the CY 2027 PFS proposed rule that after gaining initial experience with the prior savings adjustment applicable to agreement periods beginning on January 1, 2024, and in subsequent years, we have seen a relatively small number of ACOs receiving the prior savings adjustment with 82 (17 percent) of ACOs in CY 2025 receiving a prior savings adjustment and 18 (4 percent) of ACOs in PY 2024 receiving a prior savings adjustment (91 FR 44077).

In the CY 2023 PFS final rule (87 FR 69904), we also described scenarios in which ACOs with strong prior savings may not receive the prior savings adjustment. For example, as illustrated in Table 68 (87 FR 69907), pro-rating and scaling of prior savings using the 50 percent scaling factor can result in the final prior savings adjustment being smaller than the regional adjustment, even when the ACO's prior savings adjustment prior to applying the scaling factor exceeds the regional adjustment. In the CY 2027 PFS proposed rule, we stated that this dynamic may weaken incentives for ACOs to generate and sustain savings over time (91 FR 44077).

In the CY 2027 PFS proposed rule, we noted that we conducted a simulation limited to ACOs participating in the ENHANCED track with lower spending than their regional service area, because these ACOs would be directly impacted by the proposed change to the weight of the regional adjustment (91 FR 44077). The simulation applied both the proposed reduction of the regional adjustment weight from 50 percent to 35 percent and increasing the prior savings adjustment scaling factor from 50 percent to 75 percent. See the CY 2027 PFS proposed rule (91 FR 44072 through 44076) for a description of the proposed change to the regional adjustment weight. The simulation was conducted on two cohorts: 37 ENHANCED track ACOs that began an agreement period on January 1, 2024, and 107 ENHANCED track ACOs that began an agreement period on January 1, 2025. We stated that, for both cohorts, we focused on PY1 of the agreement period; 2024 and 2025, respectively (91 FR 44077). Table B–G11 of the CY 2027 PFS proposed rule reports the results for five mutually exclusive groups of ACOs (91 FR 44078). We described that: *Group 1 (had regional adjustment and still would have it, no benchmark change due to 5 percent cap)* includes ACOs that remain at the existing 5 percent cap, leaving benchmarks unchanged, as the reduction in the regional adjustment weight did not decrease the regional adjustment below the 5 percent cap. *Group 2 (had regional adjustment, now would have prior savings adjustment)* consists of ACOs that currently receive a regional adjustment and for which the proposed increase in the prior savings adjustment scaling factor is large enough to either fully offset the reduced regional adjustment, resulting in benchmarks that do not decline and may increase, or to mitigate the effect of the reduced regional adjustment to some degree as the applicable adjustment to the benchmark would change as a result of the proposed policy changes. *Group 3 (had regional adjustment and still would have it, net benchmark decrease)* includes ACOs that receive the full proposed reduction to the weight of the regional adjustment and for which the prior savings adjustment, even at the proposed 75 percent scaling factor, remains smaller than the regional adjustment. For these ACOs, the final adjustment category would remain the regional adjustment both before and after the changes, resulting in a net decrease to the benchmark. *Group 4 (subject to the current 50 percent prior savings adjustment scaling factor)* includes ACOs for which the prior savings adjustment calculated under the current 50 percent scaling factor was already the applicable adjustment prior to the proposed policy change to the regional adjustment weight; because the prior savings adjustment remains the applicable adjustment, any benchmark change for these ACOs reflects the effect of the proposed increase in the prior savings adjustment scaling factor. *Group 5 (not subject to the proposed regional adjustment weight change)* includes ACOs that are not exposed to the regional adjustment weight adjustment—either because they are higher spending or already subject to the 35 percent positive weight—but that received the increased prior savings adjustment (see footnote on Table B–G11 of the CY 2027 PFS proposed rule at 91 FR 44078). We noted in the CY 2027 PFS proposed rule that one ACO in the 2025 cohort had the population adjustment as their applicable adjustment and would continue to have it with any of the proposed changes (91 FR 44077).

TABLE B-G14: ESTIMATED BENCHMARK IMPACT OF PROPOSED REDUCTION IN REGIONAL ADJUSTMENT WEIGHT AND INCREASING PRIOR SAVINGS ADJUSTMENT

	ACOs beginning an Agreement Period on January 1, 2024			ACOs beginning an Agreement Period on January 1, 2025		
Group	Number of ACOs (N=37)*	Percent of ACOs (%)	Mean Change Per Capita Benchmark ($)	Number of ACOs (N=107)*	Percent of ACOs (%)	Mean Change Per Capita Benchmark ($)
(1) Regional Adjustment retained (no benchmark change)	0	0.0%	$0.00	0	0.0%	$0.00
(2) Had regional adjustment would transition to prior savings adjustment	9	24.3%	$29.79	42	39.3%	$16.70
(3) Had regional adjustment and would continue to have it	21	56.8%	-$113.31	31	29.0%	-$85.36
(4) Subject to the current percent prior savings adjustment	7	18.9%	$105.98	33	30.8%	$110.30
(5) Not subject to the proposed regional weight change**	21	36.2% of total (n=58)	$15.98	24	18.3% of total (n=131)	$27.71

Table notes:
* Number of ACOs subject to the proposed policy changes.
** ACOs in this group are not subject to the regional adjustment weight reduction, but where applicable, the proposed 75 percent prior savings adjustment scaling factor was applied.

As discussed in the CY 2027 PFS proposed rule, for ACOs that began an agreement period on January 1, 2025, the proposed policies would produce no meaningful net aggregate impact on benchmarks for ACOs in group 1 (91 FR 44078). After applying the reduced regional adjustment weight, no ACO remains constrained by the 5 percent cap. Of the 107 ACOs, 42 (39.3 percent) fall in Group 2, with benchmarks increasing by a mean of $16.70, 33 (30.8 percent) fall in Group 4, where the prior savings adjustment was already dominant, and 31 ACOs (29.0 percent) fall in Group 3 with benchmark decreases averaging $85.36 in magnitude. For the 2025 cohort, the increase in the scaling of the prior savings adjustment more than offsets the reduction in the weight of the regional adjustment in aggregate, producing a modest net benchmark increase concentrated among ACOs with proven savings records. The larger share of ACOs in this cohort for which the prior savings adjustment is the applicable adjustment (70.1 percent; Groups 2 and 4) reflects, in part, cohort-specific differences in benchmark composition and adjustment eligibility—specifically, a greater prevalence of ACOs with prior savings large enough that the prior savings adjustment exceeds the regional adjustment and therefore determines the final benchmark adjustment.

We noted in the CY 2027 PFS proposed rule that, for ACOs that began an agreement period on January 1, 2024, the combined effect of the two proposed policies produces a net downward aggregate impact on benchmarks (91 FR

44078 through 44079). No ACO in this cohort is constrained by the 5 percent cap, leaving most directly affected by the proposed regional adjustment weight reduction, with limited offset from the increase in the prior savings adjustment scaling factor. As a result, 21 ACOs (56.8 percent of those impacted) would experience benchmark decreases. A smaller share of ACOs hold the prior savings adjustment as their applicable adjustment (43.2 percent). Prior savings amounts are generally insufficient to exceed regional adjustments, and for these ACOs, the net effect of the two policies is a downward adjustment, consistent with the intended effect for ACOs whose benchmarks might have been inflated by the generous regional adjustment. As ACOs have additional incentives to focus on increasing savings in the future, prior savings amounts may continue to grow, resulting in different impacts than what are initially observed in these analyses.

As discussed in the CY 2027 PFS proposed rule, we extended this analysis by re-running the simulation and incorporating the proposed risk adjustments to the 5 percent cap on positive regional adjustments and to the prior savings adjustment cap (Table B–G12 at 91 FR 44079) as outlined the CY 2027 PFS proposed rule (91 FR 44082 through 44087).

TABLE B-G15: ESTIMATED IMPACT OF PROPOSED REGIONAL ADJUSTMENT WEIGHT REDUCTION, INCREASING PRIOR SAVINGS ADJUSTMENT, AND RISK-ADJUSTED CAPS ON ACO BENCHMARK ADJUSTMENTS

	ACOs beginning an Agreement Period on January 1, 2024			ACOs beginning an Agreement Period on January 1, 2025		
Group	**Number of ACOs (N=37)***	**Percent of ACOs (%)**	**Mean Change Per Capita Benchmark ($)**	**Number of ACOs (N=107)***	**Percent of ACOs (%)**	**Mean Change Per Capita Benchmark ($)**
(1) Regional Adjustment retained (no benchmark change)	0	0.0%	0.00	0	0.0%	0.00
(2) Had regional adjustment, would transition to prior savings adjustment	9	24.3%	13.97	41	38.3%	7.22
(3) Had regional adjustment and would continue to have it	21	56.8%	-115.91	32	29.9%	-93.72
(4) Subject to the current percent prior savings adjustment	7	18.9%	107.03	33	30.8%	121.36
(5) Subject to the population adjustment and would transition to regional adjustment	0	0	0	1	0.9	11.03

Table notes:

* Number of ACOs subject to the proposed policy changes.

We discussed in the CY 2027 PFS proposed rule that the results in Table B–G12 (91 FR 44079) under the proposed risk-adjusted 5 percent cap are largely consistent with those in Table B–G11 (91 FR 44078) (91 FR 44079 through 44080). The distribution of ACOs across Groups 2 through 4 remains largely unchanged, and the reduction in the weight of the regional adjustment continues to be the primary driver of benchmark changes in both cohorts. The similar results between both analyses are a result of three factors. First, weighted mean risk scores in this sample are clustered near 1.0 (approximately 0.94 to 0.99 across enrollment statuses and cohorts), so risk-adjusting the caps changes their values only modestly (between 1 to 6 percent) and generally does not

materially affect ACOs' effective regional or prior savings adjustments. Second, for most ACOs eligible for the prior savings adjustment, the scaling factor is the applicable constraint rather than the cap; therefore, modifying a non-binding cap has little or no effect on the adjustment. Third, the reduction in the weight of the regional adjustment from 0.50 to 0.35 produces benchmark impacts substantially larger than those associated with risk-adjusting the caps, making it an important driver of changes to the benchmark under both analyses.

We stated that, to strengthen incentives and mitigate impacts from ACOs' past performance on future agreement periods, we proposed increasing the prior savings adjustment scaling factor, program-wide, from 50 percent to 75 percent, beginning with agreement periods starting January 1, 2027, and subsequent agreement periods (91 FR 44080). We noted that we have heard from interested parties that the prior savings adjustment scaling factor should be 100 percent to encourage further savings and address rebasing concerns (91 FR 44080). However, we stated that we believe that increasing the prior savings adjustment scaling factor above 75 percent would limit incentives for ACOs to continue to decrease spending in second and subsequent agreement periods, since they would be rewarded largely for previously demonstrated savings and would not be incentivized to continue to decrease costs (approaching 100 percent reward if the prior savings adjustment scaling factor is above 75 percent) (91 FR 44080). We stated that without a sufficient incentive level to decrease spending, this would jeopardize the ability of the Shared Savings Program to generate future savings to the Trust Funds (91 FR 44080). We also stated that we believe that a prior savings adjustment scaling factor of 75 percent strikes the appropriate balance between encouraging long-term participation in the program and encouraging ACOs to save, while also supporting savings to the Trust Funds (91 FR 44080).

Table B–G13 of the CY 2027 PFS proposed rule (91 FR 44081) shows simulated results of the proposal to increase the prior savings adjustment scaling factor to 75 percent while holding the weight on the regional adjustment constant. Table B–G13 of the CY 2027 PFS proposed rule (91 FR 44081) is divided into several sections that correspond to the various criteria ACOs would be required to meet to receive the proposed prior savings adjustment. The first segment of the Table (rows [A] and [B]) identifies the total number of ACOs entering a new agreement period in the respective performance year (PY 2024 or PY 2025) and what proportion of all ACOs starting an agreement period in that performance year were reconciled in one or more benchmark years. This is the first eligibility criterion ACOs must meet to receive the prior savings adjustment. The second segment of the Table (row [C]) identifies the proportion of ACOs, among those reconciled in one or more benchmark years, that had positive prorated average prior savings, which is the second criterion of the CMS methodology. All ACOs that do not receive a regional adjustment and have positive prorated average prior savings would receive some benefit from the prior savings adjustment. However, ACOs that receive a positive regional adjustment and have positive prorated average prior savings would only receive a benefit if the prior savings adjustment is greater than the positive regional adjustment the ACO otherwise would have received. The third section in Table B–G13 (row [D]) identifies the proportion of ACOs that were simulated to actually receive the prior savings adjustment among ACOs that were reconciled in one or more benchmark years. The fourth segment in Table B–G13 (row [E]) summarizes the positive impact of the prior savings adjustment relative to the regional adjustment the ACO would otherwise have received for ACOs that were simulated to receive the prior savings adjustment. We stated that this table demonstrates that more ACOs could receive the prior savings adjustment instead of the regional adjustment in later agreement periods when increasing the scaling factor for the prior savings adjustment to 75 percent (91 FR 44080).

TABLE B-G16: MODELED IMPACT OF 50 PERCENT AND 75 PERCENT PRIOR SAVINGS ADJUSTMENT SCALING FACTORS ON PY 2025 BENCHMARKS FOR 2024 AND 2025 STARTERS

	50% Prior Savings Adjustment Scaling Factor	75% Prior Savings Adjustment Scaling Factor
[A] ACOs Entering a New Agreement Period in 2024 or 2025	336	336
[B] ACOs Reconciled in One or More Benchmark Years	256	256
Percent of ACOs in [B] out of total in [A]	76%	76%
[C] ACOs with Positive Pro-rated Average Prior Savings Among ACOs Reconciled in One or More Benchmark Years	223	223
Percent of ACOs in [C] out of total in [B]	87%	87%
[D] ACOs Whose Final Adjustment Includes Adjustment for Prior Savings Among ACOs Reconciled in One of More Benchmark Years	82	137
Percent of ACOs in [D] out of total in [C]	37%	61%
[E1] Net Benefit to Benchmarks from Prior Savings Adjustment Relative to Regional Adjustment Otherwise Received ($) Under 50% Prior Savings Adjustment Scaling Factor (Calculated Among ACOs in [D] that began an agreement period on January 1, 2024)		
Minimum		$0.85
Average		$45.72
Maximum		$113.87
[E2] Net Benefit to Benchmarks from Prior Savings Adjustment Relative to Regional Adjustment Otherwise Received ($) Under 75% Prior Savings Adjustment Scaling Factor (Calculated Among ACOs in [D] that began an agreement period on January 1, 2025)		
Minimum		$0.52
Average		$62.01
Maximum		$157.53

In the CY 2023 PFS final rule (87 FR 69907), we explained our belief that incorporating an adjustment for prior savings—when more advantageous for ACOs than the regional adjustment—would help limit the negative ratchet effects of benchmark rebasing. Under the existing benchmarking methodology, savings an ACO achieves in one agreement period can reduce its rebased benchmark for a subsequent agreement period by lowering the historical spending that forms the basis for that benchmark. To illustrate the effect of the proposed scaling factor increase in reducing the impacts from rebasing: if an ACO reduces per capita expenditures by $1,000 relative to a $10,000 benchmark, its rebased benchmark would otherwise decrease to $9,000. Under the current 50 percent scaling factor, the prior savings adjustment restores $500, yielding a benchmark of $9,500. Under the proposed 75 percent scaling factor, $750 would be restored, resulting in a benchmark of $9,750 and a smaller effective downward adjustment of the benchmark.

As discussed in the CY 2027 PFS proposed rule, the proposed increase to the prior savings adjustment scaling factor from 50 percent to 75 percent would provide additional relief from rebasing while continuing to incentivize ACOs to achieve further savings in future agreement periods (91 FR 44081). We stated that this change would shift a subset of ACOs from receiving the regional adjustment to receiving the prior savings adjustment, as the larger prior savings adjustment becomes more likely to exceed the regional adjustment (91 FR 44081). We noted that ACOs with higher regional or population adjustments would remain largely unaffected, while those with moderate to high levels of prior savings would particularly benefit (91 FR 44081).

We stated in the CY 2027 PFS proposed rule that, although MedPAC has previously urged CMS to use the prior savings adjustment to phase out the regional adjustment entirely,[327] we continue to disagree that a full phase-out is appropriate (91 FR 44081). We stated that we believe that the regional adjustment continues to provide valuable incentives, and that ACOs that are efficient relative to their regions should continue to receive a benchmark adjustment that recognizes that efficiency, consistent with our longstanding goal of reducing disincentives for high-performing ACOs that successfully lower spending (91 FR 44081). We added that we also proposed to reduce the maximum weight applied to the regional adjustment for lower-

[327] Medicare Payment Advisory Commission (MedPAC) comment on the CY 2023 PFS proposed rule. *https://www.medpac.gov/wp-content/uploads/2022/09/09022022_Part_B_2023_CMS1770P_MedPAC_COMMENT_v2_SEC.pdf.*

spending ENHANCED track ACOs (91 FR 44081). That taken together, these proposals are intended to better balance incentives between regionally efficient ACOs and those that have demonstrated program success, through a history of earning shared savings, while further mitigating the ratcheting effects that may occur when prior savings are incorporated into future benchmarks (see the CY 2027 PFS proposed rule at 91 FR 44072 through 44076 for details on the proposed regional adjustment changes) (91 FR 44081 and 44082).

We proposed that this policy would apply for agreement periods beginning on January 1, 2027, and in subsequent years (91 FR 44082).

We proposed to revise § 425.658(c), describing calculation of the per capita prior savings adjustment, to include proposed revised paragraph (c)(2), with the calculation methodology applicable for agreement periods beginning on January 1, 2027, and in subsequent years. Currently paragraph (c)(2) of § 425.658 is reserved (91 FR 44082). We stated in the CY 2027 PFS proposed rule that under proposed § 425.658(c)(2), we would specify the use of a scaling factor of 75 percent (91 FR 44076 through 44082), and a risk adjusted 5 percent cap (91 FR 44085 through 44087) in determining the amount of the prior savings adjustment an ACO may receive (if eligible) (91 FR 44082). Specifically, for agreement periods beginning on January 1, 2027, and in subsequent years, if an ACO is eligible for the prior savings adjustment as determined in § 425.658(b)(3), the prior savings adjustment would equal the lesser of the following: (i) 75 percent of the pro-rated average per capita amount computed in § 425.658(b)(3)(ii); or (ii) a single per capita value that would be the result of risk adjusting the 5 percent cap (91 FR 44085 through 44087).

We also proposed the following technical and conforming changes to other provisions of § 425.658, for completeness and clarity (91 FR 44082):

- In § 425.658(c)(1) introductory text, we proposed to add a new first sentence to specify the existing provisions on calculation of the per capita prior savings adjustment apply for agreement periods beginning on or after January 1, 2024 and before January 1, 2027.
- In § 425.658(d), describing CMS' comparison of the per capita prior savings adjustment with the regional adjustment and the population adjustment, in determining which (if any) adjustment applies to an ACO's benchmark, we proposed to amend the existing cross-reference to § 425.658(c)(1) to refer instead more generally to § 425.658(c).

We sought comment on our proposal to increase the prior savings adjustment scaling factor from 50 percent to 75 percent for agreement periods beginning on January 1, 2027, and in subsequent years, and the proposal to specify related provisions in the Shared Savings Program regulations in § 425.658(c)(2), as well as proposed technical and conforming changes to other provisions of § 425.658.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to increase the prior savings adjustment scaling factor, stating that it would help mitigate the ''ratchet effect'' and provide incentives for ACOs to generate and sustain savings. A few commenters appreciated CMS's proposal to address rebasing concerns, stating that ACOs that have successfully generated savings should not be penalized in future agreement periods, and allowing ACOs to retain a greater portion of savings generated would strengthen financial incentives to remain in the Shared Savings Program over time. A commenter stated that a stronger prior savings adjustment would help incentivize long-term participation and continued improvement, especially for rural ACOs with limited opportunities to add new beneficiaries or organizations. Another commenter stated that this proposal was especially important for organizations serving high-needs patients, who require more resource-intensive interventions to achieve savings.

Response: We thank commenters for their support and agree that this proposal would help to mitigate the ratchet effect by returning to an ACO's benchmark an amount that reflects a greater portion of its success in lowering growth in expenditures. We agree that this would encourage ACOs to generate additional savings and provide incentives for ACOs to sustain savings in the Shared Savings Program.

We also agree with commenters that increasing the prior savings adjustment would help incentivize long-term participation and continued improvement, including for rural ACOs and those serving high-needs patients. We acknowledge the commenter's emphasis on the importance of this proposal for organizations serving high-needs patients whose care may be more resource intensive, and we believe the proposed modification to the prior savings adjustment scaling factor would better align benchmark adjustments with true clinical complexity and encourage participation among organizations engaged in providing high-needs care.

Comment: Some commenters supported the proposal and encouraged CMS to expand the prior savings adjustment to recognize savings generated across other CMS accountable care models. These commenters cited that accounting for savings across all models would allow ACOs to carry forward their historical savings into Shared Savings Program benchmarks, ensuring protection against benchmark decay regardless of the specific model.

Response: We appreciate the recommendation to expand the calculation of the prior savings adjustment to include savings generated across other CMS accountable care models. CMS accountable care models, such as those available through the CMS Innovation Center, have different methods to make determinations of shared savings and losses, creating challenges in comparing the results of these models to the results in the Shared Savings Program. There are also other differences, such as organizational and participation list configurations, that may not be comparable between models and the Shared Savings Program. Shared Savings Program policies designed to take into account these methodological considerations would benefit from public feedback solicited through notice and comment rulemaking, so we will take these suggestions under consideration and continue to monitor savings and losses in other models and how this relates to considerations for future proposed changes to the prior savings adjustment.

Comment: A couple of commenters recommended that the regional adjustment and prior savings adjustment changes be considered in tandem rather than approving one but not the other. A couple of commenters recommended that CMS allow ACOs to apply the prior savings adjustment and the regional efficiency adjustment together instead of receiving whichever adjustment is highest. Another commenter supported the proposal and recommended that CMS use the greater of 75 percent of the prorated average per capita prior savings amount or a single per capita value that would be the result of risk adjusting the 5 percent cap, rather than the lesser of the two.

Response: While we believe the revisions to the regional adjustment and the prior savings adjustment complement one another, we do not believe they are inextricably linked such that either depends on the other or that they must be adopted together. Each independently furthers program goals: the reduced maximum weight applied

to the positive regional adjustment moderates benchmark advantages for lower-spending ENHANCED track ACOs, and the increased prior savings adjustment scaling factor mitigates the effects of rebasing for ACOs that have generated savings.

As discussed in section III.G.5.c.(2) of this final rule, we are finalizing the reduction in the maximum positive regional adjustment weight for lower spending ACOs, entering their second agreement period, in the ENHANCED track.

Regarding the recommendation to apply the prior savings adjustment and the regional adjustment together, we do not agree that these adjustments should be combined. Including both of these adjustments would potentially overly inflate historical benchmarks to the point where ACOs would need to do little to collaborate and coordinate care for beneficiaries to generate savings. This would limit incentives for ACOs to continue to generate savings in second and subsequent agreement periods, and risk program savings that ACOs generate for the Trust Funds.

With regard to the commenter recommending that CMS use the greater of 75 percent of the prorated average per capita prior savings amount or a single per capita value that would be the result of risk adjusting the 5 percent cap, we continue to believe that the proposed methodology (for example, the prior savings adjustment would equal the lesser of the following: (i) 75 percent of the pro-rated average per capita amount; or (ii) a single per capita value that would be the result of risk adjusting the 5 percent cap) appropriately balances the goals of encouraging long-term participation, recognizing prior savings, maintaining consistency with the broader benchmark framework, and protecting program integrity. We are not adopting the commenter's suggestion to use the greater of' 75 percent of the prorated average per capita prior savings amount or a single per capita value that would be the result of risk adjusting the 5 percent cap because the cap functions to ensure that the adjustment does not exceed a ceiling. Using the greater of the two values would convert the cap into a floor, in which ACOs with prorated prior savings above the cap would receive an adjustment with no upper limit, while ACOs with prorated prior savings below the cap would receive the full capped amount regardless of the savings they generated. The 5 percent cap protects the Medicare Trust Funds against extreme or outlier positive adjustments that could inflate an ACO's benchmark to the point where the ACO could generate shared savings without decreasing expenditures.

Comment: A few commenters supported CMS's efforts to reduce the benchmark ratchet effect but were concerned that a 75 percent scaling factor may not fully address the issue. A few commenters recommended increasing the prior savings adjustment scaling factor more than we proposed, for example, increasing it from 50 percent to 95 percent. These commenters stated that a 95 percent scaling factor would eliminate most of the penalty for early success, allowing ACOs to invest in the first agreement period. Another commenter recommended that CMS continue evaluating additional refinements that recognize historical savings generated by ACOs and preserve strong incentives for sustained investment in care transformation, care coordination, and population health management.

Another commenter supported CMS's efforts to reduce the ratchet effect but was concerned that the proposal would not effectively address the issue for ACOs that have participated in the Shared Savings Program for many years. This commenter was concerned that the proposed change, in combination with the proposed reduction to the regional adjustment, would disproportionately negatively affect ACOs that achieved regional efficiency early in their participation. This commenter stated that these ACOs may have fewer opportunities to generate additional savings, because the prior savings adjustment considers only the final three years of an agreement period rather than an ACO's complete savings history. This commenter was concerned that the proposal may have the unintended consequence of further reducing incentives for long-term ACOs to maintain investments in care transformation.

Response: As we stated in the CY 2027 PFS proposed rule (91 FR 44080), we believe increasing the prior savings adjustment scaling factor above 75 percent would limit incentives for ACOs to continue to decrease spending in subsequent agreement periods, since they would be rewarded for previously demonstrated savings and would not be incentivized to continue to decrease costs (approaching 100 percent reward if the prior savings adjustment scaling factor is above 75 percent). Increasing the prior savings adjustment scaling factor to 95 percent would not provide a sufficient incentive level to decrease spending, and this could jeopardize the ability of the Shared Savings Program to generate future savings to the Trust Funds. We believe that a prior savings adjustment scaling factor of 75 percent strikes the appropriate balance between encouraging long-term participation in the program and encouraging ACOs to save, while also supporting savings to the Trust Funds.

A few commenters described their concerns related to the ''benchmark ratchet effect,'' and we describe similar impacts as a result of ''rebasing'' a historical benchmark. When an ACO begins a new agreement period, its historical benchmark is rebased using more recent expenditure experience, including expenditure reductions the ACO achieved in earlier periods. As a result, savings generated by an ACO in a prior agreement period may lower the benchmark against which its performance is measured in a subsequent agreement period. As described in the CY 2027 proposed rule (91 FR 44081), ACOs with higher regional or population adjustments would remain largely unaffected, while those with moderate to high levels of prior savings would particularly benefit. The prior savings adjustment and the regional adjustment are both intended to mitigate what the commenters described as the benchmark ''ratchet'' effect, but they do so differently. The regional adjustment reduces the benchmark's dependence on an ACO's own historical expenditures by reflecting its spending relative to its regional service area; it does not directly account for savings the ACO generated. The prior savings adjustment, by contrast, adds back to the rebased benchmark a portion of the savings the ACO generated in its prior agreement period, directly offsetting the downward effect of rebasing on that ACO. Because an ACO receives the higher of the positive regional adjustment or the prior savings adjustment, the reduced regional adjustment weight combined with the increased prior savings adjustment scaling factor means that, for a subset of ACOs with prior savings, the prior savings adjustment will become the applicable adjustment. For these ACOs, the benchmark adjustment will be tied more directly to the savings they generated, which is the specific source of what the commenter describes as the ratchet effect. We acknowledge that the prior savings adjustment considers savings from only the final 3 years of an agreement period and will not fully offset rebasing for all ACOs; however, we believe the increased scaling factor provides more targeted relief from rebasing while preserving incentives for ACOs to achieve further savings.

We do not believe that mitigating the effects of benchmark rebasing is inconsistent with maintaining

incentives for ongoing efficiency improvements. We also do not agree that ACOs should financially benefit from early-agreement period efficiency gains in perpetuity; using the most recent 3 years of performance provides up-to-date information on prior savings performance while maintaining accountability for continued improvement. Additionally, we use the most recent year prior to the start of the agreement period (benchmark year 3) to establish the regional adjustment. This provides a similar method based on recency of information, to compare the highest performance in the ACO's regional efficiency and prior agreement period savings, which allows CMS to include the highest recent performance in the ACOs applicable historical benchmark adjustment.

Comment: A commenter recommended that existing ACOs be allowed to gain the benefit of the prior savings adjustment during the next reconciliation process rather than just renewal. This commenter suggested that ACOs be given the opportunity to renew early or a mid-agreement adjustment during the reconciliation period.

Response: We acknowledge the commenter's suggestion to allow existing ACOs to benefit more quickly from an increase in the prior savings adjustment scaling factor. However, we do not believe it would be appropriate to make mid-agreement period modifications to an ACO's benchmark through the annual financial reconciliation process. Because the adjustment is tied to the establishment of a benchmark for a new agreement period, applying it during an ongoing agreement period would be inconsistent with the current benchmarking methodology framework. Also, as the commenter requested, there are presently options to early renew during the annual application cycle for ACOs that do not want to wait until the end of their agreement period to be eligible to receive the 75 percent prior savings adjustment scaling factor.

Comment: Several commenters supported increasing the prior savings adjustment scaling factor but were concerned that it would not effectively mitigate benchmark ratcheting unless the benchmark cap was also raised from 5 percent to at least 7 percent. One of these commenters stated that because the prior savings adjustment is bound by that cap, the combined proposed policies could reduce the value of investments in care coordination and delivery transformation.

Response: We appreciate comments describing concerns about the interaction of the proposal to increase the prior savings adjustment scaling factor and the benchmark cap. We discuss our response to comments about the benchmark cap in section III.G.5.e. of this final rule.

Comment: We received a few comments in opposition to the proposal to increase the prior savings adjustment scaling factor from 50 to 75 percent. These comments expressed concerns that restoring prior savings to later benchmarks allows an ACO to receive repeated rewards for a change achieved once and could reduce the likelihood that incentive payments will eventually translate into lower Medicare spending. A few commenters stated there would be a fundamental problem with a voluntary program incentivizing participation in the program through overly generous approaches that mitigate the ratchet effect, rather than focusing on approaches that maintain generated savings. These commenters did not believe that continued participation in the program should require CMS to return past savings through higher future benchmarks.

Response: We acknowledge the commenters' concerns about the proposal to increase the prior savings adjustment scaling factor. We disagree that the prior savings adjustment provides repeated rewards for a change achieved only once. Rather, increasing the prior savings adjustment scaling factor from 50 percent to 75 percent provides relief from the effects of rebasing while still preserving incentives for ACOs to achieve further savings and high-quality care in future agreement periods. With regard to the commenter's statement that ACOs leaving the program in response to the benchmark ''ratchet'' effect indicates a fundamental flaw in voluntary ACO models, we continue to believe that appropriately balanced benchmark policies, such as the proposed revisions to the prior savings adjustment scaling factor and the regional adjustment in sections III.G.5.d and III.G.5.c.(2) of this final rule, can reward successful performance while maintaining accountability for continued improvement. Increasing the prior savings adjustment scaling factor from 50 percent to 75 percent provides relief from the effects of rebasing while still preserving incentives for ACOs to achieve further savings and high-quality care in future agreement periods. Our analyses indicate that increasing the scaling factor would strengthen incentives for continued participation among successful ACOs while maintaining accountability for ongoing performance improvement.

After consideration of public comments, we are finalizing our proposal to increase the prior savings adjustment scaling factor from 50 percent to 75 percent, for agreement periods beginning on January 1, 2027, and in subsequent years.

We did not receive public comments on our proposal to specify related provisions in the Shared Savings Program regulations in § 425.658(c)(2), as well as proposed technical and conforming changes to other provisions of § 425.658, and therefore, we are finalizing those as proposed.

e. Risk Adjust the 5 percent Cap on Upward Adjustments to the Historical Benchmark

(1) Background

For agreement periods beginning on January 1, 2025, and in subsequent years, in calculating the historical benchmark, CMS applies the highest of three upward adjustments for which the ACO is eligible: a positive regional adjustment, prior savings adjustment, or population adjustment, as described at § 425.652(a)(8)(ii)(B)(*1*). Each of these adjustments is subject to a cap of 5 percent of national per capita OM expenditures for the assignable beneficiary population, a limit first established in the CY 2018 PFS final rule (83 FR 68072).

In the June 2016 final rule (81 FR 37973), we introduced a regional adjustment to the ACO's historical benchmark. In the CY 2023 PFS final rule (87 FR 69915 through 69923), we finalized the application of a cap on the negative regional adjustment at negative 1.5 percent of national per capita expenditures for Parts A and B services and further modified the adjustment to limit its negative impact on ACO historical benchmarks. In the CY 2024 PFS final rule (88 FR 79185 through 79196), we further modified the regional adjustment to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment.

In the June 2015 final rule (80 FR 32785 through 32791), we established a prior savings adjustment to account for the average per capita amount of savings generated during an ACO's prior agreement period. We removed the adjustment in the June 2016 final rule (81 FR 37954 through 37992) and then reinstated it in the CY 2023 PFS final rule (87 FR 69898 through 69915), for renewing and re-entering ACOs beginning January 1, 2024. In the CY 2024 PFS final rule (88 FR 79196 through 79200), we modified the prior

savings adjustment to account for changes in savings due to compliance actions or reopenings of prior determinations.

In the CY 2025 PFS final rule (89 FR 61887 through 61892), we introduced the health equity benchmark adjustment (HEBA), which adjusts upward an ACO's historical benchmark based on the number of dually eligible or Low-Income Subsidy (LIS)-enrolled beneficiaries served. With the CY 2026 PFS final rule (90 FR 49831 through 49834), we renamed the HEBA to the ''population adjustment'' to more accurately reflect the nature of the adjustment.

In the CY 2027 PFS proposed rule we stated that the positive regional adjustment, prior savings adjustment, and population adjustment are all capped at 5 percent of national per capita OM expenditures for the assignable beneficiary population (91 FR 44082). Further, we stated that the population adjustment calculation considers the difference between the 5 percent cap and the higher of regional adjustment, prior savings adjustment, or no adjustment (in the case where the regional adjustment is negative or the ACO is not eligible for the prior savings adjustment) (91 FR 44082)[328]. We noted that, more generally, the 5 percent cap mitigates the potential risk of CMS paying ACOs shared savings payments that are the result of extreme or outlier positive adjustments to the benchmark (91 FR 44082).

(2) Revisions

We stated in the CY 2027 PFS proposed rule that ACOs serving medically complex populations with higher CMS–HCC risk scores (relative to the national assignable population) have expressed concern that the current 5 percent cap applied to the three upward adjustments to the historical benchmark (regional adjustment, prior savings adjustment, and population adjustment) is too restrictive (91 FR 44082). Specifically, when the cap is applied as a flat percentage without accounting for the degree to which the ACO serves a medically complex population, it imposes a hard ceiling that suppresses the historical benchmark. Rather than allowing the benchmark adjustments to reflect the actual higher costs required to care for these complex patients, the flat 5 percent cap limits the three upward adjustments. These ACOs have requested that the higher clinical complexity, higher CMS–HCC risk scores, and higher cost of providing care to their assigned beneficiary populations be considered when establishing a cap for adjustments to the historical benchmark. Risk adjusting the 5 percent caps accounts for the severity and case mix of each ACO's assigned beneficiary population, allowing a higher positive adjustment ceiling for ACOs serving medically complex populations while still fulfilling the cap's original purpose of safeguarding CMS against extreme or outlier positive benchmark adjustments. Beyond addressing ACO concerns, risk adjusting the 5 percent cap would encourage ACOs to enroll and manage higher acuity, higher cost beneficiaries, who stand to benefit most from coordinated care, by allowing the cap to scale upwards with the average CMS–HCC risk scores of their populations relative to the national average.

We added that, to better align benchmark adjustments with true clinical complexity and encourage participation among organizations engaged in providing high-needs care, we proposed to risk adjust the 5 percent cap on each of the upward adjustments to the historical benchmark: the positive regional adjustment, the prior savings adjustment, and the population adjustment (91 FR 44082).

(a) Proposal To Risk Adjust the 5 percent Cap on Positive Regional Adjustments to the Historical Benchmark

As discussed in the CY 2027 PFS proposed rule, we proposed to risk adjust the 5 percent cap on positive adjustments to the national per capita dollar amount for each Medicare enrollment type (ESRD, Disabled, Aged/Dual, and Aged/non-dual), used to calculate the regional adjustment to the historical benchmark, according to the following steps (91 FR 44083):

- Step 1—Identify the national per capita expenditure amount for the enrollment type for BY3.
- Step 2—Identify the ACO's weighted average CMS–HCC risk score for the enrollment type for BY3.[329]
- Step 3—By enrollment type, calculate the product of the amounts identified in Step 1 and Step 2.
- Step 4—By enrollment type, calculate the cap for the enrollment type at 5 percent of the product derived in Step 3.
- Step 5—Apply the risk-adjusted 5 percent cap calculated in Step 4 to the ACO's preliminary regional adjustment for the enrollment type. The preliminary regional adjustment refers to the regional adjustment amount for the enrollment type (that is, the per capita dollar amount) before any caps are applied.[330]

++ Step 5(i)—Identify the ACO's preliminary regional adjustment for the enrollment type.

++ Step 5(ii)—Evaluate whether the value identified in Step 5(i) is greater than the risk-adjusted 5 percent cap determined in Step 4. If yes, set regional adjustment for the enrollment type at the risk-adjusted 5 percent cap calculated in Step 4. If no, set the regional adjustment for the enrollment type as the value identified in Step 5(i).

In the CY 2027 PFS proposed rule, we illustrated how the proposed calculation methodology would be applied, considering the following hypothetical example in which positive adjustments are applied to the regional adjustment for all enrollment types for the ACO (91 FR 44083 through 44084).

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[328] 42 CFR 425.656; 42 CFR 425.658; 42 CFR 425.662.

[329] For more information on the calculation of the weighted average CMS–HCC risk score, we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

[330] For more information on the calculation of the preliminary regional adjustment for the enrollment type, we refer readers to section 4.1.2 step 5 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

TABLE B-G17: HYPOTHETICAL EXAMPLE OF STEPS FOR RISK ADJUSTING THE 5 percent CAPS ON POSITIVE REGIONAL ADJUSTMENTS TO HISTORICAL BENCHMARKS

	Amount Under Current Policy (No Risk Adjustment Applied to 5 percent Caps)	Amount Under Proposed Policy (Risk Adjustment Applied to 5 percent Caps)
Step 1: Identify the national per capita expenditure amount for the enrollment type for BY3.		
ESRD	$121,092.11	$121,092.11
Disabled	$18,266.87	$18,266.87
Aged/dual	$30,290.30	$30,290.30
Aged/non-dual	$15,943.88	$15,943.88
Step 2: Identify the ACO's weighted average CMS-HCC mean risk score for the enrollment type for BY3.		
ESRD	NA	1.1022
Disabled	NA	0.9249
Aged/dual	NA	1.0648
Aged/non-dual	NA	1.0366
Step 3: By enrollment type, calculate the product of the amounts identified in Step 1 and Step 2.		
ESRD	NA	$133,467.72
Disabled	NA	$16,895.03
Aged/dual	NA	$32,253.11
Aged/non-dual	NA	$16,527.43
Step 4: By enrollment type, calculate the cap for the enrollment type as 5 percent of the product derived in Step 3. (Under current policy, the cap is calculated as 5 percent of the amount identified in Step 1.)		
ESRD	$6,054.61	$6,673.39
Disabled	$913.34	$844.75
Aged/dual	$1,514.51	$1,612.66
Aged/non-dual	$797.19	$826.37
Step 5: Apply the risk-adjusted 5 percent cap calculated in Step 4 to the ACO's preliminary regional adjustment for the enrollment type.		
Step 5(i) Identify the ACO's preliminary regional adjustment for the enrollment type.*		
ESRD	$376.91	$376.91
Disabled	$905.00	$905.00
Aged/dual	$3,036.48	$3,036.48
Aged/non-dual	$883.08	$883.08

TABLE B-G18: HYPOTHETICAL EXAMPLE OF STEPS FOR RISK ADJUSTING THE 5 percent CAPS ON THE PRIOR SAVINGS ADJUSTMENT TO HISTORICAL BENCHMARKS

	Amount Under Current Policy (No Risk Adjustment Applied to 5 percent Caps)	Amount Under Proposed Policy (Risk Adjustment Applied to 5 percent Caps)
Step 1: Identify the national per capita expenditure amount for the enrollment type for BY3.		
ESRD	$100,000.00	$100,000.00
Disabled	$12,000.00	$12,000.00
Aged/dual	$20,000.00	$20,000.00
Aged/non-dual	$12,000.00	$12,000.00
Step 2: Identify the ACO's weighted average CMS-HCC risk score by enrollment type for BY3.		
ESRD	NA	1.1022
Disabled	NA	0.9249
Aged/dual	NA	1.0648
Aged/non-dual	NA	1.0366
Step 3: By enrollment type, calculate the product of the amounts identified in Step 1 and Step 2.		
ESRD	NA	$110,222.22
Disabled	NA	$11,098.52
Aged/dual	NA	$21,296.18
Aged/non-dual	NA	$12,439.56
Step 4: By enrollment type, calculate 5 percent of the product derived in Step 3. (For the calculation under current policy, calculate 5 percent of the values identified in Step 1.)		
ESRD	$5,000.00	$5,511.11
Disabled	$600.00	$554.93
Aged/dual	$1,000.00	$1,064.81
Aged/non-dual	$600.00	$621.98
Step 5: Identify the proportion of the ACO's assigned beneficiaries within each enrollment type.		
ESRD	0.007	0.007
Disabled	0.052	0.052
Aged/dual	0.055	0.055
Aged/non-dual	0.886	0.886
Step 6: To calculate the final risk-adjusted 5 percent national expenditure value by enrollment type, multiply the risk-adjusted 5 percent amounts from Step 4 by the enrollment proportions from Step 5.		
ESRD	$35.00	$38.58
Disabled	$31.20	$28.86
Aged/dual	$55.00	$58.56
Aged/non-dual	$531.60	$551.07
Step 7: Create a single prior savings cap value by summing the products from Step 6 across enrollment types.		
Prior savings cap	$652.80	$677.07
Step 8: Multiply the prorated average per capita prior savings by the 75 percent scaling factor.*		
Prorated average per capita savings from BY1, BY2, and BY3	$900.00	$900.00
Proposed 75 percent scaling factor (Under current policy, use 50 percent scaling factor)	50%	75%
Weighted prorated average prior savings	$450.00	$675.00
Step 9: If the ACO is eligible for a prior savings adjustment, set the prior savings adjustment as the lesser of: [A] the prior savings cap calculated in Step 7, and [B] the weighted prorated average prior savings calculated in Step 8.		
Prior savings adjustment	$450.00	$675.00

* For more information on the calculation of the prorated average per capita prior savings, we refer readers to step 6c of section 4.1.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

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We stated that an average CMS–HCC risk score of 1.000 indicates that the ACO's population risk aligns with the national assignable population average, while scores above 1.000 identify populations with higher-than-average risk and scores below 1.000 identify populations with lower-than-average risk (91 FR 44084). By risk-adjusting the 5 percent caps for each enrollment group, the caps would become tailored

to each ACO's specific risk profile for BY3. In this hypothetical example, the caps for the ESRD, Aged/Dual, and Aged/Non-Dual groups increase to reflect elevated risk levels, while the cap for the Disabled group decreases to reflect a lower risk profile for that group. This hypothetical example provided in the CY 2027 PFS proposed rule illustrated how a single ACO may experience both increased and decreased 5 percent caps across enrollment types, depending on each enrollment type's average risk relative to the national assignable population (91 FR 44084). Notably, the proposed risk adjustment policy applies exclusively to the 5 percent caps on positive adjustments; caps for negative adjustments remain unchanged under the proposed policy (91 FR 44084).

We proposed to revise and republish § 425.656(c)(3), to include the proposed approach to calculating the caps on regional adjustment amounts applicable for agreement periods beginning on January 1, 2027, and in subsequent years, as well as the existing calculation of the caps on the regional adjustment amounts that would apply for agreement periods beginning on or after January 1, 2024, and before January 1, 2027 (91 FR 44084).

Under new § 425.656(c)(3)(ii), we proposed to specify the approach to calculating the cap on regional adjustment amounts, applicable for agreement periods beginning on January 1, 2027, and in subsequent years (91 FR 44084). Accordingly, we proposed to specify that CMS caps the per capita dollar amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under § 425.656(c)(2) at a dollar amount as described in the provisions that follow in subparagraphs (A) and (B), inclusive of the provisions included thereunder (91 FR 44084 through 44085).

Under new § 425.656(c)(3)(ii)(A), we proposed to specify that, for positive adjustments, the per capita dollar amount for a Medicare enrollment type would be capped at a dollar amount calculated as follows (91 FR 44085):

- As specified in proposed § 425.656(c)(3)(ii)(A)(*1*), we would calculate the product of the following: (i) the amount of national per capita expenditures for Parts A and B services under the OM fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary; and (ii) the ACO's weighted average risk score for the enrollment group for BY3.[332]
- As specified in proposed § 425.656(c)(3)(ii)(A)(*2*), we would calculate 5 percent of the enrollment type-specific product determined in § 425.656(c)(3)(ii)(A)(*1*).

Under new § 425.656(c)(3)(ii)(B), we proposed to specify that, for negative adjustments, the per capita dollar amount for a Medicare enrollment type would be capped at a dollar amount equal to negative 1.5 percent of national per capita expenditures for Parts A and B services under the OM program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary (91 FR 44085).

The provided the following list to summarize the proposed amendments to the structure and organization of § 425.656(c)(3) (as revised and republished) in the CY 2027 PFS proposed rule (91 FR 44085):

- We proposed to specify the existing provisions of § 425.656(c)(3), describing the caps on regional adjustment amounts based on a percentage of national per capita expenditures for the assignable beneficiary population for BY3, under new § 425.656(c)(3)(i). Accordingly, we proposed to:

++ Add a sentence at the start of the introductory text of new § 425.656(c)(3)(i) specifying the applicability of the calculation for agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

++ Redesignate existing paragraphs (c)(3)(i) and (ii) of § 425.656 (specifying the cap on positive adjustments and negative adjustments, respectively) as paragraphs (c)(3)(i)(A) and (B).

- We proposed to specify the proposed caps on regional adjustment amounts, applicable for agreement periods beginning on January 1, 2027, and in subsequent years, in new § 425.656(c)(3)(ii) (previously described in this section).

We sought comment on the proposal to risk adjust the 5 percent caps on positive regional adjustment amounts, applicable for agreement periods beginning on January 1, 2027, and in subsequent years, and related proposed changes to the Shared Savings Program regulations at § 425.656(c)(3) (as revised and republished). Since commenters generally addressed this proposal in conjunction with the proposals in section III.G.5.e.(2)(b) and (c) of the CY 2027 PFS proposed rule, please refer to section III.G.5.e.(2).(c) of this final rule, where we summarize and respond to comments on all three sections.

(b) Proposal to Risk Adjust the 5 Percent Cap on the Prior Savings Adjustment to the Historical Benchmark

In the CY 2027 PFS proposed rule, we proposed to risk adjust the 5 percent cap on national per capita dollar amount for each Medicare enrollment type (ESRD, Disabled, Aged/dual, and Aged/non-dual), used in determining the prior savings adjustment to the historical benchmark, according to the following steps (91 FR 44085):

- Step 1—Identify the national per capita expenditure amount for the enrollment type for BY3.
- Step 2—Identify the ACO's weighted average CMS–HCC risk score by enrollment type for BY3.
- Step 3—By enrollment type, calculate the product of the amounts identified in Steps 1 and 2.
- Step 4—By enrollment type, calculate 5 percent of the product derived in Step 3.
- Step 5—Identify the proportion of the ACO's assigned beneficiaries within each enrollment type by dividing the number of assigned beneficiaries within each enrollment type by the total number of assigned beneficiaries.
- Step 6—To calculate the final risk-adjusted 5 percent national expenditure value by enrollment type, multiply the risk-adjusted 5 percent amounts from Step 4 by the enrollment proportions from Step 5.
- Step 7—Create a single prior savings cap value by summing the products from Step 6 across enrollment types.
- Step 8—Multiply the prorated average per capita prior savings by the 75 percent scaling factor.[333]
- Step 9—If the ACO is eligible for a prior savings adjustment, set the prior savings adjustment as the lesser of: the prior savings cap calculated in Step 7,

[331] Refer to the Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (herein for brevity ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14'').

[332] For more information on the calculation of the weighted average risk score we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

[333] For more information on the calculation of the prorated average per capita prior savings, we refer readers to step 6c of section 4.1.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

and the weighted prorated average prior savings calculated in Step 8.

In the CY 2027 PFS proposed rule, we illustrated how the proposed calculation methodology would be applied, considering the following hypothetical example in which the prior savings adjustment is applied for the ACO (91 FR 44085 through 44086).

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TABLE B-G18: HYPOTHETICAL EXAMPLE OF STEPS FOR RISK ADJUSTING THE 5 percent CAPS ON THE PRIOR SAVINGS ADJUSTMENT TO HISTORICAL BENCHMARKS

	Amount Under Current Policy (No Risk Adjustment Applied to 5 percent Caps)	Amount Under Proposed Policy (Risk Adjustment Applied to 5 percent Caps)
Step 1: Identify the national per capita expenditure amount for the enrollment type for BY3.		
ESRD	$100,000.00	$100,000.00
Disabled	$12,000.00	$12,000.00
Aged/dual	$20,000.00	$20,000.00
Aged/non-dual	$12,000.00	$12,000.00
Step 2: Identify the ACO's weighted average CMS-HCC risk score by enrollment type for BY3.		
ESRD	NA	1.1022
Disabled	NA	0.9249
Aged/dual	NA	1.0648
Aged/non-dual	NA	1.0366
Step 3: By enrollment type, calculate the product of the amounts identified in Step 1 and Step 2.		
ESRD	NA	$110,222.22
Disabled	NA	$11,098.52
Aged/dual	NA	$21,296.18
Aged/non-dual	NA	$12,439.56
Step 4: By enrollment type, calculate 5 percent of the product derived in Step 3. (For the calculation under current policy, calculate 5 percent of the values identified in Step 1.)		
ESRD	$5,000.00	$5,511.11
Disabled	$600.00	$554.93
Aged/dual	$1,000.00	$1,064.81
Aged/non-dual	$600.00	$621.98
Step 5: Identify the proportion of the ACO's assigned beneficiaries within each enrollment type.		
ESRD	0.007	0.007
Disabled	0.052	0.052
Aged/dual	0.055	0.055
Aged/non-dual	0.886	0.886
Step 6: To calculate the final risk-adjusted 5 percent national expenditure value by enrollment type, multiply the risk-adjusted 5 percent amounts from Step 4 by the enrollment proportions from Step 5.		
ESRD	$35.00	$38.58
Disabled	$31.20	$28.86
Aged/dual	$55.00	$58.56
Aged/non-dual	$531.60	$551.07
Step 7: Create a single prior savings cap value by summing the products from Step 6 across enrollment types.		
Prior savings cap	$652.80	$677.07
Step 8: Multiply the prorated average per capita prior savings by the 75 percent scaling factor.*		
Prorated average per capita savings from BY1, BY2, and BY3	$900.00	$900.00
Proposed 75 percent scaling factor (Under current policy, use 50 percent scaling factor)	50%	75%
Weighted prorated average prior savings	$450.00	$675.00
Step 9: If the ACO is eligible for a prior savings adjustment, set the prior savings adjustment as the lesser of: [A] the prior savings cap calculated in Step 7, and [B] the weighted prorated average prior savings calculated in Step 8.		
Prior savings adjustment	$450.00	$675.00

* For more information on the calculation of the prorated average per capita prior savings, we refer readers to step 6c of section 4.1.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

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As discussed in the CY 2027 PFS proposed rule, in this scenario, the ACO's prior savings adjustment would be higher under the proposed risk-adjusted caps than under current policy, driven by two key changes (91 FR 44086 through 44087). First, the risk-adjusted prior savings cap in Step 7 is higher than the non-risk-adjusted cap, reflecting the ACO's higher-than-average risk profile and allowing the ACO to retain a larger share of its prior savings before being capped. Second, the proposed increase to the prior savings adjustment scaling factor from 50 percent to 75 percent further raises the available adjustment amount. We noted that, together these updates ensure that the prior savings adjustment reflects recent patient complexity (91 FR 44087).

As described in the CY 2027 PFS proposed rule (91 FR 44076 through 44082), we proposed to specify in revised § 425.658(c)(2) the methodology for calculating the per capita prior savings adjustment applicable for agreement periods beginning on January 1, 2027, and in subsequent years. Under proposed § 425.658(c)(2) (as revised), we would specify the use of a scaling factor of 75 percent (91 FR 44076 through 44082), and the proposed risk adjusted 5 percent cap (91 FR 44082 through 44087) in determining the amount of the prior savings adjustment an ACO may receive (if eligible). Specifically, for agreement periods beginning on January 1, 2027, and in subsequent years, if an ACO is eligible for the prior savings adjustment as determined in § 425.658(b)(3), the prior savings adjustment would equal the lesser of the following: (i) 75 percent of the pro-rated average per capita amount computed in § 425.658(b)(3)(ii); or (ii) a single per capita value that would be the result of risk adjusting the 5 percent cap.

With respect to risk adjusting the 5 percent cap, we proposed to specify related provisions in revised § 425.658(c)(2)(ii) (91 FR 44087). Specifically, we proposed that, for agreement periods beginning on January 1, 2027, and in subsequent agreement periods, CMS calculates a single per capita value as follows (91 FR 44087):

Under § 425.658(c)(2)(ii)(A), we proposed to specify that CMS would calculate the product of the following for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) (91 FR 44087)—

- The national per capita expenditures for Parts A and B services under the original OM FFS program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary; and
- The ACO's weighted average CMS–HCC risk score for that enrollment type for BY3.[334]

Under § 425.658(c)(2)(ii)(B), we proposed that CMS would calculate 5 percent of each enrollment type-specific product determined in § 425.658(c)(2)(ii)(A). And that, under § 425.658(c)(2)(ii)(C), CMS would calculate the single per capita value as a person-year weighted average[335] by multiplying each of these enrollment type-specific values (determined in accordance with § 425.658(c)(2)(ii)(B)) by the proportion of the ACO's assigned beneficiaries within that particular enrollment type and then summing the results (91 FR 44087).

We also proposed a technical and conforming change in § 425.672(c)(2)(iv), describing adjustment of calculation of national per capita OM expenditures for assignable beneficiaries for purposes of capping the prior savings adjustment (among other factors) for SAHS billing activity occurring in CY 2024 or subsequent calendar years (91 FR 44087). More specifically, in § 425.672(c)(2)(iv), we proposed to amend the existing reference to § 425.658(c)(1)(ii), to refer instead to § 425.658(c)(1)(ii) and (c)(2)(ii) (as we proposed) (91 FR 44087).

We sought comment on the proposal to risk adjust the 5 percent cap used in calculating the value of the prior savings adjustment to the historical benchmark for agreement periods beginning on January 1, 2027, and in subsequent years. We also sought comment on the proposed calculation of the risk adjusted 5 percent cap as specified in proposed revisions to § 425.658, in paragraph (c)(2)(ii), as well as a proposed technical and conforming change to § 425.672(c)(2)(iv). Since commenters generally addressed this proposal in conjunction with the proposals in section III.G.5.e.(2)(a) and (c) of the CY 2027 PFS proposed rule, please refer to section III.G.5.e.(2).(c) of this final rule, where we summarize and respond to comments on all three sections.

(c) Proposal To Risk Adjust the 5 Percent Cap on the Population Adjustment to the Historical Benchmark

We proposed to risk adjust the 5 percent cap on national per capita expenditures for each Medicare enrollment type (ESRD, Disabled, Aged/dual, Aged/non-dual), used to calculate the population adjustment, according to the following steps (91 FR 44087):

- Step 1—Identify the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D Low-Income Subsidy (LIS) or are dually eligible for Medicare and Medicaid. Under existing policy, which we do not propose to change, an ACO with a proportion less than 15 percent is ineligible to receive the population adjustment.
- Step 2—Calculate risk-adjusted 5 percent of the national per capita expenditures for assignable beneficiaries as a single value by employing the following steps:

++ Step 2(i)—Identify the national per capita expenditures for assignable beneficiaries by enrollment type in BY3.

++ Step 2(ii)—Identify the ACO's weighted average CMS–HCC risk score by enrollment type for BY3.[336]

++ Step 2(iii)—By enrollment type, calculate the product of the amounts identified in Step 2(i) and Step 2(ii).

++ Step 2(iv)—By enrollment type, calculate the risk-adjusted, capped national per capita expenditures as 5 percent of the product derived in Step 2(iii).

++ Step 2(v)—Identify the proportion of the ACO's assigned beneficiaries within each enrollment type.

++ Step 2(vi)—To calculate the final risk-adjusted 5 percent national expenditure by enrollment type, multiply the amount from step 2(iv) by the enrollment proportions from Step 2(v).

++ Step 2(vii)—Sum the values in Step 2(vi) to express the risk-adjusted 5 percent of the national per capita expenditures for assignable beneficiaries as a single value.

- Step 3—Calculate population adjustment scaler by employing the following steps:

[334] For more information on the calculation of the weighted average CMS–HCC risk score we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14. *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0.*

[335] For more information on the calculation of the person-year weighted average we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14. *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0.*

[336] For more information on the calculation of the weighted average CMS–HCC risk score, we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

++ Step 3(i)—Identify the regional adjustment (expressed as a single value) and the prior savings adjustment.[337]

++ Step 3(ii)—Calculate the scaler as the difference between the values in Step 2(vii) and the higher of the regional adjustment and prior savings adjustment identified in Step 3(i).

[337] For more information on the calculation of the regional adjustment (expressed as a single value) and prior savings adjustment, we refer readers to sections 5 and 6 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

• Step 4—Calculate the population adjustment as the product of the values derived in Step 1 and Step 3(ii), for an ACO eligible for the population adjustment.

In the CY 2027 PFS proposed rule, we illustrated how the calculation methodology would be applied, considering the following hypothetical example in which the population adjustment is calculated for an ACO with generally higher risk beneficiaries than the national assignable population (91 FR 44088). We also noted in the CY 2027 PFS proposed rule that by proposing to risk adjust the caps for the regional adjustment and prior savings adjustment, this directly influences the population adjustment an ACO receives (91 FR 44088); we included a hypothetical example (Table B–G16 of the CY 2027 PFS proposed rule at 91 FR 44089) that assumed increased regional and prior savings adjustment amounts under the policy.

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TABLE B-G19: HYPOTHETICAL EXAMPLE OF STEPS FOR RISK ADJUSTING THE 5 percent CAPS ON THE POPULATION ADJUSTMENT TO HISTORICAL BENCHMARKS

	Amount Under Current Policy (No Risk Adjustment Applied to 5 percent Caps)	Amount Under Proposed Policy (Risk Adjustment Applied to 5 percent Caps)
Step 1: Identify the proportion of assigned beneficiaries with LIS or dual status.		
Proportion of LIS or dual beneficiaries for the performance year (if less than 15 percent, ACO is ineligible to receive population adjustment)	0.20	0.20
Step 2: Calculate risk-adjusted 5 percent of the national per capita expenditures for assignable beneficiaries as a single value		
Step 2(i): Identify the national per capita expenditures for assignable beneficiaries by enrollment type in BY3.		
ESRD	$100,000.00	$100,000.00
Disabled	$12,000.00	$12,000.00
Aged/dual	$20,000.00	$20,000.00
Aged/non-dual	$12,000.00	$12,000.00
Step 2(ii): Identify the ACO's weighted average CMS-HCC risk score by enrollment type for BY3.		
ESRD	NA	1.1022
Disabled	NA	0.9249
Aged/dual	NA	1.0648
Aged/non-dual	NA	1.0366
Step 2(iii): By enrollment type, calculate the product of the amounts identified in Step 2(i) and Step 2(ii).		
ESRD	$100,000.00	$110,222.22
Disabled	$12,000.00	$11,098.52
Aged/dual	$20,000.00	$21,296.18
Aged/non-dual	$12,000.00	$12,439.56
Step 2(iv): By enrollment type, calculate the risk-adjusted, capped national per capita values as 5 percent of the product derived in Step 2(iii).		
ESRD	$5,000.00	$5,511.11
Disabled	$600.00	$554.93
Aged/dual	$1,000.00	$1,064.81
Aged/non-dual	$600.00	$621.98
Step 2(v): Identify the proportion of the ACO's assigned beneficiaries within each enrollment type.		
ESRD	0.007	0.007
Disabled	0.052	0.052
Aged/dual	0.055	0.055
Aged/non-dual	0.886	0.886
Step 2(vi): To calculate the final risk-adjusted 5 percent national expenditure by enrollment type, multiply the amount from Step 2(iv) by the enrollment proportions from Step 2(v)		

	Amount Under Current Policy (No Risk Adjustment Applied to 5 percent Caps)	Amount Under Proposed Policy (Risk Adjustment Applied to 5 percent Caps)
ESRD	$35.00	$38.58
Disabled	$31.20	$28.86
Aged/dual	$55.00	$58.56
Aged/non-dual	$531.60	$551.07
Step 2(vii): Sum the values in Step 2(vi) to express the risk-adjusted 5 percent of the national per capita expenditures for assignable beneficiaries as a single value.		
Summed, capped BY3 national assignable expenditures.	$652.80	$677.07
Step 3: Calculate the population adjustment scaler.		
Step 3(i): Identify the regional adjustment (expressed as a single value) and the prior savings adjustment.		
Regional adjustment	$375.00	$400.00
Prior savings adjustment	$335.00	$350.00
Step 3(ii): Calculate the scaler as the difference between the values in Step 2(vii) and the higher of the regional adjustment or prior savings adjustment in Step 3(i).		
Population adjustment scaler	$277.80	$277.07
Step 4: Calculate the population adjustment as the product of the values derived in Step 1 and Step 3(ii).		
Population adjustment	$55.56	$55.41

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In the CY 2027 PFS proposed rule we stated that, because the population adjustment scales based on the difference between 5 percent of risk-adjusted national assignable expenditures and the greater of the regional adjustment or prior savings adjustment, the proposed risk adjustments to the regional adjustment and prior savings adjustment caps would directly influence the final adjustment value an ACO receives (91 FR 44089 through 44090).

For ACOs with higher-risk populations, the regional adjustment and prior savings adjustment will likely increase under the proposed policy, as expressed in the hypothetical example (Table B–G15 of the CY 2027 PFS proposed rule at 91 FR 44086). We noted that, on the one hand, these increases reduce the available margin for the population adjustment by increasing the amount being subtracted from the scaler (for example, Steps 3(i) and 3(ii)) (91 FR 44090). On the other hand, the risk-adjusted 5 percent cap for the population adjustment also increases for these ACOs with higher-risk populations, expanding the ceiling for the population adjustment amount (for example, Step 2(vii)) (91 FR 44090). We concluded that, consequently, the mechanisms of the CY 2027 PFS proposed rule ensure that whichever adjustment an ACO ultimately receives is not limited by a flat 5 percent capped ceiling (91 FR 44090).

In the CY 2027 PFS proposed rule we stated that, based on an internal analysis simulating PY 2025 performance for 228 ACOs that entered new agreement periods beginning on January 1, 2025, risk adjusting the 5 percent cap on the regional adjustment, prior savings adjustment, and population adjustment would have the effect of increasing ACO benchmarks by an average of $2.98 (a 0.02 percent aggregate increase) (91 FR 44090).[338] We noted that among ACOs seeing a higher adjustment under this approach, benchmarks increased by an average of $84.18 (0.30 percent), while those ACOs with lower adjustments saw an average decrease of $27.66 (-0.22 percent) (91 FR 44090). About half of ACOs (111 of 228, or 49 percent) had no change in their benchmark value under a risk-adjusted 5 percent cap for all three adjustments. While some ACOs (82 of 228, or 36 percent) had lower benchmarks under this approach, the magnitude of change for these ACOs was smaller than the gains made for ACOs that had an increase in their benchmarks (35 of 228, or 15 percent).

We discussed that, among 91 ACOs receiving the regional adjustment as their adjustment category, these ACOs would have an average final adjustment that is $16.69 lower or 2.58 percent lower under the proposed policies compared to the current policy (91 FR 44090). And noted that, conversely, for the 8 ACOs that received the prior savings adjustment as their adjustment category, these ACOs would have an average final adjustment that is $142.21 higher or 14.42 percent higher, and 16 ACOs receiving the population adjustment would have an adjustment that is $69.10 higher or 12.61 percent higher (91 FR 44090). We stated that an additional 111 ACOs would see no change to their final adjustment under the proposed policy, 98 ACOs would have changes small enough that they ultimately would not impact benchmarks, and 2 ACOs changed the adjustment type received under the proposed policy (one with increased benchmarks and the other with decreased benchmarks as a result of the proposed policy and resultant change in adjustment type) (91 FR 44090).

We concluded that the simulation suggests that risk adjusting the caps will result in higher caps on positive

[338] Internal analysis simulating PY 2025 performance for 228 ACOs that entered new agreement periods beginning on January 1, 2025, applying the proposed policy to risk adjust the 5 percent caps on the regional adjustment, prior savings adjustment, and population adjustment. Simulation results were compared to PY 2025 performance on PY 2025 final historical benchmarks to determine the impact of the proposed policies.

adjustments for ACOs with above-average risk, which we believe may attract ACOs that serve more clinically complex populations with higher CMS–HCC risk scores or encourage existing ACOs to expand to include ACO providers and suppliers who serve such clinically complex populations (91 FR 44090).

We proposed to revise and republish § 425.662(b)(2), to include the proposed approach to calculating the population adjustment applicable for agreement periods beginning on January 1, 2027, and in subsequent years, as well as the existing calculation of the population adjustment which would apply for agreement periods beginning on January 1, 2025, or January 1, 2026 (91 FR 44090).

We proposed to specify the existing provisions of § 425.662(b)(2), describing the calculation of the population adjustment, under new paragraph § 425.662(b)(2)(i). Accordingly, we proposed to add a sentence at the start of the introductory text of new § 425.662(b)(2)(i) specifying the applicability of the calculation for agreement periods beginning on January 1, 2025, or January 1, 2026 (91 FR 44090).

Under new § 425.662(b)(2)(ii), we proposed to specify the calculation of the population adjustment scaler applicable for agreement periods beginning on January 1, 2027, and in subsequent years (91 FR 44090). We proposed to calculate a scaler as the difference between: § 425.662(b)(2)(ii)(A), specifying a single per capita value that is the risk adjusted 5 percent cap, and § 425.662(b)(2)(ii)(B), specifying the highest among the regional adjustment (expressed as a single value), the per capita prior savings adjustment, or no adjustment (in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment) (specified in new § 425.662(b)(2)(ii)(B)) (91 FR 44090).

We proposed the following provisions to state how we would calculate the single per capita value reflecting the risk adjusted 5 percent cap (91 FR 44090). Under § 425.662(b)(2)(ii)(A)(*1*), we proposed to calculate the product of the following bulleted items for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) (91 FR 44090)—

- The national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary; [339] and
- The ACO's weighted average CMS–HCC risk score for that enrollment type for BY3.[340]

Under proposed § 425.662(b)(2)(ii)(A)(*2*), we proposed that CMS would calculate 5 percent of each enrollment type-specific product determined in § 425.662(b)(2)(ii)(A)(*1*). Under § 425.662(b)(2)(ii)(A)(*3*), CMS would calculate a single per capita value as a person-year weighted average [341] by multiplying each of these enrollment type-specific products (determined in accordance with § 425.662(b)(2)(ii)(A)(*2*)) by the proportion of the ACO's assigned beneficiaries within that particular enrollment type, then summing the results (91 FR 44090).

We sought comment on the proposal to risk adjust the 5 percent cap used for calculating the population adjustment to the benchmark applicable for agreement periods beginning on January 1, 2027, and in subsequent years, and related proposed changes to the Shared Savings Program regulations at § 425.662(b)(2) (as revised and republished).

The following is a summary of the comments we received on sections III.G.5.e.(2).(a), (b), and (c) of the CY 2027 PFS proposed rule and our responses:

Comment: Many commenters supported our proposals to risk adjust the five percent cap on upward adjustments to the historical benchmark. Some commenters expressed that risk adjusting the five percent cap to the historical benchmark would increase the fairness and accuracy of calculations for those serving medically complex and higher risk populations.

Response: We thank commenters for their support and agree that risk adjusting the 5 percent cap will result in higher caps on positive adjustments for ACOs with above-average risk, which we believe may attract ACOs that serve more clinically complex populations with higher CMS–HCC risk scores or encourage existing ACOs to expand to include ACO providers and suppliers who serve such clinically complex populations.

Based on updated internal analysis simulating PY 2025 performance for 225 ACOs that entered new agreement periods beginning on January 1, 2025 and had their financial performance reconciled for that performance year, risk adjusting the 5 percent cap on upwards adjustments would have the effect of increasing ACO benchmarks by an average of $1.97 (a 0.01 percent aggregate increase).[342] By risk-adjusting the 5 percent cap, 34 ACOs would have seen benchmarks increase by an average of $79.76 (0.31 percent), 81 ACOs would have seen benchmarks decrease by an average of $27.99 (-0.09 percent), and half of ACOs (111 of 225, or 49 percent) would have had no change in their benchmarks.

The proposed policy would have increased the final adjustment amount for 8 ACOs receiving the Prior Savings Adjustment ($142.37 or 14.46 percent higher with risk-adjusted cap) and 14 ACOs receiving the Population Adjustment ($62.17 or 9.73 percent higher with risk-adjusted cap). For 90 ACOs with decreased final adjustment amounts as a result of the policy, the average change (-$16.90 or -2.63 percent) would have been of smaller absolute magnitude than the changes for ACOs positively impacted by the policy. Under the updated simulation, 111 ACOs either had no material change in their final adjustment amount or received no adjustment. As in the initial simulation, 2 ACOs would have changed the adjustment type received under the proposed policy.

Comment: Some commenters opposed our proposal to risk adjust the five percent cap on upward adjustments to the historical benchmark citing general concerns around increased complexity and reduced predictability.

Response: We appreciate the comments expressing concerns. We believe the inclusion of risk adjustment as part of the calculation of the 5 percent cap on upward adjustments to the historical benchmark helps properly account for the differences in populations that ACOs serve. Any additional complexity that results from this risk adjustment is outweighed by the benefits for ACOs serving high-risk

[339] We note that in the CY 2025 PFS final rule (89 FR 98158), we explained in detail how we calculate the national assignable expenditure amount used in this calculation, although the provision codified in § 425.662(b)(1) is more general.

[340] For more information on the calculation of the weighted average risk score we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

[341] For more information on the calculation of the person-year weighted average we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

[342] Please note, at the time of this final rule publishing performance year 2025 financial reconciliation results have not yet been released to ACOs. We anticipate embargoed and unembargoed performance year 2025 financial reconciliation results to be shared with ACOs shortly after the finalization of this final rule.

medically complex populations and the incentive the risk adjustment will create for additional ACOs to care for a broad beneficiary population. Additionally, the 5 percent cap risk adjustment is based on the ACO's population assigned at the end of the performance year, which is summarized in the information provided to ACOs in quarterly reports, so the ACO will have an understanding of what the risk adjustment to the 5 percent cap will be prior to it being finalized during financial reconciliation.

Comment: Commenters suggested we change the five percent cap on upward adjustments, with many commenters suggesting raising the cap from five percent to seven percent, creating a tiered cap structure, or establishing a floor to the risk adjustment. Most commenters urged CMS to ensure that this policy does not negatively impact ACOs and encouraged CMS to increase the cap on upward adjustments to the historical benchmark. Many commenters also suggested that CMS consider a tiered cap structure where benchmark adjustments increase based on the duration of an ACO's or its participant TINs participation in the program so that CHCs and other providers are not disadvantaged because their ACO has successfully reduced expenditures over multiple agreement periods.

Several supportive commenters suggested establishing a floor to the risk adjustment to mitigate any negative impacts to ACOs and to avoid penalizing ACOs with healthier patient populations. Many commenters urged CMS to ensure that the cap only has a positive effect on ACOs and to not allow for a downward cap adjustment for ACOs with average risk scores below 1.0.

Another commenter stated that the 5 percent ceiling remains the single largest financial limitation preventing the Shared Savings Program from reaching its full potential and the failure to address this financial obstacle has contributed to the lack of progress on CMS priorities such as increasing specialist integration in ACOs and improving ACO coordination with community-based organizations for addressing patient social needs.

Response: We appreciate comments describing concerns and recommendations regarding the 5 percent cap to the historical benchmark. We considered many similar comments when we established the 5 percent cap in the December 2018 final rule (83 FR 68022 and 68023). We recognize that there are tradeoffs in adopting any cap and that limiting the magnitude of positive adjustments could reduce incentives for participation or further cost reduction efforts among ACOs that have low costs, whether due to efficiency, patient mix, or limited patient access to services. We also considered commenters' recommendations to increase the cap. However, we remain concerned that a higher cap could result in larger upward benchmark adjustments that may substantially reduce savings to Medicare, and may reduce the incentives for ACOs to continue to increase savings and performance, particularly given the other benchmark methodology changes finalized in this rule, the effects of which we will continue to monitor. Accordingly, we continue to believe that a risk-adjusted 5 percent cap on the benchmark adjustments will protect the Medicare Trust Funds from excessive positive adjustments that may limit savings to Medicare and improve incentives for participation among higher-cost ACOs, particularly in combination with the increased prior savings adjustment scaling factor adopted in this rule. We also believe that risk adjusting the 5 percent cap will improve the fairness and accuracy of the cap calculation since it will scale to account for how ACO populations relate to the national population. By risk adjusting the 5 percent cap, ACOs caring for beneficiaries that are higher risk and more medically complex than the national population will receive an increase to their cap, while ACOs caring for beneficiaries that are lower risk and less medically complex than the national average would experience a decrease to account for differing beneficiary populations. Both the CY 2027 PFS proposed rule (91 FR 44090) and our updated analysis, discussed previously, indicate that about half of ACOs had no change in their benchmark value under a risk-adjusted 5 percent cap for all three adjustments. While some ACOs under both analyses had lower benchmarks under this approach, the magnitude of change for these ACOs was smaller than the gains made for ACOs that had an increase in their benchmarks. We note that the policy preserves the cap as a limit on excessive upward benchmark adjustments while reducing unintended constraints on ACOs that serve higher-risk, higher-cost populations, and ensuring that the amount of the adjustment does not inflate an ACO's benchmark to the point where the ACO is likely to generate shared savings without decreasing expenditures.

Comment: Commenters had suggestions for additional protections and monitoring for FQHCs and complex patient populations because of the impact risk adjusting the five percent cap on upward adjustments will have on their patient population. Another commenter encouraged CMS to continue monitoring changes in risk-score benchmark adjustments to ensure they reflect differences in patient health status and clinical complexity. Some commenters encouraged CMS to continue evaluating whether the 5 percent cap is appropriately calculated to account for the needs and complexity of populations served by essential hospital ACOs. A commenter who opposed risk adjusting the 5 percent cap on the benchmark adjustments suggested that CMS reconsider implementing this proposal until CMS can demonstrate that this change does not disproportionately disadvantage safety-net and FQHC-serving ACOs.

Response: We appreciate the comments describing concerns and recommendations. Risk adjusting the 5 percent cap accounts for the severity and case mix of each ACO's assigned beneficiary population, allowing a higher positive adjustment ceiling for ACOs serving medically complex populations while still fulfilling the cap's original purpose of safeguarding CMS against extreme or outlier positive benchmark adjustments. We acknowledge commenters' concerns that FQHCs and other safety-net providers may face challenges in fully capturing diagnoses, such that CMS–HCC risk scores may not fully reflect the clinical complexity of the populations they serve. We will continue to evaluate the effect of this policy on ACOs that include FQHCs and other safety-net healthcare providers and will consider whether refinements are warranted for future rulemaking.

Comment: Several commenters offered alternatives to risk adjusting the 5 percent cap in ways they felt would better reflect an ACO's actual population. A commenter proposed that CMS calculate the cap on a base capturing the ACO's full case mix—applying the ACO's prospective risk profile to the national per capita expenditure base so the ceiling scales with the population served. Multiple commenters worried the change would reward diagnostic coding over efficient care delivery. They urged CMS to base any accommodation for health-status changes on measures resistant to discretionary coding and cautioned against using risk adjustment to further expand what a commenter viewed as an already-generous set of upward benchmark adjustments. Another commenter, wary of tying the cap to

HCC scores, suggested CMS instead adjust for an ACO's demographic risk score.

Commenters who appreciated the proposal's intent nonetheless cautioned that it would add complexity while still relying on outdated data, and that introducing another risk-based component could reduce benchmark predictability. Another commenter asked CMS to retain the existing cap until it can show the proposed methodology improves benchmark accuracy without creating unnecessary volatility or complexity.

Response: We appreciate comments with recommendations regarding ACO risk profiles, including the recommendation to use demographic risk scores in place of CMS–HCC risk scores and support for scaling the adjustment ceiling using the ACO's risk profile. We believe our proposal to risk-adjust the 5 percent cap directly achieves the goal of scaling the benchmark ceiling to reflect beneficiary clinical complexity, while continuing to utilize the CMS–HCC model as the most technically precise method to capture case mix and severity. While we acknowledge concerns regarding diagnostic coding intensity when using CMS–HCC risk scores to determine an ACO's risk profile, we believe that relying strictly on demographic risk scores would fail to capture true patient acuity and could disadvantage ACOs with populations that are sicker than the national demographic baseline, and this may incentivize ACOs to select patients with healthier demographic baselines. Demographic risk scores, which reflect only beneficiary characteristics such as age, sex, Medicare eligibility, and original reason for Medicare entitlement, would not fully capture patient acuity relative to what is further accounted for with CMS–HCC risk scores that also incorporate beneficiaries' diagnoses, which are stronger predictors of expected expenditures and of the resources required to care for a given population. On balance, we believe the benefits of more accurately aligning the cap with an ACO's underlying beneficiary risk profile outweigh concerns regarding potential coding incentives, particularly given the fact that the 5 percent cap remains in place to limit excessive upward benchmark adjustments.

After considering public comments, we are finalizing our proposals to risk adjust the 5 percent cap on each of the upward adjustments to the historical benchmark: the positive regional adjustment, the prior savings adjustment, and the population adjustment, for agreement periods beginning on January 1, 2027, and in subsequent years. Specifically, we are finalizing, without modification, our proposal to revise and republish § 425.656(c)(3) to include the proposed approach to calculating the caps on regional adjustment amounts applicable for agreement periods beginning on January 1, 2027, and in subsequent years, as well as the existing calculation of the caps on the regional adjustment amounts that would apply for agreement periods beginning on or after January 1, 2024, and before January 1, 2027. As described in section III.G.5.d.(2) of this final rule, we are finalizing, without modification, to specify in revised § 425.658(c)(2) the methodology for calculating the per capita prior savings adjustment applicable for agreement periods beginning on January 1, 2027, and in subsequent years. With respect to risk adjusting the 5 percent cap, we are finalizing as proposed to specify related provisions in revised § 425.658(c)(2)(ii). Lastly, we are finalizing, without modification, our proposal to revise and republish § 425.662(b)(2) to include the finalized approach to calculating the population adjustment applicable for agreement periods beginning on January 1, 2027, and in subsequent years, as well as the existing calculation of the population adjustment which would apply for agreement periods beginning on January 1, 2025, or January 1, 2026.

We are finalizing, without modification, a technical and conforming change in § 425.672(c)(2)(iv), describing adjustment of calculation of national per capita OM expenditures for assignable beneficiaries for purposes of capping the prior savings adjustment (among other factors) for SAHS billing activity occurring in CY 2024 or subsequent calendar years. More specifically, in § 425.672(c)(2)(iv), we are finalizing as proposed amendments to the existing reference to § 425.658(c)(1)(ii), to refer instead to § 425.658(c)(1)(ii) and (c)(2)(ii).

f. Incentivize New Participation Through a Growth Adjustment to the Historical Benchmark

(1) Background

(a) Background on Adjusting the Historical Benchmark

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established, updated, and reset at the start of each agreement period under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for OM beneficiaries assigned to the ACO. The benchmark shall be reset at the start of each agreement period. Section 1899(d)(1)(B)(ii) of the Act also provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Under this authority, over time we have adopted a variety of methods to adjust the historical benchmark to meet certain policy goals.

Relying on our authority under section 1899(d)(1)(B)(ii) of the Act, we codified benchmarking policies applicable to all ACOs in agreement periods beginning on January 1, 2024, and in subsequent years at § 425.652 (88 FR 79174 through 79208). We referred readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991; December 2018 final rule, 83 FR 68005 through 68030; CY 2023 PFS final rule, 87 FR 69875 through 69928; CY 2024 PFS final rule, 88 FR 79174 through 79208; CY 2025 PFS final rule, 89 FR 98155 through 98166; and CY 2026 PFS final rule, 90 FR 32690 through 32692).

In the CY 2023 PFS final rule, we adopted policies to modify the regional adjustment under § 425.656 (87 FR 69915 through 69923) and to reinstate a prior savings adjustment under § 425.658 (87 FR 69898 through 69915). The prior savings adjustment policy permitted some renewing or re-entering ACOs to receive an adjustment to their benchmarks to account for savings generated in performance years that correspond to the benchmark years of their new agreement periods. The modifications to the regional adjustment limited the impact of negative regional adjustments on ACO historical benchmarks and further incentivized program participation among ACOs serving high-cost beneficiaries.

In the CY 2024 PFS final rule (88 FR 79185 through 79196), we modified the regional adjustment policy further to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment. In the CY 2024 PFS final rule (88 FR 79196 through 79200), we also modified the prior savings adjustment policy further to account for the following: a change in savings earned by the ACO in a benchmark year due to compliance action taken to address avoidance of at-risk

beneficiaries; or a change in the amount of savings or losses for a benchmark year as a result of a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315.

In the CY 2025 PFS final rule, we finalized provisions in §§ 425.652(a)(8) and 425.662 specifying the methodology for calculating the health equity benchmark adjustment (HEBA) to the historical benchmark, determining an ACO's eligibility for the adjustment, and the applicability of the adjustment (89 FR 61890 and 61891). In the CY 2025 PFS final rule, we noted the limitations of benchmarks based on historically observed spending, as they could be set too low if they are based on the spending of a population of underserved communities. The HEBA was finalized to provide additional financial resources to ACOs serving these populations, and to encourage those ACOs to attract and retain beneficiaries from communities that have faced challenges related to accessing care (89 FR 61887). The adjustment is calculated based on the number of beneficiaries an ACO serves who are either enrolled in the Medicare Part D Low-Income Subsidy (LIS) program or are dually eligible for Medicare and Medicaid, offering a targeted mechanism to reflect the needs of higher-risk populations.

In the CY 2026 PFS final rule, we renamed the HEBA as the ''population adjustment'' for clarity under § 425.662 (90 FR 32683 through 32685). This finalized revision more accurately reflects the nature of the adjustment, which accounts for the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS program or dually eligible for Medicare and Medicaid.

(b) Methodology for Determining the Applicability of a Regional Adjustment, Prior Savings Adjustment, or Population Adjustment to the ACO's Historical Benchmark, for Agreement Periods Beginning on or After January 1, 2025

In the CY 2027 PFS proposed rule, we discussed that we calculate three adjustments to the historical benchmark under the benchmarking methodology for agreement periods beginning on January 1, 2025, and in subsequent years (91 FR 44091). We noted that these adjustments are a regional adjustment (§ 425.656), prior savings adjustment (§ 425.658), and the population adjustment (§ 425.662) (91 FR 44091). We stated that we then determine whether to apply one of the three adjustments or no adjustment to the ACO's historical benchmark (§ 425.652(a)(8)(ii)) (91 FR 44091).

In the CY 2027 PFS proposed rule, we discussed the following overview of how, under this methodology, we currently calculate the adjustment to apply when establishing benchmarks for ACOs entering an agreement period beginning on January 1, 2025, and in subsequent years (91 FR 44091 through 44092):

- *Step 1:* We calculate the capped regional adjustment expressed as a single dollar value as specified in § 425.656. We calculate the regional adjustment to the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ Under § 425.656(c)(3), we cap the per capita dollar amount for each Medicare enrollment type at a dollar amount equal to a percentage of national per capita expenditures for Parts A and B services under the OM program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

—Under § 425.656(c)(3)(i), for positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

—Under § 425.656(c)(3)(ii), for negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 1.5 percent of the national per capita expenditure amount for the enrollment type for BY3.

++ Under § 425.656(d)(1), we express the regional adjustment as a single value by taking a person year[343] weighted average of the Medicare enrollment type-specific regional adjustment values.

- *Step 2:* For eligible ACOs, we calculate the capped prior savings adjustment as specified in § 425.658. Under § 425.658(c)(1), we calculate an adjustment to the historical benchmark to account for savings an ACO generated in the 3 years prior to the start of the ACO's current agreement period for renewing or re-entering ACOs that were reconciled for one or more PYs in the Shared Savings Program during this period.
- *Step 3:* For eligible ACOs, we calculate the capped population adjustment as specified in § 425.662. Under § 425.662(b), we calculate an adjustment to the historical benchmark to offer a targeted mechanism to reflect the needs of higher-risk populations and account for ACOs with 15 percent or more assigned beneficiaries enrolled in LIS or dually eligible for Medicare and Medicaid during the PY.
- *Step 4:* We determine the final adjustment to the benchmark, as specified in § 425.652(a)(8)(ii). We compare the regional adjustment calculated in accordance with § 425.656, the prior savings adjustment calculated in accordance with § 425.658, and the population adjustment calculated in accordance with § 425.662.

++ Under § 425.652(a)(8)(ii), the ACO receives the highest of the positive adjustments for which it is eligible. The adjustments are calculated as described in § 425.656(c), § 425.658(c), or § 425.662(b), respectively, and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i) or the population adjustment under § 425.662(b)(3), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO does not receive an adjustment to its benchmark.

(c) Background on Incentivizing Growth in the Shared Savings Program

In the proposed rule we noted that, in recent years, we have repeatedly emphasized our interest in promoting growth in the Shared Savings Program through the policies we have established (91 FR 44092). In the CY 2024 PFS final rule, we stated, ''This rulemaking also seeks to further advance Medicare's overall value-based care strategy of growth [. . .] through the Medicare Shared Savings Program'' (88 FR 78819). We reiterated this aim in the CY 2025 PFS final rule (89 FR 97711) and CY 2026 PFS final rule (90

[343] To calculate person years: We sum the number of Shared Savings Program-eligible months (beneficiaries are only assigned a monthly enrollment status for months in which they are alive on 1st of the month, enrolled in both Parts A and B, and not enrolled in a Medicare Group Health Plan for the month) for each assigned beneficiary for each Medicare enrollment type; we then divide this number by 12 (the number of months in a calendar year). Refer to the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14, Section 3.1 Calculating ACO-Assigned Beneficiary Expenditures.

FR 49768). Many of the Shared Savings Program policies finalized through past rulemaking have either directly or indirectly focused on increasing ACO participants in the program and increasing the number of beneficiaries receiving care from ACOs. For example, in the CY 2024 PFS final rule (88 FR 79139 through 79163) we modified the step-wise beneficiary assignment methodology by adding a new third step that uses an expanded period of time to identify if a beneficiary has received at least one primary care service from an ACO professional. This change, taken with all other changes in the CY 2024 PFS final rule, was designed to enhance program growth (88 FR 78819), making more than 331,000 additional beneficiaries eligible for assignment, and increasing overall participation in the Shared Savings Program. Based on an internal analysis of CY 2024 primary care services, nearly 300,000 active individual practitioners with specialties used in assignment and billing assignment eligible services had not participated in a Shared Savings Program ACO or CMS Innovation Center model initiative involving shared savings during the 6-year period from 2019 through 2024.

In the proposed rule we discussed that we have seen increasing participation in the Shared Savings Program since the start of the program in 2012, with 3 million beneficiaries assigned to Shared Savings Program ACOs in the program's first year and over 12 million beneficiaries assigned to Shared Savings Program ACOs as of January 2026 (91 FR 44092). We also stated that we have observed that when participation in the program increases, we see increases in both quality improvements for beneficiaries and increased savings to the Trust Funds (91 FR 44092). The Shared Savings Program has had 8 consecutive years of generating savings for Medicare relative to benchmarks, with over $12 billion in total savings,[344] and with an upward trend in savings year over year.[345] Additionally, we have observed that Shared Savings Program ACOs have demonstrated improved quality performance over time and higher quality performance relative to other physician groups, suggesting that the Shared Savings Program is achieving savings while improving quality of care. In the proposed rule we stated that, based on an internal CMS analysis of 87 Shared Savings Program ACOs that participated continuously in the Shared Savings Program between 2014 and 2023, Shared Savings Program ACOs showed statistically significant and substantial improvement across seven comparable CMS Web Interface quality measures used during that period, where quality performance improved across a wide range of clinical practice areas including screening and preventive measures and control of health conditions such as hypertension and diabetes (91 FR 44092). We referred readers to Table B–G17 in the proposed rule (91 FR 440093) for details on the quality performance of these 87 Shared Savings Program ACOs. As discussed further in the CY 2027 PFS proposed rule (91 FR 44046 through 44059) Shared Savings Program ACOs have been transitioning to new quality measure collection types over the last several years and are now being assessed on the APP Plus quality measure set, that can pose limitations on comparing Shared Savings Program ACOs' most recent quality performance to their historical performance. We noted specifically that Shared Savings Program ACOs have transitioned from reporting on a sampling methodology (for example, web interface) to reporting on a broader patient population, which could impact comparisons on quality performance (91 FR 44092).

We noted, however, that there is evidence that Shared Savings Program ACOs perform better than their MIPS counterparts under the new quality reporting collection types. In PY 2024, Shared Savings Program ACOs scored better than comparable MIPS groups on all three electronic clinical quality measures (eCQMs) in the APP Plus quality measure set, with the difference being statistically significant for two of those measures (Quality ID: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan ($p < .001$) and Quality ID: 236 Controlling High Blood Pressure ($p < .01$) (90 FR 50002)) (91 FR 44092). We stated that Shared Savings Program ACOs also performed better than comparable MIPS groups on two of the three MIPS CQMs in the APP Plus quality measure set and the difference was statistically significant for one measure (Quality ID: 236 Controlling High Blood Pressure ($p < .01$) (90 FR 50002)) (91 FR 44092). We referred readers to Table B–G17 of the proposed rule (91 FR 44093) for an overview of Shared Savings Program ACOs' PY 2024 quality performance relative to comparable MIPS Groups. We stated that, informed by the historical performance of the Shared Savings Program on savings and quality improvement by healthcare providers and for beneficiaries assigned to a Shared Savings Program ACO, we are interested in identifying additional incentives to grow participation in the Shared Savings Program and expand the reach of cost savings and improved quality of care (91 FR 44093).

[344] Additional information on past years Shared Savings Program Performance Year Finance and Quality Results is available at: *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results*

[345] The Regulatory Impact Analysis reviews evidence that aggregate savings measured by benchmarks have been supported by observation of lower (higher) per capita spending trends in markets with earlier (later) ACO adoption.

TABLE B-G20: QUALITY PERFORMANCE AMONG 87 ACOS WHO PARTICIPATED IN THE SHARED SAVINGS PROGRAM CONTINOUSLY FROM PY 2014 to 2013

Quality #	Measure Title (CMS Web Interface)	PY 2014 Mean	PY 2023 Mean	Difference
001	Diabetes: Glycemic Status Assessment Greater Than 9% (Inverse measure)**	20.47	9.21	–11.25*
110	Preventive Care and Screening: Influenza Immunization	58.66	71.64	+12.98*
112	Breast Cancer Screening	62.51	81.53	+19.03*
113	Colorectal Cancer Screening	56.74	78.53	+21.79*
134	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	37.34	82.06	+44.73*
238	Controlling High Blood Pressure	67.32	80.20	+12.88*
318	Falls: Screening for Future Fall Risk	46.80	91.43	+44.62*

*Indicates statistically significant differences between ACOs in PY 2014 and 2023 ($p < .05$). The Difference column represents the mean PY 2023 ACO performance rate minus the mean PY 2014 ACO performance rate.
** This is an inverse measure, and a lower number indicates better quality performance.
Long–participating ACOs N=87.

TABLE B-G21: PY 2024 QUALITY MEASURES THAT SHARED SAVINGS PROGRAM ACOs PERFORMED BETTER ON THAN COMPARABLE MIPS GROUPS

Quality #	Measure Title	Difference in Mean ACO and MIPS Group Performance Rates for PY 2024 (%)*
	eCQMs	
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-3.75**
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	9.11****
236	Controlling High Blood Pressure	3.39***
	MIPS CQMs	
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-7.63**
236	Controlling High Blood Pressure	8.59***
321	**CAHPS for MIPS**	0.08
CAHPS-1	Getting Timely Care, Appointments, and Information	2.47***
CAHPS-5	Health Promoting and Education	0.84
CAHPS-6	Shared Decision Makin	0.08
CAHPS-7	Health Status and Functional Status	0.11
CAHPS-11	Stewardship of Patient Resources	0.17
	Administrative Claims	
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	-0.59**

*The numbers in this column represent the mean ACO performance rate minus the mean MIPS group performance rate for each measure.
**This is an inverse measure, and a lower number indicates better quality performance.
***Indicates statistically significant differences between ACOs and comparable MIPS groups ($p < 0.01$).
****Indicates statistically significant differences between ACOs and comparable MIPS groups ($p < 0.001$).

In the proposed rule we noted, as described previously, we have observed substantial evidence that the Shared Savings Program both generates savings and improves quality of care for beneficiaries (91 FR 44093). We also have observed there are still healthcare providers and beneficiaries not yet in accountable care relationships, and there is additional potential to increase participation in the Shared Savings Program and thereby continue to grow savings to the Medicare Trust Funds while improving the quality of care for beneficiaries. We stated that, although the number of primary care practitioners participating in a Shared Savings Program ACO has steadily grown over

time, a targeted incentive that encourages ACOs to recruit new practitioners and the beneficiaries they serve may help offset some of the initial investment costs associated with first time participation (91 FR 44093). We added that, as of PY 2024, there were 12.3 million beneficiaries that were eligible to be assigned to a Shared Savings Program ACO but were not assigned to an ACO (91 FR 44093). Approximately 11.1 million of these beneficiaries were not part of any shared savings initiative in PY 2023 or PY 2024, 6.7 million of which were primarily served by one of the aforementioned 300,000 practitioners who had no shared savings experience during the 6-year period from 2019 through 2024. We stated that ACOs may seek to recruit these practitioners and in turn provide care for their beneficiary populations if a well-designed incentive could help reduce certain financial barriers to recruitment and initial participation (91 FR 44093).

(d) Background on Determining Risk Experience

In the December 2018 final rule (83 FR 67894 through 67899), we finalized the definitions of performance-based risk Medicare ACO initiative, and what it means for an ACO to be deemed experienced and inexperienced with performance-based risk Medicare ACO initiatives under § 425.20. Under paragraph (1) of the definition of ''experienced with performance-based risk Medicare ACO initiatives,'' an ACO is considered experienced if the ACO (or a plurality of its ACO participants) has participated in a CMS initiative that requires an ACO to participate under a two-sided model (with shared savings and losses) such as Level E of the BASIC track and the ENHANCED track of the Shared Savings Program or other Innovation Center ACO models such as ACO REACH.[346] Under paragraph (2) of the definition, an ACO is also considered experienced if forty percent or more of the ACO's participants participated in a performance-based risk Medicare ACO initiative in any of the 5 most recent performance years. This means either the ACO itself (as a legal entity) has participated in such a program, or 40 percent or more of its participating provider groups (TINs) participated in such a program during any of the five performance years prior to the start of the ACO's agreement period. An ACO is considered inexperienced with performance-based risk Medicare ACO initiatives if its legal entity has never participated in a Medicare program with shared savings and shared losses and if less than 40 percent of its participating provider groups (TINs) participated in such programs during each of the 5 performance years prior to the start of the ACOs agreement period. ACOs that are inexperienced with performance-based risk Medicare ACO initiatives can typically qualify for certain participation options in the Shared Savings Program that are not otherwise available.

(2) Growth Adjustment to the Historical Benchmark

Relying on our authority under section 1899(d)(1)(B)(ii) of the Act, we proposed a growth adjustment to the historical benchmark applicable to ACOs in agreement periods beginning on January 1, 2027, and in subsequent years (91 FR 44094). We proposed a growth adjustment to offer a method of upwardly adjusting an ACO's historical benchmark that is applied in addition to the existing regional adjustment, prior savings adjustment, and population adjustment, up to the proposed cap of 5 percent of ACO risk-adjusted national per capita expenditures. The growth adjustment directly targets those ACOs that are actively engaged in expanding their beneficiary population and provide a financial incentive to reward growth above what we typically observe. To promote growth in the Shared Savings Program, this upward adjustment to the historical benchmark is designed to reward ACOs for recruiting ACO professionals inexperienced with value-based care arrangements who are also serving beneficiaries new to value-based care. Through the growth adjustment, we intend to provide a greater financial incentive for ACOs to recruit ACO professionals who are inexperienced with value-based care arrangements and serve more beneficiaries new to value-based care by increasing the likelihood that an ACO would earn shared savings and by potentially increasing the amount of shared savings earned.

We stated that under proposed § 425.652(a)(8)(iii), an ACO receives a growth adjustment, if applicable, in addition to the highest of the positive adjustments for which it is eligible, either the regional adjustment, prior savings adjustment, or population adjustment to the benchmark (91 FR 44094). As discussed in the proposed rule, an ACO is required to meet the eligibility criteria as described elsewhere in this section of this final rule to receive the growth adjustment to the historical benchmark (91 FR 44094). We noted that the proposed risk-adjustment of the 5 percent cap (91 FR 44082 through 44087), would operate synergistically with the growth adjustment, in that ACOs that are eligible for a growth adjustment may receive a greater adjustment with a risk-adjusted cap if the beneficiaries newly assigned to their ACO through newly recruited ACO professionals are also medically complex and high-risk beneficiaries (91 FR 44094).

Additionally, we noted that the proposed modifications to the prior savings adjustment to increase the scaling factor (91 FR 44076 through 44082) would complement the growth adjustment (91 FR 44094). Specifically, we noted that ACOs that receive a growth adjustment may generate larger performance year gross savings that would be accounted for in the calculation of future prior savings adjustments, thereby carrying a portion of the growth adjustment forward to a subsequent agreement period (91 FR 44094). Additionally, we noted that increasing the prior savings adjustment scaling factor from 50 percent to 75 percent, ACOs that receive a growth adjustment and generate gross savings would then be able to carry a larger portion of that growth adjustment forward to the subsequent agreement period through the larger prior savings adjustment (91 FR 44094). We stated that the use of a proration factor, which is not subject to modifications under this proposed rule, to calculate the prior savings adjustment based on changes in the assigned beneficiary population size also helps ensure that growth adjustments that might be awarded in the prior agreement period are only carried forward to the subsequent agreement period if the ACO maintains its overall size (91 FR 44094). If the ACO were to decrease in size, the ACO would receive a smaller prior savings adjustment and thus carry forward a smaller portion of the growth adjustment from the prior agreement period.

We proposed to calculate the growth adjustment as the product of the ACO's ''new growth'' share described in the proposed rule (91 FR 44094 through 44099) and the incentive factor described in the proposed rule (91 FR 44099 and 44100).

(a) Determine the ACO's ''New Growth'' Share of Assigned Beneficiary Person Years

As discussed in the proposed rule, to identify the ACO's new growth share of assigned beneficiary person years, CMS

[346] Refer to the Participation Options Report available to applicant ACOs on the Accountable Care Organization-Management System (ACO–MS) for other Innovation Center ACO models including ACO REACH.

would first need to identify the ACO's new growth (91 FR 44094). By new growth, we stated that we mean the number of beneficiaries (in person year terms) that are new to the Shared Savings Program that are brought into the program by ACO professionals who are inexperienced in shared savings initiatives (91 FR 44094). We proposed to identify shared savings initiatives for the purpose of determining the growth adjustment (as defined at § 425.664(b)(1)) as an initiative implemented by CMS, including the Shared Savings Program (as defined at § 425.664(b)(1)(i)), the Innovation Center ACO models ((as defined at § 425.664(b)(1)(ii)) (for example, ACO REACH, LEAD, etc.), or other initiatives that may be specified by CMS ((as defined at § 425.664(b)(1)(ii)) (91 FR 44094).[347]

In the proposed rule, we specified the criteria to meet this proposed definition throughout this section of this final rule under § 425.664 (91 FR 44094 through 44095). We stated that, to identify the ACO's new growth, we must first identify the ACO professionals who are inexperienced in shared savings initiatives (91 FR 44095). We added that the second step is then to determine the number of beneficiaries (in person year terms) that are new to the Shared Savings Program that are brought into the program by these inexperienced ACO professionals (91 FR 44095).

Therefore, we first proposed to define ACO professionals inexperienced with shared savings initiatives under § 425.664(b)(2) similar to the way we define how ACOs are ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' in § 425.20 (91 FR 44095). Under § 425.664(b)(2), we proposed that for an ACO professional to be considered inexperienced in a shared savings initiative for the growth adjustment (as defined at § 425.664(b)(1)), the ACO professional must not have billed primary care services through a participant in the Shared Savings Program, or participated in an Innovation Center ACO model, or other initiative specified by CMS for one or more performance years in any of the 5 performance years directly preceding the start of the ACO's current agreement period (91 FR 44095). We stated that, in other words, for an ACO professional to be considered experienced in a shared savings initiative, described as follows, the ACO professional must have billed primary care services through a participant in the Shared Savings Program, or participated in an Innovation Center ACO model, or other initiative specified by CMS, for one or more performance years of any of the 5 performance years directly preceding the start of the ACO's current agreement period (91 FR 44095).

We discussed in the proposed rule that, among the ACO professionals who we determine to be inexperienced in a shared savings initiative under § 425.664(b)(2), we then determine the number of beneficiaries (in person year terms) that are new to the Shared Savings Program that are brought into the program by these inexperienced ACO professionals under § 425.664(b)(3) (91 FR 44095). To determine the number of these beneficiaries (in person year terms), we first need to determine an assigned beneficiary's experience in shared savings initiatives. To do so, we proposed applying a similar definition as used to identify inexperienced ACO professionals to determine beneficiary experience in shared savings initiatives under § 425.664(b)(2) (91 FR 44095). Thus, under § 425.664(b)(3) we proposed that for an ACO assigned beneficiary to be considered inexperienced with a shared savings initiative, the ACO assigned beneficiary was not included in assignment in financial reconciliation to a Shared Savings Program ACO, Innovation Center ACO model, or other initiative specified by CMS in the performance year that corresponds to the ACO's BY3[348] under § 425.664(b)(3) (91 FR 44095). We stated that, in other words, for an ACO assigned beneficiary to be considered experienced with a shared savings initiative, the beneficiary would have to have been assigned to a Shared Savings Program ACO, Innovation Center ACO model, or other initiative specified by CMS and included in financial reconciliation for the performance year that corresponds to the ACO's BY3 (91 FR 44095).

Under § 425.664(b)(4), we proposed to measure new growth for each ACO in a given performance year as: (1) the number of assigned beneficiary person years inexperienced with a shared savings initiative; that (2) have an ACO professional who is inexperienced with a shared savings initiative as the ACO professional who provided the highest number of primary care services (as defined at § 425.20) at the ACO within the assignment window, or to whom the beneficiary was voluntarily aligned (91 FR 44095). We stated that, to qualify as new growth, both characteristics must be present (91 FR 44095). Under § 425.664(b)(4), we proposed to determine which ACO professional provided the highest number of primary care services (as defined at § 425.20) included in assignment for each assigned beneficiary at the ACO during the assignment window for the relevant performance year, or to whom the beneficiary voluntarily aligned. Refer to the example provided in Step 1 (91 FR 44095).

TABLE B-G22: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 1

Step 1: Calculate an ACO's new growth for the applicable performance year	New Growth = Number of assigned beneficiary person years inexperienced with a shared savings initiative that have an ACO professional inexperienced with shared savings initiatives as the primary ACO professional that provided the highest count of primary care services. New Growth = 3,000 assigned beneficiary person years.

[347] We will monitor for other similar models and initiatives in the future.

[348] Throughout this section, the assignment associated with the performance year that corresponds to the ACO's BY3 refers to the point in time from which to determine growth in assigned beneficiaries. For example, for an ACO that may begin an agreement period on January 1, 2027, we mean the final assignment list for PY 2026; we do not mean the benchmark year assignment list for BY 2026, which is the ACO's BY3. We use this as the point of comparison, so that we can determine the growth in assignment that occurred prior to the start of the agreement period relative to the applicable performance year, which will not be as clearly reflected if we used the current agreement period's participant list and BY3 assignment.

We proposed as a guardrail to ensure that measured new growth is contributing to overall growth in the program, only ACOs that grow and maintain their size, as measured by the count of assigned beneficiary person years, are eligible to receive an incentive, we proposed to cap new growth (91 FR 44095). We proposed to cap new growth to ensure ACOs are not only recruiting inexperienced ACO professionals and beneficiaries but additionally are maintaining their existing practitioner and beneficiary populations over the course of their agreement period, thus contributing to overall growth in the program (91 FR 44095). We stated that under § 425.664(c), the first step to determine whether the cap on new growth applies, is to determine the overall growth as the difference between the number of beneficiary person years assigned to the ACO during final assignment in the performance year and the number of beneficiary person years assigned to the ACO during final assignment in the PY that corresponds to the ACO's BY3 (91 FR 44095). We proposed that, if the ACO is a new entrant or re-entering ACO, the overall growth is equal to the number of assigned beneficiary person years in the performance year (91 FR 44095).

As discussed in the proposed rule. for re-entering ACOs, defined under § 425.20, overall growth will also be set equal to the number of assigned beneficiaries in the performance year (91 FR 44095). We proposed to handle re-entering ACOs in this way because they may have had a multi-year gap in participation since their prior participation agreement, be heavily comprised of ACO participants from multiple prior ACOs, or may have split off from another ACO (91 FR 44095 through 44096). Therefore, for ACOs that are new or re-entering, we would not have a comparable way to measure overall growth as we do for ACOs that are not new or re-entering (for example, using the performance year that corresponds to the ACO's BY3 from which to calculate the ACO's overall growth for the performance year). In an analysis of all re-entering ACOs between PY 2022 and PY 2026, two-thirds of re-entering ACOs had a smaller assigned beneficiary population than in their prior participation agreement. The complex nature of re-entering ACOs' composition makes it difficult to determine a fair and accurate beneficiary count to be used in determining a baseline for capped new growth. Only providing the incentive to inexperienced ACO professionals and beneficiary who have not been assigned to an ACO in the final assignment for the PY that corresponds to the ACO's BY3 ensures that only the new growth is counted toward the incentive and acts as a guardrail to mitigate any unintended incentives created by the treatment of re-entering ACOs as new entrants. For example, any currently participating ACOs that terminate and immediately re-enter, or that split into multiple new re-entering ACOs would still need to add additional inexperienced ACO professionals and beneficiaries to their organization to receive the growth adjustment. We noted that ACO professionals and beneficiaries added during the previous agreement period, prior to terminating and re-entering would not be considered inexperienced, and therefore would not count towards the incentive (91 FR 44096). We added that this mitigates against the possibility that an ACO might terminate and re-enter to set their baseline count of beneficiaries to zero (91 FR 44096).

TABLE B-G23: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 2

Step 2: Determine overall growth	overall growth = Number of assigned beneficiary person years in the PY minus the number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 (if applicable). If the ACO is a new entrant or re-entering, the overall growth is equal to the number of assigned beneficiary person years in the PY Continuing ACO Example: Number of assigned beneficiary person years in the PY = 11,000 Number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 = 5,000 overall growth = 11,000 - 5,000 = 6,000 assigned beneficiary person years New Entrant or Re-Entering ACO Example: Number of assigned beneficiary person years in the PY = 11,000 Number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 = 0 overall growth = 11,000 - 0 = 11,000 assigned beneficiary person years

We discussed in the proposed rule that the third step to determine the cap on the new growth is to take the lesser of the new growth and the overall growth under § 425.664(d) (we referred to Example Tables 1 through 4 of the proposed rule for examples of this calculation) (91 FR 44096). We noted that, for new entrant ACOs that did not participate prior to the current agreement period, assuming zero assigned beneficiary person years for the performance year corresponding to the ACO's BY3, the overall growth in the number of assigned beneficiary person years, which will determine the cap on the new growth, will be equivalent to the total number of assigned beneficiary person years in the current performance period (91 FR 44096). As described elsewhere in the proposed rule, we proposed to treat re-entering ACOs the same as new entrant ACOs for the purposes of this calculation as well (91 FR 44096). We noted in the proposed rule that the cap effectively would not apply for new entrant ACOs and re-

entering ACOs because new growth and the total number of assigned beneficiaries in a performance year will always be the same (91 FR 44096). We referred readers to the example provided in Step 3 of the proposed rule (91 FR 44096).

TABLE B-G24: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 3

Step 3: Determine capped new growth	Capped new growth = the lesser of the new growth determined in Step 1 and the overall growth determined in Step 2. overall growth = 6,000 assigned beneficiary person years new growth = 3,000 assigned beneficiary person years capped new growth = 3,000 assigned beneficiary person years

We recognized that there are typically new ACO professionals who join Shared Savings Program ACOs annually, as well as new beneficiaries assigned to Shared Savings Program ACOs annually (91 FR 44096). We stated that the intent of the growth adjustment is to provide a financial incentive to reward growth above what we typically observe (91 FR 44096). Accordingly, under § 425.664(e), we proposed to apply the minimum new growth thresholds in Table B–G22 for each performance year of an agreement period above which the ACO would need to grow with ACO professionals that have not previously participated in shared savings initiatives and beneficiaries that have not previously been assigned to an ACO to receive the growth adjustment (91 FR 44096).

Under § 425.664(e), we proposed determining the minimum new growth threshold on a relative basis, defined as the person years of the minimum new growth divided by total assigned beneficiary person years, and on an absolute basis, defined as the number of person years of the minimum new growth for the PY according to Table B–G22 of the proposed rule at 91 FR 44097 (91 FR 44096 through 44097). We proposed to determine the threshold on both an absolute and relative basis to ensure parity and equal opportunity for ACOs of various sizes to receive the incentive (91 FR 44097). We noted that for example the relative threshold creates an incentive for ACOs that are smaller, in which small additions in assigned beneficiaries would substantially impact the ACO's relative size (91 FR 44097). Whereas, the absolute threshold creates an incentive for ACOs that are larger to recruit practices that may not otherwise substantially impact the relative size of those ACOs. We proposed the following absolute and relative minimum new growth thresholds for PY1 through PY5 (91 FR 44097):

TABLE B-G25: ABSOLUTE AND RELATIVE MINIMUM "NEW GROWTH" THRESHOLDS OVER AN AGREEMENT PERIOD

	PY 1	PY 2	PY 3	PY 4	PY 5
Absolute Minimum New Growth Threshold	100	300	600	900	1200
Relative Minimum New Growth Threshold	0.5%	1.5%	3.5%	5.5%	7.5%

In the proposed rule, we identified these minimum thresholds by analyzing Shared Savings Program ACO program data from 2017 through 2026 (91 FR 44097). We stated that to identify a proposed minimum threshold for each performance year, we looked at ACOs that began their second or subsequent agreement period (that is, not new or re-entering ACOs) on or before January 1, 2022 that were still participating through the start of 2026 and experienced new growth (as we now propose to define it) (91 FR 44097). CMS then set the threshold at the 25th percentile of new growth, based on the observed inflection point in the distribution of new growth for each performance year. We noted that, while we understand that many ACOs experience some natural growth, we intend the growth adjustment as an incentive for ACOs to actively engage in expanding their beneficiary population that is inexperienced and expand their ACO participants who are inexperienced (91 FR 44097). We determined that setting the threshold at the 25th percentile [349] was sufficient to make the distinction between natural population variation and those ACOs that were actively recruiting new participants and growing their ACOs, while maintaining reasonable growth rates for ACOs of all sizes, as demonstrated by ACOs in this analysis. We proposed that only ACOs that exceed this threshold in a given year would qualify for the growth adjustment (91 FR 44097).

We stated that this analysis showed that new growth steadily increased among ACOs in this sample in each year relative to the PY that corresponds to the ACO's BY3, but the rate of increase was not consistent or linear (91 FR 44097). As discussed in the proposed rule, the thresholds approximately matched observed rates of growth year to year among the ACOs in this sample (91 FR 44097). We stated that the thresholds increase in each subsequent performance year to account for natural changes in the assigned beneficiary and ACO professional populations (91 FR

[349] The absolute and relative distribution of new growth among all ACOs *and* ACOs experiencing growth was a right-skewed L-shaped distribution with many ACOs experiencing little to no growth, a few experiencing extreme growth, and the middle set experiencing some growth. The first slope change (that is, inflection point) distinguished the majority of ACOs who experienced little to no new growth as defined in this proposed rule and in § 425.664(b)(4) from those who may have made composition changes to increase their ACO size. Among ACOs who participated for a full agreement period and experienced new growth, the first inflection point occurred at approximately the 25th percentile.

44097).[350] Thus we proposed to measure new growth relative to the performance year that corresponds to the ACO's BY3 (91 FR 44097). The larger thresholds in later performance years ensures that measured new growth is primarily the result of ACOs targeting intentional growth and not natural composition changes. We proposed that we will periodically re-evaluate the determined thresholds, and if changes to these thresholds are needed we would expect the updates to be on a performance year basis (rather than agreement period basis) (91 FR 44097). We noted that we would propose changes to the minimum new growth thresholds in rulemaking (91 FR 44097). And that we expect that updates to these thresholds will be infrequent to provide additional predictability in the proposed growth adjustment (91 FR 44097).

Under § 425.664(e), we proposed to determine which minimum new growth threshold is applied to an ACO by taking the lesser of the absolute and relative thresholds after we convert the relative threshold to beneficiary person years by multiplying the relative threshold by the ACO's total assigned beneficiary person years in the PY (91 FR 44097). We referred readers to the example provided in Step 4 of the proposed rule (91 FR 44097).

TABLE B-G26: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 4

Step 4: Determine which minimum new growth threshold is applied	Minimum new growth threshold applied = the lesser of the relative minimum new growth threshold and the absolute minimum new growth threshold. Absolute minimum new growth threshold = 100 assigned beneficiary person years. Relative minimum new growth threshold = 0.5% assigned beneficiary person years x total assigned beneficiary person years (11,000) = 55 assigned beneficiary person years. Minimum new growth threshold applied = 55 assigned beneficiary person years.

As discussed in the proposed rule, the new growth above the minimum and below the cap is the amount of newly assigned beneficiary person year growth eligible for the growth incentive (91 FR 44098). Under § 425.664(f), we proposed to calculate new growth above the minimum and below the cap, which is the portion of new growth for which ACOs may be eligible to receive a growth adjustment, as the difference between the new growth and the minimum new growth threshold, or 0, if negative (91 FR 44098). We proposed to calculate new growth above the minimum and below the cap in this way so that ACOs are rewarded for contributing to overall growth in the Shared Savings Program (91 FR 44098). We stated that the minimum thresholds in conjunction with the cap ensures CMS is rewarding ACOs engaged in actively expanding their assigned population with beneficiaries not currently in an accountable care relationship (91 FR 44098). We referred readers to the example provided in Step 5 of the proposed rule (91 FR 44098).

TABLE B-G27: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 5

Step 5: Determine new growth above minimum and below the cap	New growth above the minimum and below the cap = the difference of capped new growth determined in Step 3 and the minimum new growth threshold applied in Step 4. Capped New Growth = 3,000 assigned beneficiary person years Minimum new growth threshold applied = 55 assigned beneficiary person years New growth above the minimum and below the cap = 3,000 - 55 = 2,945 assigned beneficiary person years.

We said that to facilitate the calculation of a per capita growth adjustment to be applied to the historical benchmark, we must first calculate this new growth as a proportion of the ACO's total assigned beneficiary person years (91 FR 44098). Therefore, we proposed to determine an ACO's new growth share (91 FR 44098). Under § 425.664(g), we proposed to determine the new growth share as the ratio of the new growth above the minimum and below the cap divided by the ACOs number of assigned beneficiary person years for the PY (91 FR 44098). This value will be multiplied by the incentive factor to determine the growth adjustment to the historical benchmark. We referred readers to the example provided in Step 6 of the proposed rule (91 FR 44098).

[350] In other words, the composition of ACOs' beneficiary and ACO professional populations are not static. ACOs experience population changes as time passes. As more time passes, more changes will occur. These changes are the natural result of employment changes among ACO professionals, and changes in care patterns among beneficiaries—both of which occur even in organizations not engaged in actively expanding. Since growth is measured against a fixed time period, and the number of changes increases over time, the thresholds need to increase as the time relative to the PY corresponding to the ACO's BY3 increases.

TABLE B-G28: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 6

Step 6: Calculate new growth share	New Growth Share = new growth above the minimum and below the cap determined in Step 5 divided by the number of assigned beneficiary person years in the PY. New growth above the minimum and below the cap = 2,945 Number of assigned beneficiary person years in the PY = 11,000 New growth share = 2,945 / 11,000 = 0.268.

We provided four example scenarios for determining the new growth share for hypothetical ACOs over an agreement period to illustrate the multiple steps of the calculation, using the minimum new growth thresholds established in Table B–G22 of the proposed rule at 91 FR 44097 (91 FR 44098).

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EXAMPLE 1: NEW GROWTH CAPPED BY OVERALL GROWTH OVER AN AGREEMENT PERIOD

		Base	PY1	PY2	PY3	PY4	PY5
	Total assigned person years	5000	11000	11000	12000	13000	7000
Step 1	New growth person years		3000	1500	2000	2500	3000
Step 2	Overall growth [Total assigned person years in PY - Base]		6000	6000	7000	8000	2000
Step 3	Capped new growth [Step 1 ≤ Step 2]		3000	1500	2000	2500	2000
Step 4	Minimum new growth threshold applied		55	165	420	715	490
Step 5	New growth above the minimum and below the cap [Step 3 – Step 4]		2945	1335	1580	1785	1510
Step 6	New growth share [Step 5 ÷ Total assigned person years in PY]		0.268	0.121	0.132	0.137	0.216

EXAMPLE 2: LARGE ACO WITH ABSOLUTE THRESHOLD APPLIED OVER AN AGREEMENT PERIOD

		Base	PY1	PY2	PY3	PY4	PY5
	Total assigned person years	50000	55000	56000	57000	58000	56000
Step 1	New growth person years		1000	1500	2000	2500	3000
Step 2	Overall growth [Total assigned person years in PY - Base]		5000	6000	7000	8000	6000
Step 3	Capped new growth [Step 1 ≤ Step 2]		1000	1500	2000	2500	3000
Step 4	Minimum new growth threshold applied		100	300	600	900	1200
Step 5	New growth above the minimum and below the cap [Step 3 – Step 4]		900	1200	1400	1600	1800
Step 6	New growth share [Step 5 ÷ Total assigned person years in PY]		0.016	0.021	0.025	0.028	0.032

EXAMPLE 3: NEW ENTRANT OR RE-ENTERING ACO WHERE BASE EQUALS ZERO OVER AN AGREEMENT PERIOD

		Base	PY1	PY2	PY3	PY4	PY5
	Total assigned person years	0	10000	11000	12000	13000	11000
Step 1	New growth person years		1000	1500	2000	2500	3000
Step 2	Overall growth [Total assigned person years in PY - Base]		10000	11000	12000	13000	11000
Step 3	Capped new growth [Step 1 ≤ Step 2]		1000	1500	2000	2500	3000
Step 4	Minimum new growth threshold applied		50	165	420	715	770
Step 5	New growth above the minimum and below the cap [Step 3 – Step 4]		950	1335	1580	1785	2230
Step 6	New growth share [Step 5 ÷ Total assigned person years in PY]		0.095	0.121	0.132	0.137	0.203

EXAMPLE 4: SLOW "NEW GROWTH" AND GROWTH DECLINED IN LATER PY OVER AN AGREEMENT PERIOD

		Base	PY1	PY2	PY3	PY4	PY5
	Total assigned person years	5000	5000	6000	7000	8000	6000
Step 1	New growth person years		100	150	250	50	0
Step 2	Overall growth [Total assigned person years in PY - Base]		0	1000	2000	3000	1000
Step 3	Capped new growth [Step 1 ≤ Step 2]		0	150	250	50	0
Step 4	Minimum new growth threshold applied		25	90	245	440	420
Step 5	New growth above the minimum and below the cap [Step 3 – Step 4]		0	60	5	0	0
Step 6	New growth share [Step 5 ÷ Total assigned person years in PY]		0	0.01	0.001	0	0

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(b) Determine the ACO's Incentive Factor

To determine a dollar amount for the proposed adjustment to the historical benchmark, under § 425.664(h), we proposed to establish an incentive factor, which would be the per capita dollar amount that would convert the new growth share into dollar terms (91 FR 44099). The proposed incentive factor would be based on a percentage of the ACO's per capita historical benchmark and when multiplied against the new growth share will determine the dollar amount added to an ACO's historical benchmark (91 FR 44099). We proposed to determine an ACO's incentive factor as an ACO-specific per capita dollar amount (91 FR 44099). We proposed to calculate this per capita dollar amount as 5 percent of the per capita historical benchmark before the regional adjustment, prior savings adjustment, or population adjustment is applied, expressed as a single value (91 FR 44099). The CMS Office of the Actuary (OACT) provided information to support that 5 percent of the ACO's unadjusted historical benchmark is sufficient to incentivize recruitment of inexperienced ACO professionals while balancing savings in the program, and is described in the Regulatory Impact Analysis, in section VI. of this final rule. We stated that calculating the incentive factor as a percentage of the ACO's unique historical benchmark ensures the adjustment is specific to the ACO and provides a greater incentive, especially for ACOs caring for medically complex high-cost beneficiaries, than just a flat dollar for all ACOs (91 FR 44099). We referred to the example of the determination of the Incentive Factor provided in Step 7 in the proposed rule (91 FR 44099).

TABLE B-G29: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 7

Step 7: Determine the incentive factor	Incentive factor = 5% of historical benchmark before adjustment is applied historical benchmark before adjustment is applied = $13,000 incentive factor = $13,000 x 5% = $650

Table B–G27 of the proposed rule is an example scenario of determining the ACO's incentive factor for a hypothetical ACO over an agreement period (91 FR 44100).

TABLE B-G30: CALCULATION OF THE INCENTIVE FACTOR OVER AN AGREEMENT PERIOD

		PY1	PY2	PY3	PY4	PY5
	Historical Benchmark before Adjustments are Applied ($)	13,000	15,500	14,500	16,000	15,750
	Percentage Applied to the Historical Benchmark	5%	5%	5%	5%	5%
Step 7	Incentive Factor ($)	650.00	775.00	725.00	800.00	787.50

(c) Determine the ACO's Growth Adjustment to the Historical Benchmark

Under § 425.664(I)(1), we proposed to calculate the growth adjustment as the product of the ACO's new growth share, defined in the proposed rule (91 FR 44094 through 44099), and the ACO's incentive factor, defined in the proposed rule (91 FR 44099 and 44100). Refer to the example provided in Step 8 of the proposed rule (91 FR 44100).

TABLE B-G31: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 8

Step 8: Determine the growth adjustment to the historical benchmark	Determine the growth adjustment to the historical benchmark = new growth share determined in Step 6 and the incentive factor determined in Step 7 new growth share = 0.268 incentive factor = $650 growth adjustment to the historical benchmark = $174.02

Under § 425.652(a)(8)(iii), we proposed that the growth adjustment amount would be added to the highest of the positive regional adjustment, prior savings adjustment, and population adjustment, or no adjustment, and the total amount could not exceed 5 percent of national per capita OM expenditures, adjusted for risk (if finalized), as discussed in the proposed rule (91 FR 44082 through 44090), otherwise if not finalized, the total amount could not exceed the existing 5 percent of national per capita OM expenditures, not adjusted for risk. Refer to the example provided in Step 9 of the proposed rule (91 FR 44100).

TABLE B-G32: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 9

Step 9: Determine the final adjustment to the historical benchmark	Final adjustment to the historical benchmark = sum of the growth adjustment to the historical benchmark determined in Step 8 and the highest of the regional adjustment, prior savings adjustment, and the population adjustment, not to exceed 5% of the risk-adjusted national assignable FFS expenditures expressed as a single value; otherwise, the existing 5% of national per capital OM expenditures, not adjusted for risk. growth adjustment to the historical benchmark = $174.02 highest of the regional, prior savings, or population adjustment if applicable = $125 5% of the national FFS expenditures expressed as a single value = $350 final adjustment to the historical benchmark = $299.02

As discussed in the proposed rule, to follow is an example scenario of determining an ACO's growth adjustment and Final Adjustment to the Historical Benchmark (91 FR 44100 through 44101).

TABLE B-G33: DETERMINATION OF THE GROWTH ADJUSTMENT AND FINAL ADJUSTMENT TO THE BENCHMARK OVER AN AGREEMENT PERIOD

		PY1	PY2	PY3	PY4	PY5
Step 6	"New Growth" Share	0.268	0.121	0.132	0.137	0.216
Step 7	Incentive Factor ($)	650.00	775.00	725.00	800.00	787.50
Step 8	Growth Adjustment ($)	174.02	94.06	95.46	109.85	169.88
	Regional, Prior Savings, or Population Adjustment, if Applicable ($)	125.00	230.00	75.00	350.00	410.00
	Growth Adjustment + Highest Applicable Adjustment ($)	299.02	324.06	170.46	459.85	579.88
	Risk-Adjusted Cap on Adjustments to the Benchmark, not to exceed 5% of National Assignable FFS Expenditures, expressed as a Single Value, if finalized. Otherwise, the Existing 5% National Assignable FFS Expenditures, expressed as a Single Value Not Adjusted for Risk. ($)	350.00	400.00	475.00	500.00	500.00
Step 9	Final Adjustment to the Benchmark ($)	299.02	324.06	170.46	459.85	500.00

TABLE B-G34: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1

Step 1: Calculate an ACO's new growth for the applicable performance year	new growth = number of assigned beneficiary person years inexperienced with a shared savings initiative that have an ACO professional inexperienced with shared savings initiatives as the primary ACO professional that provided the highest count of primary care services new growth = 3,000 assigned beneficiary person years
Step 2: Determine overall growth	overall growth = number of assigned beneficiary person years in the PY minus the number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 (if applicable). If the ACO is a new entrant or re-entering, the overall growth is equal to the number of assigned beneficiary person years in the PY Continuing ACO Example: Number of assigned beneficiary person years in the PY = 11,000 Number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 = 5,000 overall growth = 11,000 - 5,000 = 6,000 assigned beneficiary person years New Entrant or Re-Entering ACO Example: Number of assigned beneficiary person years in the PY = 11,000 Number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 = 0 overall growth = 11,000 - 0 = 11,000 assigned beneficiary person years
Step 3: Determine capped new growth	Capped new growth = the lesser of the new growth determined in Step 1 and the overall growth determined in Step 2. overall growth = 6,000 assigned beneficiary person years new growth = 3,000 assigned beneficiary person years capped new growth = 3,000 assigned beneficiary person years
Step 4: Determine which minimum new growth threshold is applied	Minimum new growth threshold applied = the lesser of the relative minimum new growth threshold and the absolute minimum new growth threshold absolute minimum new growth threshold = 100 assigned beneficiary person years relative minimum new growth threshold = 0.5% assigned beneficiary person years x total assigned beneficiary person years (11,000) = 55 assigned beneficiary person years minimum new growth threshold applied = 55 assigned beneficiary person years
Step 5: Determine new growth above minimum and below the cap	New growth above the minimum and below the cap = the difference of capped new growth determined in Step 3 and the minimum new growth threshold applied in Step 4 capped new growth = 3,000 assigned beneficiary person years minimum new growth threshold applied = 55 assigned beneficiary person years

We summarized the proposed steps of the calculation of the growth adjustment as follows in Table B–G31 of the proposed rule (91 FR 44101 through 44103).

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	new growth above the minimum and below the cap = 3,000 - 55 = 2,945 assigned beneficiary person years
Step 6: Calculate new growth share	New growth share = new growth above the minimum and below the cap determined in Step 5 divided by the number of assigned beneficiary person years in the PY new growth above the minimum and below the cap = 2,945 number of assigned beneficiary person years in the PY = 11,000 new growth share = 2,945 / 11,000 = 0.268
Step 7: Determine the incentive factor	Incentive factor = 5% of historical benchmark before adjustment is applied historical benchmark before adjustment is applied = $13,000 incentive factor = $13,000 x 5% = $650
Step 8: Determine the growth adjustment to the historical benchmark	Determine the growth adjustment to the historical benchmark = new growth share determined in Step 6 and the incentive factor determined in Step 7 new growth share = 0.268 incentive factor = $650 growth adjustment to the historical benchmark = $174.02
Step 9: Determine the final adjustment to the historical benchmark	Final adjustment to the historical benchmark = sum of the growth adjustment to the historical benchmark determined in Step 8 and the highest of the regional adjustment, prior savings adjustment, and the population adjustment, not to exceed 5% of the risk-adjusted national assignable FFS expenditures expressed as a single value; otherwise, the existing 5% of national per capital OM expenditures, not adjusted for risk. growth adjustment to the historical benchmark = $174.02 highest of the regional, prior savings, or population adjustment if applicable = $125 5% of the national FFS expenditures expressed as a single value = $350 final adjustment to the historical benchmark = $299.02

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We sought comment on the proposal to apply a growth adjustment to the historical benchmark in addition to the existing regional, prior savings and population adjustments, up to the existing 5 percent cap on upward adjustments to the historical benchmark, or if finalized, the risk-adjusted 5 percent cap described in section III.G.5.e. of this final rule for agreement periods beginning on January 1, 2027, and in subsequent years. See section III.G.5.f.(3) of this final rule for a summary of the comments and out responses.

(3) Timing of Applicability

We proposed to apply the growth adjustment proposal for agreement periods beginning on January 1, 2027, and in subsequent years (91 FR 44103). We stated that, if finalized, for ACOs with agreement periods beginning on January 1, 2027, we would use CY 2022 through CY 2026 as the 5-year period used to determine whether ACO professionals are inexperienced with shared savings initiatives (91 FR 44103). We stated that for ACOs with agreement periods beginning on January 1, 2027, we would use CY 2026 as the 1-year period to determine whether beneficiaries are inexperienced with shared savings initiatives for ACOs (91 FR 44103).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most comments supported the proposed growth adjustment, citing that a direct financial incentive to recruit inexperienced ACO professionals would encourage ACOs to increase the number of clinicians and beneficiaries in value-based care. A comment applauded the incentives for ACOs to serve beneficiaries new to value-based care and noted that promoting and ensuring patients receive longitudinal relationship-based care

improves health outcomes. Another comment commended CMS for proposing the growth adjustment to be applied on top of the highest baseline adjustment (prior savings, regional, or population adjustments). They believe this ensures ACO's are incentivized to recruit inexperienced clinicians and take on the financial costs.

Response: We appreciate these comments supporting our proposals. The growth adjustment methodology is designed to target growth above expected levels and adjust the benchmark based on the expected net savings associated with newly aligned beneficiaries.

Comment: A comment was opposed to the proposal because the commenter was concerned the growth adjustment would incentivize inequitable financial advantages based on provider or beneficiary growth rather than performance. Another comment had concerns about the proposed magnitude of the incentive factor, which was proposed as 5 percent of the per capita historical benchmark (before the regional adjustment, prior savings adjustment, or population adjustment is applied). The comment noted that at 5 percent, the growth adjustment may exceed the level of savings reasonably expected from new participants and referenced CMS evaluations and MedPAC findings as the basis of their concerns, indicating that historical ACO gross savings have generally been around 2 percent rather than the proposed 5 percent adjustment.

Response: We appreciate comments describing concerns and recommendations. The growth adjustment methodology is designed to target growth above expected levels through the application of a minimum new growth threshold that is equal to normal ACO growth. In response to a commenter's concern, the application of a minimum new growth threshold limits the potential for inequitable financial advantages based on provider or beneficiary growth.

Additionally, in response to another commenter's concern regarding the magnitude of the incentive factor, the adjustment is calibrated based on the expected net savings associated with newly assigned beneficiaries, thereby linking the magnitude of the incentive to expected program value. Additionally, as noted in the proposed rule, the CMS Office of the Actuary (OACT) provided information to support that 5 percent of the ACO's unadjusted historical benchmark is likely to incentivize recruitment of inexperienced ACO professionals while balancing savings in the program (further information is also described in the Regulatory Impact Analysis of this rule, in section VI. of this final rule). Regarding the comment that historical ACO gross savings have generally been around 2 percent rather than the proposed 5 percent adjustment, CMS has found in the 3 most recently reconciled performance years, gross savings have been near 5 percent of the ACOs benchmark (PY 2023 4.0 percent, PY 2024 4.7 percent, and PY 2025 4.7 percent), suggesting that additional savings payments ACOs may receive because of the growth adjustment would likely be offset by additional savings generated from the new beneficiaries cared for by the ACOs receiving the adjustment.[351]

We will monitor the relationship between the amount of the growth adjustment to benchmarks, Shared Savings Program participation growth and realized savings and consider whether additional refinements are needed if experience indicates that incentive payments are not commensurate with program savings.

Comment: A couple of comments strongly opposed the proposed growth adjustment. These comments cited that increased benchmarks could carry on into later agreement periods and directly reward changes in organizational composition and create incentives to recruit TINs or NPIs that maximize the benchmark. One of these comments suggested CMS should treat provider participant list changes as a source of selection and require analyses that hold provider composition constant. Similarly, a comment cautioned that the policy could incentivize large ACOs to expand primarily for financial gain and recommended CMS monitor for excessive growth and implement safeguards for ACOs whose enrollment growth substantially exceeds regional norms. A couple of comments encouraged CMS to evaluate the growth adjustment policy over time to measure its effectiveness and ensure that mature ACOs with limited growth opportunities are not disadvantaged compared to expanding ACOs.

Response: We appreciate the comments expressing concerns regarding potential incentives associated with changes in ACO participation composition. The proposed policy was designed to create incentives that naturally phase out over time, since as more providers, suppliers and beneficiaries join ACOs there would be fewer providers, suppliers and beneficiaries that would qualify as ''new.'' This design helps support the goals of bringing new providers and suppliers inexperienced with value-based care into a Shared Savings Program ACO and mitigates long-term incentives for ACOs to maximize benchmarks. We will continue to monitor the methodology, including patterns of ACO growth and changes in ACO participation composition, to ensure the policy is achieving its intended goal of encouraging appropriate participation in the Shared Savings Program and is not creating unintended incentives or opportunities for benchmark manipulation.

Comment: A comment opposed the proposed growth adjustment. This comment cited that it would add complexity to the benchmark methodology. Another comment supported CMS's growth adjustment proposal, but the commenter recommended more comprehensive benchmark reforms that avoid the need to layer an additional adjustment because it can further complicate benchmarking.

Response: We appreciate the comments' concerns regarding the additional complexity associated with the growth adjustment. We acknowledge that incorporating a growth adjustment adds complexity to the benchmark methodology. However, we believe the added growth adjustment is warranted because the adjustment is intended to encourage targeted growth in participation of providers, suppliers, and beneficiaries who are new to value-based care arrangements, consistent with the Shared Saving Program's goals of expanding participation and encouraging organizations to bring new healthcare providers into accountable care. Without this adjustment, ACOs may have fewer incentives to include such providers, suppliers, and beneficiaries, which could limit the Program's ability to expand value-based care and the related benefits of improving quality of care and reducing cost. To help ACOs understand and operationalize the growth adjustment, CMS is currently developing resources to support ACOs' understanding of which ACO professionals would be counted as new growth for future performance years as well as further describing the growth adjustment in the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications.

[351] Please note, at the time this rule is being finalized, performance year 2025 financial reconciliation results have not yet been released to ACOs. We anticipate embargoed and unembargoed performance year 2025 financial reconciliation results to be shared with ACOs shortly after the finalization of this final rule.

We also appreciate the comment recommending broader benchmark reforms. CMS continually evaluates the Shared Savings Program benchmarking methodology and considers potential improvements that promote participation, maintain incentives for coordinated, high-quality care, and ensure program integrity. At this time, we believe the growth adjustment is an important and targeted refinement that addresses a specific concern regarding the treatment of growth in ACO provider, supplier, and beneficiary populations, and we will continue to evaluate for possible future benchmark reforms.

Comment: A comment suggested that CMS pursue participation incentives that do not increase ACO historical benchmarks. The comment suggested a temporary per-beneficiary-per-month payment for beneficiaries newly brought into ACOs, which could be phased out as providers gain experience in accountable care. Another comment suggested CMS pursue prospective payments that function like true capitation, paying predictable amounts up front without retrospective reconciliation.

Response: We thank the commenters for their recommendations. We recognize the potential value of alternative incentives, including per-beneficiary-per-month or prospective payment approaches. We continue to evaluate these options, for example, through the Request for Information on Developing Prospective Payment in the Shared Savings Program (see 91 FR 43935 through 43946). However, we believe the growth adjustment represents a targeted refinement to the existing benchmark methodology that advances similar goals by encouraging participation among ACO providers, suppliers, and beneficiaries new to value-based care. As discussed previously, the adjustment is designed to provide a temporary benefit that naturally phases out over time as fewer providers, suppliers, and beneficiaries qualify as ''new.''

Comment: Some comments recommended that CMS broaden eligibility for the growth adjustment by counting all beneficiary growth, regardless of whether newly assigned beneficiaries are associated with a new or existing ACO professional or have prior experience with shared savings initiatives. These comments generally agreed with CMS's goal of increasing the number of beneficiaries in accountable care relationships but expressed concern that the proposed growth adjustment restrictions would reduce the incentive for ACOs to grow their beneficiary populations, particularly when growth occurs through existing ACO professionals. Other comments recommended removing the requirement that ACO professionals be new to value-based care, arguing that the policy may not recognize growth resulting from practices that expand their Medicare fee-for-service beneficiary populations or add healthcare professionals. Another commenter recommended basing the adjustment solely on beneficiaries new to value-based care rather than ACO professionals, citing concerns that facility-focused ACOs may have relatively few inexperienced providers and therefore may be less likely to benefit from the adjustment. A comment also encouraged CMS to ensure that the adjustment appropriately accounts for the costs associated with onboarding and supporting ACO professionals and beneficiaries who are new to value-based care.

Response: We appreciate the comments' recommendations. The methodology is intended to encourage participation by ACO professionals and their beneficiaries who are new to value-based care, rather than to incentivize all beneficiary growth regardless of its source. Financially incentivizing all beneficiary growth regardless of its source could inappropriately account for growth that would have already occurred absent the growth adjustment incentives. For this reason, we decline to remove the requirement that newly assigned beneficiaries be associated with ACO professionals who are new to value-based care or to otherwise expand the adjustment to include all beneficiary growth. While such policies may increase the number of beneficiaries eligible for the adjustment, they would broaden the incentive beyond the specific participation growth that the policy is intended to encourage.

Similarly, we decline to remove the requirement that ACO professionals be new to value-based care or to base the adjustment solely on beneficiaries. The methodology is designed to incentivize growth in accountable care participation among both ACO providers/suppliers and beneficiaries and to calibrate the adjustment based on the expected savings associated with newly assigned beneficiaries. We believe this approach appropriately balances incentives for participation growth with stewardship of Trust Fund resources and appropriately accounts for the expected value associated with bringing new ACO professionals and beneficiaries into accountable care arrangements.

Comment: Many comments expressed support for the growth adjustment and noted that its ability to encourage participation may be strengthened by raising the current 5 percent cap on upward adjustments to the historical benchmark.

Response: We appreciate the comments' recommendations. We direct commenters to section III.G.5.e. of this final rule, where we discuss our finalized policy to risk adjust the 5 percent cap on upward adjustments to the historical benchmark used in calculating benchmark adjustments. As discussed in that section, we believe risk adjusting the 5 percent cap appropriately addresses concerns regarding the cap's application while maintaining an appropriate balance between encouraging participation and safeguarding Trust Fund resources. Therefore, we decline at this time to further raise or remove the cap.

Comment: Some comments encouraged CMS to publish the growth adjustment incentive factor methodology and projected ACO level impacts in the final rule so ACOs can evaluate before participation decisions. Likewise, a couple of comments encouraged CMS to provide meaningful implementation support, including education, data resources, and clear operational guidance, to help organizations new to accountable care be successful in their participation.

Response: We appreciate the comments' recommendations. In addition to the methodology provided in the proposed rule, where we provided a step-by-step methodology and calculation example (91 FR 44101 through 44103), CMS is currently developing resources to support ACOs' understanding of ACO professionals that would be counted as new growth for future performance years as well as further describing the growth adjustment in the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications.

Comment: A couple of comments generally supported CMS's efforts to address benchmarking concerns in the Shared Savings Program but encouraged CMS to evaluate if these proposed changes meaningfully reduce barriers for independent, Nurse Practitioner-led ACOS that often lack the historical claims volume the methodology favors.

Response: We appreciate the comments supporting our efforts and that included recommendations. We will continue to assess whether the methodology is achieving its intended goal of encouraging broader participation in the Shared Savings

Program, including among smaller and independent organizations.

Comment: A comment supported the growth adjustment policy if the adjustment rewards new accountable care and not ACO consolidation. They stated the adjustment should reward ACOs for increasing access to high-quality care and producing measurable outcomes. A couple of comments suggested enhancing the proposed growth adjustment for ACOs in rural or medically underserved communities through an additional benchmark adjustment or multiplier. This addition would recognize the unique challenges rural organizations encounter in initiating and sustaining ACO participation.

Response: We appreciate the comments in support and for emphasizing the importance of rewarding new accountable care participation from a broad group of organizations, including independent practices and rural healthcare providers. We note that for organizations that have not previously participated in an ACO, many of which are rural and provide care in underserved communities, the growth adjustment may provide the financial incentives and support needed for these organizations to overcome previous barriers that may have prevented participation. We also agree that the growth adjustment participation incentives should promote increased access to high-quality care for beneficiaries. We note that we previously finalized policies for the Shared Savings Program that may directly or indirectly support rural ACOs, including the option to receive advance investment payments (AIP) as described at § 425.630 and policies that benefit low revenue ACOs (which tend to be small, rural, and physician-only ACOs) as described at § 425.600 (*Selection of risk model*) and § 425.605(h) (*Calculation of shared savings for BASIC track ACOs not meeting MSR requirements*). Additionally, as discussed in section III.G.7 of this final rule, we are finalizing as proposed our policy to modify the methodology and use description for Advanced Investment Payments to encourage low-revenue ACOs that are inexperienced with risk to participate in the Shared Savings Program, including rural ACOs. We will monitor the implementation of the growth adjustment and its impact on ACO participation.

After considering public comments, we are finalizing the growth adjustment as proposed. Specifically, we are finalizing, without modification, our proposal to add new § 425.664 to codify calculating the growth adjustment to the historical benchmark. Additionally, we are finalizing as proposed revisions to § 425.652(a)(8)(iii) to codify that the growth adjustment amount will be added to the highest of the positive regional adjustment, prior savings adjustment, and population adjustment, or no adjustment, and the total amount cannot exceed 5 percent of national per capita OM expenditures, adjusted for risk as discussed in section III.G.5.e of this final rule. We are also finalizing as proposed our amendment to § 425.650 is amended in paragraph (a) by removing the references ''§§ 425.652 through 425.662'' and adding in their place the references ''§§ 425.652 through 425.664''.

g. Reform the Accountable Care Prospective Trend (ACPT) Component of the Benchmark Update Factor

(1) Background

As finalized in the December 2018 final rule (83 FR 68024 through 68030), we used our statutory authority under section 1899(i)(3) of the Act to adopt the policy under which we update the historical benchmark using a blend of national and regional growth rates, rather than the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as required under section 1899(d)(1)(B)(ii) of the Act. In accordance with § 425.601(b), applicable for agreement periods beginning on or after July 1, 2019, and before January 1, 2024,[352] we update the historical benchmark for an ACO for each performance year using a blend of national and regional growth rates between BY3 and the performance year. To update the benchmark, we make separate calculations for expenditure categories for each of the following populations of beneficiaries based on Medicare enrollment type: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, aged/non-dual eligible for Medicare and Medicaid (§ 425.601(b)(1)).

The national-regional blend is a weighted average of national FFS and regional growth rates between BY3 and the performance year for the applicable Medicare enrollment type (§ 425.601(b)(4)). The national growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for BY3 and the performance year for assignable beneficiaries (as defined at § 425.20) identified for the 12-month calendar year corresponding to each year (§ 425.601(b)(2)). Regional growth rates are computed using expenditures for the ACO's regional service area for BY3 and the performance year (§ 425.601(b)(3)). To calculate regional expenditures, we determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year and determine the ACO's regional expenditures as specified under § 425.601(c) and (d) and § 425.601(b)(3)(i) and (ii).

As noted, the national and regional growth rates are blended together by taking a weighted average of the two. The weight assigned to the national component of the national-regional blend for a given Medicare enrollment type is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year (as calculated in § 425.601(a)(5)(v) and § 425.601(b)(4)(i)). The weight assigned to the regional component of the national-regional blend for a given Medicare enrollment type is equal to 1 minus the weight applied to the national growth rate (§ 425.601(b)(4)(ii)). Under this approach, as an ACO's penetration in its regional service area increases, the weight applied to the national component of the national-regional blend increases and the weight applied to the regional component decreases.

The national and regional growth rates are blended together by taking a weighted average of the two. Specifically, for each Medicare enrollment type, the national-regional blended growth rate is equal to the sum of the following: (1) the growth rate for national assignable FFS expenditures for BY3 to the performance year multiplied by the weight assigned to the national component; and (2) the average growth rate for regional FFS expenditures for BY3 to the performance year based on the ACO's regional service area multiplied by the weight assigned to the regional component (87 FR 69881). In accordance with § 425.601(a)(5), we also use blended national-regional growth rates to trend forward expenditures for each benchmark year (BY1 and BY2) to BY3 dollars, making separate calculations for each Medicare enrollment type.

We summarized commenters' concerns about using the blended national-regional growth rates for benchmarking in the CY 2023 PFS final

[352] § 425.652 applies to ACOs that started agreement periods in 2025 and 2026. However, for simplicity, we have cited the provisions in § 425.601 in this background section to describe how the ACPT fits into the bigger picture of benchmark adjustments, and the same policies apply to ACOs to which § 425.652 applies.

rule (87 FR 69879 through 69881). Specifically, ACOs and other interested parties expressed concerns regarding the dynamic under which an ACO that reduces costs for its own assigned beneficiaries also reduces its average regional costs, resulting in a relatively lower benchmark for the ACO under the blended national-regional growth rates used to trend and update the ACO's historical benchmark. As summarized in the CY 2022 PFS final rule, ACOs and other interested parties also have suggested that this dynamic particularly disadvantages ACOs with high market penetration in their regional service areas, which may tend to be ACOs operating in rural areas (86 FR 65296 through 65299).

In the CY 2023 PFS final rule, we implemented new policies effective beginning with performance year 2024 to address these concerns by incorporating a prospectively set projected administrative growth factor, a variant of the modified United States Per Capita Cost (USPCC) called the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each performance year in the ACO's agreement period (87 FR 69882 through 69898). Incorporating this prospective trend in the update to the benchmark insulates a portion of the annual update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and helps to address the impact of increasing market penetration by ACOs in a regional service area on a growth factor that only uses blended national-regional rates. Under that methodology, because the ACPT is set prospectively at the outset of an agreement period, any savings generated by ACOs during the agreement period are not reflected in the ACPT. Accordingly, incorporation of the ACPT allows for benchmarks to increase beyond actual spending growth rates as ACOs slow spending growth. We noted that the use of the three-way blend to update ACOs' benchmarks should incentivize both greater savings by ACOs and greater program participation. We also noted that we believed that because incorporating the ACPT into the update would reduce the degree to which an ACO's savings negatively impact its benchmark through the regional trend component of the update, the ACPT would help to address the disproportionate impact of an ACO's savings on the benchmark update for ACOs with a high market share (87 FR 69882).

In addition, as discussed in the Regulatory Impact Analysis for the CY 2023 PFS proposed rule (87 FR 46427), we projected that this approach for use of an ACPT/national- regional three-way blended update factor, in combination with other proposed changes to the statutory payment model in the CY 2023 PFS proposed rule, as well as then-current policies established using the authority of section 1899(i)(3) of the Act (87 FR 46403 through 46404), would not increase program expenditures relative to those under the statutory payment model. Since we have established the three-way blended update factor, we have continued to reexamine this projection to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied, and we have found continued compliance with section 1899(i)(3)(B) of the Act.

Under § 425.660, the three-way blend is calculated as the weighted average of the ACPT (one-third) and the existing national-regional blend (two-thirds) for use in updating an ACO's historical benchmark between BY3 and the performance year. As we described in the CY 2023 PFS final rule, we calculate the ACPT component of the blended annual update using an annualized growth rate based on 5-year projections in per capita spending as of the start of an ACO's agreement period as specified in § 425.660(b)(2)(ii). We use an annualized growth rate based on 5-year projections in per capita spending as of the start of an ACO's agreement period to align the ACPT with the 5-year agreement periods used under the Shared Savings Program. The CMS Office of the Actuary projects the ACPT, which is a modification of the FFS United States Per Capita Cost (USPCC) growth trend projections used annually for establishing Medicare Advantage rates. We set the ACPT growth factors for an ACO's entire 5-year agreement period near the start of the agreement period (87 FR 46163). The ACPT factors remain unchanged throughout the ACO's agreement period, providing a degree of certainty to ACOs.

Similar to the production of FFS USPCCs, for a given agreement period cohort (that is, ACOs with the same agreement period start date) and performance year, OACT produces two separate, modified USPCC values for ESRD and non-ESRD aged/disabled populations (as described in § 425.660(b)(2)). In the CY 2023 PFS final rule (87 FR 69882), we described the modified USPCC values as reflecting an exclusion of payments for indirect medical education (IME), disproportionate share hospitals (DSH), and supplemental payment for IHS/Tribal Hospitals and hospitals located in Puerto Rico, and including payments associated with hospice claims (87 FR 69882). Subsequently, for a given ACO and performance year, the two modified USPCCs serve as inputs into the calculation of four separate ACPT values, one for each of four Medicare enrollment types: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid (87 FR 69882). In turn, each of these enrollment-type specific ACPT values is used to calculate an ACO's four enrollment-type specific three-way blended update factors (as described in § 425.652(b)(4)).

As we have previously noted (87 FR 69896), we expect in any year the ACPT could overestimate or underestimate the actual growth rate of expenditures of the national assignable population. In the CY 2023 PFS final rule (87 FR 69882–69888), we included the following factors in the design of the three-way blended update factor to mitigate impacts in differences between the ACPT and the actual growth rate of expenditures for the national assignable population:

- The ACPT is one-third of the three-way blended update factor; the remaining two-thirds of the blend are based on the national-regional trend, which reflects actual national and regional spending growth.
- As part of the ACPT calculation, the ACPT is expressed as a flat dollar amount and is risk-adjusted, which may benefit low growth/low spending ACOs and ACOs serving medically complex populations.
- We established a guardrail policy where, if an ACO generates losses for a performance year that meet or exceed its minimum loss rate (MLR) (for two-sided model ACOs) or negative minimum savings rate (MSR) (for one-sided model ACOs) under the three-way blended update factor, we will recalculate the ACO's updated benchmark using the two-way national-regional blended update factor. If the ACO generates a smaller amount of losses using the two-way blend, we will use this smaller amount to determine the ACO's responsibility for shared losses, if applicable.
- If we determine that expenditure growth has differed significantly from projections made at the start of the agreement period due to unforeseen circumstances, such as an economic recession, pandemic, or other factors, a reduction in the weight placed on the ACPT may be considered. We have sole discretion to determine whether an

unforeseen circumstance exists that warrants a reduction to the weight of the ACPT and the reduced weight that will apply to the ACPT.

The CY 2024 modified USPCC cumulative growth rates (2023 to 2024) that were corrected and posted in July 2026 and used to calculate ACPT values for ACOs with an agreement period starting on January 1, 2024, were 5.5 percent for the aged/disabled population and 5.1 percent for the ESRD population.[353] [354] However, the CY 2024 actual cumulative growth rate of expenditures for the national assignable population was 8.4 percent for the aged/disabled population (2.9 percentage points higher than projected) and 6.9 percent for the ESRD population (1.8 percentage points higher than projected).[355] When the ACPT is lower than the actual national FFS expenditure growth, it could reduce or eliminate shared savings for ACOs. For CY 2024, we determined that unforeseen circumstances occurred, as it was observed that there were unanticipated billing patterns and unexpectedly high increases in multiple categories of Part A and B spending, most notably Part B drugs. This represented a substantial discrepancy between projected and actual growth rates for CY 2024, and it materialized in the context of the COVID–19 Public Health Emergency that imparted material and complex effects on Medicare trend experience over a multi-year period extending into the first half of 2023. This difference between the projected and actual growth rates for CY 2024 represented a material impact across the Shared Savings Program and led to our decision to reduce the ACPT's weight in the three-way blend from one-third (⅓) to one-sixth (⅙) in CY 2024. In CY 2024, the three-way blend for the growth factor was based on 5/6th weight of the national-regional trend and 1/6th weight on the ACPT.[356] [357]

(2) Revisions

(a) Performance Year-Specific Modified USPCC Annualized Growth Rates Used To Construct ACPT Values

As discussed in the proposed rule, for agreement periods beginning on or after January 1, 2027, we proposed to establish performance year-specific modified USPCC annualized (year-over-year) growth rates used to construct ACPT values that would apply to the performance year regardless of an ACO's agreement period start date (91 FR 44105). We stated that this would replace the current approach under which the modified USPCC annualized growth rates used to construct ACPT values are established on an agreement period-specific basis, as illustrated in Table B–G32 of the proposed rule (91 FR 44105). We noted that this proposal would not change the methodology by which CMS would calculate the modified USPCC annualized growth rates for any given performance year (91 FR 44105). We also noted that this proposal would only change the timing of the calculation and publicly reporting of modified USPCC annualized growth rates (91 FR 44105).

TABLE B-G35: STATUS QUO AND PROPOSED BASES FOR CALCULATING ANNUALIZED GROWTH RATES

Approach	Agreement Period Start Year	Basis for Calculating Modified USPCC Annualized Growth Rates
Status Quo	2024	Agreement Period
	2025	
	2026	
Proposed	2027	Performance Year
	2028	
	2029	

Specifically, for agreement periods beginning on or after January 1, 2027, and in subsequent years, we proposed that CMS would no longer calculate a fixed five-year schedule of annualized growth rates at the start of an ACO's agreement period (91 FR 44105). We stated that instead in the summer of the year preceding a given performance year, CMS would calculate and publicly report the modified USPCC annualized growth rates applicable to that performance year (91 FR 44105). This means that, although ACOs would no longer receive a five-year set of enrollment type-specific ACPT values near the beginning of the agreement period, they would still receive advance notice of the modified USPCC annualized growth rate used to calculate enrollment type-specific ACPT values for a given performance year in the year preceding that performance year. As illustrated in Table B–G33 of the proposed rule, in the late spring or early summer preceding the start of the first performance year of an agreement

[353] Shared Savings and Losses, Assignment and Quality Performance Standard Methodology: Specifications of the Accountable Care Prospective Trend (ACPT) and Three-Way Blended Benchmark Update Factor (Version 5). Page 16. *https://www.cms.gov/files/document/medicare-ssp-acpt-specifications.pdf*. Centers for Medicare and Medicaid Services (2026).

[354] Centers for Medicare and Medicaid Services (2026). Announcement of Calendar Year (CY) 2026 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. Page 14–15. [2026 Announcement]. *https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents/2026*.

[355] Observed cumulative growth in national assignable expenditures for the aged/disabled population and ESRD populations applicable to financial reconciliation for PY 2024 were determined in an internal analysis conducted by CMS.

[356] Information regarding the announcement for the CY 2024 actual cumulative growth rates and the determination that unforeseen circumstance occurred resulting in the decision to reduce ACPT's weight in the three-way blend was disseminated to Accountable Care Organizations via the June 30, 2025, Issue 7 Spotlight Article, an internal communication distributed by the Centers for Medicare & Medicaid Services (CMS) to ACOs.

[357] CY 2024 Projected ESRD Modified USPCC Annualized Growth Rates and Aged/Disabled Modified USPCC Annualized Growth Rates are available at: Shared Savings and Losses, Assignment and Quality Performance Standard Methodology: Specifications of the Accountable Care Prospective Trend (ACPT) and Three-Way Blended Benchmark Update Factor. Pages 6–7. *https://www.cms.gov/files/document/medicare-ssp-acpt-specifications.pdf*. Centers for Medicare and Medicaid Services (2025).

period, an ACO would be able to review the performance year-specific modified USPCC annualized growth rates publicly reported, applicable to the first performance year (91 FR 44105 through 44106). For example, CMS will publicly report the PY 2027 modified USPCC annualized growth rates used to calculate ACO-level ACPT values in conjunction with the release of this final rule. Then, during each subsequent performance year through the remainder of the agreement period, the ACO would receive a newly calculated set of ACPT values based on the performance year-specific modified USPCC annualized growth rates calculated and published in the summer preceding that performance year. For example, CMS will publicly report the PY 2028 ESRD and aged/disabled modified USPCC annualized growth rates in late spring or early summer 2027. These rates will be used to calculate PY 2028 enrollment type-specific ACO-level ACPT values (that is, PY1 values for ACOs entering agreement periods on January 1, 2028, and PY2 values for ACOs entering agreement periods on January 1, 2027). These ACO-level ACPT values will be provided to ACOs during PY 2028.

TABLE B-G36: APPLICATION OF PERFORMANCE YEAR-SPECIFIC MODIFIED USPCC ANNUALIZED GROWTH RATES FOR ACOS ENTERING AGREEMENT PERIODS BEGINNING ON JANUARY 1, 2027, AND IN SUBSEQUENT YEARS

Year rate is published[2]	Performance year to which rate applies	ACOs entering agreement periods in 2027	ACOs entering agreement periods in 2028	ACOs entering agreement periods in 2029
2026	CY 2027: Values based on 2027 modified USPCC annualized growth rates	Receives PY1 ACPT	-	-
2027	CY 2028: Values based on 2028 modified USPCC annualized growth rates	Receives PY2 ACPT	Receives PY1 ACPT	-
2028	CY 2029: Values based on 2029 modified USPCC annualized growth rates	Receives PY3 ACPT	Receives PY2 ACPT	Receives PY1 ACPT
Under this approach, overlapping agreement period cohorts would use the same modified USPCC annualized growth rate for the same calendar year corresponding to a performance year. Note 1: In this table, ACPT refers to the PY-specific ESRD and aged/disabled modified USPCC annualized growth rates used to calculate enrollment type-specific ACO-level ACPT values, which are provided to ACOs during the applicable performance year. Note 2: CMS will publicly report the PY 2027 modified USPCC annualized growth rates in conjunction with the release of this final rule. For subsequent performance years, CMS will publicly report the rates in late spring or early summer of the preceding calendar year.				

As illustrated in Table B–G34 of the proposed rule, under the current approach, modified USPCC annualized growth rates calculated on an agreement period basis may differ across agreement period cohorts (91 FR 44106).

TABLE B-G37: SUMMARY OF PROJECTED ESRD AND AGED/DISABLED MODIFIED USPCC ANNUALIZED GROWTH RATES, CORRESPONDING TO AGREEMENT PERIODS BEGINNING ON JANUARY 1, 2024, AND JANUARY 1, 2025

Population	Agreement Period Start Year	PY1	PY2	PY3	PY4	PY5
ESRD	2024	5.1%	7.5%	5.5%	5.5%	8.0%
	2025	7.5%	5.7%	5.5%	5.2%	5.6%
Aged/Disabled	2024	5.5%	4.8%	5.7%	5.8%	4.3%
	2025	5.6%	5.7%	6.0%	5.0%	6.1%

Notes: The projected ESRD and Aged/Disabled modified USPCC annualized growth rates as of July 2026.
Source: Shared Savings and Losses, Assignment and Quality Performance Standard Methodology, Specifications of the Accountable Care Prospective Trend (ACPT) and Three-Way Blended Benchmark Update Factor, Version 5

As discussed in the proposed rule, establishing performance year-specific modified USPCC annualized growth rates would improve consistency across agreement periods by ensuring that, for a given performance year, the same modified USPCC annualized growth rates for that year would apply to all ACOs regardless of agreement period start date (91 FR 44106). For example, at reconciliation for PY 2028, the same modified USPCC annualized growth rates would apply to ACOs that entered agreement periods on January 1, 2027, and January 1, 2028. We noted that neither cohort of ACOs would face different modified USPCC annualized growth rates for that performance year solely because their agreement periods began in different years (91 FR 44106).

We stated that we continue to believe that the prospective character of the ACPT is an important feature that benefits ACOs by providing a degree of certainty regarding their annual benchmark updates (91 FR 44106). However, as we acknowledged in the

CY 2023 PFS final rule, establishing modified USPCC annualized growth rates at the start of an ACO's agreement period means that ACOs entering agreement periods in different years could be subject to higher or lower updates based on how projections differ across agreement periods. Thus, the current approach poses a tradeoff between long-term predictability (over a five-year agreement period) and inconsistency across agreement period cohorts. Under this approach, our goal is to thoughtfully recalibrate the balance of that tradeoff by forgoing some predictability in favor of greater consistency and, in turn, fairness across agreement period cohorts. Specifically, we noted that although ACOs would no longer receive a fixed five-year schedule of modified USPCC annualized growth rates near the beginning of the agreement period, they would receive advance notice of the modified USPCC annualized growth rates in the late spring or early summer of the year preceding a given performance year, thus preserving the ACPT's core design as a prospectively-set external factor that provides ACOs with a degree of certainty regarding their annual benchmark update, as originally intended, albeit on a shorter time horizon (1 year rather than 5 years) (91 FR 44106). We stated that, at the same time, applying a consistent modified USPCC annualized growth rate to all ACOs reconciled for a given performance year, regardless of their agreement period start date, would promote greater fairness by reducing the disparities that currently arise when different start dates result in different growth rates, which can advantage or disadvantage certain ACOs (91 FR 44106). Lastly, we noted that the approach may reduce operational complexity by ensuring that, in a given performance year, there is a single set of underlying modified USPCC annualized growth rates used to calculate ACPT values, rather than a unique set of modified USPCC annualized growth rates that are specific to each agreement period cohort of ACOs being reconciled for that performance year (91 FR 44106 through 44107).

We sought comment on this proposal. Because commenters generally addressed this proposal in conjunction with the proposals in sections III.G.5.g.(2)(b), (c), and (e), and the notice in section III.G.5.g.(2)(d), please see section III.G.5.g.(2)(e) where we summarize and respond to comments on all III.G.5.g.(2) sections.

(b) Guardrail on the Difference Between the Modified USPCC Cumulative Growth Rate and the Actual Cumulative Growth Rate of Expenditures for the National Assignable Population for Agreement Periods Beginning on or After January 1, 2027

As discussed in the proposed rule, for agreement periods beginning on or after January 1, 2027, we proposed to establish a guardrail on instances in which the modified USPCC cumulative growth rates used to construct ACPT values differ substantially from observed cumulative growth in national assignable expenditures (91 FR 44107). Specifically, we proposed to establish a guardrail that would not allow the modified USPCC cumulative growth rate for each of the ESRD population and the Aged/Disabled population to be more than 1.0 percentage point below or 1.5 percentage points above the corresponding observed cumulative growth in national assignable expenditures for that population, respectively (where the percentage point thresholds are rounded to the nearest tenth of a percentage point) (91 FR 44107). We stated that we would apply the guardrail at reconciliation for a given performance year. Hereafter, we refer to the difference between the modified USPCC cumulative growth rate and observed cumulative growth in national assignable expenditures as ''delta modified USPCC'' (91 FR 44107).

We stated that establishing guardrail thresholds that are fixed over an agreement period, rather than thresholds that widen or narrow, acknowledges that the realized path of delta modified USPCC over an agreement period cannot be known in advance with sufficient certainty (91 FR 44107). That is, the extent to which delta modified USPCC widens or narrows over an agreement period depends on the extent to which projection errors in a given year offset the projection error that's accumulated over prior years. This is an outcome that can only be known at financial reconciliation for a given performance year. Therefore, whereas establishing thresholds that widen or narrow reflects a prospective assumption about the trajectory that delta modified USPCC will take over an agreement period, establishing fixed thresholds applies a consistent tolerance for delta modified USPCC to each performance year in recognition of the fact that delta modified USPCC may widen or narrow over an agreement period.

We stated that proposing to set the guardrail threshold levels asymmetrically at −1.0 percentage point and +1.5 percentage points, as opposed to a tighter, wider, or symmetrical guardrail range, primarily reflects a policy judgment about the appropriate approach to limit the effects of unusually large delta modified USPCC at financial reconciliation for a given performance year (91 FR 44107). The proposed threshold levels are not based on predictions of the path that delta modified USPCC will take over an agreement period (91 FR 44107). Rather, they establish the bounds within which delta modified USPCC would be addressed (91 FR 44107). In proposing these levels, we stated that we aim to balance several considerations: protection of ACOs from the financial consequences of unusually large cumulative under-projection (substantially negative delta modified USPCC); protection of the Medicare Trust Funds from the financial consequences of unusually large cumulative over-projection (substantially positive delta modified USPCC); and preservation of the original policy aims of the ACPT (that is, to allow for benchmarks to increase beyond actual spending growth even as ACOs slow spending growth) (91 FR 44107).

In proposing these levels, we stated that we also considered alternative approaches (91 FR 44107). For example, a tighter guardrail threshold would provide greater protection to ACOs and the Medicare Trust Funds from delta modified USPCC. However, we stated that it could also undermine the prospective design of the ACPT if it results in the frequent application of the guardrail (91 FR 44107). Conversely, we noted that a wider guardrail was also considered and such a guardrail could be applied less frequently than a tighter guardrail and, in turn, may preserve the prospective design of the ACPT to a greater degree, but the wider guardrail could also potentially expose the Medicare Trust Funds and ACOs to harms associated with substantially positive or substantially negative delta modified USPCC (91 FR 44107). We also considered a symmetrical guardrail that would apply equally in cases of both substantially positive and substantially negative delta modified USPCC (91 FR 44107). However, we noted that we believe that an asymmetric guardrail that imposes a tighter bound on substantially negative delta modified USPCC and a wider bound on substantially positive delta modified USPCC would more directly protect ACOs from the harms associated with substantially negative delta modified USPCC while still allowing ACOs to

benefit from modestly positive delta modified USPCC, consistent with the prospective design of the ACPT (91 FR 44107). Lastly, we stated that, while historical delta modified USPCC values have informed the reasonableness of the proposed thresholds, they have not determined the threshold levels themselves, as the path that delta modified USPCC takes over any agreement period cannot be known in advance and may differ across agreement periods (91 FR 44107). Taken together, the proposed threshold levels of −1.0 percentage point and +1.5 percentage points are best understood as reasonable policy calibrations that, we believe, strike an acceptable balance of the considerations discussed previously. We stated that we also believe that the guardrail as proposed would be consistent with the original policy aims of the ACPT, as well as program goals of predictability, fairness, and administrative feasibility (91 FR 44107). We sought comment on the proposed threshold levels, including whether a tighter guardrail, a wider guardrail, or a modification of any of the approaches discussed in this paragraph, would represent a better balance of the considerations discussed previously.

As discussed in the proposed rule, the following steps illustrate how the proposed guardrail on delta modified USPCC would operate in practice at reconciliation for a given performance year for agreement periods beginning on or after January 1, 2027 (91 FR 44107 through 44109):

Step 1: Calculate the applicable delta modified USPCC values.

As illustrated in Table B–G35 of the proposed rule (91 FR 44108), at reconciliation for a given performance year, CMS would calculate two delta modified USPCC values for each agreement period cohort: one for the ESRD population, and one for the Aged/Disabled population. For a given population, delta modified USPCC would be equal to the modified USPCC cumulative growth rate minus the observed cumulative growth in national assignable expenditures. Because delta modified USPCC values are constructed at the agreement period cohort, performance year, and population levels, they apply uniformly to all ACOs within a given cohort for a given performance year.

TABLE B-G38: HYPOTHETICAL EXAMPLE OF STEP 1 (CALCULATE THE APPLICABLE DELTA MODIFIED USPCC VALUES)

Population	Modified USPCC Cumulative[1] Growth Rate	Observed Cumulative[1] Growth in National Assignable Expenditures	Delta Modified USPCC[2]
ESRD	4.0%	4.5%	-0.5 percentage points
Aged / Disabled	3.0%	5.0%	-2.0 percentage points

Notes:
[1] – "Cumulative" reflects the period from a given ACO's BY3 to the applicable performance year.
[2] – At reconciliation for a given performance year, delta modified USPCC for each population and agreement period cohort equals the modified USPCC cumulative growth rate minus observed cumulative growth in national assignable expenditures.

Step 2: Determine whether each delta modified USPCC falls outside the guardrails.

As illustrated in Table B–G36 of the proposed rule (91 FR 44108), once calculated, each population-specific delta modified USPCC value would then be compared with the previously mentioned guardrail thresholds (−1.0 percentage point and +1.5 percentage points). If delta modified USPCC for either population falls within the guardrail thresholds (that is, greater than or equal to −1.0 percentage point and less than or equal to +1.5 percentage points), no guardrail adjustment would apply for a population, and the corresponding enrollment type-specific ACPT values initially calculated for that performance year would remain unchanged. If delta modified USPCC falls outside the guardrail thresholds (that is, less than −1.0 percentage point or greater than +1.5 percentage points) for one or both of the populations, a guardrail adjustment would apply.

TABLE B-G39: HYPOTHETICAL EXAMPLE OF STEP 2 (DETERMINE WHETHER EACH DELTA MODIFIED USPCC FALLS OUTSIDE THE GUARDRAILS)

Population	Delta Modified USPCC	Guardrails[1]		Does Guardrail Adjustment Apply?
		Lower Bound	Upper Bound	
ESRD	-0.5 percentage points	-1.0 percentage point	+1.5 percentage points	No (delta modified USPCC falls inside bounds)
Aged / Disabled	-2.0 percentage points	-1.0 percentage point	+1.5 percentage points	Yes (delta modified USPCC falls outside bounds)

Notes:
[1] - The lower and upper bounds shown here reflect fixed thresholds of -1.0 percentage point (lower bound) and +1.5 percentage points (upper bound) applied to both the ESRD delta modified USPCC and the Aged/Disabled delta modified USPCC.

Step 3. Calculate the guardrail-adjusted modified USPCC cumulative growth rate, as applicable.

As illustrated in Table B–G37 of the proposed rule (91 FR 44108), for a given population, if delta modified USPCC falls below the lower guardrail threshold, the applicable modified USPCC cumulative growth rate would be replaced with a guardrail-adjusted value equal to the observed cumulative growth in national assignable expenditures minus 1.0 percentage points. If delta modified USPCC falls above the upper guardrail threshold, the applicable modified USPCC cumulative growth rate would be replaced with a guardrail-adjusted value equal to the observed cumulative growth in national assignable expenditures plus 1.5 percentage points.

TABLE B-G40: HYPOTHETICAL EXAMPLE OF STEP 3 (CALCULATE THE GUARDRAIL-ADJUSTED MODIFIED USPCC CUMULATIVE GROWTH RATE)

Population	Delta Modified USPCC (Step 1)	Applicable Guardrail (Step 2)	Observed Cumulative Growth in National Assignable Expenditures	Original Modified USPCC Cumulative Growth Rate	Guardrail-Adjusted Modified USPCC Cumulative Growth Rate
ESRD[1]	-0.5 percentage points	Not Applicable	4.5%	4.0%	No adjustment (4.0% used)
Aged / Disabled[2]	-2.0 percentage points	-1.0 percentage point	5.0%	3.0%	4.0%

Notes:

1 – For the ESRD population, there would be no guardrail adjustment because the ESRD delta modified USPCC calculated in Step 1 would have been determined to fall within the guardrail thresholds in Step 2. Therefore, the ESRD-specific ACPT values initially calculated for that performance year would still apply.

2 – For the Aged/Disabled population, the guardrail-adjusted modified USPCC cumulative growth rate would equal 4.0 percent, or the observed cumulative growth in national assignable expenditures minus 1.0 percentage points because the Aged/Disabled delta modified USPCC calculated in Step 1 would have been determined to fall below the lower guardrail threshold in Step 2. In turn, the ACPT values for the Disabled, Aged/Dual, and Aged/Non-Dual populations initially calculated for that performance year would be recomputed in Step 4 using the guardrail-adjusted modified USPCC cumulative growth rate.

Step 4. Recompute ACPT values, as applicable.

If a guardrail adjustment applies (as determined in Step 2), the corresponding enrollment type-specific ACPT values initially calculated for that performance year would be recomputed using the guardrail-adjusted modified USPCC cumulative growth rate (calculated in Step 3) rather than the original modified USPCC cumulative growth rate. For the ESRD population, the guardrail-adjusted modified USPCC cumulative growth rate would be used to recompute ACPT values applicable to the ESRD enrollment type. For the Aged/Disabled population, the guardrail-adjusted modified USPCC cumulative growth rate would be used to recompute ACPT values applicable to the Disabled, Aged/Dual-Eligible, and Aged/Non-Dual-Eligible enrollment types. The recomputed ACPT values would then be used to construct the three-way blended update factors, updated historical benchmarks, and, in turn, shared savings and losses calculations for the applicable performance year.

The procedures described in the proposed rule would be applied at financial reconciliation for each performance year of an ACO's agreement period (91 FR 44109). The application of a guardrail on delta modified USPCC in a given performance year would affect only the ACO-level ACPT values and downstream shared savings and losses calculations applicable to that performance year. This is appropriate because delta modified USPCC is, by definition, a comparison of the cumulative modified USPCC growth rate to the cumulative observed growth in national assignable expenditures. Thus, the guardrail calculation of each performance year already accounts for projection error accumulated through prior years by construction. For example, in Table B–G38 of the proposed rule (91 FR 44109), the delta modified USPCC for PY3 reflects cumulative projection error through PY3. As a result, any guardrail adjustment applied in PY1 or PY2 would not need to be carried forward into PY3 because the cumulative structure of the guardrail calculation for PY3 would have incorporated the cumulative effect of projection errors from PY1 and PY2.

TABLE B-G41: ILLUSTRATIVE APPLICATION OF THE PY-SPECIFIC GUARDRAIL APPLICATION (EFFECTS IN ONE PY DO NOT CARRY OVER TO SUBSEQUENT PYS)

Performance Year	Modified USPCC Annualized Growth Rate	Modified USPCC Cumulative Growth Rate	Observed Cumulative Growth in National Assignable Expenditures	Delta Modified USPCC	Does Guardrail Adjustment Apply?	Guardrail-Adjusted Modified USPCC Cumulative Growth Rate Used to Recompute PY ACPT
PY1	5.7%	5.7%	6.8%	-1.1%	Yes, lower bound	5.8%
PY2	5.4%	11.4%	12.3%	-0.9%	No	No adjustment (11.4% used)
PY3	5.4%	17.4%	14.0%	3.4%	Yes, upper bound	15.5%

Notes:
The guardrail applies in PY1 and PY3, but not in PY2. The PY1 adjustment affects only the PY1 ACPT and does not carry forward into PY2. Instead, the guardrail is reassessed independently in each performance year using the delta modified USPCC applicable to that performance year.

We sought comment on this proposal. Because commenters generally addressed this proposal in conjunction with the proposals in sections III.G.5.g.(2)(a), (c), and (e), and the notice in section III.G.5.g.(2)(d), please see section III.G.5.g.(2)(e) where we summarize and respond to comments on all III.G.5.g.(2) sections.

(c) Retroactive Guardrail on Substantially Negative Delta Modified USPCC for Agreement Periods Beginning on January 1, 2024, and Before January 1, 2027

As discussed in the proposed rule, for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, we proposed to establish a guardrail on instances in which the modified USPCC cumulative growth rates used to construct ACPT values are substantially lower than observed cumulative growth in national assignable expenditures (91 FR 44110). Specifically, beginning at reconciliation for PY 2025 for ACOs currently in an agreement period, and for future performance years in their agreement periods, we proposed to establish a guardrail that would not allow the modified USPCC cumulative growth rate to be more than 1.0 percentage point below the corresponding observed cumulative growth in national assignable expenditures (where the percentage point threshold is rounded to the nearest tenth of a percentage point) (91 FR 44110). In other words, this proposed retroactive guardrail would be applied at reconciliation for any remaining performance years for agreement periods that began on January 1, 2024 (that is, PY 2025 through 2028), January 1, 2025 (that is, PY 2025 through 2029), and January 1, 2026 (that is, PY 2026 through 2030) (91 FR 44110).

We proposed to apply this proposal retroactively because it adjusts the methodology used in determining shared savings and losses for a performance year and for agreement periods that have already started (91 FR 44110). We stated that applying this proposal retroactively would either have no effect or a positive effect on an ACO's determinations of shared savings and losses, and no ACOs would be harmed by retroactively applying this proposed policy (91 FR 44110). Section 1871(e)(1)(A) of the Act prohibits substantive changes in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act from being applied retroactively to items and services furnished before the effective date of the change unless, as permitted under paragraph (ii), the Secretary determines that failing to apply the change retroactively would be contrary to the public interest. We stated that we believe it is appropriate to extend this retroactive applicability to PY 2025 for consistency with future performance years and for the reasons described in the subsequent paragraph (91 FR 44110).

As discussed in the proposed rule, failing to apply this proposed policy retroactively for agreement periods beginning on January 1, 2024, and before January 1, 2027, would be contrary to the public interest (91 FR 44110). We acknowledged that some ACOs may feel unfairly punished by forcing them to assume financial risk when the modified USPCC is a substantial under-projection compared to actual growth, and no ACO would experience reduced shared savings or increased shared losses by retroactively applying this proposed policy (91 FR 44110). We stated that this is especially the case in comparison to ACOs with agreement periods beginning on or after January 1, 2027, that would be protected from financial risk if the delta modified USPCC is substantially negative simply because their agreement period would start after the potential implementation date of the proposed policy (91 FR 44110). A substantially negative delta modified USPCC would cause greater harm to ACOs with agreements starting January 1, 2024, January 1, 2025, or January 1, 2026, than for ACOs with agreement periods beginning on or after January 1, 2027, especially because of the potential for these negative projection and mis-estimation errors to compound over multiple years. Specifically, for a given ACO, substantially negative delta modified USPCC would result in corresponding lower ACPT values, which would, in turn, potentially result in lower shared savings or greater shared losses than would occur for a similar ACO with an agreement period beginning on or after January 1, 2027. Such a consequence would be outside an ACO's control, potentially undermining both participation in and the sustainability of the Shared Savings Program and the public's faith in CMS as a fair partner. We noted that we are compelled to propose a retroactive remedy for a substantially negative delta modified USPCC because all ACOs covered by this proposed policy will either benefit from it or will be unaffected by it (91 FR 44110). Also, we stated that the proposed policy likely will not place additional administrative burden upon ACOs, CMS, or other interested parties (91 FR 44110).

We stated that ACOs participating in the Shared Savings Program and other ACOs that may be considering joining the Shared Savings Program may be less likely to join or continue to participate

in a program where applications of policy based on agreement period start date, which such ACOs may perceive to be arbitrary, can reduce shared savings or increase shared losses (91 FR 44110). Having more ACOs than what is typical terminating their participation in the Shared Savings Program could negatively affect the sustainability of the program. The Shared Savings Program financial methodology and the procedures we have utilized in the past to address projection errors in the ACPT provide a means to account for instances of substantially negative delta modified USPCC. However, we noted that these remedies to address projection errors under our current policies can only be used if an unforeseen circumstance occurs and we determine the negative effects of an under-projected delta modified USPCC to be substantial enough to affect ACOs (91 FR 44110). As a result, this can create uncertainty for ACOs on whether CMS would address projection errors with delta modified USPCC. The delta modified USPCC is a factor that directly affects whether an ACO receives shared savings, and ACOs can easily measure the impact of the delta modified USPCC on their shared savings. In recognition of the differing circumstances that could warrant accounting for errors, we have not established a set amount of difference between the modified USPCC and national expenditure trends that we consider to be a substantial enough under-projection to implement a remedy. This uncertainty can create challenges for ACOs to be able to plan what their benchmark could be and how they will achieve savings against such benchmark.

As discussed in the proposed rule, for some ACOs, the uncertainty in the difference between the modified USPCC and national expenditure trends may either discourage new ACOs from joining the Shared Savings Program or cause some ACOs to leave the program, which goes against our goal to encourage more ACOs to participate in the Shared Savings Program (91 FR 44110). We stated that if we do not remedy projection errors in update factors that directly affect the amount of shared savings earned by ACOs, this could cause a loss of faith by ACOs, healthcare providers, and the public in CMS's ability to effectively administer the Shared Savings Program, substantially reducing ACO and healthcare provider participation in the program (91 FR 44110). Reduced participation, in turn, would significantly diminish the savings to the Medicare Trust Funds, the quality of care improvements for Medicare beneficiaries resulting from ACO participants in the Shared Savings Program, and reduce the coordination of care performed for Medicare beneficiaries when obtaining items and services from ACO providers and suppliers. For these reasons, we stated that it would be contrary to the public interest for CMS to fail to retroactively apply our proposed policy mitigating this issue (91 FR 44110). With our proposed policy, we noted that ACOs will know the lower-bound limit on the difference between the modified USPCC and national expenditure trends for the duration of their entire agreement period and have more confidence participating in the Shared Savings Program (91 FR 44110 through 44111).

As discussed in the proposed rule, the following steps illustrate how the proposed guardrail on substantially negative delta modified USPCC would operate in practice at reconciliation for a given performance year, beginning with reconciliation for PY 2025, for agreement periods beginning on or after January 1, 2024, and before January 1, 2027 (91 FR 44111 through 44113). We noted that Step 1 and Step 4 (with the exception of calculating benchmark-based loss sharing limits for ACOs participating in a two-sided risk track) would be operationally identical to those applied to agreement periods beginning on or after January 1, 2027 (91 FR 44111). Moreover, in Steps 2 and 3, we stated that the only methodological difference relative to Steps 2 and 3 applied to agreement periods beginning on or after January 1, 2027, is that we would not apply an upper guardrail threshold of 1.5 percentage points on delta modified USPCC for agreement periods beginning on or after January 1, 2024, and before January 1, 2027 (91 FR 44111).

For completeness and clarity, all four steps were illustrated in the proposed rule (91 FR 44111).

Additionally, we stated that similar to the two-sided guardrail on delta modified USPCC in a given performance year for agreement periods beginning on or after January 1, 2027, the application of a guardrail on substantially negative delta modified USPCC in a given performance year for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, would only impact the ACPT values and downstream shared savings and losses calculations applicable to that performance year (91 FR 44111). We stated that the effects of applying a guardrail on substantially negative delta modified USPCC in one performance year would not carry over into subsequent performance years (91 FR 44111).

Step 1: Calculate the applicable delta modified USPCC values.

As illustrated in Table B–G39 of the proposed rule (91 FR 44111), at reconciliation for a given performance year, beginning with PY 2025, CMS would calculate two delta modified USPCC values for each agreement period cohort: one for the ESRD population, and one for the Aged/Disabled population. For a given population, the delta modified USPCC would be equal to the modified USPCC cumulative growth rate minus the observed cumulative growth in national assignable expenditures. Because delta modified USPCC values are constructed at the agreement period cohort, performance year, and population levels, they apply uniformly to all ACOs within a given cohort for a given performance year.

Step 2: Determine whether each delta modified USPCC is less than -1.0 percentage point.

TABLE B-G42: HYPOTHETICAL EXAMPLE OF STEP 1 (CALCULATE THE APPLICABLE DELTA MODIFIED USPCC VALUES)

Population	Modified USPCC Cumulative[1] Growth Rate	Observed Cumulative[1] Growth in National Assignable Expenditures	Delta Modified USPCC[2]
ESRD	6.5%	4.5%	+2.0 percentage points
Aged / Disabled	3.0%	5.0%	-2.0 percentage points

Notes:
[1] – "Cumulative" reflects the period from a given ACO's BY3 to the applicable performance year.
[2] – At reconciliation for a given performance year, delta modified USPCC for each population and agreement period cohort equals the modified USPCC cumulative growth rate minus observed cumulative growth in national assignable expenditures.

As illustrated in Table B–G40 of the proposed rule (91 FR 44111), once calculated, each population-specific delta modified USPCC value would then be compared with the previously mentioned guardrail threshold (- 1.0 percentage point). If delta modified USPCC is greater than or equal to -1.0 percentage point, no guardrail adjustment would apply, and the corresponding enrollment type-specific ACPT values initially calculated for that performance year would remain unchanged. If delta modified USPCC is less than -1.0 percentage point, a guardrail adjustment would apply.

TABLE B-G43: HYPOTHETICAL EXAMPLE OF STEP 2 (DETERMINE WHETHER EACH DELTA MODIFIED USPCC IS LESS THAN -1.0 PERCENTAGE POINT)

Population	Delta Modified USPCC	Guardrails[1]		Does Guardrail Adjustment Apply?
		Lower Bound	Upper Bound	
ESRD	+2.0 percentage points	-1.0 percentage point	None	No (Upper bound guardrail does not apply for ACOs that began an agreement period prior to January 1, 2027)
Aged / Disabled	-2.0 percentage points	-1.0 percentage point	None	Yes (delta modified USPCC less than lower bound)

Notes:
1 - The lower and upper bounds shown here reflect a fixed threshold of -1.0 percentage point applied to both the ESRD delta modified USPCC and the Aged/Disabled delta modified USPCC.

Although the ESRD delta modified USPCC of +2.0 percentage points is greater than the upper guardrail threshold of +1.5 percentage points for agreement periods beginning on or after January 1, 2027, this threshold would not apply for ACOs in agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

Step 3. Calculate the guardrail-adjusted modified USPCC cumulative growth rate, as applicable.

As illustrated in Table B–G41 of the proposed rule (91 FR 44112), for a given population, if delta modified USPCC is less than the lower guardrail threshold, the applicable modified USPCC cumulative growth rate would be replaced with a guardrail-adjusted value equal to the observed cumulative growth in national assignable expenditures minus 1.0 percentage point.

TABLE B-G44: HYPOTHETICAL EXAMPLE OF STEP 3 (CALCULATE THE GUARDRAIL-ADJUSTED CUMULATIVE GROWTH RATE)

Population	Delta Modified USPCC (Step 1)	Applicable Guardrail (Step 2)	Observed Cumulative Growth in National Assignable Expenditures	Original Modified USPCC Cumulative Growth Rate	Guardrail-Adjusted Modified USPCC Cumulative Growth Rate
ESRD[1]	+2.0 percentage points	Not Applicable	4.5%	6.5%	No adjustment (6.5% used)
Aged / Disabled[2]	-2.0 percentage points	-1.0 percentage points	5.0%	3.0%	4.0%

Notes:
1 - For the ESRD population, there would be no guardrail adjustment because the ESRD delta modified USPCC calculated in Step 1 would have been determined to fall above the guardrail threshold in Step 2. Therefore, the ESRD-specific ACPT values initially calculated for that performance year would still apply.
2 - For the Aged/Disabled population, the guardrail-adjusted modified USPCC cumulative growth rate would equal 4.0 percent, or the observed cumulative growth in national assignable expenditures minus 1.0 percentage points because the Aged/Disabled delta modified USPCC calculated in Step 1 would have been determined to fall below the guardrail threshold in Step 2. In turn, the ACPT values for the Disabled, Aged/Dual, and Aged/Non-Dual populations initially calculated for that performance year would be recomputed in Step 4 using the guardrail-adjusted modified USPCC cumulative growth rate.

Step 4. Recompute ACPT values, as applicable.

If a guardrail adjustment applies (as determined in Step 2), the corresponding enrollment type-specific ACPT values initially calculated for that performance year would be recomputed using the guardrail-adjusted modified USPCC cumulative growth rate (calculated in Step 3) rather than the original modified USPCC cumulative growth rate. For the ESRD population, the guardrail-adjusted modified USPCC cumulative growth rate would be used to recompute ACPT values applicable to the ESRD enrollment type. For the Aged/Disabled population, the guardrail-adjusted modified USPCC cumulative growth rate would be used to recompute ACPT values applicable to the Disabled, Aged/Dual-Eligible, and Aged/Non-Dual-Eligible enrollment types.

As discussed in the proposed rule, the recomputed ACPT values would then be used to construct the three-way blended update factors, updated historical benchmarks, and, in turn, shared savings and losses calculations for the applicable performance year (91 FR 44112). However, in calculating the benchmark-based loss recoupment limit for a given ACO participating in a two-sided risk track, we would use as its basis the lesser of the two updated benchmarks calculated before and after application of the retroactive guardrail. This would be done to account for the unlikely scenario in which an ACO's benchmark-based loss recoupment limit increases under the retroactive guardrail and, as a result of that increase, the ACO is rendered liable for greater shared losses than would otherwise occur in the absence of the retroactive guardrail. This would ensure that no ACO could be harmed as a result of implementing this proposed policy.

We sought comment on this proposal. Because commenters generally addressed this proposal in conjunction with the proposals in sections III.G.5.g.(2)(a), (b), and (e), and the notice in section III.G.5.g.(2)(d), please see section III.G.5.g.(2)(e) where we summarize and respond to comments on all III.G.5.g.(2) sections.

(d) Delay in Financial Reconciliation for Performance Year 2025

As discussed in the proposed rule, proposing to implement this guardrail to take effect starting with PY 2025, including PY 2025 financial reconciliation, will result in a delay in PY 2025 financial reconciliation and delay providing financial results and shared savings payments to ACOs, pending the issuance of the CY 2027 PFS final rule and confirmation that we ultimately finalize the proposal for the lower bound guardrail policy (91 FR 44112). We stated that CMS plans to issue PY 2025 financial results and distribute shared savings payments in November 2026 and December 2026, respectively, in accordance with the finalized policy (91 FR 44112). This is necessary because, to complete the reconciliation process, we need to have a final value established for the ACPT for PY 2025.

Under our proposed retroactive, lower-bound guardrail policy, the ACPT for ACOs with agreement periods starting in PY 2024 would be 15.3 percent for ESRD beneficiaries and 14.7 percent for Aged/Disabled beneficiaries (91 FR 44112). We stated that for ACOs with agreement periods starting in PY 2025 under our proposed policy, the ACPT would be 7.7 percent for ESRD beneficiaries and 5.7 percent for Aged/Disabled beneficiaries (91 FR 44112). As described in the proposed rule (91 FR 44110 through 44112), all of the ACOs covered by our proposed policy for PY 2025 financial reconciliation would either benefit from it or would be unaffected by it (91 FR 44112).

We stated in the proposed rule that if our policy is not implemented and no other action is taken to adjust the ACPT, the unadjusted ACPT for ACOs with agreement periods starting in PY 2024 would be 13.0 percent for ESRD beneficiaries and 10.6 percent for Aged/Disabled beneficiaries (91 FR 44112). We noted that for ACOs with agreement periods starting in PY 2025 if the ACPT is not changed, the unadjusted ACPT would be 7.5 percent for ESRD beneficiaries and 5.6 percent for Aged/Disabled beneficiaries (91 FR 44112). We stated that if we do not implement our policy, ACOs with agreement periods starting in either 2024 or 2025 would otherwise receive less shared savings or have no change in their shared savings payments (91 FR 44112).

As discussed in the proposed rule, the goal of this policy is to address the under-estimate of the modified USPCC compared to national expenditure trends (91 FR 44112). We stated that the proposal also would ensure that as soon as PY 2025 financial reconciliation occurs, ACOs would not be subject to the risk of modified USPCC values being

included in the three-way blended growth factor that are substantially lower than the national assignable expenditure trends solely because of the starting date of an ACO's agreement period (91 FR 44112). We noted that the proposed ACPT lower bound policy also can be applied in the same manner for ACOs with agreement periods starting either January 1, 2024, or January 1, 2025, which would lead to a consistent ACPT lower bound policy regarding the relationship between the ACPT and the national assignable expenditures, if we finalize our proposal to establish a guardrail as described in the proposed rule (91 FR 44112 through 44113). For the reasons noted in this section, stated that we believe that a delay to financial reconciliation is necessary so that ACOs that participated in PY 2025 can immediately benefit if this proposed lower bound guardrail policy is finalized (91 FR 44113).

We sought comment on this proposal. Because commenters generally addressed this proposal in conjunction with the proposals in sections III.G.5.g.(2)(a), (b), (c), and (e), and the notice in section III.G.5.g.(2)(d), please see section III.G.5.g.(2)(e) where we summarize and respond to comments on all III.G.5.g.(2) sections.

(e) Amendments to Shared Savings Program Regulations

We proposed the following amendments to § 425.605 (91 FR 44113):

- Revise paragraph (i)(2)(i) introductory text to remove the phrase ''paragraph (i)(2)(ii) of this section'' and add in its place the phrase ''paragraph (i)(2)(ii) or (i)(2)(iii) of this section, as applicable''.
- Add new paragraph (i)(2)(iii) to specify that for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, applicable to performance years 2025 and subsequent performance years remaining in these agreement periods, CMS calculates the benchmark-based loss recoupment limit as follows:

++ Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year prior to the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

++ Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year after the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

++ Calculates the product of the percentage specified in paragraph (d)(1)(iii)(D)(2), (d)(1)(iv)(D)(2), and (d)(1)(v)(D)(2) of this section, as applicable, and the lesser of the ACO's total benchmark expenditures calculated according to paragraphs (i)(2)(iii)(A) and (i)(2)(iii)(B) of this section.

We proposed the following amendments to § 425.610 (91 FR 44113):

- In paragraph (l)(2) introductory text, remove the phrase ''paragraph (l)(3) of this section'' and add in its place the phrase ''paragraphs (l)(3) or (l)(4) of this section, as applicable'';
- Add new paragraph (l)(4) to specify that for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, applicable to performance years 2025 and subsequent performance years remaining in these agreement periods, the amount of shared losses for which an eligible ACO is liable may not exceed 15 percent of the lesser of the following:

++ Total benchmark expenditures calculated as the product of an ACO's per capita updated benchmark expenditures for the performance year prior to the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

++ Total benchmark expenditures calculated as the product of an ACO's per capita updated benchmark expenditures for the performance year after the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

We proposed to revise the entirety of § 425.660 with provisions on the ACPT. In summary, we proposed the following amendments to § 425.660 (91 FR 44113):

Revise paragraph (a) to provide a general explanation of the ACPT and specify that the methodology by which CMS calculates and adjusts a projected growth rate called the Accountable Care Prospective Trend (ACPT) is described in § 425.660. We stated that we would also specify that CMS incorporates the ACPT into the blended update factor described in § 425.652(b) when updating an ACO's benchmark for each performance year of the agreement period, for agreement periods beginning on January 1, 2024, and in subsequent years (91 FR 44113).

Revise paragraph (b) on the determination of the ACPT to specify in the introductory text that an ACPT is a flat dollar amount calculated using one or more annualized growth rates based on national FFS Medicare expenditures projected by the CMS Office of the Actuary. We stated that we would specify in paragraphs (b)(1) through (b)(6), the provisions on CMS' determination of the ACPT for a Medicare enrollment type for each performance year, as follows (91 FR 44113):

As discussed in the proposed rule, paragraph (b)(1) of § 425.660 specifies provisions on CMS' calculation of annualized projected growth rates (91 FR 44113). We stated that this provision explains that the annualized projected growth rates are calculated as an annual rate of growth in projected expenditures relative to the prior year (91 FR 44113). Further, we stated that CMS projects annualized per capita growth in Parts A and B FFS expenditures for each performance year of the ACO's agreement period. In calculating the annualized projected growth rates, CMS would do all of the following (91 FR 44113):

- Exclude IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals;
- Make separate expenditure calculations for the ESRD and Aged/Disabled populations; and
- Calculate one or more annualized projected growth rates for the ESRD population of beneficiaries, and one or more annualized growth rates for the Aged/Disabled population of beneficiaries, as follows:

++ Using a uniform annualized projected rate of growth over each of the 5 performance years of the 5-year agreement period (for agreement periods beginning on or after January 1, 2024, and before January 1, 2027), or for each performance year (for agreement periods beginning on January 1, 2027, and in subsequent years), as applicable; or

++ If using a uniform annualized projected rate of growth is determined not to reasonably fit the anticipated growth curve (for example, if growth is expected to be above- or below-average in the short-run and return to more typical levels later in the agreement period), we stated that we would apply an alternative annualization technique using two or more annualized growth rates reflecting the projected rates of growth during the 5 performance years comprising the 5-year agreement period (for agreement periods beginning on or after January 1, 2024, and before January 1, 2027), or for each performance year (for agreement periods beginning on January 1, 2027, and in subsequent years), as applicable (91 FR 44114).

Proposed paragraph (b)(2) of § 425.660 specifies that, for each performance year, CMS calculates cumulative

projected growth rates relative to the ACO's benchmark year (BY) 3, using the annualized projected growth rates, determined in accordance with proposed paragraph (b)(1) of § 425.660, for each population of beneficiaries: the ESRD population and the Aged/Disabled population.

Proposed paragraph (b)(3) of § 425.660 specifies provisions on CMS' calculations to express a cumulative projected growth rate as a flat dollar amount. Accordingly, for each performance year, we stated that CMS would multiply the applicable cumulative projected growth rate described in proposed paragraph (b)(2) of § 425.660 by BY3 truncated national per capita FFS Medicare expenditures for assignable beneficiaries for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) identified for the 12-month calendar year corresponding to BY3 to express the cumulative projected growth rate as a flat dollar amount as follows (91 FR 44113 through 44114):

- The ESRD cumulative projected growth rate would be used for the ESRD population.
- The Aged/Disabled cumulative projected growth rate would be used for the following populations: disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

Under proposed paragraph (b)(4) of § 425.660, we stated that we would maintain the existing provision on risk adjusting the flat dollar amount but add a related description to serve as a heading for clarity and consistency (91 FR 44114).

Under proposed paragraph (b)(5) of § 425.660, we stated that we would maintain the existing provision on calculating ACO-specific ACPT growth rates but add a related description to serve as a heading and make other revisions for clarity and consistency (91 FR 44114).

Under proposed new paragraph (b)(6) of § 425.660, we stated that we would specify provisions on the timing of calculations, which include the following (91 FR 44114):

- Under new paragraph (b)(6)(i), with provisions applicable for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, we stated that we would specify the following (91 FR 44114):

++ At the beginning of the ACO's agreement period, we stated that CMS calculates the annualized projected growth rates for all performance years of the ACO's agreement period in accordance with proposed paragraph (b)(1) of § 425.660. These annualized projected growth rates remain fixed over the ACO's agreement period (91 FR 44114).

++ For a given performance year, we stated that CMS calculates an ACO-specific ACPT value, in accordance with proposed paragraphs (b)(2) through (b)(5) of § 425.660, using the annualized projected growth rates calculated at the beginning of the ACO's agreement period (91 FR 44114).

- Under new paragraph (b)(6)(ii), with provisions applicable for agreement periods beginning on January 1, 2027, and in subsequent years, we specified the following (91 FR 44114):

++ In the calendar year preceding a given performance year, CMS calculates the annualized projected growth rates in accordance with proposed paragraph (b)(1) of § 425.660 for that performance year.

++ For a given performance year, CMS calculates an ACO-specific ACPT value, in accordance with proposed paragraphs (b)(2) through (b)(5) of § 425.660, using the annualized projected growth rates calculated in the preceding calendar year.

Under new paragraph (c) of § 425.660, we stated that we would specify provisions on the recomputation of the ACPT based on the guardrail policies described in the proposed rule (91 FR 44114). Specifically, at financial reconciliation for a given performance year, we stated that CMS may recompute the ACO-specific ACPT value for a Medicare enrollment type initially determined at paragraph (b)(5) of § 425.660 for that performance year, to address under-projection or over-projection of the ACPT (as applicable), as follows (91 FR 44114):

- In paragraph (c)(1), for agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

++ For performance year 2025, and any subsequent performance years of the ACO's agreement period, CMS separately calculates for the ESRD and Aged/Disabled populations the difference between the cumulative projected growth rates calculated in proposed paragraph (b)(2) of § 425.660 and the cumulative observed growth in per capita expenditures for the national assignable FFS population.

++ For the ESRD and Aged/Disabled populations separately, if this difference is less (more negative) than −1.0 percentage point (for example, −1.5, −2.0, −3.0), we stated that CMS would recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at proposed paragraph (b)(5) of § 425.660. CMS would calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with proposed paragraphs (b)(3) through (b)(5) of § 425.660, using the cumulative observed growth in expenditures for the national assignable FFS population minus 1.0 percentage point (91 FR 44114).

++ If this difference is greater than (less negative) or equal to −1.0 percentage point (for example, −0.9, −0.5, 0.5), we stated that CMS would not recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at proposed paragraph (b)(5) of § 425.660 (91 FR 44114).

- In paragraph (c)(2) of § 425.660, for agreement periods beginning on January 1, 2027, and in subsequent years.

++ CMS separately calculates for the ESRD and Aged/Disabled populations the difference between the cumulative projected growth rates calculated in proposed paragraph (b)(2) of § 425.660 and the cumulative observed growth in per capita expenditures for the national assignable FFS population.

++ For the ESRD and Aged/Disabled populations separately, if this difference is less (more negative) than −1.0 percentage point (for example, −1.5, −2.0, −3.0), CMS would recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at proposed paragraph (b)(5) of § 425.660. We stated that CMS would calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with proposed paragraphs (b)(3) through (b)(5) of § 425.660, using the cumulative observed growth in expenditures for the national assignable FFS population minus 1.0 percentage point (91 FR 44114).

++ If this difference is greater than or equal to +1.5 percentage points, we stated that CMS would recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at proposed paragraph (b)(5) of § 425.660 (91 FR 44114). We stated that CMS would calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with proposed paragraphs (b)(3) through (b)(5) of § 425.660, using the cumulative observed growth in expenditures for the national assignable FFS population plus 1.5 percentage point (91 FR 44114).

++ If this difference is greater than (less negative) or equal to −1.0 percentage point and less than or equal to +1.5 percentage points (for example,

between −1.0 and +1.5, inclusive), CMS would not recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at proposed paragraph (b)(5) of § 425.660.

We sought public comment on the proposed reforms to the ACPT component of the benchmark update factor, described in section II.G.5.g of the CY 2027 PFS proposed rule. The following is a summary of the comments we received on each of the proposals described in II.G.5.g.(2).(a), (b), (c), and (e), as well as the notice described in II.G.5.g.(2).(d) that reconciliation for PY 2025 will be delayed until after the release of the CY 2027 PFS final rule, and our responses.

Comment: Many commenters broadly supported one or more of the proposed ACPT reforms. Commenters emphasized their support due to the potential for greater benchmark accuracy and predictability; protection from projection error outside an ACO's control; greater consistency and fairness across agreement-period cohorts; improved financial planning and investment certainty; and support for continued or expanded Shared Savings Program participation. Some commenters highlighted the value of these protections particularly for smaller, rural, physician-led, safety-net, and high-needs ACOs. Many commenters recommended finalizing the package of annual performance-year rates, prospective guardrails, and retroactive downside protection; the specific combinations discussed varied by commenter.

Response: We thank commenters for their support. We agree that the three ACPT reforms described previously operate together to preserve an external prospective trend while improving consistency across cohorts and limiting the consequences of substantial projection error for both ACOs and CMS.

Comment: Many commenters supported calculating performance-year-specific modified USPCC annualized growth rates and applying the same rates for a given performance year regardless of agreement-period start date. These commenters stated that this approach would reduce differences attributable to agreement start dates, avoid reliance on projections that may become obsolete over a five-year period, improve operational simplicity and transparency, and reduce inequities across cohorts or incentives to time agreement entry. Some commenters also expected rates calculated closer to the performance year to better reflect current spending conditions.

A commenter noted that setting ACPT growth factors at the start of a five-year agreement period had provided certainty, while also emphasizing that subsequent divergence between projected and actual growth materially harmed ACOs. Other commenters favored annual, performance-year-specific rates because they would better reflect current conditions and apply consistently across agreement-period cohorts. Some commenters also recommended releasing the applicable ACPT rate before the beginning of each performance year, including through a summer release schedule, so that ACOs would have the rate in time for financial and operational planning. These comments distinguished advance publication from annual calculation because an annually determined rate would not provide the same planning value if it were not made available sufficiently before the performance year.

Response: We thank commenters for their support for performance year-specific modified USPCC annualized growth rates. As described previously, CMS will publicly report the PY 2027 modified USPCC annualized growth rates in conjunction with the release of this final rule. For subsequent performance years, CMS will calculate and publicly report the modified USPCC annualized growth rates in late spring or early summer of the preceding calendar year. Our proposal will maintain the prospective character of the ACPT, which will provide ACOs with a degree of certainty regarding their annual benchmark updates, promote greater fairness among ACOs by having a consistent modified USPCC annualized growth rate apply to all ACOs reconciled for a given performance year, and reduce some of the operational complexity of calculating and applying the ACPT as part of the three-way blended growth factor. It is understandable that some ACOs may want additional advance knowledge of the prospective ACPT trend for a performance year, while others may find the advance notice prior to performance years (relative to how the ACPT was provided after the start of Performance Year 1 in agreement periods that started January 1, 2024 and 2025) may be useful to assist ACOs with their financial planning. Again, our goal is to recalibrate the balance of that tradeoff by forgoing some predictability in favor of greater consistency and, in turn, fairness across agreement period cohorts and eliminating disparate effects on the growth rates of historical benchmarks for ACOs because of when an ACO started its agreement period.

Comment: Many commenters supported limiting the effect of divergence between projected and observed expenditure growth for agreement periods beginning in 2027. These commenters described the guardrails as preventing shared savings or losses from being driven by forecasting error unrelated to ACO performance, improving financial stability, and restoring confidence in the benchmarking methodology. Several commenters characterized the guardrails as a more durable response to under-projection than temporary adjustments to the ACPT's weight. Some specifically supported the asymmetric design because it could allow ACOs to share in more savings than losses while preserving room for the ACPT to mitigate benchmark ratcheting. Some commenters viewed the proposed approach as preserving a meaningful role for prospective trends while protecting ACOs and CMS from substantial projection errors.

Multiple commenters referenced estimates of substantial financial effects from under-projection. These estimates reflected different periods and formulations. Commenters cited estimated reductions in total ACO revenue of $154 million for PY 2024 and exceeding $700 million for PY 2025 as evidence of the need for a durable corrective mechanism.

Response: We thank commenters for their support for our proposals to apply guardrails on delta modified USPCC. Regarding the asymmetric design, we previously stated that we believe that an asymmetric guardrail that imposes a tighter bound on substantially negative delta modified USPCC and a wider bound on substantially positive delta modified USPCC would more directly protect ACOs from the harms associated with substantially negative delta modified USPCC while still allowing ACOs to benefit from modestly positive delta modified USPCC, consistent with the prospective design of the ACPT. We believe that the proposed threshold levels are reasonable policy calibrations that strike an appropriate balance and are consistent with the original policy aims of the ACPT, as well as program goals of predictability, fairness, and administrative feasibility.

Comment: Many commenters supported retroactive application of the lower-bound guardrail for eligible existing agreement-period cohorts. These commenters viewed retroactivity as correcting under-projection outside ACOs' control, preserving shared savings that otherwise could be reduced or eliminated, improving fairness and confidence in CMS as a program

partner, and supporting continued ACO participation and investment. A commenter supported CMS's stated approach to retroactive rulemaking, stating that significant risks from non-retroactive application can justify a retroactive remedy and strongly supporting application of the revised ACPT methodology to all agreement periods that include the ACPT.

Some commenters emphasized that smaller, rural, safety-net, independent-practice, and high-needs ACOs may be particularly vulnerable to benchmark volatility, citing factors such as smaller populations, concentrated costs, local market variation, and limited financial reserves. These commenters stated that protection against excessive under-projection could create a more stable environment for participation and investment.

Response: We thank commenters for their support for the retroactive guardrail on substantially negative delta modified USPCC. We agree that applying this policy retroactively for agreement periods beginning on January 1, 2024, and before January 1, 2027, would be appropriate to mitigate the effects of substantially negative delta modified USPCC outside an ACO's control, including undermining participation in and the sustainability of the Shared Savings Program, which would limit ACOs' ability to continue to provide coordinated care and improve the quality of care provided to assigned beneficiaries and weaken the public's faith in CMS as a fair partner. Accordingly, we believe it is appropriate to implement this policy retroactively, because not doing so would be contrary to the public interest.

Further, as we stated in the proposed rule (91 FR 44110), the retroactive guardrail is designed to ensure that ACOs in agreement periods beginning on or after January 1, 2024, and before January 1, 2027, would either benefit or be unaffected by its application. Preliminary analyses of PY 2025 financial reconciliation calculations indicate that applying the retroactive guardrail would produce favorable or unchanged financial outcomes across affected ACOs, consistent with the policy's design. At the program level, the analysis indicates that the guardrail would increase aggregate shared savings, modestly reduce aggregate shared losses, and result in favorable financial performance category transitions for some ACOs.

Comment: A commenter acknowledged that establishing performance year-specific modified USPCC annualized growth rates could simplify the methodology, apply the same annual rates to all ACOs regardless of start date, and improve accuracy of projections by calculating them closer to the performance year. However, the commenter expressed concern that the approach would reduce predictability and make calculations more susceptible to annual abnormalities in expenditure growth. Accordingly, the commenter recommended that CMS not finalize the performance-year-specific growth-rate proposal pending additional analysis of the impacts and public comment, while strongly supporting guardrails if CMS proceeds. Another commenter stated that the proposal's financial effects and implementation were difficult to assess without clarification as to whether the ACPT adjustment would apply to all ACOs at once or only as ACOs renew their benchmarks. That commenter recommended delaying implementation until CMS provides additional analysis of financial effects across geographic regions for stakeholder review and engagement.

Response: We appreciate commenters' recognition of our objective of improving benchmark predictability and limiting forecasting inaccuracies. While commenters requested additional analysis, clarification, or safeguards before we implement the performance-year-specific growth-rate proposal, we disagree that further delay is warranted. This policy addresses a structural inconsistency and operational complexity under the current methodology. Absent this policy, ACOs reconciled for the same performance year may receive different modified USPCC annualized growth rates solely because their agreement periods began in different years. A performance year-specific rate will eliminate that as a source of cross-cohort inconsistency. This policy will apply to agreement periods beginning on January 1, 2027, and in subsequent years. ACOs in existing agreement periods will continue to use agreement-period-specific rates, subject to the retroactive guardrail on substantially negative delta modified USPCC described previously.

We recognize that establishing performance year-specific modified USPCC annualized growth rates may produce different ACPT values, and therefore different financial effects, than retaining agreement period-specific rates. However, we do not believe that delaying finalization of the policy pending additional modeling is warranted. The primary purpose of the policy is to eliminate a structural source of cross-cohort inconsistency under the current methodology, in which the ACPT values applicable to ACOs being reconciled for the same performance year may be based on different modified USPCC annualized growth rates solely because their agreement periods began in different years. This policy will ensure that all ACOs covered by the policy that are being reconciled for the same performance year will receive adjustments based on the same modified USPCC annualized growth rates.

We also do not believe that calculating modified USPCC annualized growth rates on a performance-year-specific basis would necessarily make the ACPT more vulnerable to annual abnormalities in expenditure growth. Under either approach to calculating modified USPCC annualized growth rates (that is, on a performance year-specific basis or an agreement period-specific basis) the ACPT relies on projected annual expenditure growth and therefore may overestimate or underestimate observed growth. The principal difference between the existing methodology and our proposal for performance year-specific modified USPCC annualized growth rates is timing: under the current methodology, projected annualized growth rates may be established up to five years before the applicable performance year, whereas the proposed policy uses projections calculated closer to the year in which they apply. Calculating modified USPCC annualized growth rates on a performance year-specific basis may incorporate more current information, but timing alone does not necessarily establish or alter the trajectory of delta modified USPCC for a given ACO, and the guardrails separately limit the financial effects of substantial cumulative under- or over-projection at reconciliation. We will monitor the implementation effects of this policy across geographic regions, ACO types, and beneficiary populations and will consider future refinements if warranted.

Comment: A commenter welcomed CMS's responsiveness to stakeholder concerns about the ACPT but cautioned against over-correcting the methodology and eliminating the gap between projected and observed spending growth that can preserve savings incentives. The commenter argued that an effective administrative benchmark should remain below counterfactual spending growth while exceeding actual spending growth, thereby retaining incentives for ACO participation. The commenter noted that this principle is recognized in the LEAD Model. The commenter did not recommend alternative numerical thresholds.

Response: We appreciate the commenter's concern about preserving the wedge between projected and

observed spending growth to maintain savings opportunities and participation incentives. We interpret this concern as being related to whether the upper bound of the two-sided guardrail could constrain over-projection too much and diminish the ACPT's ability to mitigate the benchmark ratchet effect. As discussed previously, we selected an asymmetric guardrail with a wider upper bound to preserve greater room for modestly positive delta modified USPCC while limiting unusually large over-projection. We believe the +1.5 percentage point upper threshold balances protection of the Medicare Trust Funds from the financial consequences of unusually large cumulative over-projection and preservation of the core design feature of the ACPT as a prospectively-set external factor that allows benchmarks to increase beyond actual spending growth even as ACOs slow spending growth. We will monitor whether and the extent to which the finalized upper threshold constrains the wedge between projected and observed expenditure growth in a manner that materially weakens savings incentives. Based on our evaluation of implementation experience, we may consider future refinements if warranted, including additional adjustments or safeguards.

Comment: Some commenters supported the proposed reforms while identifying remaining limitations in the ACPT's underlying design. These commenters identified several distinct limitations. Some commenters stated that under-projection could leave benchmarks below actual expenditure growth. A commenter estimated that the proposed 1.0 percentage point lower guardrail would provide less relief than reducing the ACPT's weight to zero. Other commenters cautioned that national trends may not reflect local spending or utilization patterns. These qualifications generally did not alter commenters' support for finalizing the proposed guardrails as an immediate improvement.

Commenters offered several longer-term methodological alternatives. Some commenters recommended replacing national trends with regional trends, particularly for smaller ACOs concentrated in one market; excluding ACO beneficiaries from reference trends to more directly address national and regional ratcheting; and explicitly accounting for major shifts in technology, policy, or clinical pricing that may affect ACOs unevenly. Other commenters supported the guardrails as an interim improvement but recommended eliminating the ACPT, returning to the prior benchmark trend methodology, or developing a more transparent and operationally straightforward alternative. These commenters viewed the need for guardrails, retrospective corrections, annual recalculation, and reconciliation adjustments as evidence of limitations in the ACPT's underlying design.

A commenter additionally requested alternatives that would allow rural providers with small Medicare Part B populations or limited financial reserves to continue transitioning from fee-for-service to advanced payment models without mandatory downside risk. The commenter linked this recommendation to rural providers' financial instability and to fragmented payment arrangements across Medicare and other payers. Although broader than the proposed ACPT mechanics, the recommendation reflects a distinct concern about whether benchmark reforms alone are sufficient to sustain rural participation.

Response: We thank commenters who expressed support for the proposed reforms while identifying purported limitations in the ACPT's underlying design. As we developed the proposed reforms, we assessed whether reducing the weight of the ACPT component of the three-way blended update factor from one-third to zero would be preferable to implementing a retroactive guardrail on substantially negative delta modified USPCC. Based on that assessment, we determined that, from a harm-reduction standpoint, the retroactive guardrail is preferable because it is designed to have exclusively beneficial or neutral effects for all ACOs (increased or unchanged shared savings or decreased or unchanged shared losses), whereas eliminating the ACPT can potentially have harmful effects (increased shared losses or decreased shared savings). We arrived at this determination after comparing outcomes of both approaches (down-weighting to zero versus a retroactive guardrail) against the same status quo baseline; that is, one-third weight applied to the ACPT component of the three-way blended update factor and no guardrail on delta modified USPCC, independent of the performance year in question.

Relative to that baseline, eliminating the ACPT would mean that an ACO's updated benchmark would be based entirely on the two-way national-regional blended update factor rather than the three-way blended update factor. For many ACOs, this can result in higher benchmarks and therefore can be potentially beneficial. However, for ACOs where regional growth may be sufficiently below national growth, substituting the two-way national-regional blended update factor for the three-way blended update factor could result in lower benchmarks even in the presence of substantially negative delta modified USPCC. Stated another way, when a given ACO's ACPT is greater than its two-way national-regional blended update factor, eliminating the ACPT is not necessarily beneficial and could be harmful to the ACO's financial reconciliation results.

By contrast, compared to the same baseline, in the presence of substantially negative delta modified USPCC, the retroactive guardrail can only result in an increased benchmark, by construction. This is because, in the presence of substantially negative delta modified USPCC, the only component of the three-way blended update factor that can change is the ACPT, and it can only be made larger than it would otherwise be in the absence of the guardrail. Furthermore, because the retroactive guardrail design incorporates a benchmark-based loss-recoupment limit protection feature (as discussed regarding ''Step 4. Recompute ACPT Values, as Applicable'' in CY 2027 PFS proposed rule (91 FR 44112)), there is no scenario in which an ACO could be rendered liable for greater shared losses than would otherwise occur in the absence of the retroactive guardrail. This benchmark-based loss recoupment limit protection feature will apply only to the retroactive guardrail on substantially negative delta modified USPCC for ACOs in agreement periods that began on or after January 1, 2024, and before January 1, 2027, beginning with reconciliation for PY 2025. It will not apply to agreement periods beginning on or after January 1, 2027.

More broadly, while we appreciate some commenters' views that the need for guardrails, retrospective corrections, annual recalculation, and reconciliation adjustments justifies the elimination of the ACPT entirely from the Shared Savings Program's financial reconciliation methodology, we disagree. Rather, for the reasons we discussed when we incorporated it into the financial methodology (87 FR 69881 through 69899), we continue to view the ACPT as an important tool for mitigating benchmark ratcheting and being a prospective measure of expenditure growth that makes benchmark updates more predictable. We view recent experience as evidence that the ACPT would benefit from refinement rather than elimination. Such refinements include safeguards against substantial delta modified USPCC, which may reflect projection error rather than ACO spending

performance, as well as performance year-specific modified USPCC annualized growth rates that ensure an ACO's agreement period start date does not determine the rate applicable at financial reconciliation for a given performance year.

Regarding other longer-term methodological alternatives, we appreciate commenters' suggestions to lengthen agreement periods, derive benchmarks from county rates, replace national trends with regional trends, exclude ACO beneficiaries from reference trends, and more explicitly account for major shifts in technology, policy, or clinical pricing that may affect ACOs unevenly. These recommendations would materially redesign the ACPT methodology or other aspects of the Shared Savings Program benchmark methodology beyond the scope of the proposed reforms. We will continue to monitor and consider whether implementation of these suggestions could be appropriate in the future, and we remain open to considering additional refinements through future rulemaking, if warranted.

We also appreciate the separate recommendation that CMS provide participation alternatives that would allow rural providers with small Medicare Part B populations or limited financial reserves to continue transitioning to advanced payment models without mandatory downside risk. That recommendation concerns Shared Savings Program participation and financial risk requirements more broadly than the ACPT methodology addressed by these proposals. Therefore, while we are not adopting such an alternative as part of these proposals, we will continue to consider the circumstances of rural providers, including the effects of beneficiary volume and participation requirements, in evaluating potential future program policies.

Comment: A commenter supported the guardrail concept but recommended applying the methodology consistently across agreement periods. Specifically, the commenter recommended extending both the upper and lower guardrails to existing agreement periods rather than applying the two-sided guardrail only to agreement periods beginning in 2027 and applying only the lower guardrail retroactively. The commenter stated that this approach would treat similarly situated ACOs equitably and provide consistent protection against trend misestimation.

Separately, some commenters proposed different refinements to the guardrail design, including symmetrical guardrails, tighter thresholds, or alignment with approaches used in the LEAD model. These recommendations reflected differing views and did not establish consensus on a specific alternative.

Response: We appreciate commenters' recommendations for consistent guardrails across agreement periods. We proposed a retroactive guardrail on substantially negative delta modified USPCC to protect ACOs in existing agreement periods from assuming financial risk when the modified USPCC is a substantial under-projection compared to actual growth, based on our observation of substantially negative delta modified USPCC occurring in both PY 2024 and PY 2025, affecting ACOs that entered agreement periods that began on January 1, 2024, and January 1, 2025. For those ACOs, failing to implement the retroactive guardrail at reconciliation for the remaining performance years of existing agreement periods, beginning with reconciliation for PY 2025, would potentially result in ACOs earning lower shared savings or incurring greater shared losses than would otherwise occur if the retroactive guardrail were applied and substantially negative delta modified USPCC were to persist.

Such consequences would be largely outside any given ACO's control and could potentially undermine both participation in and the sustainability of the Shared Savings Program and the public's faith in CMS as a fair partner. Specifically, over the course of an agreement period, if substantially negative delta modified USPCC persists and remains unconstrained, the adverse financial effects could either discourage new ACOs from joining the Shared Savings Program or cause some ACOs to leave the program. Reduced participation could significantly diminish savings to the Medicare Trust Funds, limit improvements in the quality of care provided to Medicare beneficiaries, and reduce the coordination of care for Medicare beneficiaries when obtaining items and services from ACO providers and suppliers. For these reasons, we believe it would be contrary to the public interest for CMS to fail to apply retroactively our proposed policy mitigating this issue. This rationale does not equivalently apply to a retroactive upper guardrail on substantially positive delta modified USPCC for existing agreement periods, which is effectively what the commenter is suggesting with the stated interest of treating ACOs across agreement periods equitably and providing consistent protection against trend misestimation. Thus, at this time, we do not believe that there is sufficient basis to apply a retroactive guardrail on substantially positive delta modified USPCC.

Separately, we appreciate commenters' suggestion that we consider other refinements to the guardrail design, such as symmetrical guardrails, tighter thresholds, or alignment with approaches used in other accountable care models (for example, the LEAD model). We have stated that the thresholds we have proposed represent a reasonable policy calibration that balances protecting ACOs and the Medicare Trust Funds from substantial misestimation of national expenditure growth on the one hand and preserving the prospective design objectives of the ACPT on the other. We remain open to considering future refinements to guardrail design features through rulemaking if warranted.

Comment: Some commenters expressed concern about delaying PY 2025 financial reconciliation results or shared savings payments. These commenters linked the delay to clinician compensation, practice cash flow, provider distributions, vendor commitments, care-management staffing, and investments in population health and care transformation. A commenter also requested clarification as to whether the later reconciliation cadence would be limited to PY 2025.

Commenters proposed several distinct approaches to reducing disruption from delayed PY 2025 reconciliation. Some requested provisional payments on the original timeline, potentially with a withhold to protect CMS against overpayment, followed by supplemental payments or a true-up after final guardrail values are available. Others requested provisional reconciliation results without necessarily requesting an interim payment. Additional commenters requested interim ACO-specific financial reports, including results under the existing and proposed methodologies, or early confirmation of the revised timeline to support cash-flow planning. Separately, commenters recommended that CMS avoid delaying reconciliation for ACOs whose results are not affected by the guardrail.

Commenters additionally requested transparent annual calculations, timely ACO-specific information explaining how the ACPT and guardrails affect each benchmark, disclosure of the assumptions underlying annual updates, and early confirmation of reconciliation timelines. Commenters stated that these approaches would preserve the benefit of retroactive protection while reducing disruption to

practice cash flow, provider compensation, staffing, and care-transformation investments; improve financial planning; allow ACOs to validate results; and support communication with participating providers.

Response: We thank commenters for raising concerns about the delayed PY 2025 financial reconciliation process and the potential effects on clinician compensation, provider distributions, cash flow, staffing, vendor commitments, and investments in care management and population health. Although we recognize these concerns, we continue to believe that it is appropriate to delay PY 2025 financial reconciliation until after the release of the CY 2027 PFS final rule. We made this decision based on a careful consideration of several factors unique to PY 2025, principally the observation of substantially negative delta modified USPCC affecting both the 2024 and 2025 agreement period cohorts for PY 2025, our determination that the proposed retroactive guardrail on substantially negative delta modified USPCC would be the most effective tool with which to protect affected ACOs from otherwise adverse financial consequences, and the practical need to finalize the retroactive guardrail in the CY 2027 PFS final rule before it could be implemented at reconciliation for PY 2025. In the CY 2027 PFS proposed rule, we provided ACOs with notice about our decision to delay PY 2025 financial reconciliation to allow them to plan accordingly as needed.

We also considered commenters' recommendations regarding provisional payments, provisional reconciliation results, and similar interim approaches, and suggestions that ACOs unaffected by the retroactive guardrail be reconciled separately and on an earlier schedule. While we appreciate the intent of these recommendations, we do not believe such approaches are operationally feasible under the circumstances, and the significant additional complexity these approaches would create would substantially increase the risk of creating errors in financial reconciliation calculations. Given the limited interval between finalization of this policy and completion of PY 2025 financial reconciliation, we do not believe that establishing provisional payment or interim reporting processes or conducting separate reconciliation cycles for different groups of ACOs, would provide sufficient additional benefit to justify the substantial added operational complexity, risk, and administrative burden associated with implementing them. As a result, CMS balanced these multiple perspectives and will be providing PY 2025 financial reconciliation and dissemination of Financial Reconciliation Settlement Reports shortly after the CY 2027 PFS final rule is released.

We also appreciate commenters' requests for timely information regarding ACPT calculations, guardrail implementation, and benchmark updates. Through published program specifications, CMS already publicly reports the methodologies used to calculate the ACPT. Further, with the finalization of performance year-specific modified USPCC annualized growth rates in this final rule, the published program specification will publicly report performance-year-specific modified USPCC annualized growth rates in the calendar year preceding the applicable performance year, beginning with the rates applicable to PY 2027. In addition, ACO-specific benchmark and reconciliation reports provide detailed information regarding benchmark calculations, including the components used to construct enrollment type-specific ACPT values. We believe these materials provide transparency regarding the calculation and application of the ACPT and associated guardrail policies and will continue to support ACOs' financial planning and operational decision-making.

Finally, we do not currently expect to delay financial reconciliation for future performance years. As stated previously, the circumstances that necessitated delaying PY 2025 financial reconciliation arose because the retroactive guardrail had not yet been finalized and therefore could not be incorporated into reconciliation calculations until finalization in the CY 2027 PFS final rule. With finalization of this policy, we expect the retroactive guardrail to be available for application in future performance years without requiring a similar delay, although CMS retains discretion to make operational decisions as warranted by future circumstances.

Comment: Some commenters requested continued evaluation of the reforms, including monitoring whether the ACPT remains aligned with actual expenditure growth, whether the guardrails adequately address projection error, and whether effects vary across ACO types, geographic markets, or patient populations. These commenters recommended revisiting the methodology or guardrail parameters in future rulemaking if experience shows continued benchmark suppression or unintended effects. Commenters also recommended that CMS evaluate whether the proposed thresholds remain sufficiently protective during periods of unusually rapid medical cost inflation and whether the upper threshold preserves sufficient room for the ACPT to mitigate benchmark ratcheting.

A commenter cautioned that guardrails tied to national expenditure growth may not reflect the spending patterns of ACOs serving medically complex populations. The commenter stated that such a guardrail could limit an ACO's benchmark update when higher expenditure growth reflects legitimate changes in the needs of its assigned population rather than inefficient care. The commenter recommended that CMS evaluate whether additional adjustments or safeguards are necessary for ACOs serving high need populations.

Other commenters also urged CMS to monitor whether the guardrails protect ACOs from artificially low benchmarks without unduly insulating them from meaningful accountability for spending or unfavorable expenditure trends. Lastly, a couple of commenters cautioned against combining guardrails with other upward benchmark adjustments in a manner that could systematically insulate ACOs from unfavorable trends and requested separate reporting of budgetary consequences.

Response: As discussed previously, we intend to monitor the delta modified USPCC, the application of guardrails on delta modified USPCC, and the combined effects of these guardrails and other policies on program-relevant metrics related to the commenters' concerns. We remain open, in principle, to reconsidering these thresholds in future rulemaking if implementation experience indicates that refinement is warranted. Lastly, we appreciate the recommendation related to budgetary consequences of the guardrails, and we will continue to work with the OACT to ensure our program policies continue to produce savings to the Trust Funds.

After careful consideration of public comments, we are finalizing the proposed reforms of the ACPT component of the benchmark update factor with a correction at § 425.660 to clarify that the guardrail will be ''greater than +1.5'' (as discussed in the example at 91 FR 44108 of the CY 2027 PFS proposed rule) rather than ''greater than or equal to +1.5'' (which was drafted in error at 91 FR 44114 of the CY 2027 PFS proposed rule). Specifically, we are finalizing the following policies as follows:

- For agreement periods beginning on January 1, 2027, and in subsequent years, we are finalizing, without

modification, our proposal to establish performance year-specific modified USPCC annualized growth rates to construct ACPT values.

- For agreement periods beginning on January 1, 2027, and in subsequent years, we are finalizing, without modification, our proposal to establish a guardrail that would not allow the modified USPCC cumulative growth rate for each of the ESRD population and the Aged/Disabled population to be more than 1.0 percentage point below or 1.5 percentage points above the corresponding observed cumulative growth in national assignable expenditures for that population, respectively, where the percentage-point thresholds are rounded to the nearest tenth of a percentage point.
- For agreement periods beginning on or after January 1, 2024, and before January 1, 2027, we are finalizing, without modification, our proposal to establish a retroactive guardrail that would not allow the modified USPCC cumulative growth rate to be more than 1.0 percentage point below the corresponding observed cumulative growth in national assignable expenditures, where the percentage-point threshold is rounded to the nearest tenth of a percentage point. This retroactive lower guardrail will apply beginning at reconciliation for PY 2025, where applicable, and for the remaining performance years of agreement periods that began on January 1, 2024 (that is, PYs 2025 through 2028), January 1, 2025 (that is, PYs 2025 through 2029), and January 1, 2026 (that is, PYs 2026 through 2030).

We are also finalizing, without modification, our proposed revisions to § 425.605. Specifically, we are finalizing as proposed, the following amendments to § 425.605:

- Revise paragraph (i)(2)(i) introductory text to remove the phrase ''paragraph (i)(2)(ii) of this section'' and add in its place the phrase ''paragraph (i)(2)(ii) or (i)(2)(iii) of this section, as applicable''.
- Add new paragraph (i)(2)(iii) to specify that for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, applicable to performance years 2025 and subsequent performance years remaining in these agreement periods, CMS calculates the benchmark-based loss recoupment limit.

We are also finalizing, without modification, our proposed revisions to § 425.610. Specifically, we are finalizing as proposed, the following amendments to § 425.610:

- In paragraph (l)(2) introductory text, remove the phrase ''paragraph (l)(3) of this section'' and add in its place the phrase ''paragraphs (l)(3) or (l)(4) of this section, as applicable''.
- Add new paragraph (l)(4) to specify that for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, applicable to performance years 2025 and subsequent performance years remaining in these agreement periods, the amount of shared losses for which an eligible ACO is liable may not exceed 15 percent of the lesser of the following:

++ Total benchmark expenditures calculated as the product of an ACO's per capita updated benchmark expenditures for the performance year prior to the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

++ Total benchmark expenditures calculated as the product of an ACO's per capita updated benchmark expenditures for the performance year after the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

6. Beneficiary Engagement

a. Proposal To Allow ACOs To Reduce or Eliminate Part B Cost Sharing

(1) Background

We believe that ACOs play a key role in strengthening beneficiary engagement in their care; accordingly, we intend to continue expanding the tools available to ACOs to support this work. Improving beneficiary engagement allows the benefits of receiving care from healthcare providers who are part of an ACO to be more tangible and may ultimately result in improved quality and efficiency of care for beneficiaries, helping us meet our goals of improving beneficiary outcomes and reducing unnecessary spending.

As part of the effort to strengthen beneficiary engagement, in the CY 2025 Physician Fee Schedule final rule, CMS finalized the prepaid shared savings option (89 FR 98132). This payment option is available to current Shared Savings Program ACOs with a history of earning shared savings and is intended to expand access to performance year savings that encourages investment in staffing, healthcare infrastructure, and additional services for beneficiaries. Under § 425.640(e)(1), ACOs participating in the prepaid shared savings option are required to spend a specific portion of the prepaid shared savings amount on direct beneficiary services, improving the quality of care beneficiaries receive. As discussed in section III.G.6. of the CY 2027 PFS proposed rule, ACO interest in receiving prepaid shared savings has been limited, and we proposed to discontinue the participation option in future years. However, we believed a component of prepaid shared savings, providing ACOs the ability to reduce or eliminate cost sharing for certain Part B items and services, is a valuable tool to offer eligible ACOs. Cost sharing support for Part B items and services was offered in the ACO REACH model and allows ACO participants not to collect cost sharing amounts (in whole or in part) from eligible beneficiaries for eligible Part B items and services. In the ACO REACH model, ACOs and ACO participants enter into cost sharing support arrangements for the ACO to reimburse the ACO participant for beneficiary cost sharing amounts not collected. In the ACO REACH model, ACOs have wide flexibility to determine the beneficiaries and items and services that will be eligible for cost sharing support, but ACOs are prohibited from waiving Part B cost sharing support for items that may have a higher risk of fraud, waste, or abuse, such as durable medical equipment, prosthetics, orthotics, prescription drugs or supplies.

Part B cost sharing support is the third most used Beneficiary Engagement Incentive in the ACO REACH model with 41 percent of ACOs reporting that they had implemented it by 2025 or were planning to implement in 2026.[358] Additionally, interested parties have identified Part B cost sharing support as a valuable tool for ACOs to engage beneficiaries in their care.[359]

In 2026, the standard Medicare Part B monthly premium is $202.90, with a $283 annual deductible.[360] After the deductible is met, beneficiaries generally pay 20 percent of the Medicare-approved amount for items and services, such as doctor visits and durable medical equipment, with no limit on out-of-pocket costs. While most beneficiaries have supplemental insurance that covers the 20 percent cost sharing, including Medigap plans, employer sponsored plans, and Medicaid, some beneficiaries do not. In 2023, 3.5 million Medicare FFS

[358] CMS Innovation Center. December 2025. ACO REACH Pulse Check Survey Preliminary Results. Internal Analysis.

[359] HCTTF and NAACOS: Reimagining Beneficiary Engagement in Accountable Care Models. 2026. Available at *https://www.naacos.com/wp-content/uploads/2026/03/Reimagining-Beneficiary-Engagement-in-Accountable-Models_2026.pdf.*

[360] 2026 Medicare Parts A & B Premiums and Deductibles, Fact Sheet, November 14, 2025. Available at *https://www.cms.gov/newsroom/fact-sheets/2026-medicare-parts-b-premiums-deductibles.*

beneficiaries (13 percent) lacked additional supplemental coverage.[361] These beneficiaries were more likely to have modest incomes (between $20,000 and $40,000 per person) compared to all Medicare FFS beneficiaries in 2023.[362] Beneficiaries with higher out of pocket costs receive less medical care than those with supplemental coverage.[363] While not all of this difference in care may be due to financial concerns, higher out of pocket costs may cause patients to skip or postpone necessary care and result in worsening health outcomes.[364] Offering Part B cost sharing support would allow ACOs to remove cost barriers for beneficiaries to receive items and services that will positively impact their health, which is consistent with the goals of the Shared Savings Program of improved quality and efficiency of care for beneficiaries.

While only one Shared Savings Program ACO receiving prepaid shared savings chose to reduce or eliminate Part B cost sharing support in the first year, that experience may not reflect future demand for this flexibility, given that only four ACOs elected to receive prepaid shared savings. Based on the ACO REACH model experience and the number of Medicare FFS beneficiaries without supplemental insurance, Shared Savings Program ACOs may be very interested in using this flexibility, were it available, simple to administer, and easy to implement. Additionally, we think providing ACOs the ability to reduce or eliminate Part B cost sharing support will better enable them to bill the new modifiers where appropriate as finalized in section II.D of this final rule, without increasing costs for ACO beneficiaries. These modifiers are intended to better account for the complexity of visits in the ACO context, including the cognitive work of providing longitudinal care and accountability for a beneficiary's total cost of care.

As discussed in section III.G.6.a.(2)(f) of the CY 2027 PFS proposed rule, CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§§ 1001.952(ii)(1) and (2) of this title) is available to protect remuneration exchanged under Part B cost sharing support arrangements and patient incentives in the form of Part B cost sharing support furnished to beneficiaries under the Shared Savings Program that meets the requirements of this section and the anti-kickback statute safe harbor requirements set forth at § 1001.952(ii) of this title.

(2) Revisions

(a) Eligibility, Application Procedure and Contents

To establish the ability for ACOs to offer Part B cost sharing support, we proposed in § 425.304(e)(1) that eligible ACOs may, subject to certain conditions and safeguards, enter into Part B cost sharing support agreements with ACO participants, under which ACO participants reduce or eliminate cost sharing for those categories of eligible Part B items and services and eligible beneficiaries identified by the ACO. This cost sharing support could include both Medicare FFS deductible and coinsurance amounts, or either of the two.

To help ensure that only ACOs capable of complying with program requirements have the ability to offer cost sharing support, we proposed to limit the ability to reduce or eliminate Part B cost sharing to those eligible ACOs that have submitted a Part B cost sharing support application and for which CMS has approved their application to participate for that agreement period or the remainder of that agreement period.

In addition to the eligibility requirement, CMS would design application criteria to collect information important for determining ACO compliance with the requirements of new § 425.304(e) while minimizing administrative burden to ACOs. ACOs would be required to submit an implementation plan in their application to provide Part B cost sharing support. ACOs will have substantial flexibility to design a Part B cost sharing support implementation plan that will be operationally and financially feasible for the ACO. As long as ACOs follow CMS procedures and accurate information is submitted to CMS, ACOs may independently determine the categories of beneficiaries and items and services for which they will reduce or eliminate Part B cost sharing.

We proposed to establish the application procedures in § 425.304(e)(3)(i). An ACO must submit a Part B cost sharing support implementation plan in the form and manner and by a deadline specified by CMS. The implementation plan must include the following:

- The categories of eligible beneficiaries for which the ACO plans to make Part B cost sharing support available.
- The categories of eligible Part B items and services for which the ACO plans to make Part B cost sharing support available.
- A description of how the ACO's planned Part B cost sharing support strategy meets at least one of the clinical goals in § 425.304(e)(4)(iii).
- The procedures the ACO will implement to ensure that ACO participants that have entered into a Part B cost sharing support arrangement with the ACO have access to the most current list of beneficiaries eligible to receive Part B cost sharing support.
- A requirement for the ACO to submit to CMS a complete and accurate list of ACO participants that have entered into a Part B cost sharing support arrangement according to paragraph (e)(5)(i) of this section.
- An attestation that, in any marketing or communications regarding the availability of Part B cost-sharing support, the ACO and its ACO participants will not represent such support as a substitute for supplemental insurance coverage or encourage beneficiaries to reduce or terminate such coverage. Of note, this requirement would not prohibit ACOs from communicating the availability of Part B cost-sharing support, provided such communication complies with this limitation and those outlined at § 425.310.
- Such other information as may be specified by CMS.

We intend this application process to ensure that ACOs have a fully developed strategy that complies with § 425.304(e) prior to implementing a strategy for reducing or eliminating Part B cost sharing support for eligible beneficiaries.

We proposed at § 425.304(e)(3)(ii) that CMS would evaluate an ACO's application to determine whether the ACO satisfies the requirements of § 425.304 and would approve or deny the application. CMS could reject the ACO's application to reduce or eliminate Part B cost sharing on the basis of one or more of the following:

- The ACO's and the ACO participant's history of noncompliance in the Shared Savings Program.

[361] Cubanski J, Neuman T and Ochieng N, KFF. A Snapshot of Sources of Coverage Among Medicare Beneficiaries. 2025. Available at: *https://www.kff.org/medicare/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/.*

[362] Ibid.

[363] Roberts E, Glynn A, Donohue J, et al. Consequences of Health Insurance Cost Sharing Among Low-Income Medicare Beneficiaries: Evidence from Benefit Cliffs in Medicaid and Medicare's Prescription Drug Subsidy Program. Health Serv Res. 2020;55(Suppl 1):98–99. *https://doi.org/10.1111/1475-6773.13470.*

[364] Hamel L, Lopes L, Montero A, Presiado M, and Sparks G. Americans' Challenges with Health Care Costs. KFF. 2026. Available at *https://www.kff.org/health-costs/americans-challenges-with-health-care-costs/.*

- The ACO's history of noncompliance in CMS Innovation Center ACO models.
- Whether the implementation plan complies with the requirements of § 425.304.
- Such other factors as we deem reasonable to protect the integrity of the Shared Savings Program, including concerns that the use of Part B cost sharing support may contribute to fraud, waste or abuse.

Part B cost sharing support can impact beneficiaries and ACO participants financially and therefore requires an ACO to maintain compliance with the requirements and guardrails laid out in this section to protect beneficiaries and ACO participants. We believe historical compliance with Shared Savings Program requirements and CMS Innovation Center model requirements is important for establishing experience that suggests the ACO is capable of providing Part B cost sharing support in alignment with program requirements. For example, if an ACO or an ACO participant has a history of noncompliance and we therefore issued pre-termination actions under § 425.216, we would want to review the facts of those actions to determine whether the ACO's application to provide Part B cost sharing support should be approved. Additionally, if CMS receives additional information through claims analysis or other avenues that suggest that particular usage patterns of the Part B cost sharing support may be contributing to fraud, waste or abuse, CMS may not accept an ACO's application that proposes similar strategies.

In the event that an ACO wants to make a change to its implementation plan, we proposed at § 425.304(e)(3)(iii) that the ACO must submit a description of the change to CMS in a form and manner and by a deadline or deadlines specified by CMS. CMS would evaluate the proposed change and either approve or reject it based on whether it complies with the factors outlined at proposed § 425.304(e)(3)(ii). CMS intends to provide further information regarding the process for updating the implementation plan through subregulatory guidance.

We sought comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported this proposal and thought that giving ACOs the ability to reduce or eliminate Part B cost sharing would reduce financial barriers, increase beneficiary access to care coordination services, and improve beneficiary care especially for beneficiaries facing chronic health conditions.

Response: We appreciate the supportive comments and agree that giving ACOs the ability to offer Part B cost sharing support will improve beneficiary care.

Comment: A commenter requested that CMS provide additional information regarding implementation of Part B cost sharing in ACO REACH, to help ACOs evaluate the potential financial and operational impact of participation.

Response: We appreciate the interest in the implementation of Part B cost sharing support in ACO REACH; however, this is outside the scope of this proposal. CMS has shared the available data through the ACO REACH evaluation reports available at the ACO REACH webpage.[365]

Comment: A few comments opposed this proposal because not all ACOs will have the same financial resources available to invest in Part B cost sharing support, which may result in unequal support for beneficiaries and may steer beneficiaries towards clinicians who are able to participate in cost sharing support. A comment recommended that CMS develop an incentive for smaller, independent and rural practitioners to assist them with offering Part B cost sharing support. Some comments also requested mechanisms for CMS to fund cost sharing support so the financial burden does not fall on ACOs and their ACO participants.

Response: We appreciate the comments expressing concerns regarding ACOs' ability to offer Part B cost sharing support. We understand that not all ACOs will have the ability to make the same investment in Part B cost sharing support. Participation in Part B cost sharing support is optional, and we hope that the significant flexibilities ACOs have in designing their Part B cost sharing support strategies will allow many ACOs to develop strategies that work for their ACOs. While we understand that not all ACOs will feel capable of offering Part B cost sharing support, we believe that it is important to increase the number of tools ACOs have available to improve beneficiary access to healthcare as a means of better coordinating beneficiaries' receipt of healthcare items and services and fostering high quality and efficient care. CMS will continue to monitor the impact of Part B cost sharing support in the program to understand if it significantly impacts beneficiary healthcare provider choice. At this time, CMS is not able to financially assist ACOs with funding for Part B cost sharing support but will continue to review the potential impacts of this flexibility to understand the impact on total cost of care for beneficiaries and potential future initiatives in this area.

Comment: Commenters requested CMS ensure that the program requirements do not become overly burdensome for ACOs. Another commenter requested additional application flexibility for ACOs, including the ability to apply multiple times throughout the performance year. A commenter noted they supported the policy but expressed concern about the burden of operationalizing it.

Response: We appreciate comments expressing concerns about administrative burden and intend to minimize burden where possible to help ensure that ACOs can focus on implementing Part B cost sharing support and better serving beneficiaries. To make Part B cost sharing support available earlier, we intend to offer a one-time, off-cycle application opportunity in 2027, rather than waiting until the annual application cycle for implementation in 2028 or later. While we recognize that multiple application opportunities would provide additional flexibility for ACOs, at this time, after the planned 2027 off-cycle application opportunity, we intend to use the regular application cycle and do not plan to offer multiple application opportunities each calendar year, as this would increase operational complexity and administrative burden for CMS. We will evaluate the experience and implementation of the Part B cost sharing option. We continue to be interested in receiving feedback on ways to reduce burden and may propose future adjustments to program requirements through rulemaking and provide additional subregulatory guidance once this flexibility is available to ACOs.

Comment: Several commenters requested that ACOs be offered additional flexibilities, like the post-discharge home visit waiver or care management home visit waiver, currently offered under the CMS Innovation Center ACO models, or the ability to offer an annual wellness visit once per performance year, instead of every 12 months. Commenters also requested that CMS remove cost sharing for a variety of services, including for APCM services. Commenters also requested a cost sharing waiver be

[365] *https://www.cms.gov/priorities/innovation/innovation-models/aco-reach.*

available to healthcare providers outside of the ACO for various services.

Response: We appreciate comments expressing interest in additional flexibilities for ACOs, including those flexibilities offered under ACO models offered by the CMS Innovation Center. These suggestions are beyond the scope of the Part B cost sharing support proposals we are finalizing in this final rule, however we are looking into additional flexibilities that could benefit ACOs, healthcare providers and beneficiaries. We hope to expand the options available to ACOs participating in the Shared Savings Program in future years.

After consideration of public comments, we are finalizing the eligibility, application, and implementation plan requirements for Part B cost sharing without modification as follows:

Section 425.304(e) establishes that ACOs, subject to certain conditions and safeguards, may apply for and if approved enter into Part B cost sharing support arrangements with ACO participants, under which the ACO participants reduce or eliminate cost sharing for those categories of eligible Part B items and services and eligible beneficiaries identified by the ACO. This cost sharing support could include both or either of Medicare FFS deductible and coinsurance amounts.

To allow ACOs to participate as quickly as possible, CMS will collect applications in early 2027 and approve participation by the second quarter of 2027, with a target date of April 1, 2027. This will allow ACOs to begin offering cost sharing support for services furnished on or after April 1, 2027. After the first application review period, CMS will conduct the application cycle for ACOs to reduce or eliminate Part B cost sharing as part of, and in conjunction with, the Shared Savings Program application process under § 425.202, with instructions and timelines published on the Shared Savings Program's website.[366] We will provide further information regarding the process, including the application format and specific requirements, such as the deadline for submitting applications, through subregulatory guidance. The Part B cost sharing support application review process will provide an ACO with feedback and an opportunity to clarify or revise its application. In conjunction with the application process laid out at § 425.202, ACOs will have their next opportunity (after the first application review period) to apply to provide beneficiaries with Part B cost sharing support in the summer of 2027 with an effective start date of January 1, 2028.

(b) Part B Cost Sharing Support Requirements

We proposed in § 425.304(e)(4) to specify the program requirements for reducing or eliminating Part B cost sharing. We intend our proposal to allow ACOs to reduce or eliminate Part B cost sharing to improve the quality and efficiency of items and services furnished to Medicare beneficiaries by giving ACOs additional tools to encourage beneficiaries to utilize high value care. We recognize that there are a multitude of strategies that could be successful when reducing or eliminating Part B cost sharing for beneficiaries, and these strategies will likely differ by ACO. Our goal with this proposal was to provide ACOs with significant flexibility to design a strategy that works for their organization while still maintaining safeguards for beneficiaries, healthcare providers, and CMS.

In § 425.304(e)(4)(i), we proposed the basic eligibility requirements for a beneficiary to receive Part B cost sharing support for a specific item or service. An eligible beneficiary must be an assignable beneficiary as defined at § 425.20 and must not have secondary insurance that covers the associated Part B cost sharing support obligation. Examples of secondary insurance could include a Medigap plan, Medicaid coverage, or other supplemental coverage through a beneficiary's employer or union. A beneficiary's eligibility may vary based on the item or service for which the ACO intends to reduce or eliminate cost sharing, based on their secondary insurance coverage. If a beneficiary's secondary insurance covers cost sharing support for some items and services but not all, ACOs may reduce or eliminate cost sharing support reductions for items and services that are not covered by the secondary insurance. This requirement would ensure the beneficiaries receive the benefits of reducing or eliminating cost sharing, and not insurers. To ensure that Part B cost sharing support is focused on improving the quality and efficiency of items and services beneficiaries receive, ACOs may only reduce or eliminate Part B cost sharing for beneficiaries whose overall health is expected to be improved or maintained by receiving the associated Part B item or service. This requirement is in place to reiterate that ACOs and ACO participants may not reduce or eliminate Part B cost sharing simply to increase reimbursements to healthcare providers through the provision of unnecessary items and services to beneficiaries.

Proposed § 425.304(e)(4)(ii) would allow ACOs to reduce or eliminate beneficiary cost sharing for all Medicare FFS Part B items and services except durable medical equipment, prosthetics, orthotics, supplies, and prescription drugs. We believe these excluded items have a higher risk potential for fraud, waste and abuse related to reducing or eliminating cost sharing, and this proposed policy aligns with the excluded items in the ACO REACH model. We intend to continue monitoring potential high-risk items and services and may add or remove items and services from this list in future years through notice and comment rulemaking.

While ACOs would have significant flexibility to determine the groups of beneficiaries and items and services for which they intend to reduce or eliminate Part B cost sharing, we proposed in § 425.304(e)(4)(iii) that an ACO's Part B cost sharing support must meet one or more of the following clinical goals for each beneficiary:

- Adherence to a treatment regime.
- Adherence to a drug regime.
- Adherence to a follow-up care plan.
- Management of a chronic disease or condition.

This is intended to focus ACO use of cost sharing support on goals that will improve or maintain the overall health of eligible beneficiaries. While ACOs would have substantial flexibility to design their strategy for reducing or eliminating Part B cost sharing, CMS believes it is important that these strategies focus on a clear theory of action for meeting certain clinical goals.

Additionally, we sought comment on whether CMS should make information regarding beneficiaries' supplemental health insurance coverage available to ACOs to assist them with determining beneficiary eligibility for and implementing Part B costs sharing support in accordance with the proposed requirements discussed previously in this section. We also sought comment on the specific data elements ACOs would need for this purpose, how frequently such information should be provided and any appropriate limitations or safeguards governing its use.

CMS currently shares certain beneficiary-identifiable data with ACOs under our regulations at 42 CFR part 425, subpart H. We believe the disclosure of this additional information would be consistent with our existing data sharing framework, which is based

[366] *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos.*

on HIPAA Privacy Rule provisions governing disclosures for ''health care operations'' provided the relevant regulatory conditions are satisfied. Under 45 CFR 164.506(c)(4), a covered entity may disclose protected health information to another covered entity for the recipient's health care operations when each entity has or had a relationship with the individual who is the subject of the information, the information pertains to that relationship, and the disclosure is for a health care operations activity described in paragraphs (1) or (2) of the definition of ''health care operations'' at 45 CFR 164.501. Those activities include quality assessment and improvement activities, population-based activities relating to improving health or reducing healthcare costs, and evaluating healthcare provider performance. CMS will offer only the information reasonably necessary to support implementation of Part B cost-sharing support and would establish appropriate limitations and safeguards governing its use and redisclosure.

We sought comment on whether supplemental coverage information would help enable ACOs to administer Part B cost-sharing support effectively; the particular data elements, level of detail and frequency of updates needed; and whether additional data would be necessary for ACOs to operationalize this flexibility. After consideration of comments on this topic, CMS may finalize policy to share supplemental coverage information with ACOs.

We proposed to add § 425.304(e)(4), to establish standards for the implementation of Part B cost sharing support. We sought comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters requested that CMS allow eligibility for Part B cost sharing support for a variety of specific beneficiaries and services, including offering cost sharing support to beneficiaries not assigned to an ACO, beneficiaries receiving services through community health centers or Federally Qualified Health Centers (FQHCs), beneficiaries experiencing financial hardship, beneficiaries with supplemental coverage, offering it for durable medical equipment, prosthetics, orthotics, supplies, prescription drugs, behavioral health, remote monitoring services, care coordination services, behavioral health integration services, collaborative care model services, care related to opioid use disorder, advanced primary care management, transitional care management, advance care planning services, and principal illness navigation.

Response: We appreciate comments expressing interest in offering Part B cost sharing support for a wide range of beneficiaries and services. We have attempted to provide significant flexibility to ACOs in designing their plans to implement Part B cost sharing support. In order to be eligible for Part B cost sharing, beneficiaries must be either assigned or assignable, depending on the ACO's selection of assignment methodology, must not have secondary insurance that covers the associated Part B cost sharing obligation, and their overall health must be expected to be improved or maintained by receiving the associated Part B item or service. Assuming they meet other requirements, beneficiaries experiencing financial hardship or receiving services through community health centers or FQHCs on the list of ACO participants that have entered into a Part B cost sharing support arrangement will be eligible to receive cost sharing support. While FQHC and community health centers bill institutional claims, they are ultimately paid through the Part B Trust Fund and are eligible to reduce or eliminate Part B cost sharing for beneficiaries if they are participating in a Shared Savings Program ACO. Additionally, beneficiaries with supplemental coverage may also be eligible for cost sharing support if their supplemental insurance does not cover cost sharing for the specific service for which an ACO offers cost sharing support. CMS will not permit ACOs to cover cost sharing for a service when a beneficiary has supplemental insurance that will also cover cost sharing for that service, as none of the financial benefit would reach the beneficiary in that situation.

In terms of covered services, ACOs are permitted to provide Part B cost sharing support for all Part B items and services except durable medical equipment, prosthetics, orthotics, supplies and prescription drugs. This includes most of the items and services commenters requested, including care coordination, behavioral health and remote monitoring services. We appreciate concerns regarding the exclusion of durable medical equipment, prosthetics, orthotics, supplies and prescription drugs, and understands many beneficiaries may face challenges with cost sharing related to these items and services. To protect program integrity and consistent with how the cost sharing waiver was implemented in the CMS Innovation Center's ACO models, we do not believe they are appropriate to include at this time. We also do not believe it is appropriate to include beneficiaries who are not assigned or assignable to the ACO as the ACOs are not at least potentially financially accountable for these beneficiaries, which generates additional financial risk to CMS if a beneficiary is encouraged to receive unnecessary services when cost sharing is reduced. CMS will continue to review the exclusion of these items and services and may propose to add or remove items and services from the exclusion list through notice and comment rulemaking in future years.

Comment: Some commenters requested that CMS require or encourage ACOs to explain how they will focus on beneficiaries with cost-related barriers to care, keep eligibility information current, avoid burdensome processes for beneficiaries to receive cost sharing support, avoid restrictions on care, offer accessible information, provide prompt assistance, and connect beneficiaries to additional financial resources.

Response: We appreciate comments expressing interest in implementation requirements for Part B cost sharing support. At this time, ACOs will need to include the information detailed in new § 425.304(e)(3)(i) in their implementation plan. This includes information regarding the beneficiaries and items and services the ACOs identify for Part B cost sharing support; information on how the ACO intends to meet advance beneficiary adherence to a treatment regime, drug regime, follow-up care plan or management of a chronic disease or condition; and information on how the ACO will ensure ACO participants have access to the most current list of eligible beneficiaries, among other requirements. While many of the additional requirements noted by the commenters are worthy goals, and in some cases already required or incentivized by the Shared Savings Program, including requirements to promote patient engagement and coordinate care, CMS declines to add additional implementation requirements to Part B cost sharing support at this time. ACOs are expending their own resources to implement Part B cost sharing support, and we decline at this time to add additional requirements that could increase administrative burden and discourage ACO participation. We will continue to monitor the implementation of Part B cost sharing support to determine if additional requirements are appropriate to add in the future.

Comment: A commenter suggested that CMS allow two-sided ACOs to use reductions in beneficiaries' Part B coinsurance and deductible costs as a managed care tool to reward beneficiaries for receiving their care at preferred healthcare providers selected by the ACO. The commenter also suggested allowing two-sided ACOs to provide Part B premium rebates and supplemental services (for example, non-medical emergency transportation, nutrition, vision, hearing, and dental services) to beneficiaries in the future.

Response: We appreciate these suggestions, however, we believe it is important that Part B cost sharing support be focused on removing financial barriers to improve beneficiary health. While many beneficiaries may find value in seeing ACO participants who offer cost sharing support and continue to see those healthcare providers, the purpose of the Part B cost sharing support must be to meet one or more of the following clinical goals: adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition. It must not be intended to reward beneficiaries for seeing specific healthcare providers. ACOs are already permitted to provide in-kind services to beneficiaries if they comply with the requirements in § 425.304(b); these must also not be distributed as a reward for seeing specific healthcare providers. We will continue to review additional flexibilities to extend to ACOs and appreciate the feedback regarding the ability to offer Part B premium rebates.

Comment: A commenter requested CMS ensure that the cost sharing arrangements do not create incentives for beneficiaries to drop supplemental coverage, as they may not be able to obtain comparable coverage later.

Response: We appreciate this concern and agree that the potential for Part B cost sharing support from ACOs is not a replacement for supplemental coverage. For ACOs that offer the cost sharing reduction option, ACOs will be required to attest that, in any marketing or communications regarding the availability of Part B cost-sharing support, the ACO and its ACO participants will not be allowed to represent such support as a substitute for supplemental insurance coverage or encourage beneficiaries to reduce or terminate such coverage as outlined in § 425.304(e)(3)(i)(F).

Comment: A commenter requested that CMS provide ACOs with a list of beneficiaries by attributed physician who are eligible for cost sharing support. Commenters also requested data on beneficiary secondary insurance coverage.

Response: We appreciate the interest in data to support ACOs in implementing Part B cost sharing support. In terms of helping ACOs to identify beneficiaries who could potentially be eligible for the Part B cost sharing support, we already distribute a list of assigned or assignable beneficiaries to all ACOs, depending on their selection of assignment methodology, prior to the start of each performance year and on a quarterly basis. The Shared Savings Program primarily attributes beneficiaries based on where they receive the plurality of their primary care, when considering the ACO participants as a group, and does not assign beneficiaries through individual clinicians outside of the voluntary alignment process. However, in assignment list reports, CMS identifies the three NPIs which provided the most primary care services to beneficiaries during the 12 month assignment window. Additionally, CMS makes available to ACOs claims data that would allow ACOs to identify the healthcare provider or providers where the beneficiaries receive the majority of their care, which could assist ACOs in identifying where eligible beneficiaries are likely to receive eligible services. Leveraging the quarterly assignment list report information, we are also working towards sharing additional data on beneficiary secondary insurance coverage with ACOs who are approved to offer Part B cost sharing support and will share additional information via subregulatory guidance.

Comment: A commenter raised concerns that the restriction limiting cost-sharing support to beneficiaries ''whose overall health is expected to be improved or maintained by receiving the associated Part B item or service'' may make such relief inaccessible to those who need it. The commenter stated that this restriction could be interpreted in various ways by ACOs and applied unfairly to exclude some patients, citing as an example that individuals may benefit from a service or item that is diagnostic or alleviates pain or enhances well-being, even if it is uncertain whether it will improve or maintain their health.

Response: We appreciate the concern. CMS interprets improving or maintaining a beneficiary's overall health broadly in the context of § 425.304(e)(4)(i)(C), and services that are diagnostic or improve quality of life would qualify. Each ACO will develop their own implementation plan as their resources permit that also meets some of the needs of their beneficiary population. Once these plans are submitted to CMS with the application, we will be able to review and provide determinations on individual scenarios.

Comment: A commenter asked CMS to clarify that the Part B cost-sharing elimination and reduction cannot directly be used to pay beneficiaries for achieving certain health outcomes or behaviors.

Response: We appreciate this request and are making clear that the purpose of the Part B cost sharing support must not be to reward beneficiaries for achieving certain health outcomes or behaviors. It must be used to advance at least one of the following clinical goals: adherence to a treatment regime, drug regime or follow-up care plan or management of a chronic disease or condition, and must only be offered for services expected to improve or maintain a beneficiary's overall health.

Comment: A commenter requested that as CMS expands options for covering beneficiary cost sharing, that CMS explore options to mitigate the negative effects of the ''lesser of'' policy and prohibit ACO participants from using Medicaid enrollment information shared for purposes of cost-sharing coverage to discriminate against dually eligible individuals.

Response: We believe this commenter is partially referencing policies that allow state Medicaid programs to pay healthcare providers less than the full Medicare cost-sharing amount if the Medicare payment rate for the service exceeds the Medicaid state plan rate for the service. Healthcare providers are prohibited from billing beneficiaries for the difference in these reimbursement rates. We appreciate the concern, however Medicaid reimbursement of cost-sharing amounts is outside the scope of this proposal. Regarding the concern about discrimination against dually eligible individuals, many beneficiaries with Medicaid coverage do not have to pay cost sharing for many Part B items and services because Medicaid covers the cost sharing amount, and it would be inappropriate to offer to cost sharing support to a beneficiary who does not pay cost sharing. Some beneficiaries with Medicaid coverage may have some cost sharing obligation for Medicare Part B items and services, so ACOs would be permitted to cover any cost sharing obligation for cost sharing not covered by Medicaid.

After considering public comments, we are finalizing this policy as proposed. Specifically, we are establishing § 425.304(e)(4), which details Part B cost sharing support requirements establishing beneficiary

eligibility requirements and prohibiting providing cost sharing support for DMEPOS and prescription drugs, as well as establishing that cost sharing support must be used to advance at least one of the following clinical goals, adherence to a treatment regime, drug regime or follow-up care plan or management of a chronic disease or condition, and must only be offered for services expected to improve or maintain a beneficiary's overall health.

(c) Part B Cost Sharing Support Arrangements

When an ACO chooses to reduce or eliminate Part B cost sharing, it must partner with ACO participants to implement this reduction or elimination of cost sharing for beneficiaries. In practice, the ACO would reduce or eliminate the cost sharing for an eligible beneficiary in partnership with the ACO participant, which would not collect cost sharing amounts (in whole or in part) from eligible beneficiaries for certain eligible Part B items and services. As this may have significant financial implications for practitioners, ACOs may only establish Part B cost sharing support arrangements with their ACO participants on a voluntary basis, as described later is this section. ACOs must also communicate the relevant implementation information, including how ACO participants will be reimbursed for reduced or waived Part B cost sharing, prior to ACO participants agreeing to participate. In § 425.304(e)(5)(i), we proposed that ACOs must have a written agreement with each ACO participant that has agreed to reduce or eliminate Part B cost sharing for eligible beneficiaries under a Part B cost sharing support arrangement with the ACO. The terms of the cost sharing support agreement must include all of the following:

- The categories of eligible beneficiaries and eligible Part B items and services for which the ACO participant may reduce or eliminate cost sharing.
- A requirement that the ACO participant reduce or eliminate cost sharing in accordance with the ACO's approved implementation plan.
- The amount and frequency with which the ACO will reimburse the ACO participant for the cost sharing amounts not collected.
- A requirement for ACO participants to maintain copies of records that identify each beneficiary who received a reduction or elimination of Part B cost sharing, the type and date of service for which cost sharing support was provided, and the dollar amount of the cost sharing support.
- The ability for the ACO or ACO participant to terminate the Part B cost sharing support agreement if the ACO or ACO participant fails to comply with the requirements of this section.
- A requirement that the ACO or ACO participants will not market to beneficiaries the availability of the Part B cost sharing support as a substitute for their supplemental insurance coverage.

All cost sharing support provided to beneficiaries must be provided in accordance with the ACO's implementation plan and the cost sharing support agreement between the ACO and ACO participant. We proposed in § 425.304(e)(5)(ii)(A) and (B) that an ACO participant cannot be required by an ACO to participate in an ACO's Part B cost sharing support arrangement and, an ACO can participate in Part B cost sharing support, under an approved implementation plan, even if not all of its ACO participants agree to participate. While we believe reducing or eliminating Part B cost sharing is an important tool to offer ACOs, ACOs must not pressure their ACO participants into providing Part B cost sharing support. ACOs would be required to permit ACO participants to choose whether they wish to participate. CMS expects that some ACO participants would decide not to participate and that ACOs would be able to implement a reduction or elimination of Part B cost sharing for eligible beneficiaries if only a portion of their ACO participants were to opt in.

Additionally, to avoid inappropriate conflicts of interest, we proposed in § 425.304(e)(5)(iii) that the ACO would be required to finance all payments made to ACO participants under the cost sharing support agreements from the ACO's own funds. For example, ACOs may not partner with local businesses outside the ACO to fund cost sharing reimbursements to healthcare providers.

We proposed to add § 425.304(e)(5) to establish the standards discussed previously in this section for the cost sharing support agreements ACOs must develop for ACO participants that choose to reduce or eliminate Part B cost sharing. We sought comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Rather than requiring the ACO to fund or reimburse waived cost-sharing amounts, a commenter recommended that CMS allow flexibility for the individual ACO participants to determine whether to reduce or eliminate Part B coinsurance for care management services, citing variation in patient populations, financial resources, and operational structures across ACO participants.

Response: We believe this comment indicates a potential misunderstanding of the proposal. Participation in Part B cost sharing support is voluntary at the ACO level; an ACO must affirmatively apply and be approved by CMS to offer Part B cost sharing support. Nothing mandates that an ACO adopt Part B cost sharing support. ACO participant-level participation is also voluntary—proposed § 425.304(e)(5)(ii)(A) explicitly states an ACO participant cannot be required by the ACO to participate in a cost sharing support arrangement, and proposed § 425.304(e)(5)(ii)(B) states the ACO can participate with only some ACO participants opting in. We anticipate ACOs and ACO participants would strategize together to develop the Implementation Plan in order to discuss and plan for the unique variations in patient populations. This commenter's requested ''flexibility'' appears to be consistent with what CMS proposed.

Comment: Some commenters supported the ability of ACOs to reduce or eliminate cost sharing but believed healthcare providers, including safety-net providers like FQHCs or Registered Nurses, should not experience a reduction in compensation.

Response: We appreciate these concerns, but we believe it is important to give ACOs and ACO participants flexibility to negotiate their own cost-sharing reimbursement arrangements. Participation in Part B cost sharing support is voluntary for both ACOs and individual ACO participants, so if the ACO and ACO participant cannot agree on an appropriate reimbursement arrangement, the ACO participant can choose not to participate and continue to receive full cost sharing from beneficiaries.

Comment: A commenter suggested that CMS allow Medicare Bad Debt Claims for Part B cost sharing amounts that are not reimbursed to ACO participants in accordance with the Cost Sharing Support Arrangements.

Response: We appreciate this suggestion, however, Medicare bad debts are derived from unpaid coinsurance and deductible amounts for covered services and are only allowable when the criteria at 42 CFR 413.89 are met. A breach in the Part B Cost Sharing Support Arrangement between the ACO and ACO participant would not qualify as allowable Medicare bad debts. Additionally, the ACO participant should not revert to billing a beneficiary who was offered cost-sharing support if

an ACO fails to reimburse the ACO participant under the Part B Cost Sharing Support Arrangement.

After consideration of public comments, we are finalizing this policy as proposed. Specifically, we are finalizing § 425.304(e)(5), which details the required elements of the Part B cost sharing support arrangements ACOs must establish between the ACO and their ACO participants.

(d) Record Retention

To maintain the ability for CMS to monitor the implementation of the reduction or elimination of Part B cost sharing and resolve any identified compliance issues, we proposed to require that ACOs must keep detailed records on the reduction or elimination of Part B cost sharing for beneficiaries. We proposed in § 425.304(e)(6)(i) that the ACO must maintain copies of the written Part B cost sharing support agreements with ACO participants, as well as the following records.

- Records that identify each beneficiary who received a reduction or elimination of Part B cost sharing.
- Records that document the type and date of the Part B item or service for which Part B cost sharing was reduced or eliminated.
- Records that document the dollar amount of Part B cost sharing that was reduced or eliminated; and
- Records that document the ACO participant that furnished the item or service for which cost sharing support was reduced or eliminated.

Additionally, we proposed at § 425.304(e)(6)(ii) that the ACO must provide the records specified in paragraph (e)(6)(i) upon CMS' request. For example, CMS may request these records if disputes arise that are elevated to CMS or if CMS has any reason to believe there may be non-compliance with a cost sharing support requirement. We may also conduct periodic audits to ensure compliance with this requirement.

We proposed to add § 425.304(e)(6) to establish the standards discussed previously in this section for the record retention related to the reduction or elimination of Part B cost sharing. We sought comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters requested public reporting of the use of Part B cost sharing support, including that ACOs be required to publicly report their cost sharing strategies and that CMS report on its use. Commenters also suggested CMS evaluate uptake and outcomes of the cost sharing support.

Response: We appreciate comments expressing interest in public reporting on the use of Part B cost sharing support. We are still considering how to balance minimizing burden for ACOs and ACO participants and the transparency value that public reporting requirements provides. While we are not currently planning to require ACOs to publicly report their use of Part B cost sharing support, primarily because they are using their own resources to support beneficiaries, we may consider for future rulemaking whether to propose to revise these requirements. We will continue to internally evaluate the uptake and outcomes of this flexibility.

After consideration of public comments, we are finalizing this policy as proposed. Specifically, we are adding § 425.304(e)(6) to mandate that the ACO maintain copies of the written Part B cost sharing support agreement with ACO participants, as well as records documenting specific details about the beneficiaries and the items and services which received cost sharing support.

(e) Addressing Compliance Problems

To protect both beneficiaries and healthcare providers, CMS proposes in § 425.304(e)(7) that at any time, CMS may suspend or prohibit the ACO or any ACO participant from participating in a Part B cost sharing support arrangement if CMS determines that the ACO or ACO participant has failed to comply with any of the requirements of Part 425. This suspension or prohibition will be effective, in CMS's discretion, regardless of whether the ACO has corrected or otherwise resolved the noncompliance.

We proposed to add § 425.304(e)(7) to establish the standards discussed previously in this section for compliance and enforcement policies related to the reduction or elimination of Part B cost sharing. We sought comments on these proposals.

We did not receive public comments on this provision, and therefore, we are finalizing it as proposed.

(f) OIG Safe Harbor Authority

In section III.G.6.a.(2)(f) of the CY 2027 PFS proposed rule, starting at 91 FR 44118, we stated that should the proposed policies be finalized, we expect to make a determination that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§§ 1001.952(ii)(1) and (2) of this title) is available to protect remuneration exchanged under certain financial arrangements and patient incentives that may be permitted under the final rule. Specifically, we stated that we expect to determine that the CMS-sponsored models safe harbor would be available to protect the following: remuneration exchanged under Part B cost sharing support arrangements between the ACO and ACO participant and patient incentives in the form of Part B cost sharing support furnished to eligible beneficiaries.

We proposed to add new § 425.304(e)(2) that notes that CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§§ 1001.952(ii)(1) and (2) of this title) is available to protect remuneration exchanged under Part B cost sharing support arrangements between ACOs and ACO participants, and patient incentives in the form of Part B cost sharing support furnished to eligible beneficiaries under the Shared Savings Program that meet all of the requirements of this section and the anti-kickback statute safe harbor requirements set forth at § 1001.952(ii) of this title.

We sought comments on this proposal to allow ACOs to reduce or eliminate Part B cost sharing beginning in 2027, with a target date of April 1, noting that the application process for this first performance year will occur during early 2027.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter requested clarity on how the anti-kickback safe harbor and physician self-referral law (commonly referred to as the ''Stark Law'') apply to this proposal.

Response: CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§ 1001.952(ii)(1) and (2) of this title) is available to protect remuneration exchanged under Part B cost sharing support arrangements between ACOs and ACO participants, and patient incentives in the form of Part B cost sharing support furnished to eligible beneficiaries under the Shared Savings Program that meet all of the requirements of this section and the anti-kickback statute safe harbor requirements set forth at § 1001.952(ii) of this title.

Shared Savings Program that meet all of the requirements of this section and the anti-kickback statute safe harbor requirements set forth at § 1001.952(ii) of this title.

Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payor) for any improperly referred designated health services. Exceptions to the physician self-referral law are codified at 42 CFR part 411, subpart J.[367] In addition, for ACOs participating in the Shared Savings Program, the Office of the Inspector General and CMS jointly published Medicare program waivers for participating ACOs.[368] Additional information regarding the physician self-referral law is available on the CMS website.[369]

After consideration of public comments, we are finalizing this policy as proposed. Specifically, we are adding new § 425.304(e)(2) that notes that CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§§ 1001.952(ii)(1) and (2) of this title) is available to protect remuneration exchanged under Part B cost sharing support arrangements between ACOs and ACO participants, and patient incentives in the form of Part B cost sharing support furnished to eligible beneficiaries under the Shared Savings Program that meet all of the requirements of this section and the anti-kickback statute safe harbor requirements set forth at § 1001.952(ii) of this title.

b. Proposal To Discontinue Availability of the Option for Prepaid Shared Savings

(1) Background

In the CY 2025 PFS final rule (89 FR 97710), CMS finalized prepaid shared savings, a payment option for ACOs that meet the eligibility criteria under § 425.640 (89 FR 98134). This new payment option provides prepaid shared savings to ACOs with a history of earning shared savings while participating in the Shared Savings Program (89 FR 98134). These payments would be distributed on a quarterly basis and would be recouped from shared savings CMS determines the ACO to have earned during the annual financial reconciliation cycle (89 FR 98134). Prepaid shared savings are the advanced payment of shared savings that are expected to be earned by the ACO and are covered under the Shared Savings Distribution Waiver (89 FR 98134 referencing 80 FR 66726).

In the CY 2025 PFS final rule, certain policies, including both existing policies and new policies adopted in the final rule, relied upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determined would improve the quality and efficiency of items and services furnished under the Medicare program, and that would not result in program expenditures greater than those that would result under the statutory payment model (89 FR 98085). This included allowing eligible ACOs to receive prepaid shared savings, as described in the final rule (89 FR 98085). Such a change to our payment methodology for prepaid shared savings was expected to improve the quality and efficiency of care and was not expected to result in a situation in which the payment methodology resulted in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act (89 FR 98085). As described in the Regulatory Impact Analysis in the CY 2025 PFS final rule, the impact of prepaid shared savings alone was projected to be nominal. Both at the mean and at the 90th percentile the projected net impacts on Medicare spending rounded to zero (89 FR 98526). We noted at the time that there was a high degree of uncertainty regarding whether (a) a meaningful number of ACOs would choose this option given the requirements for how prepayments must be spent, and (b) the potential impact (if any) that participation in this option would have on the cost of care (89 FR 98525).

Uptake of this payment option has been very low. Only four ACOs participated in prepaid shared savings in 2026, the first year the payment option was available. This is likely due to a number of factors, many of which were raised by commenters during CY 2025 PFS rulemaking (89 FR 98136).

As part of the prepaid shared savings option under § 425.640(e)(1)(ii), ACOs participating in prepaid shared savings must spend at least 50 percent of prepaid shared savings on direct beneficiary services in each performance year. These include, but are not limited to: cost-sharing support for Part B beneficiaries; certain vision, hearing and dental services; beneficiary meals; nutrition support; tenancy support and sustaining services, housing assistance, utility support, caregiver support services; services to address social isolation, home visits; and transportation services.[370] Under § 425.640(e)(1)(i), ACOs may also elect to spend up to 50 percent of their prepaid shared savings on staffing (for example, hiring physicians or mid-level healthcare providers or staff education) and healthcare infrastructure investments (for example, improving practice management or electronic health record systems) in each performance year. ACOs participating in prepaid shared savings are prohibited from using prepaid shared savings for any expense other than those allowed under § 425.640(e)(1), including but not limited to the following: management company or parent company profit; performance bonuses; provision of medical services covered by Medicare; cash or cash equivalent payments to patients; and items or activities unrelated to ACO management and operations of an ACO or beneficiary care (§ 425.640(e)(2)). In the CY 2025 PFS final rule (89 FR 98141), we stated that the prepaid shared savings policy was developed to improve the quality and efficiency of items and services furnished to Medicare beneficiaries. We explained that the requirement that ACOs spend at least 50 percent of their prepaid shared savings on direct beneficiary services is important for meeting those goals. Direct beneficiary services like vision, hearing and dental, and other services that are evidence-based and medically appropriate for the beneficiary based on clinical risk factors, have the potential to improve beneficiary health outcomes, reduce costs, and improve beneficiary engagement and willingness to receive care from a healthcare provider affiliated with an ACO. We believed financially successful ACOs are likely to have already made significant investments in staffing and healthcare infrastructure, as they are necessary for the functioning of an ACO. We also noted the restriction on using prepaid shared savings for expenses like healthcare provider bonuses is important for ensuring that prepaid shared savings are used for expenses that directly improve beneficiary care (89 FR 98141).

Additionally, to monitor compliance with ACO use of the prepaid shared

[367] *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-411#subpart-J.*

[368] *https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/fraud-and-abuse-waivers#Medicare_Shared_Savings_Program.*

[369] *https://www.cms.gov/medicare/regulations-guidance/physician-self-referral.*

[370] See Prepaid Shared Savings Guidance, May 2025 Version 1 *https://www.cms.gov/files/document/prepaid-shared-savings-guidance.pdf.*

savings, CMS requires ACOs to submit an annual spend plan under § 425.640(d) detailing their planned use of prepaid shared savings to CMS as well as publicly report the total amount of prepaid shared savings received, investments made, beneficiary groups served, changes to ACO's spend plan, and an itemization of how prepaid shared savings were spent during the performance year (§ 425.308(b)(10) and § 425.640(i)). In the CY 2025 PFS final rule (89 FR 98138), we noted that we understood that submitting a detailed spend plan on the use of prepaid shared savings requires administrative work for participating ACOs. However, detailed spend plans which include information on (1) direct beneficiary services that would be provided to ACO beneficiaries; and (2) investments that would be made in the ACO with prepaid shared savings are important for monitoring that ACOs use prepaid shared savings consistent with the requirements for use and management of prepaid shared savings under § 425.640(e) (89 FR 98138). CMS expressed that it was particularly important for us to ensure ACOs use prepaid shared savings consistent with those use and management requirements because prepaid shared savings are advances of shared savings to ACOs prior to ACOs actually earning the shared savings, and must be focused on improving beneficiary outcomes and quality of care, reducing costs, improving ACO efficiency, and improving beneficiary engagement and willingness to receive care from a healthcare provider affiliated with an ACO. Those requirements also promote transparency in how ACOs are using prepaid shared savings. That transparency improves the coordination and quality of care provided by participating ACOs by facilitating their efforts to share information with each other, CMS, and the public about how they effectively used prepaid shared savings to improve the quality and efficiency of the care they provided to their beneficiaries (89 FR 98138).

In the CY 2025 PFS final rule (89 FR 98141), commenters noted that the restrictions on use of prepaid shared savings and the amount of documentation required would create significant administrative burden beyond what is already required by the Shared Savings Program. Many commenters asserted that the restrictions on the use of prepaid shared savings are unnecessary and likely to negatively impact ACO participation in prepaid shared savings (89 FR 98141). Most of the commenters disagreed with the requirement that ACOs spend at least 50 percent of prepaid shared savings on direct beneficiary services (89 FR 98141). They also commented that providing written spend plans would generate additional burden for ACOs (89 FR 98138). CMS acknowledged commenter concerns but implemented the policy largely as proposed. CMS subsequently heard similar feedback from ACOs during the first application period for prepaid shared savings, PY 2026, including that the requirement to spend at least 50 percent of prepaid shared savings on direct beneficiary services is unrealistic as there is a lack of evidence that services identified as ''direct beneficiary services'' generates sufficient return on investment for ACOs.

We continue to believe that these guardrails on the use and reporting of prepaid shared savings are important for ensuring ACOs direct these funds in a way that improves the quality and efficiency of items and services furnished to Medicare beneficiaries; however, we believe that commenters were also correct that these guardrails significantly limited participation. In CY 2025 PFS final rule (89 FR 98141), CMS anticipated that the restrictions in prepaid shared savings could reduce the number of ACOs that ultimately decide to participate in prepaid shared savings. During the PY 2026 application cycle, 23 ACOs submitted an application for prepaid shared savings and only 4 were ultimately approved to participate. The majority of applicants withdrew from consideration or were denied participation due to deficiencies with their applications. Examples of the deficiencies included submitted spend plans that did not align with the requirement that 50 percent of the funding be spent on direct beneficiary services. We believe the low participation rate reflects the administrative burden and limited financial incentive of the prepaid shared savings option for ACOs. At this time, we believe we can achieve similar outcomes with less burden and less financial risk to CMS through an alternative approach that offers ACOs the ability to reduce or eliminate Part B cost sharing as described in section III.G.6.a. of this final rule, as ACOs are already permitted to use their earned shared savings to invest in staffing and healthcare infrastructure.

(2) Revisions

Based on our experience with the prepaid shared savings option to date, we proposed to remove the prepaid shared savings option from the Medicare Shared Savings Program. Although our prior analysis assumed up to 30 ACOs per year might elect the option,[371] actual uptake has been significantly lower with only four ACOs currently participating.

We believe this limited uptake constrains the option's ability to meaningfully advance the goals for which it was established, including improving beneficiary engagement and outcomes and reducing unnecessary expenditures. At the same time, maintaining the option requires CMS to maintain annual application cycles for the prepaid shared savings option, monitor ACO participation under prepaid shared savings, distribute payments, and assume the risk of unpaid debt.

Furthermore, based on early experience with the program with few ACOs opting to participate and feedback from eligible ACOs, we anticipate that participation in the prepaid shared savings option as currently written is likely to remain limited, as we do not believe we can resolve the ACOs' concerns with the payment option while meeting the option's original goals and safeguards. For example, the requirement that ACOs spend at least 50 percent of the funding on direct beneficiary services is necessary for impacting beneficiary health outcomes and reducing costs. Similarly, spend plan requirements are necessary for monitoring and transparency purposes. Removing or substantially weakening these requirements would materially change the purpose and expected effects of the option. Given the very limited participation to date as well as limited anticipated future participation, we do not believe continuing to maintain this option is an effective and efficient use of CMS program resources.

As such, we proposed to sunset the prepaid shared savings option over the course of currently participating ACOs' agreement periods.

We proposed to revise § 425.640(b) to end ACO eligibility for prepaid shared savings beginning on January 1, 2027. Section 425.640(b)(1)(i) will be revised to read, the ACO is a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2026 or January 1, 2027. We proposed to accept one final cohort of ACOs during the PY 2027 application cycle but will no longer accept applications for this prepaid shared savings payment option after this year. We proposed to revise § 425.640(c)(1) to read, ''For an ACO renewing to enter into an agreement period beginning on January 1, 2026 or January 1, 2027, to obtain a

[371] 89 FR 98525.

determination regarding whether the ACO may receive prepaid shared savings, the ACO must submit a complete supplemental application with its application to renew for a new agreement period in the Shared Savings Program (submitted under § 425.224) in the form and manner and by a deadline specified by CMS.''

Additionally, we proposed to revise § 425.640(f)(1) to no longer distribute prepaid shared savings to ACOs after December 31, 2027. Section 425.640(f)(1)(i) will be revised to state, ''An eligible ACO entering an agreement period beginning on January 1, 2026, or January 1, 2027 will receive quarterly prepaid shared savings payments through December 31, 2027, unless the payment is withheld or terminated under paragraph (h) of this section.'' A similar change will be made to § 425.640(f)(1)(ii), which will be revised to read, ''An eligible ACO participating in an agreement period beginning on January 1, 2025, will receive quarterly prepaid shared savings payments starting with the performance year beginning on January 1, 2026, through December 31, 2027, unless the payment is withheld or terminated under paragraph (h) of this section. The ACO will not receive additional or catch-up payments for performance year 2025.'' Currently participating ACOs who receive payments for 2026 and 2027 will not receive prepaid shared savings payments beginning in 2028. Any ACO who begins participating in 2027 will receive one year of payments in 2027 and will not receive payments beginning in 2028. We intend to provide further information regarding the timing of final quarterly payments through subregulatory guidance.

We did not anticipate significant disruption among ACOs participating in the option or their beneficiaries due to (1) the low number of participants, (2) the ample notice we proposed giving ACOs to plan for the sunsetting of the prepaid shared savings option and (3) the ability of ACOs to continue to provide any ''direct beneficiary services'' through their earned shared savings. With the exception of beneficiary cost sharing support, ACOs are currently permitted to use their earned shared savings to pay for anything that is currently being covered by prepaid shared savings as both funding sources qualify for protection under the Shared Savings Program ACO Final Waivers (80 FR 66726). As discussed in section III.G.6.a. of the CY 2027 PFS proposed rule, we proposed to allow ACOs to offer beneficiary cost sharing support outside of prepaid shared savings in early 2027 so there will be no gap in an ACO's ability to offer beneficiary cost sharing support if they opt to offer it under earned prepaid shared savings.

Those ACOs who participate in the prepaid shared savings participation option in 2026 or 2027 will not see changes to the requirements of the program for the prepaid shared savings they receive. Specifically, ACOs that receive prepaid shared savings in 2026 or 2027 will continue to be able to spend the funding as outlined in § 425.640(e). ACOs are required to continue to participate in the monitoring and reporting requirements of prepaid shared savings until all prepaid shared savings have been repaid to CMS.

We still believe there is value in encouraging ACOs to engage beneficiaries with strategies and tools designed to support their health and believe there is value in supporting cash flow mechanisms for ACOs. However, the combination of these two goals in prepaid shared savings does not appear viable. We proposed under § 425.304(e) to allow all eligible ACOs to offer cost sharing support to beneficiaries beginning early 2027 as noted previously in this section. We were interested in feedback on tools ACOs would find valuable for engaging beneficiaries in hopes to expand policies in this area in future years. We were also interested in additional ways to support ACO cash flow and in feedback on the topic as outlined in the Request for Information on primary care capitation in section II.E. of the CY 2027 PFS proposed rule.

We sought comments on the proposal to eliminate the prepaid shared savings option as of January 1, 2028, noting that the last opportunity for a cohort to elect to participate in the option will be for PY 2027.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported CMS's proposal to discontinue the prepaid shared savings payment option. The commenter stated that the option has experienced limited participation and that alternative approaches may provide ACOs with greater flexibility to support beneficiary engagement. The commenter stated that simplifying the number of available payment options may reduce program complexity and allow CMS to focus resources on approaches that demonstrate stronger ACO participation and beneficiary impact.

Response: We appreciate the feedback on the proposal to discontinue the prepaid shared savings option under § 425.640. We note that prepaid shared savings was available only to eligible renewing ACOs with an established history of successfully earned shared savings, and that these payments were advances on shared savings ACOs were expected to earn, ultimately recouped through actual earned shared savings. We agree that the prepaid shared savings option has experienced limited participation and believe removing it will allow CMS to allocate program resources more efficiently to more effectively support beneficiary engagement.

Additionally, as discussed in section III.G.6.a. of this final rule, we are finalizing a new Part B cost-sharing support flexibility under § 425.304(e) that allows eligible ACOs to reduce or eliminate beneficiary cost-sharing without requiring participation in the prepaid shared savings option.

Comment: Several commenters opposed CMS's proposal to discontinue the prepaid shared savings option after the PY 2027 cohort and recommended that CMS retain the option. Commenters generally stated that prepaid shared savings could provide important upfront funding or cash flow for ACOs to invest in care transformation, infrastructure, staffing, and beneficiary services, particularly for organizations with limited access to capital, including independent, physician-led, rural, safety-net, high-needs, and other resource-constrained organizations. Commenters stated that the option has been available for too little time to determine its success based on early uptake and that low participation may reflect the option's design and administrative requirements rather than a lack of interest among ACOs. Several commenters specifically identified restrictions on allowable uses of funds, the requirement that at least 50 percent of prepaid shared savings be spent on direct beneficiary services, detailed spend-plan or documentation requirements, requirement to opt into prepaid shared savings at the start of an agreement period, payments that are not received early enough in a performance year, and other reporting, monitoring, and compliance requirements as barriers to participation.

A commenter also recommended expanded education for ACOs regarding the option and encouraging repeat applications from organizations that previously applied. Commenters stated that these modifications could make prepaid shared savings a more effective source of upfront capital for care management, clinical staffing, health information technology, data analytics,

beneficiary engagement, behavioral health integration, infrastructure, in-kind benefits like transportation, and other care transformation activities and discouraged CMS from narrowing our commitment to mechanisms that allow ACOs to build capacity and address barriers for beneficiaries.

A commenter acknowledged the limited uptake of prepaid shared savings and that programs with minimal participation may cease to be an effective use of program resources, but nevertheless recommended that CMS identify new approaches to reduce or remove resource-related barriers to entry for physician-led, rural, high-needs, and specialty-oriented ACOs.

Response: We appreciate the feedback on the proposal to discontinue the prepaid shared savings payment option. We continue to believe that the very low uptake of this option, with only four ACOs participating in PY 2026, and the high rate of denial or withdrawal applications during the PY 2026 cycle, demonstrates that the option as designed is neither achieving the intended goals nor the scale to justify the continued administrative resources CMS must devote to maintaining annual application cycles, monitoring spend plans, distributing payments, and addressing unpaid debt. We also believe that participation is unlikely to meaningfully increase over time as currently structured due to a number of issues identified by commenters.

Prepaid shared savings was specifically designed to address two issues, cash flow for ACOs as well as to encourage investments that would aid beneficiaries, such as investments in direct beneficiary services, staffing, or healthcare infrastructure. We agree with commenters that restrictions on the allowable uses of prepaid shared savings, the requirement that ACOs spend at least 50 percent of prepaid shared savings on direct beneficiary services, and the associated spend plan, documentation, and reporting requirements likely contributed to limited uptake. However, this requirement is also part of the foundation of prepaid shared savings to directly encourage investment into aid for beneficiaries. As noted in the CY 2025 PFS final rule, prepaid shared savings are only available for financially successful ACOs, who are likely to have already made significant investments in areas like staffing and infrastructure that are required for ACOs to function, and encouraging significant investment in direct beneficiary services was intended to improve beneficiary outcomes, reduce costs, and improve beneficiary engagement with an ACO. Relaxing the requirements that ACOs spend a minimum percentage of prepaid shared savings towards direct beneficiary services undermines the original intent of this policy. Additionally, we continue to believe that these requirements were important safeguards because the prepaid shared savings option involved advancing ACOs funds that they had not yet earned. We do not believe we can sufficiently relax these requirements as commenters have expressed and continue to meet the original goals of this policy.

CMS is offering ACOs the ability to provide beneficiaries with Part B cost-sharing support outside of prepaid shared savings, in order to meet some of the original goals of prepaid shared savings, including improving beneficiary outcomes, reducing costs and improving beneficiary engagement with an ACO. Outside of prepaid shared savings, ACOs are also permitted to spend on direct beneficiary services, including Part B cost sharing support, out of their own funding and we do not believe that removing prepaid shared savings will result in meaningful reductions in spending on direct beneficiary services. We believe some of the cash flow goals are being met through the Advance Investment Payment (AIP) option, described at § 425.630. Eligible ACOs receive a one-time fixed payment of $250,000, plus per-beneficiary quarterly payments for the first two performance years of their agreement period. AIP is designed to reduce upfront costs that prevent providers/suppliers from forming ACOs, caring for beneficiaries in underserved communities, and achieving long-term success in the program.

We understand that there is strong interest in additional options to support cash flow for currently participating ACOs, and we continue to explore options to meet this need, including in response to the comments provided to this proposal and through the feedback received in response to the primary care capitation RFI that was included in the CY 2027 PFS proposed rule. At this time, we do not believe that modifications to the prepaid shared savings option would sufficiently address the barriers to participation while meeting our goals to provide direct beneficiary services, support ACO cash flow and maintain appropriate safeguards. We believe the separate mechanisms discussed previously in this section could be more attractive to ACOs and help support CMS' goals.

Eligible ACOs entering an agreement period beginning on January 1, 2027 can still apply for prepaid shared savings and, if approved, would receive quarterly prepaid shared savings payments through December 31, 2027, unless the payment is withheld or terminated under paragraph (h) of § 425.640.

After consideration of public comments, we are finalizing as proposed and decline to retain or redesign the prepaid shared savings option at this time. Specifically, we are amending § 425.640 to discontinue the prepaid shared savings option as follows:

Section 425.640(b) is revised to end ACO eligibility for prepaid shared savings beginning January 1, 2027. Section 425.640(b)(1)(i) is revised to read, the ACO is a renewing ACO as defined under § 425.20 entering an agreement period beginning on ''January 1, 2026 or January 1, 2027.''

Section 425.640(c)(1) is revised to read that for an ACO renewing to enter into an agreement period beginning on ''January 1, 2026 or January 1, 2027'', to obtain a determination regarding whether the ACO may receive prepaid shared savings, the ACO must submit a complete supplemental application with its application to renew for a new agreement period in the Shared Savings Program (submitted under § 425.224) in the form and manner and by a deadline specified by CMS.

Section 425.640(f)(1) is revised to no longer distribute prepaid shared savings to ACOs after December 31, 2027.

Specifically, section 425.640(f)(1)(i) is revised to state that an eligible ACO entering an agreement period beginning on January 1, 2026 or January 1, 2027 will receive quarterly prepaid shared savings payments through December 31, 2027, unless the payment is withheld or terminated under paragraph (h) of this section.

Section 425.640(f)(1)(ii) is similarly revised to state that an eligible ACO participating in an agreement period beginning on January 1, 2025 will receive quarterly prepaid shared savings payments starting with the performance year on January 1, 2026, through December 31, 2027, unless the payment is withheld or terminated under paragraph (h). The ACO will not receive additional or catch-up payments for performance year 2025.

7. Modify the Methodology and Use Description for Advance Investment Payments

(a) Background

In the CY 2023 PFS final rule (87 FR 69782 through 87 FR 69805), we finalized the availability of the advance investment payment option, beginning on January 1, 2024. Advance investment

payments are available to eligible low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives and that are new to the Shared Savings Program. These ACOs may receive an up-front, one-time fixed payment of $250,000 and per beneficiary quarterly payments for the first two performance years of their agreement period. Eligible ACOs that apply for and receive advance investment payments receive payments determined under the methodology described in § 425.630(f)(2). Furthermore, ACOs' use of advance investment payments is subject to the requirements set forth in § 425.630(e). ACOs are permitted to use the advance investment payments to invest in increased staffing, healthcare infrastructure, and the provision of accountable care for underserved beneficiaries. Advance investment payments are intended to reduce upfront costs that prevent providers and suppliers from forming ACOs, caring for beneficiaries in underserved communities, and achieving long-term success in the Shared Savings Program. For more information about the history and development of the advance investment payment option and goals for the program, refer to the CY 2023 PFS final rule (87 FR 69782 through 87 FR 69805).

(1) Area Deprivation Index

In the CY 2023 PFS final rule (87 FR 69792 through 69800), we finalized that the amount of advance investment payments that eligible ACOs can receive over the two years of quarterly payments was based on assigned beneficiaries' area deprivation index (ADI) score, Medicare Part D Low Income Subsidy (LIS) status, and dual eligibility for Medicare and Medicaid. The maximum amount was finalized as $45 per eligible beneficiary per quarter and there was a 10,000-beneficiary cap for the calculation of quarterly payments. LIS/dual eligibility grants an ACO the maximum $45 per eligible beneficiary, whereas ADI scores provide a range of payment amounts for beneficiaries without LIS/dual eligibility.

The quarterly advance investment payment calculation methodology finalized in the CY 2023 PFS final rule (87 FR 69792 through 69800) results in an increase in payments when more beneficiaries who are LIS/dually eligible or who live in areas with high deprivation (measured by ADI), or both, are assigned to the ACO. Regarding ADI, the risk factors-based score was set to the ADI national percentile rank of the census block group in which the beneficiary resides, and higher risk factors-based scores resulted in ACOs receiving higher payment amounts for assigned beneficiaries (87 FR 69794 and 69795). ADI scores range in payment amounts from $0 for those with a risk factors-based score between 1 and 24 to the maximum $45 for those with a risk factors-based score between 85 and 100 (§ 425.630(f)(2)(iii)). The quarterly payments intend to compensate for variable ongoing operating costs that are related to the provision of care for the ACO's assigned beneficiaries.

We stated in the CY 2023 PFS final rule (87 FR 69793 and 69794) that we believed using ADI was a method for indicating beneficiaries with high needs, specifically to capture local socioeconomic factors correlated with medical disparities and underservice. We stated that the inclusion of ADI as a criterion for quarterly advance investment payments furthered CMS's goal to reduce financial barriers for new, low revenue, and inexperienced ACOs. Since the option became available January 1, 2024, we have reviewed the characteristics of ACOs electing to participate in the advance investment payment option and how ADI as well as LIS/dual eligibility are impacting ACOs' quarterly advance investment payments.

(2) Advance Investment Payment Program Post-Implementation

In PY 2024, 19 newly formed ACOs in the Shared Savings Program were participating in the new advance investment payment option, receiving more than $25.7 million in advance investment payments in their first performance year.[372] Analysis of ACOs receiving advance investment payments shows that the payment option is encouraging ACOs to form in areas where ACOs may not have otherwise formed and where other Medicare payment and delivery innovations were less likely to be present. In its first year of implementation, the advance investment payment option appeared to attract new ACOs in these communities. Compared to non-advance investment payment ACO starters in 2024, the advance investment payment ACOs were caring for more beneficiaries residing in a health provider shortage area (51.2 percent versus 34 percent) and residing in a rural location (42.1 percent versus 27.0 percent).[373] Our analysis of the advance investment payments made in PYs 2025 and 2026 also investigated which beneficiary characteristics were impacting the quarterly payment amount received by ACOs receiving advance investment payments. This analysis showed that the average share of quarterly payments attributed to ADI beneficiaries, as opposed to LIS/dual eligible beneficiaries, fluctuated by 13 percentage points between PY 2025 and PY 2026.[374]

After publication of the CY 2023 PFS final rule for the advance investment payment option, we were made aware of concerns with the lack of standardization of ADI: Scores were heavily influenced by the median home value indicator, which is one out of the 17 indicators included in the calculation of ADI.[4] The 17 indicators are combined directly and, as such, the median home value indicator, which, because it is expressed in large dollar units and has large variance, impacts ADI scores more than other indicators, in particular, the percent-based indicators (for example, percent living in poverty). Cost-of-living when primarily captured by a region's median home value is incomplete and not perfectly aligned with area deprivation, as current research testing ADI indicates. For example, analyses have shown that many regions with high median home values were flagged as low deprivation based on their ADI scores, but these areas were experiencing deprivation when looking at other ADI variables such as poverty and unemployment rates.[375] [376] We do not believe it is appropriate to continue using an indicator that is not meeting its stated goals of identifying area deprivation, and propose to revise the advance investment payment methodology to simplify and refocus on the intended outcome of reducing upfront costs that prevent providers and suppliers from forming ACOs, caring for beneficiaries in underserved communities, and achieving long-term success in the Shared Savings Program.

[372] Counts based on internal analysis of ACOs participating in the Advance Investment Payment option in PY 2024.

[373] Counts based on internal analysis of ACOs participating in the Advance Investment Payment model in PY 2024.

[374] Counts based on internal analysis of ACOs participating in the Advance Investment Payment model in PYs 2025 and 2026.

[375] Edward L. Hannan, Yifeng Wu, Kimberly Cozzens, and Brett Anderson, Health Affairs 2023. Available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.01406.*

[376] Alexander M, Azar K, Smits K, Tio A, deGhetaldi L. Health Affairs Forefront. February 2023. ACO Benchmarks Based On Area Deprivation Index Mask Inequities. Available at *https://www.healthaffairs.org/content/forefront/aco-benchmarks-based-area-deprivation-index-mask-inequities.*

(b) Revisions

(1) Removal of the Area Deprivation Index From the Advance Investment Payment Methodology

We proposed to remove ADI from the advance investment payments methodology at § 425.630(f)(2). Our proposal to remove ADI from the quarterly payment amount methodology and remove the risk factors-based score (as described in section III.G.7.2.b) necessitates adjustments to § 425.630(f)(2)(ii) and is intended to better meet the objectives of the advance investment payment option policy.

(2) Addition of the Rural Criterion to the Advance Investment Payment Methodology

While we proposed to remove ADI, we wanted to continue to encourage low-revenue ACOs that are inexperienced with risk to participate in the Shared Savings Program, including rural ACOs as noted previously in the proposed rule. Rural ACOs are currently underrepresented in the Shared Savings Program, with only 14.5 percent of TINs participating in Shared Savings Program ACOs located in rural areas in comparison to 20 percent of non-Shared Savings Program TINs.[377] This analysis of FY 2024 assigned beneficiaries, provided in section III.G.7.1.b. of the proposed rule, highlights a smaller proportion of these beneficiaries live in rural communities. We proposed adding a rural component to the payment amount calculation for determining quarterly advance investment payments and believe this addition, in conjunction with the current components targeting beneficiaries enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid, will contribute to the advance investment payment option's goal of increasing ACOs' population health management capabilities, including the provision of accountable care for underserved beneficiaries, while simplifying the calculation (87 FR 69788). This also aligns with work CMS is carrying out through the Rural Health Transformation Program that was authorized by section 71401 of the Working Families Tax Cut legislation (Pub. L. 119–21, July 4, 2025).

Through the Rural Health Transformation Program, CMS is working to strengthen rural communities across America by improving healthcare access, quality, and outcomes by transforming healthcare delivery. Encouraging ACO formation in rural areas directly supports these goals.[378] Primary residence in rural areas can be associated with barriers to accessing care, including geographic isolation, provider shortages, transportation challenges, limited broadband or technology infrastructure, and fewer locally available healthcare resources. We had hoped to address some of these access-related challenges through the inclusion of ADI in the advance investment payments methodology. However, rural residence captures a distinct set of geographic and infrastructure-related barriers.

Our internal analysis of ACO beneficiaries indicates there is limited overlap between LIS/dual eligibility and beneficiaries living in a rural area. As a result, adding a rural residence component would allow the methodology to better identify and direct the maximum quarterly payment amount to additional underserved beneficiaries who may face access-related barriers that are not otherwise captured by LIS/dual eligibility status.

As noted, we believe rurality is an appropriate geographic proxy for access-related challenges, including differences in healthcare infrastructure and workforce availability. These factors may affect an ACO's ability to form, participate, and succeed in rural areas and therefore ACOs may need a higher amount of advance investment payments to consider participating. We sought to encourage formation of ACOs in areas experiencing medical disparities and underservice and have recognized through internal analysis of assigned beneficiary characteristics that the LIS/dual eligibility statuses do not fully capture rural beneficiaries. Therefore, we proposed introducing a rural component to the advance investment payments methodology.

To calculate the advance investment payment for an eligible ACO based on the number of their rural assigned beneficiaries, we proposed establishing a beneficiary's rural residence from their latest mailing address in the CMS data systems at the time of determining advance investment payments. Furthermore, we proposed using the most recently available version of the United States Census Bureau Delineation File to determine whether a beneficiary resides in a rural county.[379] The Office of Management and Budget (OMB) makes the delineation file publicly available on the *Census.gov* website. OMB provides the delineation file and other reference files as a reliable standard for academic research and public policy development. The delineation file defines an area as micropolitan or metropolitan as having a population of 10,000 to 50,000 individuals or a population greater than 50,000 individuals, respectively. Areas where the population is less than 10,000 are considered noncore. Noncore areas are defined by identifying Federal Information Processing Standards State and County codes that are not included in the delineation file. OMB does not characterize counties as rural or urban, and we proposed to use the Federal Office of Rural Health Policy (FORHP), in the Health Resources and Services Administration, interpretation of these county designations, which considers all non-metro counties as rural.[380] We proposed that beneficiaries will be considered to be residing in a rural county for the purposes of the advance investment quarterly payment calculation, if they are non-metro, that is residing in a micropolitan or noncore area. As of July 2023, 13.8 percent of the U.S. population is living in the micropolitan or noncore areas.[381]

For the purpose of implementing changes to the advance investment payments, the use of county level data would allow for timelier implementation and sharing of data with ACOs since the delineation file is readily available and already used by CMS for internal analyses of ACOs by region. Counties are also well understood by healthcare providers and stable over time, which reduces complexity and burden for ACOs working to understand the methodology. We believe that this rural definition, in combination with the maximum payments based on beneficiary LIS/dual eligibility status, will support ACOs in caring for beneficiaries in underserved communities.

(3) Amount for All Beneficiaries to the Advance Investment Payment Methodology

We intended for these changes to the advance investment payments methodology to encourage the formation of new ACOs in underserved

[377] Counts based on internal analysis of ACOs participating in the Shared Savings Program in PY 2026.

[378] CMS Rural Health Transformation (RHT) Program. 2026 Available at *https://www.cms.gov/priorities/rural-health-transformation-rht-program/overview.*

[379] Refer *to https://www.census.gov/geographies/reference-files/time-series/demo/metro-micro/delineation-files.html.*

[380] Health Resources and Services Administration. How we Define Rural. Available at *https://www.hrsa.gov/rural-health/about-us/what-is-rural.*

[381] US Census Bureau. Metropolitan and Micropolitan. Available at *https://www.census.gov/programs-surveys/metro-micro.html.*

communities and described the proposed rural criteria for determining advance investment payments. However, as we stated in the CY 2023 PFS final rule (87 FR 69785), we do not believe in limiting advance investment payment option eligibility only to ACOs serving rural areas or areas with a high proportion of beneficiaries dually eligible for Medicaid and Medicare or Part D LIS is in line with the policy's goals. We recognize that there are beneficiaries who reside in other areas who could also benefit from the high-quality coordinated care an ACO provides. With the removal of ADI and its tiered scoring structure using risk factors-based scores, we proposed an alternative payment methodology that also accounts for non-rural beneficiaries who are not LIS/dually eligible and whose assignment may have resulted in some payment under the current advance investment payments methodology. Our experience implementing the advance investment payment option over the last few years leads us to believe ACO participation in the payment option could be more attractive with the addition of a lower flat payment amount for all beneficiaries assigned to the ACO, up to the 10,000-beneficiary cap. Therefore, we proposed that all non-rural beneficiaries who are not LIS/dually eligible beneficiaries would result in ACOs receiving a flat rate of $25 per beneficiary as part of setting each ACO's quarterly payments.

We anticipate that the change to remove ADI and add rurality as well as a payment amount for all beneficiaries not identified as LIS/dual eligible or rural will provide similar aggregate quarterly payment amounts to new advance investment payment option participants and, in keeping in line with the intent of the advance investment payment option, any new methodology developed should encourage ACOs serving populations that need financial support to begin participation in value-based care. We conducted an analysis that compared the quarterly advance investment payments for PY 2024 using the existing methodology utilizing ADI and the proposed methodology using a rural component. Results indicated that, compared to the current methodology, the proposed methodology will provide the vast majority (89.5 percent) of advance investment payment ACOs with slightly higher payments (totaling about $889,000 more per quarter or $3.6 million more per year distributed among all ACOs), which align with payment goals outlined previously in this section.[382] While we believe these proposed policy adjustments will increase support for ACO formation in rural areas, this analysis demonstrates that our proposed policies maintain support for ACOs regardless of location.

Section 1899(i)(3)(A) of the Act requires CMS to determine that advance investment payments would improve the quality and efficiency of items and services furnished to Medicare to make such payments. We believe that the updated methodology will meet this standard and improve our ability to target the populations that CMS seeks to support. Section 1899(i)(3)(B) of the Act requires CMS to determine that advance investment payments, when implemented in combination with existing modifications made to the Shared Savings Program specified in section 1899(d) of the Act, will not result in additional program expenditures. In evaluation of current program performance, the structure of advance investment payment program is successful in not increasing program expenditures, and the changes to the methodology will not affect this outcome as the overarching structure the advance investment payment option remains the same. In accordance with section 1899(i)(3) of the Act authorizing the use of alternative payment models, we proposed to update the steps at § 425.630(f)(2) to allow ACOs participating in the advance investment payment option will receive a maximum payment of $45 if the assigned beneficiary is enrolled in the Medicare Part D LIS or is dually eligible for Medicare and Medicaid or is residing in a Micropolitan or ''Noncore'' Census Status (henceforth ''rural''). Additionally, for beneficiaries outside of these categories, ACOs will receive a flat rate of $25 per beneficiary as part of setting each ACO's quarterly payments.

(4) Implementation Timeline for Revisions to the Advance Investment Payments Methodology

We proposed that changes to remove ADI and to add rurality to the quarterly payment methodology would be implemented for ACOs who apply for the advance investment payment option with an effective date of January 1, 2028, as well as for the second year of payments for ACOs who began receiving advance investment payments in 2027. This timeline allows ACOs planning to apply to the Shared Savings Program to understand the proposed methodology for the advance investment payment option prior to applying to the program in the summer of 2027.We believed that as the vast majority of the ACOs will receive slightly higher payments under the new methodology, it is a more efficient use of agency resources to move to using the updated methodology for all ACOs at the same time, instead of running two separate methodologies simultaneously.

We sought public comment on the proposed timeline for implementing changes to the advance investment payments methodology effective January 1, 2028. Specifically, we sought public comment on the following proposed revisions to the regulation text at § 425.630:

- At paragraph (f)(2)(ii) add the introductory phrase ''For performance years 2023 through 2027.''
- At paragraph (f)(2)(iii), we proposed to specify how CMS determines the amount each assigned beneficiary adds to an ACOs quarterly payment amount. At new paragraph (f)(2)(iii)(A), we describe the existing requirements on how we determine the payment amount that corresponds to the beneficiary's risk factors-based score, and related table, which we proposed to specify would be applicable for PYs 2023 through 2027. In new paragraph (f)(2)(iii)(B), we proposed to specify how we would determine the quarterly payment amount for PY 2028 and subsequent PYs. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS determines the quarterly payment amount for two categories of beneficiaries. First, an ACO will receive a quarterly payment of $45 for each beneficiary that meets any of the following criteria:
  - Is enrolled in the LIS.
  - Is dually eligible for Medicare and Medicaid.
  - Is residing in a county with rural census status (as defined at § 425.20). CMS determines the county of residence for the beneficiary based on the beneficiary's mailing address.

  Then, an ACO will receive a quarterly payment of $25 for each beneficiary who does not meet any of the criteria listed in paragraph (f)(2)(iii)(B)(1) of this section.
- At paragraph (f)(2)(iv), we proposed to specify how CMS calculates an ACO's quarterly payment amount. In new paragraph (f)(2)(iv)(A), we describe the existing process that the quarterly payment amount is the sum of the beneficiary payment amounts corresponding to each assigned beneficiary's risk factors-based score, capped at 10,000 beneficiaries, which we proposed to specify would be

[382] Based on internal analysis of ACOs participating in the Advance Investment Payment model in PY 2024.

applicable for PYs 2023 through 2027. In new paragraph (f)(2)(iv)(B), we proposed a new methodology for PY 2028 and subsequent PYs. We proposed that the ACO's quarterly payment amount will be the sum of the beneficiary payment amounts corresponding to the quarterly payments specified in paragraph (f)(2)(iii)(B) of this section. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, we will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest quarterly payment determined according to paragraph (f)(2)(iii)(B) of this section.

We also sought public comment on the proposed revisions to the regulation text at § 425.20:

Add new definition for the term ''Rural County Status'' to mean beneficiary residence in a mailing address with United States county status of Micropolitan (population of 10,000 to 50,000 individuals) or Noncore (population less than 10,000 individuals) per the Federal Office of Rural Health Policy (FORHP) county designation using the most recently available version of the United States Census Bureau Delineation File.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed policy to modify the advance investment payment methodology. Commenters believed it would support the development of new ACOs including those with rural, medically underserved or socioeconomically disadvantaged beneficiaries and would be simpler for ACOs to understand.

Response: We appreciate the supportive comments and agree that this change will simplify the policy and improve understanding while continuing to support ACOs.

Comment: Several commenters supported the addition of the rurality measure but disagreed with the removal of ADI without an alternative to preserve some recognition of area-level social or economic deprivation in the methodology. Commenters suggested additional metrics for the AIP quarterly payment calculation, including ones that account for socioeconomic or access-related barriers, including in suburban or urban areas, or other measures of beneficiary vulnerability. A commenter suggested adding a fourth criterion tied to food insecurity or nutrition risk directly. Commenters also suggested that CMS consider other targeted participation incentives to support entry into value-based care arrangements for healthcare providers that face significant barriers to participation.

Response: We appreciate comments that stated an interest in ensuring vulnerable or underserved beneficiaries have support from an ACO. We believe that this updated policy will be sufficient to support ACO formation in a variety of underserved areas and balances providing ACOs with a simpler and easier to understand methodology to calculate AIP payments. As described previously in this section, we proposed to replace the complex, tiered ADI payment scale with a straightforward two-tiered structure that provides a flat $25 quarterly payment for each beneficiary not identified as LIS, dually eligible, or rural dwelling. By providing a quarterly payment amount for all beneficiaries, capped at 10,000 assigned beneficiaries, the updated policy provides ACOs with payments for assigned beneficiaries across a range of socioeconomic circumstances while minimizing methodological complexity. We will continue to evaluate the effectiveness of advance investment payment policy and determine if future adjustments are necessary.

Comment: Several commenters recommended ongoing monitoring of the impact of advance investment payments, including monitoring the impact of the revised methodology on rural healthcare provider participation, evaluating whether it effectively reaches healthcare providers in rural and low resourced areas, reaches the same population as ADI, and revisiting the methodology if gaps are revealed.

Response: We appreciate the recommendations to evaluate the impact of advance investment payments and we intend to continue monitoring the impact of advance investment payment policy to ensure it is meeting CMS goals of supporting ACO formation and growing participation in the Shared Savings Program.

Comment: A commenter requested that CMS ask ACOs receiving advance investment payments to describe publicly how those resources are used.

Response: We appreciate the request for transparency. ACOs receiving advance investment payments are required to publicly report their use of the funding each year. CMS makes this data available at *https://data.cms.gov/medicare-shared-savings-program/advance-investment-payment-spend-plan.*

Comment: Several commenters had suggestions for other changes to the Advance Investment Payment policy, including requests to allow ACOs to keep a portion of shared savings prior to repaying AIP, or allowing high-revenue ACOs to be eligible for AIP.

Response: While we believe these suggestions are out of scope for this proposal, we continue to review AIP policy to ensure it is meeting CMS goals, and we appreciate the feedback.

After consideration of public comments, we are finalizing this policy as proposed. Specifically, we are finalizing under § 425.630(f)(2)(iii)(B) that for PY 2028 and subsequent PYs, CMS will determine the quarterly payment amount as follows:

(1) an ACO will receive a quarterly payment of $45 for each beneficiary that meets any of the following criteria:

(i) Is enrolled in the LIS.

(ii) Is dually eligible for Medicare and Medicaid.

(iii) Is residing in a county with rural census status (as defined at § 425.20). CMS determines the county of residence for the beneficiary based on the beneficiary's mailing address.

(2) an ACO will receive a quarterly payment of $25 for each beneficiary who does not meet any of the criteria listed in paragraph (f)(2)(iii)(B)(1) of this section.

Under section 425.630(f)(2)(iv)(A), for PYs 2023 through 2027, the ACO's quarterly payment amount is the sum of the beneficiary payment amounts corresponding to each assigned beneficiary's risk factors-based score, specified in paragraph (f)(2)(iii)(A) § 425.630, capped at 10,000 beneficiaries. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, CMS will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores determined according to paragraph (f)(2)(ii).

In new paragraph (f)(2)(iv)(B), for PY 2028 and subsequent PYs, the ACO's quarterly payment amount is the sum of the beneficiary payment amounts corresponding to the quarterly payments specified in paragraph (f)(2)(iii)(B) of this section. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, CMS will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest quarterly payment determined according to paragraph (f)(2)(iii)(B) of this section.

We are also finalizing revisions to the regulation text at § 425.20 to add new definition for the term ''Rural County Status'' to mean beneficiary residence in a mailing address with United States county status of Micropolitan (population of 10,000 to 50,000

individuals) or Noncore (population less than 10,000 individuals) per the Federal Office of Rural Health Policy (FORHP) county designation using the most recently available version of the United States Census Bureau Delineation File.

(5) Revisions to the Terminology of Allowable Uses

At § 425.630(e)(1), we state that an ACO must use an advance investment payment to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, healthcare infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health. We believe that the term ''social determinants of health'' is not as precise as we would prefer, and propose to replace the term with ''upstream drivers of health.'' Specifically, while the terms are similar in describing non-medical factors that can shape beneficiaries' health, ''upstream drivers of health'' more clearly describes the focus on the upstream or root causes of health outcomes. This framing does not change the types of investments that advance investment payments can be spent on, but instead more clearly identifies these investments, which include, but are not limited to, transportation, utilities and housing-related assistance, as well as services to encourage improved fitness and nutrition and promote a healthy environment. Specifically, we proposed to revise § 425.630(e)(1) to read: ''Allowable uses. An ACO must use an advance investment payment to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, healthcare infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing upstream drivers of health. Expenditures of advance investment payments must comply with the beneficiary incentive provision at § 425.304, paragraph (e)(2) of this section, and all other applicable laws and regulations.'' We sought comments on this proposal.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported this proposal and thought the revised AIP terminology was clearer and would make it easier for ACOs to use AIP funding:

Response: We appreciate the comments in support of the proposal and agree that the new term should be clearer for ACOs.

Comment: A commenter disagreed with the change and believes the original term ''social determinants of health'' was clearer for ACOs. They requested more guidance on the use of AIP funds related to this change.

Response: We appreciate the concern raised by the comment and intend to update the subregulatory guidance related to the use of AIP to ensure ACOs understand appropriate uses for the funding. The permitted uses of AIP funding are not changing because of this change in terms.

After consideration of public comments, we are finalizing this policy as proposed. Specifically, we are revising § 425.630(e)(1) to read: ''Allowable uses. An ACO must use an advance investment payment to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, healthcare infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing upstream drivers of health. Expenditures of advance investment payments must comply with the beneficiary incentive provision at § 425.304, paragraph (e)(2) of this section, and all other applicable laws and regulations.''

8. Identifying ACOs Experienced With Performance-Based Risk Medicare ACO Initiatives

a. Background

In the December 31, 2018 Shared Savings Program final rule (83 FR 67816), referred to as the Pathways to Success, CMS finalized the definition of the term, ''performance-based risk Medicare ACO initiative,'' to mean an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period (83 FR 67904). This includes Levels C, D, and E of the BASIC track, and the ENHANCED track of the Shared Savings Program. This definition also includes other Medicare ACO initiatives involving two-sided risk, such as two-sided risk CMS Innovation Center ACO Models, as may be specified by CMS (83 FR 67904).

In the December 2018 final rule, we explained that the risk experience of ACOs and their ACO participants in Medicare ACO initiatives is considered in determining which agreement track (BASIC or ENHANCED) the ACO is eligible to enter as well as the applicability of policies that phase in over time, namely the equal weighting of benchmark year expenditures, the policy of adjusting the benchmark based on regional FFS expenditures, and the phase-in of pay-for-performance under the program's quality performance standards (83 FR 67904–67907). As a factor in determining an ACO's participation options, we established requirements for evaluating whether an ACO is inexperienced with performance-based risk Medicare ACO initiatives such that the ACO would be eligible to enter into an agreement period under the BASIC track's glide path or whether the ACO is experienced with performance-based risk Medicare ACO initiatives and therefore limited to participating under the higher-risk tracks of the Shared Savings Program (either an agreement period under the maximum level of risk and potential reward for Level E of the BASIC track or the ENHANCED track) (83 FR 67894).

In the CY 2024 PFS final rule, published on November 16, 2023, we clarified our approach to identifying ACOs experienced with risk based on an ACO Participant TIN's prior participation by adding the following language to the definitions of ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' under § 425.20 (88 FR 79219 through 79220; 79543 through 79544), ''an ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.'' This was not a policy change, but an attempt to more clearly communicate ongoing operational policy.

Accordingly, as codified under § 425.20, we defined ''experienced with performance-based risk Medicare ACO initiatives'' to mean an ACO that CMS determines meets either of the following criteria:

(1) The ACO is the same legal entity as a current or previous ACO that is participating in, or has participated in, a performance-based risk Medicare ACO initiative as defined under this section, or that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-

based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

We defined ''inexperienced with performance-based risk Medicare ACO initiatives'' to mean an ACO that CMS determines meets both of the following criteria:

(1) The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined under this section, and has not deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

The established definitions of ''experienced with performance-based risk initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' were intended to support both determinations of participation options and the phase-in of requirements over time by considering ACOs' prior participation in the program (83 FR 67906).

Under § 425.20, the second prong of the ''experienced with performance-based risk initiatives'' definition relies on whether 40 percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative in any of the 5 most recent performance years. For this purpose, an ACO participant is treated as having participated when the ACO participant TIN ''was or will be included in financial reconciliation'' for one or more performance years under a qualifying two-sided initiative during the 5-year lookback. This means the ''experience'' determination is sensitive to the ACO's participant composition at the TIN level. If an ACO's participant list includes a substantial number of TINs that were recently reconciled under two-sided risk (for example, under a prior ENHANCED track or another qualifying CMS initiative), those TINs count toward the 40 percent threshold. Conversely, if an ACO's participant TINs lack such recent two-sided reconciliation history, the ACO may be treated as inexperienced for purposes of participation options.

Consistent with our TIN-based approach to evaluating prior participation, these policies rely on the financial reconciliation history associated with specific billing TINs. These policies were intended to capture TINs that at least partially participated in a performance-based risk initiative, as TINs that participate in a full or partial year are generally still included in financial reconciliation. However, we identified a category of TINs that are included in financial reconciliation for performance based-risk initiatives, but that do not have a written agreement to participate in the performance-based risk ACO initiative and thus are ineligible for the benefits of being in an ACO (such as shared savings). In ACO REACH, and other CMS Innovation Center ACO Models, a ''Legacy TIN or CCN'' means a TIN or CCN that a Participant Provider or Preferred Provider previously used for billing Medicare Parts A and B services but no longer uses to bill for those services, and includes a ''sunsetted'' Legacy TIN or CCN (a TIN or CCN that is no longer used for billing for Medicare Parts A and B services by any Medicare-enrolled provider or supplier) or an ''active'' Legacy TIN or CCN (a TIN or CCN that may be in use by a Medicare-enrolled provider or supplier that is not a Participant Provider or Preferred Provider).[383] The purpose of Legacy TINs or CCNs is to allow a provider/supplier who used to practice under an old TIN, but has begun practicing under a new TIN, to use the historical claims information to help establish an ACO's benchmark. Legacy TINs or CCNs are not considered to be ''Participant Providers'' in ACO REACH, as they do not have a written agreement to participate in the performance-based risk ACO initiative.[384] These TINs or CCNs do not receive any benefits of ACO participation, including ACO financial arrangements or use of model waivers and are not required to comply with ACO policies. Their claims history is solely used for financial reconciliation for the ACO.

However, given the current definitions of ''Experienced with performance-based risk Medicare ACO initiatives'' and ''Inexperienced with performance-based risk Medicare ACO initiatives,'' Legacy TINs or CCNs are currently included in the calculation of whether 40 percent of ACO participants have prior experience with a performance-based risk Medicare ACO initiative, as they are included in financial reconciliation for the ACO REACH model ACO. The current or prior presence of a Legacy TIN or CCN on an ACO REACH model ACO's Participant Provider List can determine whether an ACO applying to the Shared Savings Program is eligible for entry into the BASIC track glide path or is instead limited to BASIC track Level E (if low revenue) or the ENHANCED track. CMS did not anticipate the interaction between the use of Legacy TINs in CMS Innovation Center ACO models and the definitions of experienced and inexperienced with performance-based Medicare ACO initiatives when these policies were developed. We identified this interaction when it impacted a few ACOs applying to the Shared Savings Program in recent years, limiting the participation options available to the ACOs.

We believe that the inclusion of Legacy TINs and CCNs in the definitions of experienced or inexperienced with performance-based risk is overly broad and not in line with the original goals of the definition, and we proposed to amend the current regulation to exclude such TINs and CCNs from the calculation.

b. Revisions

Under the existing regulations codified in the December 2018 final rule, the definition of an ACO experienced or inexperienced with performance-based risk Medicare ACO initiatives includes consideration of ACO participant TINs in determining whether an ACO has prior experience under performance-based risk. Specifically, an ACO participant TIN is considered to have such experience if it was or will be included in the financial reconciliation of a Medicare ACO for any of the 5 most recent performance years under a qualifying two-sided model (83 FR 67895). For purposes of this determination, an ACO participant is treated as having participated in a performance-based risk initiative when its TIN was or will be included in financial reconciliation for one or more performance years during the applicable 5-year lookback period (83 FR 67895; § 425.20). As a result, the determination of whether an ACO is experienced or inexperienced with performance-based

[383] *ACO REACH Model Third Amended and Restated Participation Agreement.* Refer to page 12 under Article II Definitions for the definition of ''Legacy TIN or CCN''.

[384] *ACO REACH Model PY 2026 Participant and Preferred Provider Management Guide: https://www.cms.gov/files/document/aco-reach-py26-part-pref-provider-mgmt-guide.pdf.*

risk can depend on the composition of the ACO participant list at the TIN level.

To ensure TINs that have only been used as Legacy TINs or CCNs in CMS Innovation Center models would not be considered as experienced with risk, we proposed to exclude ACO participant TINs that did not have a written agreement to participate in a performance-based risk Medicare ACO initiative from our consideration of whether the ACO participant TIN participated in a performance-based risk Medicare ACO initiative. This consideration ultimately impacts an ACO's designation as experienced or inexperienced with performance-based risk within the Shared Savings Program. Because determining an ACO's experience with performance-based risk is based on the experience of the ACO participant TIN, we proposed to modify the regulations at § 425.20 to exclude Legacy TINs or CCNs from the definition of ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives.'' As future CMS Innovation Center models may not use the term ''Legacy TIN or CCN'' to identify these TINs or CCNs, we proposed to exclude these and similarly situated ACO participant TINs and CCNs by excluding those that did not have a written agreement to participate with the performance-based risk Medicare ACO.

We proposed revising the definition of experienced with performance-based risk Medicare ACO initiatives under § 425.20 by adding to paragraph (2), '', unless the ACO participant TIN did not have a written agreement to participate in the performance-based risk Medicare ACO initiative.'' Similarly, we proposed revising the definition of inexperienced with performance-based risk Medicare ACO initiatives under § 425.20 by adding to paragraph (2), '', unless the ACO participant TIN did not have a written agreement to participate in the performance-based risk Medicare ACO initiative.''

These proposed additions would permit CMS to exclude Legacy TINs or CCNs that did not have a written agreement to participate in the performance-based risk Medicare ACO initiative from this calculation.

We proposed that these modifications would be effective and applicable on January 1, 2027.

We sought comment on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: All commenters supported these proposals, noting that the proposed changes would provide a more accurate way of determining which participants were experienced or inexperienced with performance-based risk.

Response: We appreciate the supportive comments and agree that this policy will improve the accuracy of determining which ACOs should be considered to be experienced or inexperienced with performance-based risk.

After consideration of public comments, we are finalizing our proposals without modification beginning January 1, 2027. Specifically, we are revising the definition of experienced with performance-based risk Medicare ACO initiatives under § 425.20 by adding to paragraph (2), '', unless the ACO participant TIN did not have a written agreement to participate in the performance-based risk Medicare ACO initiative.'' Similarly, we are revising the definition of inexperienced with performance-based risk Medicare ACO initiatives under § 425.20 by adding to paragraph (2), '', unless the ACO participant TIN did not have a written agreement to participate in the performance-based risk Medicare ACO initiative.''

Considering when this final rule will be issued, and the Shared Savings Program application cycle for the January 1, 2027 start date (occurring in CY 2026), ACO applicants will have notice of this change after the deadline for submitting their applications to participate in the Shared Savings Program. Additionally, under a previously established timeline for application actions and deadlines, the application cycle required CMS to deem an applicant ACO experienced with performance-based risk in October 2026,[385] which is before this CY 2027 PFS final rule is issued.

We are committed to accurately identifying ACOs' experience with performance-based risk consistent with the policy finalized in this rule, and recognize that we are currently in an ACO application cycle for a January 1, 2027 start date. Accordingly, to mitigate the potential impact of this finalized policy on ACO applicants, following issuance of the CY 2027 PFS final rule, we will communicate to ACO applicants their status as an ACO experienced or inexperienced with performance-based risk in accordance with the policy finalized in this rule and provide them with the opportunity to change their track/level of participation based on that determination. We believe it is appropriate to accommodate this modification during the application cycle for the January 1, 2027 start date (occurring in CY 2026) to apply the most accurate definition for determining experience with performance-based risk.

9. Beneficiary Notification Requirements

a. Background

The November 2011 final rule established requirements at § 425.312 for how a Shared Savings Program ACO must notify Medicare FFS beneficiaries receiving primary care services at the point of care that the physician, hospital, or other provider/supplier is participating in a Shared Savings Program ACO (76 FR 67945 through 67946). Since then, the regulations at § 425.312 have been updated through subsequent rulemaking. Presently, under § 425.312(a)(1), an ACO is required to ensure that Medicare FFS beneficiaries are notified of the following: (i) each ACO participant and its ACO providers/suppliers are participating in the Shared Savings Program; (ii) the beneficiary's opportunity to decline claims data sharing; and (iii) the ability to, and process by which, the beneficiary may identify or change identification of a primary care provider for purposes of voluntary alignment.[386]

Section 425.312(a)(2) sets forth the manners in which ACOs or ACO participants are required to notify beneficiaries of this information. ACO participants must post signs in their facilities and, in settings in which beneficiaries receive primary care services, make standardized written notices available upon request (§ 425.312(a)(2)(i) and (ii)). In addition, ACOs must furnish standardized written notices to certain beneficiaries, with timing depending on the ACO's assignment methodology. For ACOs that have selected preliminary prospective assignment with retrospective reconciliation, the ACO or ACO participant must provide each FFS beneficiary who received at least one primary care service from certain ACO professionals in the ACO during the assignment window (or expanded window) with a standardized written

[385] Medicare Shared Savings Program, Key Application Actions and Deadlines For Agreement Periods Beginning on January 1, 2027, available at *https://www.cms.gov/files/document/key-application-actions-deadlines.pdf.*

[386] *See generally* Shared Savings Program Guidance & Specifications, Beneficiary Information section, *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations#Beneficiary_Information.*

notice at least once per agreement period. The ACO or ACO participant must provide this notice prior to or at the first primary care visit of the performance year (§ 425.312(a)(2)(iii)). For ACOs that have selected prospective assignment, the ACO or ACO participant must provide the standardized written notice to each prospectively assigned beneficiary at least once per agreement period, during the performance year for which the beneficiary is prospectively assigned to the ACO (§ 425.312(a)(2)(iv)). Additionally, in the CY 2023 PFS final rule (87 FR 69404), we finalized that the ACO or ACO participant must provide a verbal or written follow-up communication to the beneficiary no later than 180 days from the date the standardized written notice was provided and maintain record of such notice (§ 425.312(a)(2)(v)).

Over the years, the Shared Savings Program has received ongoing feedback that these beneficiary communication requirements can be operationally burdensome and may confuse beneficiaries, including causing some beneficiaries to believe they are being targeted by a fraudulent actor or have been enrolled in a managed care plan,[387] which ACOs then must work to address. Interested parties have identified that the beneficiary notice requirements implemented in some CMS Innovation Center models may be less burdensome for ACOs to implement. For example, under the ACO REACH model, ACOs must distribute beneficiary information notices by CMS-specified dates, including for beneficiaries aligned to the ACO at the start of the performance year and for beneficiaries who become aligned during the performance year.[388] Specifically, ACOs that participate in the ACO REACH model are required to distribute a beneficiary information notice by May 30 for beneficiaries who start the year aligned to the ACO and remain aligned by April 1.[389] By contrast, under the Shared Savings Program, ACOs that have selected preliminary prospective assignment with retrospective reconciliation must provide the beneficiary information notice either at or before a beneficiary's first primary care visit. Additionally, while ACOs that have selected prospective assignment are required to provide the standardized written notice in the form and manner set by CMS, we have historically required them to align with the same timing of at or before the beneficiary's first primary care visit.

We believe that fixed deadlines allow ACOs to better prepare for the distribution of the beneficiary notice, as they will have several months after the start of the year to organize their staff and resources, whereas the Shared Savings Program requirement tied to a beneficiary's first primary care visit, which could occur as early as the very beginning of the performance year, requires the ACO to be prepared to distribute the notice immediately at the start of the performance year.

b. Revisions

(1) Distribution Timing of Standardized Written Notices

We continue to believe that requiring ACOs to provide periodic beneficiary notifications affords ACOs and ACO participants an opportunity for direct engagement with beneficiaries, thereby serving to strengthen the beneficiary's relationship with the ACO and ACO participants from whom the beneficiary may receive care. The requirement to provide beneficiary notifications promotes transparency about ACO participants and their ACO providers/suppliers participating in the Shared Savings Program and educates beneficiaries on how ACO participation could improve their care experience.

At the same time, distributing these notices to beneficiaries imposes operational burden on ACOs and ACO participants. ACOs must accurately identify beneficiaries who require notification, operationalize workflows to distribute the notifications, and prepare for beneficiary questions and concerns.

We recognize that current operational timeframes can further contribute to implementation challenges. Operationally, CMS generally makes available the first beneficiary assignment list report for each PY in the month of December. We recognize this can be a very tight turnaround for ACOs to prepare beneficiary outreach processes for beneficiaries who begin receiving primary care services in the following month.

We recognize that ACOs have developed processes, workflows, or materials to meet the requirement for the timing for distributing the beneficiary notice by a deadline individualized by each beneficiary's first primary care visit. We proposed that ACOs would no longer be required to maintain those processes solely for purposes of complying with this requirement, which we believe will reduce ongoing administrative burden and expense. Nothing in this policy prohibits an ACO from continuing similar activities that it determines are beneficial, such as other beneficiary communications and marketing efforts, provided those activities comply with all otherwise applicable program requirements. We continue seeking policies that balance the benefits of beneficiary education and engagement with the burden placed on ACOs to maximize Shared Savings Program ACO participation and therefore the broad availability of ACOs and the benefits they can offer for beneficiaries. In the interest of an overall reduction in administrative burden, we proposed to modify § 425.312(a)(2)(iii) and § 425.312(a)(2)(iv) with the following changes.

First, we proposed to revise the requirement at § 425.312(a)(2)(iii) that ''[t]he standardized written notice must be furnished to all of these beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.'' We proposed that the revised language would read, ''The standardized written notice must be furnished to all of these beneficiaries by May 30, unless CMS specifies a later date during the performance year.'' We also proposed a similar change to § 425.312(a)(2)(iv) to add a new sentence to that paragraph which states, ''The standardized written notice must be furnished to all of these beneficiaries by May 30, unless CMS specifies a later date during the performance year.'' These deadlines align with those used in the ACO REACH model. Beneficiaries must still receive the notice, but we believe this would allow ACOs to better prepare to distribute the notices and better prepare to answer the subsequent beneficiary questions they typically receive. We also believe that better aligning with CMS Innovation Center policies in this area would reduce burden for ACOs that compare policies across programs and models to determine the best fit for their organization. We do not believe this revised timing requirement impacts beneficiary engagement with the ACO or ACO participant. Beneficiaries would still receive the notification, and the

[387] Reimagining Beneficiary Engagement in Accountable Care Models, A Resource Published by HCTTF and NAACOS. *https://hcttf.org/wp-content/uploads/2026/03/HCTTF-NAACOS-2026-Resource-1.pdf.*

[388] ACO REACH Model Third Amended and Restated Participation Agreement (2023 Starters), Section 5.05 Beneficiary Notifications, Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation, Last Modified: December 5, 2025.

[389] ACO REACH Model PY2025 Beneficiary Notification Process p. 2, Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation.

ACO participants will have posted signs displayed in their facilities designed to alert beneficiaries to their practitioner's participation in an ACO (§ 425.312(a)(2)(i)) and allow the beneficiaries the opportunity to engage with the practitioner further. We remind interested parties that, irrespective of the policies finalized in this final rule, ACOs will continue to be permitted to communicate more frequently or thoroughly with beneficiaries if they wish to do so, as long as they comply with the marketing requirements detailed at § 425.310(a). This includes sharing supplemental ACO marketing materials alongside the beneficiary notification.

We proposed that the change would have an effective date of January 1, 2027 and stated that we anticipated this approach would reduce the net burden to ACOs and ACO participants of providing the beneficiary notification.

We sought comments on these proposals.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed broad support or general support with additional recommendations for the proposal to change the timeline for providing the standardized written notice to require that the notice be issued by May 30 during the performance year and believe it would increase flexibility and reduce burden for participating ACOs. A few commenters requested that CMS provide the final standardized written notice and related guidance with sufficient lead time for ACOs to prepare for PY 2027.

Response: We appreciate the comments in support of the proposed revisions to § 425.312(a)(2)(iii) and (iv) and agree that the changes will increase flexibility and reduce burden for ACOs. We intend to make the final standardized written notice and related guidance available with sufficient lead time for ACOs to prepare for PY 2027.

Comment: A few commenters opposed the proposed revision to change the timeline for providing the standardized written notice to require that the notice be issued by May 30 during the performance year, noting that they believed beneficiaries should have more timely notification of a healthcare provider's ACO affiliation so that beneficiaries may decline to share their claims data or choose a new healthcare provider.

Response: We agree with the commenters that timely notification of a healthcare professional's or practice's ACO affiliation is essential for beneficiaries to make informed decisions. This policy establishes a fixed deadline of May 30 of each performance year by which beneficiaries must be notified of their healthcare provider's affiliation with an ACO, which gives ACOs the predictability to plan to send beneficiary notifications. It does not necessarily mean that the beneficiary notification would be delayed compared to the current policy, which was based on a beneficiary's first primary care visit, which could happen after the May 30 deadline. We acknowledge that, for beneficiaries whose first primary care visit occurs before May 30, the revised deadline could result in those beneficiaries receiving the notice later than under the current policy. However, we do not expect this change to meaningfully diminish beneficiaries' opportunities to learn about their healthcare provider's participation in an ACO, as beneficiaries will continue to have access to information through other mechanisms, including required signage at ACO participant's healthcare facilities (§ 425.312(a)(2)(i)), which is especially valuable for beneficiaries who have not yet received the notification. We are also considering additional ways to improve beneficiaries' general understanding about ACOs and anticipate making additional beneficiary educational resources available soon through its website. Additionally, we have shared with ACOs an updated Beneficiary Notification and Education Guidance document [390] that more clearly communicates the requirements concerning ACO marketing to beneficiaries. This guidance will also be updated to reflect the policies finalized in this rule. We are utilizing the feedback we have received to improve CMS' beneficiary-focused education and outreach efforts and believe this policy fits in the overall strategy; however, we may continue to modify these policies in future rulemaking.

Comment: Some commenters asked for clarification regarding the impact of this policy on ACOs that have selected preliminary prospective assignment with retrospective reconciliation. Specifically, commenters are seeking clarification on the interaction with this assignment selection and the timing of the beneficiary information notice deadline, as these ACOs receive several refreshes of ''assignable beneficiary'' data during the performance year.

Response: ACOs that select preliminary prospective assignment with retrospective reconciliation will be required to send a beneficiary information notice to all the beneficiaries indicated in § 425.312(a)(2)(iii), also called ''assignable beneficiaries'' (as defined in § 425.20), by May 30 of each performance year. To operationalize this requirement, ACOs should use the list of assignable beneficiaries included in the initial assignment report package delivered before the start of the performance year to identify beneficiaries who must receive the standardized written notice by May 30. While ACOs receive updates to the list of assignable beneficiaries during the performance year, generally, none of those lists arrive with sufficient time for ACOs to prepare and notify beneficiaries prior to the May 30 deadline of that performance year. ACOs receive updates to the list of assignable beneficiaries to account for beneficiaries newly receiving services from their ACO or otherwise changing eligibility for assignment to the ACO throughout the course of the year. ACOs will need to notify beneficiaries identified as ''assignable beneficiaries'' after the initial assignment report by May 30 of the subsequent year if the beneficiaries remain on the list of ''assignable beneficiaries'' included in the quarter 4 report package delivered to ACOs early in the calendar year that follows the performance year.

Comment: A commenter had an alternative suggestion on the timing of distribution of the beneficiary information notice, suggesting that (1) the ACO be required to distribute the notice within 30 days before or after the patient's first primary care visit when that visit occurs December 2; and (2) requiring notification within 7 days if the first primary care visit occurs after December 2. The commenter stated that this approach would provide greater flexibility and allow beneficiaries who did not have a primary care visit earlier in the year to receive notification closer to their actual primary care visit.

Response: We appreciate this suggestion, but we believe that establishing a singular deadline to provide the beneficiary notification will result in a greater reduction in burden for ACOs, without a significant impact on beneficiary understanding. Under the existing requirement, the ACO could provide the notice months before the beneficiary's first visit and still satisfy the requirement that the notice be provided ''prior to . . . the first primary care visit during the performance year'' (§ 425.312(a)(2)(iii)). The May 30

[390] CMS Medicare Shared Savings Program Beneficiary Notification and Education Guidance, Version 4, September 2026.

deadline provides added flexibility for ACOs without requiring notices to be distributed on a schedule tied to each beneficiary's first primary care visit. As discussed elsewhere in this section, ACOs may continue to provide additional educational information and conduct outreach to beneficiaries, including through communications tailored to their beneficiary populations, consistent with applicable program requirements. We also believe that the commenter's suggestion could be more operationally difficult for ACOs to track based on feedback we have received from ACOs regarding mapping the timing of beneficiary visits and beneficiary notices accordingly.

Comment: A commenter suggested that CMS distribute the beneficiary notice to all beneficiaries, instead of requiring ACOs to distribute a beneficiary notice, in order to further reduce burden to ACOs and participating practices.

Response: While we appreciate the suggestion that CMS' distribution of beneficiary notices would further reduce burden for ACOs, we believe there is utility in beneficiaries receiving notifications from the ACO they are assigned to, in order to build the relationship between the beneficiary and the ACO and increase the likelihood that the beneficiary understands the types of support offered by the specific ACO. It would be impractical and administratively infeasible for CMS to collect individualized information about every ACO of the sort that ACOs often distribute in conjunction with the beneficiary notice and then distribute that information to each respective ACO's assigned beneficiaries.

Comment: A few commenters recommended that CMS provide ACOs flexibility in the methods used to furnish the notice, including electronic delivery options.

Response: ACOs are currently permitted to distribute the beneficiary notice in-person at the point of care, through mail, and through electronic delivery methods, as long as it aligns with the standard written format (§ 425.312(a)(2)). We appreciate this suggestion and understand there may be confusion among ACOs regarding implementation of beneficiary information notice policy. CMS intends to release more detailed subregulatory guidance to assist ACOs with understanding the flexibilities they have in distributing the notice.

After consideration of public comments, we are finalizing this policy as proposed beginning January 1, 2027. Specifically, we are revising § 425.312(a)(2)(iii) to read, ''The standardized written notice must be furnished to all of these beneficiaries by May 30, unless CMS specifies a later date during the performance year.'' We are also adding a new sentence to § 425.312(a)(2)(iv) to read, ''The standardized written notice must be furnished to all of these beneficiaries by May 30, unless CMS specifies a later date during the performance year.''

(2) Removal of Beneficiary Follow-Up Communication

In the CY 2023 PFS final rule (87 FR 70233), CMS finalized the requirement at § 425.312(a)(2)(v) that ACOs or ACO participants provide a verbal or written follow-up communication to the beneficiary no later than 180 days from the date the standardized written notice was provided. Currently, under § 425.312(a)(2)(v)(A), ''The follow-up communication must occur no later than 180 days from the date the standardized written notice was provided.'' Section 425.312(a)(2)(v)(B) requires ACOs to retain a record of the follow-up communication and that all beneficiaries receive the follow-up communication, and to make the records available to CMS upon request.

In comments summarized in the CY 2023 PFS final rule (87 FR 69961–69963), most commenters opposed the requirement to provide beneficiary follow-up communications, expressing concern that the follow-up communication would increase administrative and operational burden for ACOs without creating meaningful additional beneficiary benefit. Commenters noted that follow-up communications may require substantial resources to operationalize, including workflows to identify beneficiaries requiring outreach, conduct and document communications, respond to beneficiary questions and maintain records demonstrating compliance. Some commenters indicated that these activities could create competing demands during clinical encounters, requiring healthcare providers to devote visit time to explaining ACO participation and value-based care concepts rather than focusing on the beneficiary's immediate clinical needs. Commenters also raised concerns that repeated communications on similar materials could contribute to beneficiary confusion rather than improve understanding. Commenters suggested we explore other strategies and work with ACOs to promote beneficiary education and engagement.

While we considered the commenters' concerns when finalizing the follow-up communication requirement in the CY 2023 PFS rule, we adopted it with the expectation that it would improve beneficiary understanding of the Shared Savings Program and give beneficiaries the opportunity to ask questions. Since its implementation, however, we have not seen evidence that the follow-up communication improves beneficiaries' understanding of ACO assignment, value-based care, or the benefits of being in an ACO. Although we proposed to eliminate the follow-up communication requirement, we remain committed to improving beneficiary education about the Shared Savings Program. We are currently researching additional ways CMS can support beneficiary education, but we do not believe the 180-day follow-up communication requirement is helping achieve that goal. As noted earlier, we recognize that ACOs have developed processes and incurred expenses to meet these requirements. While we believe removing the requirement would relieve an ongoing burden and expense, ACOs are free to continue to utilize those processes to communicate with beneficiaries if they believe they provide a benefit, as long as such processes are consistent with any other applicable program requirements.

To be responsive to interested parties' feedback, prevent potential beneficiary confusion and reduce administrative burden to ACOs and ACO participants, we proposed to remove the requirement that ACOs must provide a follow up communication as specified in § 425.312(a)(2)(v). Specifically, we proposed to remove § 425.312(a)(2)(v) in its entirety.

We proposed that this change would be effective beginning January 1, 2027.

We sought comments on this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the proposed policy and believe it would reduce burden for participating ACOs, as ACOs are already in frequent communication with their beneficiaries to help manage their care. A commenter noted that an ACO spent $12,000 last year to meet the current requirements. A few commenters encouraged CMS to continue its broader work to improve beneficiary engagement in accountable care through personalized communications.

Response: We appreciate the supportive comments and agree that the changes will reduce financial and administrative burden for participating ACOs. We continue to actively work

towards improving beneficiary engagement and education.

Comment: A few commenters opposed the removal of the beneficiary follow-up notification. A commenter stated that beneficiaries should have additional opportunities to review the notice and ask questions about the ACO. Another commenter expressed concern about eliminating this requirement absent alternative efforts to educate beneficiaries about the benefits of value-based care. Another commenter stated that instead of eliminating the follow-up notification, ACOs should be encouraged to strengthen the clarity and effectiveness of the information they provide.

Response: While we agree it is important to educate beneficiaries about ACOs and the benefits of value-based care, we do not believe the beneficiary follow-up notification is meeting these goals. Since we implemented the requirement, we have not seen evidence that the follow-up communication improves beneficiaries' understanding of ACO assignment, value-based care, or the benefits of being in an ACO. Commenters did not clarify why they believe this notice specifically accomplishes these goals. At the same time, we have heard multiple reports of beneficiary confusion and administrative burden stemming from these communications.

We continue to believe that beneficiaries should have opportunities to learn about ACOs. As discussed previously, ACO participants remain required to post signs in their facilities informing beneficiaries of their participation in an ACO, and ACOs may continue to provide additional marketing, educational information and outreach tailored to their beneficiary populations, consistent with applicable program requirements. To support this, as discussed, we have shared with ACOs an updated Beneficiary Notification and Education Guidance document, which more clearly communicates the requirements concerning ACO marketing to beneficiaries.[391] This guidance will also be updated to reflect the policies finalized in this rule. CMS is also exploring additional ways to improve beneficiary education and engagement, including through educational resources and in partnership with ACOs to help ensure that beneficiaries receive clear and effective information. We believe these approaches, together with the standardized written notice requirement, can support beneficiary understanding without the additional administrative burden associated with the required follow-up communication.

After consideration of public comments, we are finalizing this policy as proposed beginning January 1, 2027. Specifically, we are removing § 425.312(a)(2)(v) in its entirety.

10. Request for Information: Specialty Care in the Shared Savings Program

We received public comments in response to this Request for Information: Specialty Care in the Shared Savings Program, and we appreciate the thoughtful input. We will consider the comments received for future rulemaking, technical assistance, and policy development.

H. Changes to the Regulations Associated With the Ambulance Fee Schedule

1. Ambulance Fee Schedule Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Our regulations relating to coverage for ambulance services are set forth at 42 CFR part 410, subpart B. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established, as required by section 1834(l) of the Act, in 42 CFR part 414, subpart H. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610.

In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. (For a discussion about the ambulance inflation factor (AIF), please see CY 2011 PFS final rule (75 FR 73397)). We stated in the CY 2011 PFS final rule that the AIF will be announced by instruction and on the CMS website. AIF transmittals are available on CMS' website: *https://www.cms.gov/medicare/payment/fee-schedules/ambulance/afs-regulations-and-notices* and in the Medicare Claims Processing Manual, Chapter 15, section 20.4). The AFS also incorporates two permanent add-on payments at § 414.610(c)(5)(i) and three temporary add-on payments at § 414.610(c)(1)(ii) and (c)(5)(ii) to the base rate and/or mileage rate.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted July 15, 2008), amended section 1834(l)(13) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008, and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13) of the Act have been extended several times. Most recently, section 6203 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75, February 3, 2026) amended section 1834(l)(13) of the Act to extend the payment add-ons through December 31, 2027. Thus, these payment add-ons apply to covered ground ambulance transports furnished before January 1, 2028.

We proposed to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439), the CY 2015 PFS final rule with comment period (79 FR 67743), the CY 2016 PFS final rule with comment period (80 FR 71071 through 71072), the CY 2019 PFS final rule with comment period (83 FR 59681 through 59682), the CY 2024 PFS final rule with comment period (88 FR 79292 through 79293), and the CY 2026 PFS final rule with comment period (90 FR 49837)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary.

We received public comments regarding this proposal. The following is

[391] CMS Medicare Shared Savings Program Beneficiary Notification and Education Guidance, Version 4, September 2026.

the summary of the comments we received and our response.

Comment: Several commenters supported the proposal and agreed with CMS that the statutory provision is self-implementing and that these provisions are critically important to protect access to ground ambulance services.

Response: We appreciate the commenters' support of these provisions. After consideration of the public comment that we received, we are finalizing our proposal to revise 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 8, 2003) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations.

Using the methodology specified in the July 1, 2004, interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area,'' that is, to transports that originated in a rural area comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims process via the use of a data field included in the CMS—supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Most recently, section 6203 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75, February 3, 2026) amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2027. Therefore, we are continuing to apply the 22.6 percent rural bonus described in this section (in the same manner as in previous years) to ground ambulance services with dates of service before January 1, 2028, where transportation originates in a qualified rural area.

Accordingly, we proposed to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74439 through 74440), CY 2015 PFS final rule with comment period (79 FR 67743 through 67744), the CY 2016 PFS final rule with comment period (80 FR 71072), the CY 2019 PFS final rule with comment period (83 FR 59682), the CY 2024 PFS final rule with comment period (88 FR 79293), and the CY 2026 PFS final rule with comment period (90 FR 49837 through 49838)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through December 31, 2027, and does not require any substantive exercise of discretion on the part of the Secretary.

We received public comments regarding this proposal. The following is the summary of the comments we received and our response.

Comment: Several commenters supported the proposal and agreed with CMS that the statutory provision is self-implementing and that these provisions are critically important to protect access to ground ambulance services.

Response: We appreciate the commenters' support of these provisions.

After consideration of the public comment that we received, we are finalizing our proposal to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

3. Ongoing Data Collection Requirements for the Medicare Ground Ambulance Data Collection System

In the CY 2027 PFS proposed rule (91 FR 44135) we provided an announcement that we expect to address the ongoing data collection requirements for the Medicare Ground Ambulance Data Collection System in the CY 2028 PFS rulemaking to include the Medicare Payment Advisory Commission (MedPAC)'s June 15, 2026, Report to the Congress's findings: *https://www.medpac.gov/document/june-2026-report-to-the-congress-medicare-and-the-health-care-delivery-system/*.

4. Changes in Geographic Delineations for Ambulance Payment

Under section 1834(l)(2)(C) of the Act, the Secretary is required to consider appropriate regional and operational differences in establishing the AFS. Historically, the AFS has used the same geographic area designations as the acute care hospital inpatient prospective payment system (IPPS) and other Medicare payment systems to account for appropriate regional (urban and rural differences). The use of consistent geographic standards for Medicare payment provides for consistency across the Medicare program.

The current geographic areas used under the AFS effective CY 2015 are based on OMB standards published on June 28, 2010 (75 FR 37246 through 37252) and Census 2010 Bureau data (OMB Bulletin No. 13–01). For a discussion of OMB's delineation of Core-Based Statistical Areas (CBSAs) and our implementation of the CBSA definitions under the AFS, we refer readers to the preamble of the CY 2007 AFS proposed rule (71 FR 30358 through 30361), the CY 2007 PFS final rule with comment period (71 FR 69712 through 69716), CY 2015 PFS proposed rule (79 FR 40372 through 40376), CY 2015 PFS final rule with comment period (79 FR 67744 through 67750), CY 2015 PFS final rule correction notice (79 FR 78716 through 78719), CY 2016 PFS proposed rule (80 FR 41788 through 41792), and the CY 2016 PFS final rule with comment period (80 FR 71072 through 71078).

In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Commuting Survey (ACS). In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. A copy of OMB Bulletin No. 23–01 may be obtained at: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.* According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data).

OMB's 2020 Standards for Delineating Core Based Statistical Areas (86 FR

37778) defines a CBSA as a geographic entity with at least one core of at least 10,000 population, where there are two types of CBSAs. A metropolitan statistical area (MSA) is one type, with populations greater than 50,000 and a micropolitan statistical area (referred to in this discussion as a Micropolitan Area) is the other type as a CBSA associated with at least one core that has a population of at least 10,000 but less than 50,000. Counties that do not qualify for inclusion in a CBSA are deemed ''outside of a CBSA.''

The July 21, 2023 OMB Bulletin No. 23–01 contains a number of significant changes to the statistical areas in the United States and Puerto Rico. For example, our analysis shows that a total of 53 counties that were once considered part of a CBSA would be considered to be located outside of a CBSA whereas a total of 54 counties that were located outside of a CBSA would be located in a CBSA under the revised OMB delineations. We believe it is important for the ambulance fee schedule to use the latest labor market area delineations available as soon as reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts.

Additionally, in the FY 2025 IPPS final rule with comment period (89 FR 69253), we finalized our proposal to adopt OMB's revised delineations based on OMB Bulletin No. 23–01 to delineate areas for purposes of applying the IPPS wage index. Given that ambulance services is a transport benefit where payment is based on the ZIP code of the ambulance point of pickup and in response to industry requests to update the geographic delineations and the statutory requirement at sections 1834(l)(9), (l)(12)(B)(iv), (l)(13)(A)(i), and (l)(14)(C) of the Act that require that we use the most recent version of the Goldsmith Modification to determine rural census tracts within MSAs, we proposed to update the geographic delineations, consistent with historical practice, rather than proposed to continue to use the current geographic delineations.

We believe it would be appropriate to adopt the same geographic area delineations for use under the AFS as are used under the IPPS and other Medicare payment systems. Thus, we proposed to make use of the new OMB delineations as described in the July 21, 2023, OMB Bulletin No. 23–01 beginning in CY 2027, along with the geographic areas based on the most version of the Goldsmith Modification, to more accurately identify urban and rural areas for AFS payment purposes.

We believe that combining the updated OMB delineations with the Goldsmith Modification's Rural-Urban Commuting Area (RUCA) codes more realistically reflect rural and urban populations, and that the use of such delineations and codes under the AFS would result in more accurate payment. Under the AFS, consistent with our current definitions of urban and rural areas (42 CFR 414.605), MSAs would continue to be recognized as urban areas, while Micropolitan Areas and other areas outside MSAs, and rural census tracts within MSAs (as discussed later in this section), would be recognized as rural areas.

In addition to the OMB's statistical area delineations, the current geographic areas used in the AFS are, as just stated, based on the most recent version of the Goldsmith Modification. Sections 1834(l)(9), (l)(12)(B)(iv), (l)(13)(A)(i), and (l)(14)(C) of the Act require that we use the most recent version of the Goldsmith Modification to determine rural census tracts within MSAs. These rural census tracts are considered rural areas under the AFS (see § 414.605). In the CY 2015 PFS final rule with comment period (79 FR 67744 through 67750), we adopted the most recent (at that time) version of the Goldsmith Modification, designated as RUCA codes.

RUCA codes use urbanization, population density, and daily commuting data to categorize every census tract in the country. For a discussion about RUCA codes, we refer the reader to the CY 2007 PFS final rule with comment period (71 FR 69714 through 69716), the CY 2015 PFS final rule with comment period (79 FR 67745 and 67746), CY 2015 PFS final rule correction notice (79 FR 78716 through 78719), and the CY 2016 PFS final rule with comment period (80 FR 71073 through 71074).

As stated previously, on July 21, 2023, OMB issued Bulletin No. 23–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. Several modifications of the RUCA codes were necessary to take into account updated commuting data and the revised OMB delineations. We refer readers to the U.S. Department of Agriculture's Economic Research Service website for a detailed listing of updated RUCA codes found at: *https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx.*

The updated RUCA code definitions were introduced on July 31, 2025, and are based on data from the U.S. Bureau of the Census, Department of Commerce, 2020 Census of Population and Housing and the 2017–21 Census Transportation Planning Package (CTPP) special tabulation for the Department of Transportation and the American Association of State Highway and Transportation Officials. We proposed to adopt the most recent modifications of the RUCA codes beginning in CY 2027, to recognize levels of rurality in census tracts located in every county across the nation, for purposes of payment under the AFS. If we adopt the most recent RUCA codes, many counties that are designated as urban at the county level based on population would have rural census tracts within them that would be recognized as rural areas through our use of RUCA codes.

The 2020 Primary RUCA codes are as follows:

- Metropolitan core: primary commuting flow is within an urban area (UA) of 50,000 or more people (metro UA).
- Metropolitan high commuting: primary commuting flow is 30 percent or more to a metro UA.
- Metropolitan low commuting: primary commuting flow is 10 percent to 30 percent to a metro UA.
- Micropolitan core: primary flow is within an urban area of 10,000 to 49,999 people (micro UA).
- Micropolitan high commuting: primary commuting flow is 30 percent or more to a micro UA.
- Micropolitan low commuting: primary commuting flow is 10 percent to 30 percent to a micro UA.
- Small town core: primary commuting flow is within an urban area of 9,999 or fewer people (small town UA).
- Small town high commuting: primary commuting flow is 30 percent or more to a small town UA.
- Small town low commuting: primary commuting flow is 10 percent to 30 percent to a small town UA.
- Rural areas: primary commuting flow is to a tract outside an UA.

Based on this classification, and consistent with our current policy as set forth in the CY 2015 PFS final rule with comment period (79 FR 67745), we proposed to designate any census tracts falling at or above RUCA level 4.0 as rural areas for purposes of payment for ambulance services under the AFS. As discussed in the CY 2015 PFS final rule with comment period (79 FR 67745), the Federal Office of Rural Health Policy (formerly the Office of Rural Health Policy) within the Health Resources and Services Administration (HRSA) determines eligibility for its rural grant

programs through the use of the RUCA code methodology. Under this methodology, HRSA designates any census tract that falls at RUCA level 4.0 or higher as a rural census tract. In addition to designating any census tracts falling at or above RUCA level 4.0 as rural areas, under the updated RUCA code definitions, HRSA has also designated as rural census tracts those census tracts with RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people.

We refer readers to HRSA's website at: *https://www.hrsa.gov/rural-health/about-us/what-is-rural* for additional information. Consistent with the HRSA guidelines discussed previously and the policy we adopted in the CY 2015 PFS final rule with comment period (79 FR 67750), we proposed for CY 2027 to designate as rural areas those census tracts that fall at or above RUCA level 4.0. We continue to believe that this HRSA guideline accurately identifies rural census tracts throughout the country, and thus would be appropriate to apply for AFS payment purposes.

Also, consistent with the policy we finalized in the CY 2015 PFS final rule with comment period (79 FR 67749), we would not designate as rural areas those census tracts that fall at RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We have determined that it is not feasible to implement this guideline due to the complexities of identifying these areas at the ZIP code level. We do not have sufficient information available to identify the ZIP codes that fall in these specific census tracts.

Also, payment under the AFS is based on the ZIP codes; therefore, if the ZIP code is predominantly metropolitan but has some rural census tracts, we do not split the ZIP code areas to distinguish further granularity to provide different payments within the same ZIP code. We believe that payment for all ambulance transportation services at the ZIP code level provides for a more consistent and administratively feasible payment system.

For example, if we were to pay based on ZIP codes for some areas and counties or census tracts for other areas, there are circumstances where ZIP codes cross county or census tract borders and where counties or census tracts cross ZIP code borders. Such overlaps in geographic designations would overly complicate our ability to appropriately assign ambulance transportation services to geographic areas for payment under the AFS. Therefore, under the AFS, we would not designate as rural areas those census tracts that fall at RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We invited comments on this proposal.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67746), the adoption of the most current OMB delineations and the updated RUCA codes would affect whether certain areas are recognized as rural or urban. The distinction between urban and rural is important for ambulance payment purposes because urban and rural transports are paid differently. The determination of whether a transport is urban or rural is based on the point of pick-up for the transport, and thus a transport is paid differently depending on whether the point of pick-up is in an urban or a rural area. During claims processing, geographic designation of urban, rural, or super rural is assigned to each claim for an ambulance transport based on the point of pick-up ZIP code that is indicated on the claim.

Currently, section 1834(l)(12) of the Act (as amended by section 6203 of the Consolidated Appropriations Act, 2026) specifies that, for services furnished during the period July 1, 2004 through December 31, 2027, the payment amount for the ground ambulance base rate is increased by a ''percent increase'' (Super Rural Bonus) where the ambulance transport originates in a ''qualified rural area,'' which is a rural area that we determine to be in the lowest 25th percentile of all rural populations arrayed by population density (also known as a ''super rural area''). We implement this Super Rural Bonus in § 414.610(c)(5)(ii). Adoption of the revised OMB delineations and the updated RUCA codes would have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the revised OMB delineations and the updated RUCA codes.

The adoption of the new OMB delineations and the updated RUCA codes would affect whether transports are eligible for other rural adjustments under the AFS statute and regulations. For ground ambulance transports where the point of pick-up is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles (§ 414.610(c)(5)(i)). For air ambulance services where the point of pick-up is in a rural area, the total payment (base rate and mileage rate) is increased by 50 percent (§ 414.610(c)(5)(i)). Furthermore, under section 1834(l)(13) of the Act (as amended by section 6203 of the Consolidated Appropriations Act, 2026) for ground ambulance transports furnished through December 31, 2027, transports originating in rural areas are paid based on a rate (both base rate and mileage rate) that is 3 percent higher than otherwise is applicable. (See also § 414.610(c)(1)(ii)).

If we adopt OMB's revised delineations and the updated RUCA codes, ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be Micropolitan or otherwise outside of MSAs based on OMB's revised delineations or in a rural census tract of an MSA based on the updated RUCA codes (but are currently within urban areas) may experience increases in payment for such transports because they may become eligible for the rural adjustment factors discussed previously, while those ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be urban based on OMB's revised delineations and the updated RUCA codes (but are currently in Micropolitan Areas or otherwise outside of MSAs, or in a rural census tract of an MSA) may experience decreases in payment for such transports because they would no longer be eligible for the rural adjustment factors discussed previously. The use of the revised OMB delineations and the updated RUCA codes would mean the recognition of new urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2010 and 2020. As discussed previously in this section, we proposed to use the updated 2020 RUCA codes to identify rural census tracts within MSAs, such that the census tracts falling at or above RUCA level 4.0 would continue to be designated as rural areas. To determine which ZIP codes are included in each such rural census tract, we proposed to use the ZIP code approximation file developed by HRSA. This file includes the 2020 RUCA code designation for each ZIP code and can be found at: *https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.* If ZIP codes are added over time to the USPS ZIP code file (and thus are not included in the 2020 ZIP code approximation file provided to us by HRSA) or if ZIP codes are revised over time, we would determine the appropriate urban/rural designation for such ZIP code based on any updates provided on the HRSA and OMB websites located at: *https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx* and *https://www.whitehouse.gov/wp-*

content/uploads/2023/07/OMB-Bulletin-23–01.pdf.

Based on the April 2026 United States Postal Service (USPS) ZIP code file that we used in the proposed rule (91 FR 44137) to assess the impacts of the revised geographic designations; there are a total of 42,956 ZIP codes in the U.S. Table B–H1 sets forth an analysis of the number of ZIP codes that changed urban/rural status in each U.S. State and territory using the April 2026 USPS ZIP code file, the revised OMB delineations (OMB Bulletin No. 23–01), and the updated 2020 RUCA codes. Based on this data, the geographic designations for approximately 95.87 percent of ZIP codes would be unchanged by OMB's revised delineations and the updated RUCA codes. As reflected in Table B–H1, more ZIP codes would change from urban to rural (1,172, or 2.73 percent) than rural to urban (602, or 1.40 percent).

In general, it is expected that ambulance providers and suppliers in 1,172 ZIP codes within 47 States and Puerto Rico may experience payment increases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from urban to rural. The State of Maryland would have the highest percentage of ZIP codes changing from urban to rural with a total of 49, or 7.78 percent. Ambulance providers and suppliers in 602 ZIP codes within 43 States may experience payment decreases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from rural to urban. The State of South Carolina would have the highest percentage of ZIP codes changing from rural to urban (20, or 3.68 percent). Our findings are illustrated in Table B–H1.

TABLE B-H1: ZIP CODES ANALYSIS BASED ON OMB'S REVISED DELINEATIONS AND UPDATED RUCA CODES

State/ Territory*	Total ZIP Codes	Total ZIP Codes Changed Rural to Urban	Percentage of Total ZIP Codes	Total ZIP Codes Changed Urban to Rural	Percentage of Total ZIP Codes	Total ZIP Codes Not Changed	Percentage of Total ZIP Codes Not Changed
AK	276	0	0.00%	0	0.00%	276	100.00%
AL	854	20	2.34%	11	1.29%	823	96.37%
AR	727	4	0.55%	18	2.48%	705	96.97%
AS	1	0	0.00%	0	0.00%	1	100.00%
AZ	571	2	0.35%	8	1.40%	561	98.25%
CA	2730	35	1.28%	93	3.41%	2602	95.31%
CO	677	3	0.44%	22	3.25%	652	96.31%
CT	421	1	0.24%	15	3.56%	405	96.20%
DC	319	1	0.31%	0	0.00%	318	99.69%
DE	99	0	0.00%	6	6.06%	93	93.94%
EK	63	0	0.00%	0	0.00%	63	100.00%
EM	858	10	1.17%	14	1.63%	834	97.20%
FL	1516	23	1.52%	27	1.78%	1466	96.70%
FM	4	0	0.00%	0	0.00%	4	100.00%
GA	1032	5	0.48%	22	2.13%	1005	97.38%
GU	21	0	0.00%	0	0.00%	21	100.00%
HI	143	2	1.40%	0	0.00%	141	98.60%
IA	1080	7	0.65%	11	1.02%	1062	98.33%
ID	335	6	1.79%	10	2.99%	319	95.22%
IL	1630	10	0.61%	86	5.28%	1534	94.11%
IN	1002	16	1.60%	23	2.30%	963	96.11%
KY	1030	25	2.43%	23	2.23%	982	95.34%
LA	739	26	3.52%	23	3.11%	690	93.37%
MA	752	2	0.27%	27	3.59%	723	96.14%
MD	630	0	0.00%	49	7.78%	581	92.22%
ME	505	15	2.97%	14	2.77%	476	94.26%
MH	2	0	0.00%	0	0.00%	2	100.00%
MI	1186	34	2.87%	18	1.52%	1134	95.62%

State/ Territory*	Total ZIP Codes	Total ZIP Codes Changed Rural to Urban	Percentage of Total ZIP Codes	Total ZIP Codes Changed Urban to Rural	Percentage of Total ZIP Codes	Total ZIP Codes Not Changed	Percentage of Total ZIP Codes Not Changed
MN	1044	11	1.05%	10	0.96%	1023	97.99%
MP	3	0	0.00%	0	0.00%	3	100.00%
MS	541	6	1.11%	8	1.48%	527	97.41%
MT	411	1	0.24%	0	0.00%	410	99.76%
NC	1102	25	2.27%	55	4.99%	1022	92.74%
ND	419	12	2.86%	1	0.24%	406	96.90%
NE	632	0	0.00%	4	0.63%	628	99.37%
NH	292	0	0.00%	12	4.11%	280	95.89%
NJ	748	8	1.07%	5	0.67%	735	98.26%
NM	439	0	0.00%	3	0.68%	436	99.32%
NV	258	0	0.00%	3	1.16%	255	98.84%
NY	2247	33	1.47%	73	3.25%	2141	95.28%
OH	1489	42	2.82%	31	2.08%	1416	95.10%
OK	792	24	3.03%	6	0.76%	762	96.21%
OR	500	12	2.40%	15	3.00%	473	94.60%
PA	2245	19	0.85%	157	6.99%	2069	92.16%
PR	178	2	1.12%	12	6.74%	164	92.13%
PW	2	0	0.00%	0	0.00%	2	100.00%
RI	91	0	0.00%	2	2.20%	89	97.80%
SC	544	20	3.68%	21	3.86%	503	92.46%
SD	418	1	0.24%	3	0.72%	414	99.04%
TN	814	19	2.33%	20	2.46%	775	95.21%
TX	2730	60	2.20%	55	2.01%	2615	95.79%
UT	361	3	0.83%	7	1.94%	351	97.23%
VA	1277	16	1.25%	41	3.21%	1220	95.54%
VI	16	0	0.00%	0	0.00%	16	100.00%
VT	309	2	0.65%	0	0.00%	307	99.35%
WA	744	8	1.08%	7	0.94%	729	97.98%
WI	919	12	1.31%	27	2.94%	880	95.76%
WK	712	12	1.69%	5	0.70%	695	97.61%
WM	342	0	0.00%	3	0.88%	339	99.12%
WV	936	7	0.75%	66	7.05%	863	92.20%
WY	198	0	0.00%	0	0.00%	198	100.00%
Totals	**42,956**	**602**	**1.40%**	**1,172**	**2.73%**	**41,182**	**95.87%**

* ZIP code analysis includes U.S. States and Territories (FM—Federated States of Micronesia, GU—Guam, MH—Marshall Islands, MP—Northern Mariana Islands, PW—Palau, AS—American Samoa; VI—Virgin Islands; PR—Puerto Rico). Missouri is divided into east and west regions due to work distribution of the Medicare Administrative Contractors (MACs): EM—East Missouri, WM—West Missouri. Johnson and Wyandotte counties in Kansas were changed as of January 2010 to East Kansas (EK), and the rest of the state is West Kansas (WK).

For more detail on the impact of our proposals, in addition to Table B–H1, the following files are available through the Internet on the Ambulances Services Center website at: *https://www.cms.gov/medicare/coverage/ambulances-services-center;* ZIP Codes By State Changed From Urban To Rural: ZIP Codes By State Changed From Rural To Urban: List of ZIP Codes With RUCA Code Designations: and Complete List of ZIP Codes.

We invited public comments on our proposals to make use of the revised OMB delineations as set forth in the July 21, 2023 OMB Bulletin No. 23–01 and the most recent modifications of the RUCA codes as discussed previously for CY 2027 for purposes of payment under the AFS.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed update of the geographic delineations used for ambulance payment and also supported that the adoption of the revised OMB delineations and the updated RUCA codes would have no negative impacts on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the proposed changes.

Response: We appreciate the commenters' support.

Comment: An initial commenter stated that it may be the case that some ZIP codes should have a more favorable geographic designation in this round, as well as in future modifications. To address this concern raised by the initial commenter, the initial commenter and some other commenters recommended CMS adopt two additional safeguards to protect beneficiary access to ground ambulance services. The first safeguard that the commenters suggested is to maintain current geographic designation

if there are 1,000 people per square mile or fewer in the ZIP code that would be redesignated. Those commenters stated that this safeguard would protect patients in low-population-density areas from potential access problems by ensuring their ZIP code's status remains unchanged.

The second safeguard that the commenters recommended is an appeals process where an ambulance provider or supplier could ask CMS for reconsideration of a ZIP code designation within a 1-year period after the changes in geographic delineations have been finalized.

Response: None of the commenters provided specific examples of what ZIP codes should have a more favorable geographic designation. Further, we did not propose an additional methodology to preserve the current geographic designations for ZIP codes with a population density of 1,000 people per square mile or fewer. Implementing such a methodology would not be feasible given the complexities of identifying these areas at the ZIP code level. For instance, it is unclear how to account for ZIP codes that span multiple counties.

We believe that the most current OMB delineations, coupled with the updated RUCA codes more accurately reflect the urban and rural nature of areas across the county, and thus, we believe the use of the most current OMB delineations and RUCA codes under the AFS enhances the accuracy of AFS payments. Further, as discussed previously, we believe that our methodology of designating rural geographic areas by using OMB's delineations, and by using RUCA codes 4.0 and above to identify rural census tracts within MSAs, is appropriate for AFS payment purposes because it rectifies the limitations of broad county-level data, ensuring that isolated areas receive necessary higher reimbursement rates to cover higher structural operating costs.

We did not propose an appeals process where an ambulance provider or supplier could ask CMS for reconsideration of a ZIP code designation within a one-year period after the changes in geographic delineations have been finalized. If an ambulance provider or supplier has concerns about a ZIP code's delineation, they should contact OMB. If they have concerns about a ZIP code's RUCA code designation, they should contact HRSA.

Comment: Some commenters urged CMS to reconsider designating as rural areas those census tracts that fall at RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. A commenter recommended a reconsideration appeal process for ZIP codes containing census tracts that qualify as rural under RUCA 2 or 3 but do not receive a corresponding ZIP-level designation. The commenter further stated that they understand CMS's concern that it lacks an administrable method for translating tract-level RUCA 2 and 3 classifications into ZIP code designations. However, the commenter does not believe that concern is insurmountable. The commenter suggested that CMS allow a supplier or provider to petition for reconsideration by demonstrating, using HRSA's published criteria, that a majority of the census tracts or population within the ZIP code meets the RUCA 2 or 3 large-area or low-density rural criteria. Under this approach, the petitioner would provide the tract-to-ZIP crosswalk, and CMS would verify the analysis against the criteria already in use.

Response: As we stated previously, we would not designate as rural areas those census tracts that fall at RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We have determined that it is not feasible to implement this guideline due to the complexities of identifying these areas at the ZIP code level. We do not have sufficient information available to identify the ZIP codes that fall in these specific census tracts.

Also, payment under the AFS is based on the ZIP codes; therefore, if the ZIP code is predominantly metropolitan but has some rural census tracts, we do not split the ZIP code areas to distinguish further granularity to provide different payments within the same ZIP code. We believe that payment for all ambulance transportation services at the ZIP code level provides for a more consistent and administratively feasible payment system. For example, if we were to pay based on ZIP codes for some areas and counties or census tracts for other areas, there are circumstances where ZIP codes cross county or census tract borders and where counties or census tracts cross ZIP code borders. Such overlaps in geographic designations would overly complicate our ability to appropriately assign ambulance transportation services to geographic areas for payment under the AFS.

Comment: A commenter supports our proposal to classify census tracts with RUCA codes of 4.0 or higher as rural for AFS payment purposes. The commenter stated that this more granular methodology can identify rural communities that might otherwise be absorbed into a broader urban classification. However, the commenter stated that the RUCA methodology may not identify every ambulance operation that performs a predominantly rural function and recommends that CMS consider additional criteria for circumstances in which a pickup ZIP code's geographic classification does not accurately reflect the rural role of the ambulance provider or supplier or healthcare facility. The commenter stated that the potential criteria should include all of the following:

- An ambulance provider or supplier -location standard that recognizes operations for which a majority of Medicare transports serve rural communities.
- Recognition of hospitals and facilities holding a federal rural-related designation, even when their pickup ZIP codes are classified as urban.
- Consideration of low transport volumes, extended travel distances, limited hospital access, and regional referral patterns.
- Protection for air and ground medical bases serving broad rural, frontier, or medically underserved areas.
- A defined process through which ambulance providers may request review of a classification that does not accurately reflect their service responsibilities.

According to the commenter, these additional criteria would complement, not replace, the proposed RUCA methodology. The commenter stated that this additional methodology would give CMS a way to address documented circumstances in which ZIP-code classification alone does not fully capture the rural nature of an ambulance operation or the population it serves. The commenter further recommended: (1). a predominantly rural provider-supplier location standard for air ambulance bases where at least 50% of Medicare transports originate in rural or super-rural pickup ZIP codes. (2). Qualifying bases should receive the rural ground and air ambulance adjustment for all Medicare transports. Alternatively, the commenter recommended CMS should establish a review process through which a provider or supplier may demonstrate that an operation functions as a predominantly rural regional resource.

The commenter also recommended a rural base exception for a ground and air ambulance transport originating from an urban-classified hospital or other pickup location when the responding aircraft is assigned to a rural or super-rural base where the transport should receive the rural air ambulance adjustment applicable to the base, recognizing that the base must maintain

the air and ground vehicles, clinical crews, equipment, communications systems, and 24/7 readiness required to serve its rural service area.

Response: We did not propose an additional methodology or rural base exception. We believe that the most current OMB delineations, coupled with the updated RUCA codes more accurately reflect the urban and rural nature of areas across the county, and thus, we believe the use of the most current OMB delineations and RUCA codes under the AFS sufficiently enhances the accuracy of AFS payments. The payment for an ambulance transport is based on the ZIP code of the point of the ambulance pick-up.

Comment: A commenter recommended that CMS establish a five-year transition for ZIP codes that move from rural to urban under the new classifications. For these ZIP codes, the commenter stated that CMS should apply a five-year blended payment rate. According to the commenter, this approach would provide providers and suppliers and communities with a reasonable period to adjust to the payment changes and would be consistent with transition approaches CMS has used when other Medicare payment systems have adopted updated OMB delineations.

Response: We did not propose a 5-year transition period for ZIP codes that move from rural to urban (1.40 percent of ZIP codes). We believe that it is important to use the most updated OMB delineations and updated RUCA codes based on the latest census data for AFS payment purposes because it directly impacts the accuracy, fairness, and statutory compliance of health care payment and funding allocation.

Comment: A commenter supported the proposal to redesignate 12 ZIP codes in Puerto Rico from urban to rural and stated that these changes better reflect the operational reality of ambulance in the affected communities, where mountainous or coastal geography, limited road alternatives, extended response and transport times, and uneven access to appropriate receiving facilities materially increase the cost and complexity of service.

However, the commenter opposed the proposal to redesignate two ZIP codes, 00707 (Maunabo) and 00742 (Roosevelt Roads/Ceiba) from rural to urban. The commenter stated that these areas continue to present the access, travel-time, infrastructure, and destination constraints commonly associated with rural ambulance operations. The commenter further stated that the classification based on commuting patterns or broad statistical boundaries may not adequately capture prehospital realities. The commenter requested that these two ZIP codes: retain their rural designation pending an operational-access review that considers ambulance travel time, road connectivity, receiving facility capability, and unit cycle time.

Response: ZIP codes 00707 and 00742 are listed under the San Juan-Bayamón-Caguas, PR CBSA with a RUCA code of 1, Metropolitan core: primary commuting flow is within an urban area (UA) of 50,000 or more people (metro UA). We designate rural census tracts in a Metropolitan Statistical Area (MSA) falling at or above RUCA level 4.0 as rural areas. HRSA also uses this methodology. We continue to believe that this HRSA guideline accurately identifies rural census tracts throughout the country and thus would be appropriate to apply for AFS payment purposes.

Comment: A commenter supports the proposal to redesignate the 14 ZIP codes in Maine that will change their designation from urban to rural. However, the commenter opposes the proposal to redesignate the 15 ZIP codes that will change from rural to urban. The commenter also recommended that CMS reclassify the entirety of Penobscot County outside of the direct Bangor MSA as rural.

Response: The 15 ZIP codes in Maine met the criteria to change their designations from rural to urban. Penobscot County is located in the Bangor MSA according to OMB's revised delineations. If an ambulance provider or supplier has an issue with a ZIP code's delineation, they should contact OMB. If an ambulance provider or supplier has an issue with a RUCA code designation of a ZIP code, they should contact HRSA.

After consideration of public comments, we are finalizing our proposed changes to make use of the new OMB's revised delineations and the most recent modification of the RUCA codes to recognize levels of rurality in census tracts falling at or above RUCA code level 4.0 as rural areas for purposes of payment under the AFS.

I. Request for Information (RFI) on Duplicate Laboratory Testing, Imaging, and Result Sharing and Interoperability

1. Overview

Diagnostic imaging and laboratory testing are critical to determining a patient's course of treatment. Imaging data and test results are often siloed within the acquiring systems' electronic health record and inaccessible outside of those systems. Treating health care providers often do not even know of the existence of these siloed results. The inaccessibility of laboratory and imaging data due to siloing results in incomplete or delayed care management and duplicative testing, with concomitant increased costs (and in the case of duplicative diagnostic imaging, unnecessary radiation exposure).

2. Purpose of the RFI

In the CY 2027 PFS proposed rule (91 FR 44139 through 44141), we issued an RFI to gather input from interested parties—including clinicians, laboratories, imaging health care providers, health systems, payers, health IT developers, and other interested parties—to inform potential actions aimed at addressing the interoperability and duplicate testing concerns described earlier in this section.

3. Potential Mechanisms for Addressing Duplicative Payment

In the CY 2027 PFS proposed rule (91 FR 44139), we described several mechanisms we are exploring to address duplicate payment for diagnostic laboratory and image testing:

- Clarifications to billing instructions to laboratories and imaging centers on parameters of duplicate laboratory or imaging tests;
- Local Medicare Administrative Contractor (MAC) edits that would result in non-payment or reductions in payment as applicable for duplicate laboratory or imaging tests;
- Use of payment integrity levers to recoup payments from health care providers and suppliers who performed duplicate laboratory or imaging tests; and
- Application of frequency limitations to certain tests where clinically appropriate.

We noted that frequency limitations are already in use in certain contexts. For example, a Local Coverage Decision (LCD) from a MAC limits testing for Vitamin D levels (L33996—Vitamin D Assay Testing), providing that once a beneficiary has been shown to be Vitamin D deficient, further testing is medically necessary only to ensure adequate replacement has been accomplished, with annual testing thereafter being appropriate depending on the indication and other mitigating factors. We stated that we believe there are likely other diagnostic laboratory tests that should similarly be subject to frequency limitations.

We also recognized that in some cases more frequent testing is clinically justified and therefore asked for input not only on which laboratory and

imaging tests should be subject to frequency limitations, but also on what exceptions should be permitted to ensure beneficiary access is not inappropriately restricted.

We asked how CMS can enforce these limitations without restricting beneficiary access to necessary care. Specifically, we asked how practitioners can communicate clinical justification for repeat testing in specific circumstances—for example, in cases of trauma, stroke, or evolving emergencies where repeat imaging may be clinically appropriate.

We also asked for input on the following questions:

- Should CMS consider possible changes to payment policies when diagnostic tests are billed duplicatively; that is, additional imaging or diagnostic laboratory tests for the same condition? For example, is there a time period during which an image or laboratory test should automatically be considered ''duplicate'' and therefore subject to payment consequences? To which kinds of tests or subsets of tests should such policies apply?
- We asked clinicians and payors, who have likely addressed or considered these or similar issues, to share their experience and perspective.

4. Laboratory and Imaging Interoperability

Section 4003 of the 21st Century Cures Act (Pub. L. 114–255) amended section 3000 of the PHSA to add a new paragraph (10) to include a statutory definition of ''interoperability.'' Interoperability is defined to mean, with respect to health information technology, such health information technology that—(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (C) does not constitute information blocking as defined in section 3022(a) of the Public Health Service Act.

In the CY 2027 PFS proposed rule (91 FR 44140 through 44141), we described how several agencies within HHS have sought public input on interoperability for various health programs. We noted that CMS views duplicate imaging and laboratory testing as one of several use cases in which the lack of clinical interoperability causes non-trivial beneficiary harm and program integrity concerns. In recognition of that perspective, the broader department, and the Office of the National Coordinator for Health Information Technology (ONC) in particular, adopts standards that facilitate easier exchange of diagnostic clinical information and includes criteria in the ONC Health IT Certification Program that address the certification of health IT to exchange this information. In the January 30, 2026 **Federal Register** (91 FR 4054), ONC published an RFI titled, ''Request for Information: Diagnostic Imaging Interoperability Standards and Certification''. A summary of the efforts described in the January 2026 RFI (91 FR 4055), to build diagnostic imaging requirements into health IT certification, is available in the CY 2027 PFS proposed rule (91 FR 44140).

Another example of HHS seeking public input on interoperability was in the Request for Information; Health Technology Ecosystem'' which appeared in the May 16, 2025 **Federal Register** (90 FR 21034) (hereinafter ''Health Technology Ecosystem RFI''). The comments in response to the Health Technology Ecosystem RFI stated that the imaging exchange environment remains fragmented and unreliable, with ongoing dependence on CDs and DVDs and limited availability of modern, API-enabled tools that would allow patients and health care providers to access and share images seamlessly. Interested parties also raised privacy and security considerations that must be accounted for as exchange capabilities evolve. Other public feedback highlighted support for building on existing standards rather than creating entirely new exchange paradigms. Commenters explained that laboratory interoperability had similar patterns regarding data exchange, where challenges frequently stem from differing ordering workflows, variations in result reporting practices, local coding conventions, and inconsistent implementation of standards. These issues mirror broader interoperability challenges and reinforce the need for coordinated, standards-based approaches across diagnostic domains.

Other key information received in response to the Health Technology Ecosystem RFI:

- The current system of fragmented patient portals is unworkable.
- A unified, ''one-stop shop'' for health records is the universal goal.
- API access must go beyond the USCDI data set to the full electronic health information (EHI).
- Existing data access tools are insufficient.

In the CY 2027 PFS proposed rule (91 FR 44141) we explained that based on this input, we believe CMS can help improve interoperability between laboratories and physicians, hospitals, and other care delivery organizations. Specifically, participation in a national interoperability network for exchanging diagnostic imaging and laboratory results in a standardized format remains top of mind for the Department. Such participation would allow physicians, hospitals, laboratories, and other care delivery organizations to more easily access relevant clinical data to prevent the duplicate imaging and testing discussed previously in this section. We noted that network participation alone may not solve the problem. Networks must resolve fundamental technical issues like authentication (for example, are you who you say you are?); authorization (for example, are you allowed to access the data?); and patient matching (for example, what records are associated with the individual in question?). Without a reliable way to match records across systems, even well-connected networks would return incomplete or incorrect results.

We also explained that we considered building on the existing Electronic Notifications Condition of Participation (CoP) at 42 CFR 482.24(d) to require hospitals to participate in a national interoperability network. We stated that we believe that the relationship to patient health and safety is clear: timely and accurate information leads to coordinated, safer care and treatment decisions for patients. While we believe a CoP, for Medicare and Medicaid participating hospitals, would be an appropriate mechanism to drive interoperability, we also recognize that unlike other provider types the only statutorily available penalty for noncompliance with the hospital CoPs is termination from the Medicare program, as provided under section 1866(b)(2)(A) and (B) of the Act. We believe this would be overly burdensome. However, we stated that we will continue to monitor hospital advances in interoperability and may consider future rulemaking or look to other programs like the Medicare Promoting Interoperability Program or the Hospital Inpatient Quality Reporting program (IQR) or both.

Building upon the RFIs noted previously, we asked for input on the following questions specific to diagnostic laboratory and imaging interoperability:

- Because image exchange can involve substantial technical and operational costs, should HHS or CMS consider incentives to support adoption and implementation, and if so, what form should those incentives take?

- Given variability in conformance to existing laboratory and imaging exchange standards, would interested parties find value in expanded conformance testing tools, certification approaches, or implementation guidance?
- How should CMS account for cases in which repeat imaging occurs because prior imaging results were not available for timely, standards-based reuse? Should CMS consider payment, quality, or participation policies that create accountability for the initial imaging provider, furnishing entity, or facility when failure to make results reusable contributes to avoidable repeat imaging? Are there penalties or disincentives for non-compliance we should consider?
- For laboratory interoperability specifically, what barriers continue to impede exchange despite the availability of established standards, and what policy levers could help address those barriers? Should we consider incentives to support laboratory adoption and implementation of health data standards?
- Should CMS establish a minimum data standard for result shareability, for example, a United States Core Data for Interoperability (USCDI+) supplement for imaging and laboratory results, requiring all participating entities to deliver both a structured Fast Healthcare Interoperability Resources (FHIR) R4 Diagnostic Report resource and a human-readable Portable Document Format/Archive (PDF/A) rendition to the ordering health care provider's designated endpoint as a condition of Medicare payment? How should CMS address health care providers who have not yet implemented FHIR-native workflows, especially in rural areas?

We received public comment on this RFI. Commenters from a variety of interested parties, including professional organizations, hospitals, physician offices and the public provided feedback.

Comment: In general, commenters support CMS efforts to reduce costs associated with duplicative testing and imaging. However, some commenters do not support CMS denying Medicare payment for duplicative testing. These commenters noted that often times duplicate testing may be clinically necessary, and health care providers should not be penalized if access to prior results is not readily available. Some commenters expressed that improving laboratory and digital imaging interoperability should be addressed and recommend CMS work with interested parties and solicit feedback.

Response: We thank the commenters for their feedback.

IV. Updates to the Quality Payment Program

A. CY 2027 Modifications to the Quality Payment Program Reporting and Data Submission

1. Executive Summary

a. Overview

This section of this final rule outlines changes to the Quality Payment Program starting January 1, 2027, except as otherwise noted for specific provisions. We continue to move the Quality Payment Program forward, including focusing on alignment between the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Model (Advanced APM) tracks of participation, alignment with broader CMS initiatives, and new options for clinicians to participate in more meaningful ways. We aim to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through MIPS and Advanced APMs for the CY 2027 performance period/2029 payment year.

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is a value-based payment program, by which clinicians are rewarded for providing high-value, high-quality care to their patients in a cost-efficient manner. There are two ways for clinicians who provide services under the Medicare program to participate in the Quality Payment Program: MIPS and Advanced APMs. The statutory requirements for the Quality Payment Program are set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs.

For the MIPS participation track, MIPS eligible clinicians (defined at § 414.1305) [392] are subject to a MIPS payment adjustment (positive, neutral, or negative) based on their performance in four performance categories: quality, cost, improvement activities, and Promoting Interoperability. We assess each MIPS eligible clinician's performance according to established performance standards for the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a ''final score'' as defined at § 414.1305). In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at 42 CFR 414.1380(c)(1). The weights of the performance categories in the final score for the CY 2027 performance period/2029 MIPS payment year are as follows, unless a different scoring weight is assigned under 42 CFR 414.1380(c)(2): 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category.

Once calculated, each MIPS eligible clinician's final score is compared to the performance threshold established in prior rulemaking for that performance period to calculate the MIPS payment adjustment as specified in section 1848(q)(6) of the Act, such that the MIPS eligible clinician will receive in the applicable MIPS payment year: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. In calculating the MIPS payment adjustment for a MIPS eligible clinician, we account for the scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act. We then apply the MIPS payment adjustment to amounts otherwise paid under Medicare Part B for covered professional services for the MIPS eligible clinician for the applicable MIPS payment year and payments for covered professional services could be increased, decreased, or not adjusted based on the MIPS eligible clinician's final score relative to the performance threshold.

Section 1848(q) of the Act sets forth other requirements applicable to MIPS, including opportunities for feedback, targeted review, and public reporting of MIPS-eligible clinicians' performance. Section 1848(r) of the Act sets forth more specific requirements for development of measures for the cost performance category under MIPS.

For the Advanced APM participation track, if an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) or Partial QP status, they are excluded from the MIPS reporting requirements and payment adjustment (though eligible clinicians who are Partial QPs

[392] We note that the term MIPS eligible clinician is defined at § 414.1305 as including a group of at least one MIPS eligible clinician billing under a single tax identification number. We refer readers to our policies governing group reporting and scoring under MIPS as set forth at § 414.1310(e).

may elect to participate in MIPS and be subject to the MIPS reporting requirements and payment adjustment). In alignment with the application of QPP eligibility determinations, we are finalizing our proposal with modification to apply QP and Partial QP status to the TIN/NPI level. For eligible clinicians with QP and partial QP status at the individual level, we will apply partial QP status to all TIN reassignments for the NPI as codified at § 414.1425(d). Under current law, eligible clinicians who are QPs for the 2024 performance year/2026 payment year and beyond will receive an increased physician fee schedule update of 0.75 percent qualifying APM conversion factor. We note that, historically, QPs received a lump sum APM Incentive Payment in the corresponding payment year, calculated as a specified percentage of the QP's paid claims for covered professional services from the base year. Only legislation enacted by Congress can make changes to either the enhanced QP conversion factor updates or the APM Incentive Payment.

We plan to continue developing policies for the Quality Payment Program that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We continue to implement MIPS Value Pathways (MVPs) to allow for a more cohesive participation experience by connecting activities and measures from the four MIPS performance categories that are relevant to a specialty, medical condition, or a particular population.

As we move into the 10th year of the Quality Payment Program, we will be implementing the updates set forth in this section of this final rule, encouraging continued improvement in clinicians' performance with each performance year and driving improved quality of health care through payment policy.

b. Summary of Major Proposals

(1) Transforming the Quality Payment Program

The Making America Healthy Again (MAHA) initiative (*https://www.hhs.gov/maha/index.html*) represents a shift from the focus on chronic disease management and moves toward prevention and restoring foundational wellness. This initiative aims to address the root causes of poor health outcomes by reducing chronic disease rates, improving nutrition, promoting preventative care, and increasing transparency in health systems. This vision is supported by aligning policies in MIPS and APMs within the Quality Payment Program with the foundational pillars of MAHA. We are expanding the MVP portfolio to include Diabetic Disease and Hypertension MVPs that address the prevention of chronic illnesses and aim to reduce the incidence and impact of long-term conditions. In alignment with the goal of promoting preventive care and fostering a more proactive and holistic approach to health management, we are finalizing new improvement activities under the ''Advancing Health and Wellness'' subcategory within the improvement activities performance category. The improvement activities integrate concepts that address nutrition, implement lifestyle approaches to disease management, and support patient wellness to ensure a healthier future.

Through the policies described in this final rule, we intend to transform and simplify MIPS, promote the use of connected measures and activities, continue rewarding clinicians for providing high value care, and use data-driven information to help all clinicians improve care and engage patients. We are finalizing, with modification, our proposal to sunset the traditional MIPS reporting option. Specifically, we are delaying the sunset of traditional MIPS by two years until the CY 2031 performance period/2033 MIPS payment year. Therefore, beginning with the CY 2029 performance period/2031 MIPS payment year, MVPs would be the only reporting option for MIPS eligible clinicians who do not participate in a MIPS APM. Traditional MIPS will remain available through the CY 2030 performance period/2032 MIPS payment year.

(a) Transforming MIPS: MVP Strategy

MVPs will improve value, reduce burden, and inform patient choice in selecting clinicians. To support our goal of phasing out traditional MIPS and transitioning eligible clinicians to MVP reporting, we are finalizing with modification policies supporting MVP only reporting for MIPS. The MVP reporting option offers aligned measures and activities across quality, cost, improvement activities, and Promoting Interoperability performance categories, focusing on specific specialties, conditions, or patient populations to make reporting more meaningful. Specifically, we proposed that beginning in the CY 2029 performance period/2031 MIPS payment year, MIPS eligible clinicians not reporting the APM Performance Pathway(APP), would be required to report the measures and activities in a selected MVP for MIPS. However, we have reconsidered the timeline for the full transition to MVP reporting and are delaying the sunset of traditional MIPS reporting by two years to allow us to further refine MVP policies and provide additional time for clinicians to prepare for full MVP implementation.

Specifically, we are finalizing a policy to require that beginning in the CY 2031 performance period/2033 MIPS payment year, MIPS eligible clinicians not reporting the APP would be required to report the measures and activities in a selected MVP to meet MIPS reporting requirements. We are finalizing our proposal as proposed to include virtual groups in MVP reporting beginning with the CY 2029 performance period/2031 MIPS payment year to ensure all eligible clinicians can report MVPs.

(b) MIPS Value Pathways Development and Maintenance

To continue moving the healthcare community toward value-based, high-quality, safe, and cost-efficient care, we are finalizing as proposed three new MVPs around the following topics: Diabetic Disease, Hypertension, and Hospitalist.

We are also finalizing as proposed MVP maintenance updates to our MVP inventory that are aligned with the MVP development criteria and take into consideration feedback from interested parties we have received through the maintenance process. Additionally, we updated all the MVPs to include MIPS core measures. Finally, we are renaming the Rehabilitative Support for Musculoskeletal Care MVP to Rehabilitative Support MVP to better represent the measures and activities included in the MVP.

(c) APM Performance Pathway

We are finalizing our proposal as proposed to align quality measures in the APP, original quality measure set and the APP Plus quality measure set to reflect our proposed changes to measures specified for the quality performance category as discussed in section IV.A.4.b.(2) of this final rule.

(d) Fast Healthcare Interoperability Resources (FHIR) Request for Information

We are advancing quality measurement by transitioning existing quality measures and reporting processes to Fast Healthcare Interoperability Resources® (FHIR®)-based digital reporting options. In the CY 2027 PFS proposed rule, we sought input on the anticipated transition

timeline, key milestones, and implementation considerations for FHIR-based quality reporting in the Quality Payment Program and other CMS quality reporting programs (91 FR 44143)).

(e) MIPS Quality Performance Category

For the CY 2027 performance period/2029 MIPS payment year, we are finalizing our proposal, as proposed, to establish a measure set inventory of 180 MIPS quality measures, of which 177 are available in traditional MIPS and three are available only for use in MVPs. Finalized changes to the measure set inventory include 20 measure removals, 10 measure additions for CY 2027, one measure addition for CY 2028, and 43 substantive changes to existing measures.

The finalized measure removals focus on low bar process measures, measures reaching extremely topped-out status or the end of the topped-out measure lifecycle, measures that are duplicative of new or current measures, measures with limited adoption and therefore no benchmark, measures lacking robustness, and measures the steward will no longer maintain. The finalized measure additions focus on measuring patient-reported outcomes and chronic disease management. Finalized substantive changes to existing measures will ensure the measures included in MIPS continue to be meaningful and drive improvements in quality of care.

Beginning with the CY 2027 performance period/2029 MIPS payment year, we are finalizing, as proposed, the implementation of the MIPS core measure designation in traditional MIPS and MVPs. We are also finalizing, as proposed, our proposal to remove the high priority designation from MIPS quality measures and the MVP inventory. Additionally, we are finalizing our proposal, as proposed, to no longer use the high priority designation as one of the retention criteria for MIPS quality measures and the MVP inventory.

Furthermore, beginning with the CY 2027 performance period/2029 MIPS payment year, we are finalizing, as proposed, the removal of the current quality measure data submission requirement of one outcome (or one high priority measure if an outcome measure is not available) for traditional MIPS and MVP reporting and replacing it with the requirement that eligible clinicians must report at least one MIPS core measure (or, if an applicable MIPS core measure is not available, report one other MIPS non-core measure). We are also finalizing, as proposed, that if a MIPS eligible clinician does not have an available and applicable MIPS core measure, they must attest during the data submission period that a MIPS core measure is not available and applicable for them to report. The clinician will then be required to choose another measure to report instead of the MIPS core measure.

Also, we are finalizing, as proposed, that clinicians in small practices will be exempt from the proposed MIPS core measure requirement and will not need to submit an attestation if a MIPS core measure is not available and applicable to them.

Lastly, we are finalizing, as proposed, the proposals that expand the definition of the collection type to include Medicare Electronic Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs); establish the data submission criteria for Medicare eCQMs; and establish the data completeness criteria for Medicare eCQMs.

(f) MIPS Cost Performance Category

We are finalizing our proposal as proposed to update the operational list of care episodes and patient condition groups and codes to reflect coding changes identified through our annual maintenance process for MIPS cost measures.

(g) MIPS Improvement Activities Performance Category

We are finalizing the following updates to the MIPS Improvement Activity Inventory beginning with the CY 2027 performance period/2029 MIPS payment year. First, we are finalizing the addition of six new improvement activities into two subcategories: (1) Care Coordination and (2) Advancing Health and Wellness, our newest subcategory. Second, we are finalizing modifications to five existing improvement activities. Third, we are finalizing the removal of eleven improvement activities currently specified for the performance category.

(h) MIPS Promoting Interoperability Performance Category

We are finalizing, as proposed, proposals pertaining to the Office of the National Coordinator for Health Information Technology (ONC) Direct Review attestation, ONC-Authorized Certification Bodies (ONC–ACB) Surveillance attestation, definition of Certified Electronic Health Record Technology (CEHRT), Security Risk Analysis measure, Electronic Prior Authorization measure, and Electronic Prior Authorization for Prescription Drugs measure.

- Starting with the CY 2026 performance period/2028 MIPS payment year, we are finalizing, as proposed, the proposal to remove the ONC Direct Review attestation and the ONC–ACB Surveillance attestation.
- Starting with the CY 2027 performance period/2029 MIPS payment year, we are finalizing, as proposed, the following proposals:
  - ++ Modification to the definition of CEHRT to align with the applicable ONC proposals to remove certain certification criteria from the ONC Health IT Certification Program as outlined in the Health Data, Technology, and Interoperability: ONC Deregulatory Actions to Unleash Prosperity (HTI–5) final rule;
  - ++ Modification to the Electronic Prior Authorization measure by updating the measure description, and for the CY 2027 performance period, changing the measure from being a required measure to being an optional measure; and
  - ++ Removal of the Security Risk Analysis measure.
- Starting with the CY 2028 performance period/2030 MIPS payment year, we are finalizing, as proposed, the following proposal:
  - ++ Modification to the Electronic Prior Authorization measure by updating the measure description to account for additional requirements pertaining to the measure, and changing the measure to being a required measure; and
  - ++ Add a new measure, Electronic Prior Authorization for Prescription Drugs, as a required measure under the Health Information Exchange objective.

(i) MIPS Scoring

We are finalizing our proposed scoring policies consistent with the finalized MIPS core measure requirement for MIPS eligible clinicians beginning in the CY 2027 performance period/2029 MIPS payment year. Specifically, we are finalizing our proposal to assign zero measure achievement points for one quality measure for clinicians reporting data under traditional MIPS and MVP reporting, if they do not submit a MIPS core measure and do not attest during data submission that they do not have an available and applicable MIPS core measure.

We are finalizing as proposed the list of topped out measures impacted by limited measure choice in specialty measure sets and MVPs to be subject to the defined topped out measure benchmark for the CY 2027 performance

period/2029 MIPS payment year. We are finalizing our proposal to modify the publishing location of topped out measures impacted by limited measure choice and scored according to the defined topped out benchmark. We are also finalizing our proposal to apply the defined topped out benchmark for MIPS core measures that are topped out for 2 or more consecutive years.

Lastly, we are finalizing, as proposed, the following proposed modifications: The benchmarking methodology for the Medicare CQMs collection type by extending the use of flat benchmarks; establishment of a flat benchmarking methodology for the proposed Medicare eCQMs collection type; and modification of the Electronic Prior Authorization measure from being a required measure to being an optional measure worth 10 bonus points under the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year.

(j) Third-Party Intermediaries

In this final rule, we update our requirements for third-party intermediaries related to the conditions for approval of Qualified Clinical Data Registries (QCDRs) and qualified registries, remove the additional requirements for health IT vendors, and revise our remedial action and termination policies. At a high level, we are finalizing the following as proposed:

- Clarification that the additional requirements for health IT vendors no longer apply beginning with the CY 2025 performance period/2027 MIPS payment year, as health IT vendors are no longer permitted to submit MIPS data as a third-party intermediary starting in that year;
- Making minor revisions to the audit requirements;
- Modification to our policy so that third-party intermediaries that do not submit data for 1 year would be terminated;
- Revision to existing policies to specify a QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one MIPS core measure to align with the finalized proposal to removal of high priority designation from MIPS quality measures and the MIPS core measure reporting requirements in section IV.A.4.d.(1)(c)(i) of this final rule; and
- Modification to the qualified postings' policy in which changes to the information submitted should not be done after the qualified posting is publicly posted on the Quality Payment Program website (*https://qpp.cms.gov/*).

(k) Calculating MIPS Final Score

In this final rule, we are finalizing our proposal that beginning with the CY 2027 performance period/2029 MIPS payment year we will use whatever data is most current and reliable to determine if an individual MIPS eligible clinician is located in an area that has been identified as being affected by an extreme and uncontrollable circumstance (EUC). We are also finalizing, as proposed, our proposal to adjust the deadline by which clinicians will be able to submit reweighting requests for the quality, improvement activities, and Promoting Interoperability performance categories due to scenarios where a third-party intermediary did not submit data on their behalf in accordance with the applicable data submission deadlines. Specifically, we are finalizing our proposal that beginning with the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians will be able to submit reweighting requests on or before December 31st of the year preceding the relevant MIPS payment year.

(l) Public Reporting

The public reporting section of this final rule contains a policy and RFI for improvements to the CMS Compare Tools hosted by the U.S. Department of Health and Human Services (HHS) available on clinician profile pages at *https://www.medicare.gov/care-compare/* and in the Medicare Provider Data Catalog available at *https://data.cms.gov/provider-data/topics/doctors-clinicians.*

We are finalizing, as proposed, our proposal to remove the requirement preventing public reporting of any performance data reported through an MVP on new improvement activity or Promoting Interoperability (PI) measure, objective, or activity during the first year in which it is included in such MVP. Under the removal of this requirement, performance information for new improvement activities and PI measures will be publicly reported on CMS Compare Tools during the first year in which the measures and activities are included in the program, regardless of reporting option.

We also solicited feedback on improvements to the current star rating assignment methodology for quality measure scores collected under the administrative claims collection type. With more information, we can determine whether an alternative methodology for star rating assignments is more appropriate for administrative claims quality measures prior to the public reporting of these scores on clinicians' profile pages on the *Medicare.gov* Compare Tool.

(2) Advanced APM Proposals

We are finalizing the policy with modification to apply QP status, and Partial QP status, at the TIN/NPI level. For eligible clinicians with QP and partial QP status at the individual level, we will apply partial QP status to all TIN reassignments for the NPI as codified at § 414.1425(d).

We are finalizing, as proposed, our proposal to clarify language at § 414.1425(c)(5) pertaining to when QP status is lost as a result of an APM Entity terminating participation from an Advanced APM.

We are finalizing that for certain APMs where a participation list is not practicable, the APM will not provide a participation list for as a MIPS APM or APM participation for QPP purposes.

We are finalizing, as proposed, modifications to the conditions by which we award credit for Improvement Activities specified at § 414.1355 to ensure that participants receive credit.

We are finalizing modifications to the thresholds established at § 414.1430 in accordance with the Consolidated Appropriations Act, 2026.

2. Definitions

At § 414.1305, we are finalizing revisions to the definitions of the following terms:

- APM Incentive Payment
- Collection type
- High priority measure
- MVP Participant
- Participation List

These terms and definitions are discussed in detail in the relevant sections of this final rule.

3. Transforming MIPS: MIPS Value Pathway (MVP) Strategy

We play a leading role in transitioning the Federal health care system from Original Medicare payment toward value-based payment, incentivizing higher quality of care over higher quantity of care. The Merit-based Incentive Payment System (MIPS) aims to drive value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. We continue to focus on transforming health care delivery, driving higher value care, and increasing alignment with other CMS programs and initiatives to reduce burden. We intend to continue our efforts to align the Quality Payment Program with the broader aims of CMS to ensure patients receive the care they want and deserve by promoting

prevention, wellness, and chronic disease management. We are focused on achieving the best outcomes and safest care across the full care journey through innovation and collaboration. We are implementing meaningful improvements designed to strengthen healthcare delivery and advance patient outcomes. Through these efforts, we strive to create a healthcare system that not only responds to chronic disease but works proactively to prevent it.

In the CY 2022 PFS proposed rule and CY 2025 PFS final rule, we stated our intent to transform MIPS and obtain more meaningful, comparable performance data, and drive higher value care through MVPs (86 FR 39356 and 89 FR 98346) and that we intended to propose a full transition to MVP reporting along with the Alternative Payment Model (APM) Performance Pathway (APP) reporting to support movement towards value-based payment (86 FR 65394 through 65396, 87 FR 70034, and 89 FR 98346). As noted in the CY 2025 PFS proposed rule (89 FR 62012), robust MVP availability and clinician coverage would be a precursor to sunsetting traditional MIPS. Through this final rule and future rulemaking, we acknowledge that we will need to develop policies to support MVP reporting for all MIPS eligible clinicians by the CY 2031 performance period/2033 MIPS payment year. We will continue engaging with interested parties, including specialists and specialty societies, to identify gaps and opportunities, and leveraging additional policy options, as needed.

In this section, we are finalizing with modification on our proposal to sunset traditional MIPS reporting. Specifically, we are finalizing with modification to require that beginning in the CY 2031 performance period/2033 MIPS payment year, MIPS eligible clinicians, not participating in a MIPS Alternative Payment Model (APM), would be required to report the measures and activities in a selected MVP. The MVP reporting option offers aligned measures and activities across the quality, cost, improvement activities, and Promoting Interoperability performance categories. MVPs focus on specific specialties, conditions, or patient populations to make reporting more meaningful. With increased MIPS eligible clinicians reporting MVPs, MVP comparative performance data may become valuable to patients and caregivers in evaluating clinician performance and making choices about their care. We are finalizing that MIPS eligible clinicians, not participating in a MIPS APM, would be required to report the measures and activities in a selected MVP beginning in the CY 2031 performance period/2033 MIPS payment year. We are also finalizing to include virtual groups in MVP reporting beginning in the CY 2029 performance period/2031 MIPS payment year to ensure all MIPS eligible clinicians can report MVPs.

a. Overview

In the CY 2022 PFS final rule, we finalized the MVP reporting option for MIPS eligible clinicians beginning in the CY 2023 performance period/2025 MIPS payment year to serve as an additional reporting option (86 FR 65391 through 65394). Currently there are three reporting options: MVPs, traditional MIPS, and the APM Performance Pathway (APP). We noted that we created the MVP reporting option to improve value, reduce burden, and inform patient choice in selecting clinicians. We also stated the MVP framework will move MIPS forward on the path to value by offering a reporting option that connects measures and activities across MIPS performance categories, better informing and empowering patients to make decisions about their healthcare, and by helping clinicians to achieve better outcomes using robust and accessible healthcare data and interoperability (86 FR 65392).

In the CY 2027 PFS proposed rule (91 FR 44145 through 44147), we discussed our intent to propose to transform MIPS through a full transition to MVP reporting to allow reporting of both MVPs and the APP to support movement towards value-based payment. We stated that if the proposal to phase out traditional MIPS reporting for MIPS eligible clinicians not participating in a MIPS APM is finalized, there would be two reporting options for MIPS: MVPs and the APP. The transition from clinicians selecting from a large inventory of measures and activities in traditional MIPS to reporting more clinically relevant measures and activities in MVPs represents a necessary progression in MIPS if we are to achieve our intended goals of connecting measures and activities across MIPS and providing meaningful data to inform and empower patients to make decisions about their healthcare. We refer readers to the CY 2020 PFS final rule (84 FR 62946), the CY 2021 PFS final rule (85 FR 84845 through 84849), the CY 2022 PFS final rule (86 FR 65419 through 65422 and 86 FR 65396), and the CY 2023 PFS final rule (87 FR 70035) for discussion of previously finalized MVP policies and MVP-related Requests for Information (RFIs). We have made continued and substantial progress in developing an MVP inventory offering MIPS eligible clinicians the ability to report an MVP with clinically relevant measures. As discussed in section IV.A.4.a of this final rule, we previously finalized 27 MVPs and are finalizing three additional MVPs for the CY 2027 performance period/2029 MIPS payment year. Our MVP inventory will increase to 30, potentially resulting in coverage of approximately 98 percent of specialties for MIPS eligible clinicians based upon self-reported specialty designations data and MVP topic. Please see section IV.A.4.a of this final rule for more information on MVP development. Phasing out traditional MIPS reporting and advancing full implementation of MVPs will move MIPS away from a fragmented reporting approach toward a more meaningful, specialty-aligned framework. Further, MVPs will continue to advance the overall goals of MIPS to align quality and payment, foster accountability, and improve care and outcomes for people served by Medicare.

b. Background on Full MVP Implementation

The MVP framework was introduced in the CY 2020 PFS final rule (84 FR 62946 through 62948). In the CY 2022 PFS proposed rule, we noted our intent to sunset traditional MIPS in a future performance period and solicited public comments on: (1) the length of time MVP reporting should be voluntary; (2) the timing for when we should fully implement MVPs; and (3) sunsetting the traditional MIPS reporting option (86 FR 39356). Responding interested parties supported a transparent, gradual transition to MVPs with voluntary MVP reporting and adequate time to prepare for reporting an MVP (86 FR 65391 through 65396). In the CY 2022 PFS final rule, we finalized that voluntary reporting of MVPs would start in the CY 2023 performance period/2025 MIPS payment year to allow time for MVP participants and third-party intermediaries to adapt to changes in policy, reporting requirements, and updates to their technology systems (86 FR 65394 to 65396).

In the CY 2025 PFS proposed rule, we issued a Request for Information (RFI) on the development of a timeline for the full transition to MVPs beginning in the CY 2029 performance period/2031 MIPS payment year (89 FR 62011 and 62012). We noted that MVPs would support value-based payment, reduce reporting burden through more targeted and aligned measures and activities, improve comparisons among similar clinicians, and provide better information for patients. In response to the RFIs on full MVP implementation,

commenters identified several policies and activities that could support adoption, including concerns about clinicians having less flexibility to choose quality measures within an MVP. We recognize that full MVP implementation may limit the choice of measures and activities compared to those currently afforded by policies in traditional MIPS. However, MVPs include a set of clinically relevant measures and activities that provide an opportunity for MIPS performance data to better reflect clinicians' scope of care.

With the full implementation of MVPs, clinicians who are not participating in a MIPS APM would be required to select an MVP relevant to their scope of care and further choose the quality measures and improvement activities within the selected MVP that reflect the care provided. Widescale adoption of MVPs, using a standardized connected set of measures and activities for a specialty or medical condition, may generate important and meaningful information for patients to be able to compare the performance of clinicians on the same or similar sets of measures. Additionally, we refer readers to section IV.A.4.d.(1)(c)(i) of this final rule for details on the finalized MIPS core measure requirement for traditional MIPS and MVP reporting. The MIPS core measure requirement would further clarify how MVPs would emphasize and increase reporting on select quality measures that are most important to clinicians and patients and reflect the care that is central to an applicable specialty, medical condition, or episode of care. In response to feedback from interested parties that full implementation of MVPs requires the ability of all specialties to participate, we finalized six new MVPs and updated 21 previously finalized MVPs in the CY 2026 PFS final rule. (90 FR 49847). We refer readers to section IV.A.4.a.(1) of this final rule regarding the three new MVPs we are finalizing for the CY 2027 performance period/2029 MIPS payment year.

In response to the RFIs that sought feedback on full MVP implementation (89 FR 62011 through 62016), some interested parties voiced concerns that full implementation of MVPs and subgroup policies would result in increased reporting burden, particularly for multispecialty groups required to participate as subgroups for reporting an MVP beginning in the CY 2026 performance period/2028 MIPS payment year. We note that we have modified our MVP and subgroup reporting policies to address some of these concerns. Our current MVP and subgroup reporting policies are aligned with the goal for full MVP implementation and would encourage increased participation from specialists. As we have greater MVP adoption and subgroup reporting, we anticipate specialist reporting through MVPs would increase the amount of performance data available to patients when selecting a clinician (89 FR 62012). In the CY 2022 PFS final rule (86 FR 65397), we finalized the subgroup reporting option for clinicians participating in MVP reporting in response to concerns from interested parties over the prior years that large multispecialty groups often submit data that is not necessarily representative of all the clinicians that make up that group. To address concerns from interested parties on the MVP subgroup reporting burden, we finalized policies in the CY 2026 PFS final rule (90 FR 49842 through 49846) allowing a group practice to self-attest and identify the need to divide into subgroups based on the scope of care provided by clinicians in their group. We believe the potential increase in the reporting burden for larger groups to divide into subgroups is outweighed by the benefit of additional information clinicians and patients will receive through increased specialist reporting data (86 FR 65393 and 65394). We will continue to monitor subgroup participation in MVP reporting to determine potential policy changes in the future as we transition to full MVP implementation for MIPS eligible clinicians not participating in the APP.

Historically, we have received feedback from MIPS eligible clinicians in small group practices, defined at § 414.1305 as a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period, about the lack of adequate resources to successfully meet MIPS reporting requirements. To provide flexibility and to prevent additional burden for small groups we finalized a policy to maintain the MVP group reporting option for small practices, without the need for small practices to form subgroups (90 FR 49842 to 49843). We also note that MVP policies continue to offer the same scoring flexibilities for small group practices available to such practices reporting traditional MIPS finalized at § 414.1380(b)(1) (86 FR 65419 through 65422). We refer readers to sections IV.A.4.d.(1)(c)(iii) and IV.B.1.b.(1) of this final rule for details on the proposed exemption of small practices from the MIPS core measure reporting requirements and proposed scoring flexibilities for small practices.

Finally, in response to the RFI (89 FR 62011 through 62016) interested parties voiced concerns about quality measures within MVPs that cannot be scored for reasons beyond the clinician's control, such as measures without benchmarks, and the potential for some topped out measures to have a scoring cap. As noted previously, the existing scoring policies established in traditional MIPS at § 414.1380(b)(1), specific to small group practices and the scoring policies related to measures without benchmarks, measures that do not meet case minimum, and measures that do not meet data completeness requirements also apply to MVP scoring (86 FR 65419 through 65420). We acknowledge concerns from clinicians with limited choice of measures, and in the CY 2026 PFS final rule, we finalized expansion of our approach for identifying measures impacted by limited choice and subject to topped-out measure benchmarks to MVPs (90 FR 49903 through 49908). Additionally, we refer readers to section IV.B.1.b. of this final rule for newly finalized policies on the scoring of topped out measures included in MVPs, which address concerns that interested parties raised with respect to those clinicians with limited measure choice and scoring caps for topped out measures. Commenters responding to the RFI also requested that we develop scoring policies to ensure scoring between MVPs is equitable. Therefore, we solicited feedback on the future direction of MVP scoring in an RFI in the CY 2027 PFS proposed rule (91 FR 44207) seeking input on potential scoring policies to ensure fairness across MVPs.

c. Update to the Timeline for Full MVP Implementation

As discussed previously in section IV.A.3.a. of this final rule, MVP reporting became available for clinicians beginning in the CY 2023 performance period/2025 MIPS payment year (86 FR 65394 to 65396). In previous PFS rules, we stated our intention to fully transition to MVPs and to sunset traditional MIPS (85 FR 50279 and 50284, 86 FR 65394 through 65396).

We are concerned that continuing to maintain the traditional MIPS reporting option may impede MVP adoption for MIPS eligible clinicians. Additionally, it may cause slow adoption which may delay the intended benefits of MVPs, including simplification of MIPS and improving comparable clinician performance data that helps to drive value and inform clinician selection by patients. In addition, the availability of two MIPS reporting options, MVPs and traditional MIPS, creates challenges for developing and refining MVP policies over time due to limited MVP reporting resulting from continued clinician

reliance on the traditional MIPS reporting option. However, in establishing the sunset date we are also cognizant of the need to provide ample time for clinicians to prepare for full MVP reporting. Therefore, in the CY 2027 PFS proposed rule (91 FR 44147), we proposed to phase out traditional MIPS reporting for MIPS eligible clinicians not participating in a MIPS APM beginning in the CY 2029 performance year/2031 MIPS payment year. Transitioning to MVP implementation alongside the option for MIPS APM participants to participate in MIPS through the APP would support efforts to transform MIPS for clinicians and patients who rely on program performance information. We noted that traditional MIPS reporting would be available to clinicians through the CY 2028 performance period/2030 MIPS payment year. This proposed timeline would have provided a period of 6 years for voluntary MVP reporting, allowing clinicians time to engage in the development of the MVP inventory, update their systems and work processes to prepare for MVP reporting, and gain experience with MVP reporting. Clinicians would continue to be able to report through either traditional MIPS or via MVPs through the CY 2028 performance year/2030 MIPS payment year.

In the CY 2027 PFS proposed rule (91 FR 44147), we proposed that beginning in the CY 2029 performance period/2031 MIPS payment year, all MIPS eligible clinicians, with the exception of clinicians reporting through the APP, would report through an MVP. Specifically, we proposed to add under § 414.1365(a)(2) that beginning in the CY 2029 performance period/2031 MIPS payment year, except for clinicians reporting under the APP pursuant to § 414.1367, all MIPS eligible clinicians must report through an MVP. We believed that the CY 2029 performance year/2031 MIPS payment year would be an appropriate timeline for full implementation of MVPs and would offer sufficient time for MIPS eligible clinicians and groups to prepare for required MVP reporting. However, we have reconsidered the timeline and determined that additional time is needed for us to further refine the MVP policies. For example, we require additional time to increase MVP availability and transition to digital reporting. The additional time would further allow eligible clinicians to successfully transition to full MVP implementation. Therefore, as noted in section IV.A.3.c. of this final rule, we are delaying the sunset of traditional MIPS until the CY 2031 performance period/2033 MIPS payment year. We considered setting a date for the sunset of traditional MIPS that is more than five years in the future but we are concerned that delaying the sunset of traditional MIPS that far would discourage clinicians and groups from undertaking the changes necessary to successfully report MVPs. Therefore, we believe that our finalized timeline of sunsetting traditional MIPS beginning with the CY 2031 performance period/2033 MIPS payment year strikes an appropriate balance between providing additional time for clinicians to prepare for the transition to full MVP implementation and setting a timeline for the transition that offers strong encouragement for clinicians and groups to begin reporting MVPs.

As discussed in section IV.A.4.a.(1) of this final rule, we continue developing new MVPs that are relevant and meaningful for MIPS eligible clinicians. We intend to explore a range of strategies for transitioning to full MVP reporting, including, but not limited to, proposing additional MVPs. We recognize that clinicians may currently lack applicable measures and may not have an applicable MVP or may be unable to report a sufficient number of measures in an MVP. However, for subspecialists without many applicable and available measures in the MIPS measure inventory, we are aware of the need to develop reporting options or explore alternatives to reporting MVPs by the CY 2031 performance period/2033 MIPS payment year. For example, we may consider developing a process for clinicians to indicate at the time of MVP registration that no available MVP in the MVP inventory includes applicable and available measures and activities. Alternatively, we could consider expanding measure denominators as applicable to strengthen specialty coverage for clinicians with limited applicable measures. We could also consider policies that allow us to review available and applicable measures for clinicians in the selected MVP to reduce the denominator of the quality performance category to score the quality performance category with fewer than four measures.

We received public comments on this proposal to transition to MVP reporting beginning in the CY 2029 performance period/2031 MIPS payment year, except for clinicians reporting under the APP. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to sunset traditional MIPS beginning with the CY 2029 performance period/2031 MIPS payment year. Several commenters stated that the transition to MVP reporting would move the program to better accountability and improved reporting of meaningful quality data. Several commenters stated that CMS's proposed timeline would provide adequate time for clinicians to transition to MVP reporting.

Response: We thank commenters for their support and agree that the full transition to MVP reporting will result in improved reporting of meaningful quality data. We note that we have reconsidered the timeline for the full transition to MVP reporting and are delaying the sunset of traditional MIPS reporting by two years to allow us to further time to refine MVP policies. For example, we require additional time to increase MVP availability and transition to digital reporting. The additional time would further allow eligible clinicians to successfully transition to full MVP implementation. Therefore, traditional MIPS reporting will be available to clinicians through the CY 2030 performance period/2032 MIPS payment year. We considered a delay of one year, but as discussed in section IV.A.4.c. of this final rule we anticipate mandatory reporting of available FHIR-based digital quality measures (dQMs) would begin in the CY 2030 performance period/2032 MIPS payment year. Therefore, we decided that allowing an additional year of voluntary MVP reporting beyond the start of mandatory FHIR-based reporting of digital measures would better support clinicians who will be transitioning to FHIR-based digital reporting. Beginning in the CY 2031 performance period/2033 MIPS payment year, clinicians will need to participate in MIPS through an MVP or the APP.

Comment: Several commenters supported the proposal to sunset traditional MIPS beginning in the CY 2029 performance period/2031 MIPS payment year and offered recommendations for ensuring a smooth transition. A few commenters recommended that CMS provide support by working with clinicians and other interested parties to monitor negative unintended consequences and providing technical assistance to clinicians, EHR vendors, and third-party intermediaries. A few commenters recommended that CMS focus on the health IT infrastructure necessary for reporting MVPs. A commenter urged CMS to maintain stability in the MVP framework during the transition.

Response: We thank commenters for their support. We will consider the

recommendations for providing educational support as we plan communications and outreach activities to support the full transition to MVPs. We will continue to work with EHR vendors and third-party intermediaries and consider guidance for development of the health IT infrastructure necessary for reporting MVPs. We agree that it will be desirable to maintain stability in the MVP framework to the extent feasible as the transition to full MVP implementation proceeds and will take that goal into account in future rulemaking.

Comment: Several commenters encouraged CMS to offer additional flexibility in MVP reporting. A few commenters recommended that CMS closely monitor participation and performance during the transition to mandatory reporting. A commenter recommended that CMS offer fiscal leniency in the first few years of mandatory MVP reporting similar to the flexibility offered during the initial implementation of MIPS.

Response: We thank the commenters for these recommendations. We recognize that transitioning to mandatory MVP reporting may be a change for some eligible clinicians. We will monitor participation and performance data and may consider options in the future to provide flexibility in reporting requirements and scoring policies as feasible, consistent with the goals of full MVP implementation.

Comment: Many commenters expressed opposition to the sunset of traditional MIPS and stated that MVPs should remain voluntary to maintain clinician flexibility to choose the measures and activities that are most relevant to their practice. A commenter suggested that if MVPs demonstrate greater value and better alignment with clinical practice, clinicians and groups will migrate toward them, decreasing the need for traditional MIPS.

Response: We disagree with the commenters. We are concerned that maintaining traditional MIPS as a reporting option may hinder adoption of MVPs, delaying the benefits of simplification of MIPS and improving comparable clinician performance data. Although we agree that more clinicians and groups will begin reporting MVPs as they better understand the value of MVP participation, unless we establish a date for sunsetting traditional MIPS, clinicians will continue to rely on traditional MIPS, either instead of or in addition to MVPs. Maintaining both reporting options indefinitely would continue complexity in policies and operations and create challenges for evaluating the MVP performance and reporting experience and developing and refining MVP policies over time.

Comment: A few commenters expressed concern that MVPs incorporate the fundamental flaws of MIPS, including siloed performance categories, comparison of unlike clinicians, and lack of linkage between quality and cost measures. A few commenters stated that MVPs cannot accurately assess clinician performance because they are based on certain specialties or are overly broad, instead of focusing on a specific health condition, procedure, or episode of care that would be treated by the same clinician.

Response: We note that the MVP framework is built upon the statutory framework described in section 1848(q) of the Act, which requires us to include the four MIPS performance categories. However, because an MVP consists of a connected set of quality measures, cost measures, and improvement activities that are relevant to the MVP topic, clinicians would be able to choose measures and activities that are closely related. Furthermore, MVPs strengthen the relationship between the quality performance category and the cost performance category by scoring an MVP participant only on the cost measures in the MVP, which were selected because of their relevance to the MVP topic and the included quality measures. We anticipate that as more clinicians report MVPs and the measures and activities that are relevant to their scope of practice, scores will increasingly reflect comparisons of performance between similar clinicians. We note, however, that the statute requires that we compare all MIPS eligible clinicians to a single performance threshold. Regarding the commenters' concern that MVPs cannot accurately assess clinician performance because they are overly broad, we note that clinicians may choose the quality measures within an MVP that are most relevant to their scope of care provided. The MVP inventory finalized in Appendix 2 of this final rule does include several condition-focused MVPs such as Advancing Care for Heart Disease and Optimal Care for Kidney Health. However, it is not feasible to develop an MVP for every health condition, procedure or episode of care.

Comment: A few commenters opposed the sunset of traditional MIPS and expressed concern that requiring MVP reporting would create burden for small, independent, and rural practices. A commenter expressed concern that requiring MVP reporting would accelerate practice closure and decrease patient access to local clinicians.

Response: We note that MVP reporting requires clinicians in small, independent, and rural practices to report fewer quality measures when compared to the six quality measures that these clinicians are currently required to report in traditional MIPS. We are cognizant of the challenges small practices have faced in participating in MIPS and will continue to maintain existing flexibilities for small practices when MVPs are fully implemented.

Comment: Many commenters recommended that CMS maintain the traditional MIPS reporting option because the existing inventory of available MVPs is not sufficiently aligned with the care furnished by specialists and subspecialists. The commenters stated that, at a minimum, the MVP inventory should include measures relevant to 100 percent of specialties. Several commenters disagreed with CMS' estimate that the current MVP inventory provides coverage for approximately 98 percent of specialists, citing specialties such as allergy and immunology and radiation oncology as lacking a relevant MVP. A commenter compared existing and proposed MVPs to existing specialty measure sets and stated that there were gaps in specialty coverage and clinical relevance. The commenters further noted that the existence of an MVP for a given specialty (for example, ophthalmology) does not necessarily ensure meaningful quality measurement for all clinicians within that specialty. The commenters shared their concern that due to the lack of relevant measure options, clinicians may be required to report measures that are not clinically relevant to their practice in order to satisfy reporting requirements. In addition, many commenters urged CMS to ensure that MVPs include adequate measure sets for subspecialties. Many commenters expressed concern that broad specialty-based or condition-based MVPs may not fairly assess highly subspecialized clinicians, and that gaps in cost and quality measures applicable to subspecialty care and nonphysician care reduce the clinical relevance of MVPs for some clinicians, including interventional cardiologists, neuro-ophthalmologists, orthopedic sports medicine specialists, otolaryngologists, and physical therapists. A commenter stated that low MVP adoption may indicate that MVPs do not yet provide sufficient clinical relevance or flexibility to replace traditional MIPS. A few commenters recommended that CMS should retain traditional MIPS until appropriate specialty pathways are

developed, tested, and shown not to create inequitable scoring or participation barriers.

Response: We acknowledge the commenters' feedback and understand the concerns raised regarding the current availability and clinical relevance of MVPs for specialists, subspecialists, and other clinician types. The estimate that the current MVP inventory provides coverage for approximately 98 percent of clinicians reflects an assessment of the proportion of MIPS clinicians who self-reported a specialty designation that aligns with an MVP's identified target specialties. We acknowledge, however, that such alignment does not necessarily mean that the measures included in an MVP can be reported by every clinician within a specialty or subspecialty, nor does it ensure that all clinicians can meaningfully participate in a particular MVP. We will continue to work with interested parties to improve the clinical relevance, fairness, and usability of MVPs and to support clinicians in selecting the reporting option that is most appropriate for their practice. We encourage interested parties to submit potential new measures that will align with current goals and priorities during the annual Call for Measures which generally occurs in the spring of each year to fill identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS. To allow additional time for refinement of the MVP framework, as discussed in section IV.A.3.c. of this final rule, we are delaying the sunset of traditional MIPS by two years, so that the traditional MIPS reporting option is available for clinicians through the CY 2030 performance period/2032 MIPS payment year.

Comment: Many commenters expressed concern that the majority of the MVPs do not include a sufficient number of quality measures available through each collection type, limiting flexibility for clinicians to select and report measures within an MVP. The commenters recommended that MVPs include at least four quality measures under each collection type so that clinicians and group practices would not need to contract with multiple vendors to report an MVP. A few commenters noted that availability of a sufficient number of measures for each collection type would reduce reliance on QCDR measures. A few commenters also noted that including at least four measures for every collection type would enable third-party intermediaries and EHR vendors to support an MVP without being required to support every measure included in an MVP.

Response: While we acknowledge the recommendation that each MVP include at least four quality measures under each collection type, we do not believe it is appropriate to establish a universal minimum across all collection types for every MVP at this time, as measure availability and feasibility may vary by specialty, clinical topic, and reporting mechanism. However, we will continue to consider opportunities to increase the number of measures available across collection types, as appropriate, in future MVP development and maintenance to ensure flexibility and choice of measures within MVPs. We will also continue to work with measure developers, third-party intermediaries, and EHR vendors to support more flexible reporting options over time.

Comment: Many commenters recommended that CMS expand the MVP measures menu to include a sufficient number of eCQMs or dQMs to submit an MVP exclusively using an EHR. The commenters expressed concern that when an MVP does not include a sufficient number of eCQMs, it would add substantial burden to the practices because they must contract with thirdparty vendors to report other collection types. The commenters stated that electronic reporting options would help maintain existing workflows, reduce the burden of transitioning to MVPs and support broader efforts to advance digital health.

Response: As discussed in section IV.A.4.c. of this final rule, it is our intent to transition to digital quality measurement across all CMS quality reporting programs. At the same time, we do not want to increase burden by requiring clinicians currently reporting eCQMs to report using multiple collection types. We note that we are delaying the sunset of traditional MIPS reporting by two years, so that traditional MIPS reporting is available to clinicians through the CY 2030 performance period/2032 MIPS payment year. This additional time will allow us to continue to work with measure developers and interested parties to support the transition to more interoperable, digitally enabled reporting over time. As more eCQMs and dQMs become available, we will incorporate these into MVP measure sets, as appropriate, which would improve dQM alignment across CMS quality programs.

Comment: Several commenters expressed concerns that clinicians who could not report all four required quality measures would be unfairly penalized in an MVP-only reporting environment. A few commenters recommended that CMS establish a clear pathway for clinicians without an applicable MVP or who cannot meet the quality reporting requirement in an MVP. A few commenters recommended using the eligible measure applicability (EMA) process or a similar approach within the MVP framework to create a process that offered protections to clinicians from penalties and the right to appeal or request a reconsideration through processes such as targeted review. A few commenters also recommended automatic exemptions or exceptions for clinicians who do not have an applicable MVP available to report.

Response: We acknowledge the commenters' concerns regarding clinicians who may be unable to report all four required quality measures in an MVP-only reporting environment, including clinicians for whom there may not be an applicable MVP. We will consider these comments as we continue to refine MVP policies and evaluate ways to support clinicians who may face limitations in meeting MVP reporting requirements. We will also take these recommendations into account as we consider future policy development related to measure applicability, exceptions, and other flexibilities, as appropriate.

Comment: Many commenters expressed concern that the transition to MVP reporting would increase the operational burden for multispecialty groups with more than 15 clinicians as these groups would need to form subgroups and report multiple MVPs. The commenters noted that moving away from traditional MIPS reporting would significantly increase the number of quality measures required to be reported across subgroups within a group. A few commenters shared their concern that subgroup reporting would add operational complexity because they would need to configure and aggregate data at the subgroup level.

Response: In the CY 2022 PFS final rule, we finalized a policy allowing MIPS eligible clinicians to participate as subgroups when reporting MVPs beginning with the CY 2023 performance period/2025 MIPS payment year (86 FR 65392 through 65394). We stated that the intent of these policies was to move away from large multispecialty groups reporting on a single set of measures that may not be relevant or meaningful to all specialists within the group. We have also heard consistently from interested parties over the prior years that data submitted at the large group level is not always representative of the clinicians who comprise the group. We note that our subgroup policies are flexible, including

no restrictions on the composition of subgroups other than the requirement that each subgroup include one clinician who is MIPS eligible at the individual level. We also did not establish a minimum number of subgroups that must be formed because we intend for groups to form subgroups and select MVPs in the manner that best represents the scope of care the group provides. We refer readers to regulations at §§ 414.1305, 414.1318, and 414.1365 and the CY 2022 PFS final rule (86 FR 65398 through 65405), the CY 2023 PFS final rule (87 FR 70038 through 70045), the CY 2024 PFS final rule (88 FR 79323 through 79328, and CY 2026 PFS final rule (90 FR 49842 through 49846) for additional details on previously finalized subgroup policies.

Comment: Many commenters expressed concern that the transition would require groups to make significant changes to data collection, EHRs, clinician training, and workflows, and to monitor across multiple specialties billing under a single TIN. The commenters recommended that CMS maintain voluntary MVP participation and delay the sunset of traditional MIPS to give groups greater flexibility to update their infrastructure until the MVP framework is more fully developed and concerns related to specialty coverage and subgroup reporting burden for multispecialty group practices have been resolved.

Response: We recognize that the transition from traditional MIPS to MVP reporting may present operational challenges for some practices, particularly those with multiple specialties and more complex reporting structures. We thank the commenters for the feedback regarding allowing practices additional time to update their infrastructure and workflows, and their recommendation that the sunset of traditional MIPS be delayed until the MVP framework is more fully developed, including with respect to specialty coverage and subgroup-related burden. As discussed previously in this section, we are delaying the sunset of traditional MIPS, with MVP reporting required for clinicians not participating in a MIPS APM, beginning in the CY 2031 performance period/2033 MIPS payment year. We will continue to consider these concerns, including the readiness of multispecialty groups and the operational implications of subgroup reporting, in future rulemaking as we further develop and refine the MVP framework.

Comment: A few commenters requested guidance on how multispecialty groups should select the most appropriate MVPs such as those MVPs representing the highest volume of services provided by clinicians within the group or those applicable to the largest number of clinician specialty types in the group. A few commenters recommended that CMS provide guidance on the maximum number of MVPs a group would be required to report, stating that such guidance would reduce burden and help ensure that MVP reporting is operationally feasible for multispecialty group practices. A commenter recommended that CMS publish information on subgroup participation, measure applicability, and scoring before transitioning to MVP reporting so that group practices and third-party intermediaries would have sufficient time to configure their systems in advance of an MVP-only reporting environment.

Response: Regarding the commenters' request for guidance on the maximum number of MVPs a multispecialty group may need to report, we are not establishing a policy at this time because reporting needs may vary based on the size, composition, and specialty mix of the group. As we continue to refine MVP policies, we will consider providing additional subregulatory education and guidance to support the understanding of subgroup participation, MVP selection, and scoring methodologies for clinicians, groups, and third-party intermediaries.

Comment: A few commenters recommended that CMS establish a pathway for multispecialty groups to report on a single set of measures that appropriately captures multidisciplinary care, rather than requiring the formation of subgroups. A commenter recommended that CMS establish a group-level score so that clinicians who cannot be assigned to a subgroup would automatically receive the weighted average score of the subgroups within the group.

Response: We acknowledge the commenters' recommendations to allow multispecialty groups to report on a single set of measures or establish a group-level score for clinicians who cannot readily be assigned to a subgroup. Although we recognize the potential benefit of these approaches in reducing administrative burden, we have concerns that such policies could undermine the relevance of reported measures for certain clinicians and specialties and introduce additional operational and methodological complexities. Therefore, we are not adopting these policies at this time.

Comment: Many commenters stated that the transition to MVPs will require more time for practices to understand new requirements, develop their reporting infrastructure, and train clinicians. A few commenters stated that the low uptake of MVPs to date suggests there are significant barriers to MVP participation which cannot be addressed under the proposed timeframe. A few commenters expressed concern that transitioning to full MVP implementation on the proposed timeline would create administrative and technical burden. A few commenters stated that it is difficult for organizations to develop their internal processes when program requirements change frequently and that small rural practices are especially challenged. A few commenters recommended that CMS conduct pilot studies with small rural practices. A commenter expressed concern that CMS is expecting clinicians to prepare for MVPs, core measures, and modified scoring methodologies all at the same time.

Response: We recognize that clinicians and groups will need sufficient time to develop and implement the processes needed to transition from traditional MIPS reporting to MVP reporting and appreciate the challenges and burden clinicians and groups may face in implementing the MVP-related policies being finalized in this final rule. Although we acknowledge that low uptake of MVPs to date may, to some extent, reflect barriers to participation, we believe the more significant factor is the continued availability of the traditional MIPS reporting option and, therefore, are finalizing a date for sunsetting traditional MIPS. We appreciate commenters' observations about the complexity for large, multi-specialty organizations in reporting multiple MVPs and note that our subgroup policies provide significant flexibility for a multispecialty group to implement MVP reporting in the manner that best fits its clinicians and scope of care. Similarly, we note that the flexibilities in place under traditional MIPS to assist small practices in participating will remain when the transition to full MVP reporting is accomplished. As discussed previously in this section, we are delaying the sunset of traditional MIPS by two years, with required MVP reporting beginning in the CY 2031 performance period/2033 MIPS payment year, partially to provide clinicians with additional time to prepare for an MVP only reporting environment.

Comment: Many commenters urged CMS to continue traditional MIPS until measure and MVP gaps are filled and MVPs are improved. A few commenters stated that additional time is needed for

CMS, specialty societies, and registries to collaborate on measure and MVP development and testing. A commenter stated that CMS should develop a measure development plan for specialties that lack an applicable MVP and for subspecialties, clinical conditions and procedures that existing MVPs do not address. A commenter recommended that CMS delay the sunset of traditional MIPS until MVPs fully reflect the scope of patient care for large multispecialty groups. A commenter recommended that CMS consider delaying the sunset of traditional MIPS until scoring disparities between MVPs are resolved. A commenter stated that even if an Obesity Medicine MVP were developed and finalized for the CY 2028 performance period/2030 MIPS payment year, there would be only one year of voluntary reporting of the MVP before it was mandatory under the proposed timeline.

Response: We are committed to continued collaboration with specialty societies and other interested parties to develop additional MVPs, refine existing MVPs and fill measure gaps. We refer readers to the CMS Quality Measure Development Plan and the Measure Development Plan Annual Report at *https://www.cms.gov/medicare/quality/value-based-programs/quality-payment-program/measure-development* for more information on measure development priorities. With respect to the concern expressed about having only one year of voluntary reporting for a new MVP introduced in the CY 2028 performance period/2030 MIPS payment year, we note that our revised timeline for sunsetting traditional MIPS will provide three years of voluntary reporting for any new MVPs proposed and finalized for the CY 2028 performance period/2030 MIPS payment year. With respect to delaying the sunset of traditional MIPS until MVPs fully reflect the scope of care for large multispecialty groups, we note that the MVPs in our inventory offer robust measure sets addressing top health priorities and the care provided to Medicare patients and provide clinicians with a method to report more specialty-specific, condition-based or more broad-based measures. We will continue to work with interested parties to improve the clinical relevance, fairness, and usability of MVPs and to support clinicians in selecting the reporting option that is most appropriate for their practice. We encourage interested parties to submit potential new measures that will align with current goals and priorities during the annual Call for Measures to fill identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS. Regarding scoring disparities between MVPs, in the CY 2027 PFS proposed rule we solicited feedback on MVP scoring issues in an RFI, including ensuring scoring fairness across MVPs (91 FR 44206). We may consider the feedback received in response to the MVP Scoring RFI in future rulemaking.

Comment: Several commenters stated that EHR vendors, registries, and other technology partners need more time to develop, test, and deploy MVP reporting infrastructure. A commenter stated that developing and testing automated reporting capabilities across multiple specialty-specific pathways requires substantial vendor investment and time.

Response: We agree with the commenters that EHR vendors, registries, and other technology partners who support clinicians participating in the Quality Payment Program need sufficient time to develop and deploy the MVP reporting infrastructure. We anticipate the modified timeline we are finalizing in this final rule will provide sufficient time for technology partners to prepare for required MVP reporting.

Comment: Many commenters urged CMS to prioritize the transition to digital quality measurement, ensuring a successful transition to dQM reporting and sufficient availability of dQMs for all MVPs and the Ambulatory Specialty Model before sunsetting traditional MIPS. A commenter stated that CMS should delay the sunset of traditional MIPS until FHIR-based dQM infrastructure is available, operational, broadly supported across CEHRT products, and tested for most MIPS measures.

Response: We thank commenters for their feedback regarding prioritization of a successful transition to dQM reporting. We believe the modified timeline for sunsetting traditional MIPS that we are finalizing in this rule will allow clinicians and their technology partners to focus on the digital reporting transition and provide time for dQM infrastructure to become more widely available before MVP reporting requirements take effect. We note, however, conversion of existing quality measures to dQMs will require collaboration and active engagement with all measure stewards and interested parties.

Comment: Many commenters recommended that CMS delay the transition to required MVP reporting. A few commenters recommended specific timelines of three to five years beyond the proposed timeline of sunsetting traditional MIPS beginning with the CY 2029 performance period/2031 MIPS payment year. A few commenters noted that providers already face significant regulatory demands, including the transition to digital quality measures. A commenter requested a delay in the sunset of traditional MIPS for small and independent practices.

Response: We acknowledge the significant challenges clinician practices, including small and independent practices, may face in simultaneously navigating the transition to full MVP implementation and the transition to FHIR-based digital quality measures. We are therefore modifying our proposal to sunset traditional MIPS such that instead of beginning with the CY 2029 performance period/2031 MIPS payment year, it will begin with the CY 2031 performance period/2033 MIPS payment year, adding two more years of voluntary MVP reporting for all clinicians, including those in small and independent practices. With respect to commenters' recommendations to delay the sunset of traditional MIPS by three to five years, we believe that our finalized timeline of sunsetting traditional MIPS beginning with the CY 2031 performance period/2033 MIPS payment year strikes an appropriate balance between providing additional time for clinicians to prepare for the transition to full MVP implementation and setting a timeline for the transition that offers strong encouragement for clinicians and groups to begin reporting MVPs. We are concerned that setting a date for the sunset of traditional MIPS that is more than five years in the future will discourage clinicians and groups from undertaking the changes necessary to successfully report MVPs.

Comment: Several commenters stated that CMS needs more time to evaluate MVPs and the MVP reporting experience in order to demonstrate that MVPs are valid and beneficial before mandating MVP reporting. A few commenters recommended that the transition timeline should be based on readiness benchmarks instead of a predetermined date.

Response: We thank commenters for their recommendations regarding readiness criteria and will consider the feedback as we further refine the MVP inventory and MVP reporting and scoring policies. We also urge clinicians to participate in voluntary MVP reporting prior to the transition to required MVP reporting beginning in the CY 2031 performance period/2033 MIPS payment year. Voluntary MVP reporting, while traditional MIPS reporting is also available, would help clinicians gain experience and

determine any changes to their current workflows. Increased participation in MVP reporting would also provide us with additional data to further evaluate MVP performance and MVP reporting to allow us to further refine MVP policies before the transition to required MVP reporting beginning in the CY 2031 performance period/2033 MIPS payment year.

Comment: A few commenters expressed concerns regarding the MVP registration timeline, specifically noting that the current timeline to register ends before clinicians are aware of their final MIPS eligibility status. The commenters stated that this timeline could create unintended consequences as the clinicians who become subsequently MIPS eligible due to changes in licensure status or switching group practices may be unable to report an MVP. The commenters recommended that CMS align the MVP registration timeline with the timeline for release of final MIPS eligibility determinations. A commenter stated that extending the MVP registration deadline to December 31 of the applicable performance period would align with the timeframe for submitting MIPS Hardship Exception applications. Another commenter recommended that CMS establish an additional registration opportunity or an exception process for such clinicians. Another commenter questioned whether an MVP registration process would remain necessary in an MVP-only environment.

Response: As we stated in the CY 2022 PFS final rule (86 FR 65416), we established the MVP registration process to enable MVP participants and us to accurately capture the MVP selection and determine subgroup participation ahead of MIPS data submission. We recognize that the registration requirement may involve additional nuances where final MIPS eligibility determinations change for reasons outside the control of the clinician or group practice. In light of our decision to delay the sunset of traditional MIPS by two years and transition to required MVP reporting beginning in the CY 2031 performance period/2033 MIPS payment year, we will continue to consider feedback on these issues, including clinician experience with the MVP registration process and the role of registration as we move toward MVP-only reporting, in future rulemaking.

Comment: Several commenters expressed concern that sunsetting traditional MIPS could result in removal of relevant MIPS quality measures that are not currently included in the existing MVPs. The commenters further noted that removing these measures would reduce the MIPS inventory of available quality measures, limit meaningful reporting options for specialists and discourage continued investment in quality measure development. A few commenters requested additional CMS guidance regarding the future of quality measures under the QCDR and MIPS CQM collection types that are currently not included in any MVP. A commenter recommended that CMS maintain the specialty-specific measurement infrastructure to support expansion of relevant quality measures for specialists and to enable meaningful participation in MVP reporting.

Response: We acknowledge the concerns raised regarding the potential effect of sunsetting traditional MIPS on the continued availability of relevant quality measures, particularly for specialists. We recognize the importance of maintaining a robust inventory of quality measures that supports meaningful participation across specialties and encourages continued investment in quality measure development. We also recognize the value of specialty-specific measurement infrastructure, including measures reported through the QCDR and MIPS CQM collection types, in supporting clinically relevant quality reporting. As we continue to implement and refine MVP policies, we intend to consider the availability of relevant quality measures for specialists and the role of currently available MIPS quality measures that are not yet included in an MVP. We will also consider feedback on the QCDR and MIPS CQM measures as we consider future development of MVPs and related policies.

After consideration of public comments, we are finalizing with modification that beginning in the CY 2031 performance period/2033 MIPS payment year, all MIPS eligible clinicians, with the exception of clinicians reporting through the APP, would report through an MVP. Specifically, we are finalizing to add under § 414.1365(a)(2) that beginning in the CY 2031 performance period/2033 MIPS payment year, except for clinicians reporting through the APP pursuant to § 414.1367, all MIPS eligible clinicians must report through an MVP.

d. Include Virtual Groups in MVP Reporting

Section 1848(q)(5)(I) of the Act establishes the use of voluntary virtual groups for certain assessment purposes. The statute requires the establishment and implementation of a process that allows an individual MIPS eligible clinician or a group consisting of not more than 10 MIPS eligible clinicians to elect to form a virtual group with at least one other such individual MIPS eligible clinician for a performance period. As determined in statute, individual MIPS eligible clinicians and groups forming virtual groups are required to make such election prior to the start of the applicable performance period under MIPS and cannot change their election during the performance period.

In the CY 2022 PFS final rule (86 FR 65394), we finalized a delay in the availability of MVP reporting for virtual groups. We noted that there are several considerations, such as implementation burden for interested parties and us, value of MVP reporting for these clinicians versus burden, scoring policies, and other issues that must be addressed prior to allowing clinicians in virtual groups to participate in MVP reporting. Therefore, we did not include virtual groups in the previously finalized definition of an MVP participant at § 414.1305 (86 FR 65392 through 65394). However, to comply with the statute, full implementation of MVPs must include a pathway for virtual groups to participate. For this reason, in the CY 2027 PFS proposed rule (91 FR 44148), we proposed to allow virtual groups to participate in MVP reporting beginning in the CY 2029 performance period/2031 MIPS payment year. This approach would allow time for us to further refine participation criteria and address potential barriers for virtual groups to participate in MVP reporting.

To include virtual groups in MVP reporting, we proposed to revise the definition of an MVP participant at § 414.1305 to provide that, beginning in the CY 2029 performance period/2031 MIPS payment year, MVP participant means an individual MIPS eligible clinician, single specialty group, multispecialty group that meets the requirements of a small practice, virtual group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

We considered including virtual groups in MVP reporting beginning in the CY 2028 performance period/2030 MIPS payment year. We recognize that we would need to evaluate additional related policies before including virtual groups in MVP reporting. Under the current policy at § 414.1365(b), MVP participants must register during the performance period. We recognize that the inclusion of virtual groups in MVP reporting would therefore require these groups to register for MVP reporting, which would be an addition to the

existing registration requirement to form a virtual group prior to the performance period. We are exploring options to mitigate the need for virtual groups to register a second time for MVP reporting. Additionally, we noted that even with the proposed inclusion of virtual groups in MVP reporting, clinicians in virtual groups would be unable to participate as subgroups because the definition of a subgroup at § 414.1305 is limited to clinicians within a single TIN and therefore excludes virtual groups, which, by definition, are composed of clinicians across two or more TINs. Under § 414.1305, a subgroup is a subset of a group that includes at least one MIPS eligible clinician and is identified by the group TIN, a subgroup identifier, and each eligible clinician's NPI.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to allow virtual groups to report MVPs beginning with the CY 2029 performance period/2031 MIPS payment year.

Response: We thank the commenters for their support.

Comment: Several commenters urged CMS to take steps to minimize administrative burdens for virtual groups participating in MVP reporting. A few commenters recommended that CMS provide technical support and clear guidance on MVP reporting to virtual groups. A few commenters stated that CMS could streamline the registration process by combining virtual group registration and MVP registration.

Response: We agree that clinicians interested in participating in MIPS as a virtual group may need additional guidance on MVP reporting and we will explore opportunities to provide appropriate communications and education materials. We may consider the suggestion to streamline the registration process as we further develop the process for MVP reporting by virtual groups.

Comment: Several commenters expressed concerns that virtual groups will need more time to prepare for MVP reporting and recommended that CMS should make MVP reporting available to virtual groups in the CY 2028 performance period/2030 MIPS payment year or delay mandatory MVP reporting for virtual groups until they have at least one year of voluntary MVP reporting experience.

Response: We thank the commenters for their feedback regarding virtual groups' readiness to report MVPs. We agree that virtual groups would likely benefit from an opportunity to report MVPs on a voluntary basis prior to the sunset of traditional MIPS. As noted in section IV.A.3.c. of this final rule, we are delaying the sunset of traditional MIPS until the CY 2031 performance period/2033 MIPS payment year. We note that allowing virtual groups to report MVPs beginning with the CY 2029 performance period/2031 MIPS payment year will provide two years for virtual groups to report MVPs on a voluntary basis and will allow us to further develop policies and operational details necessary to implement MVP reporting for virtual groups.

After consideration of public comments, we are finalizing our proposal to allow virtual groups to report MVPs beginning with the CY 2029 performance period/2031 MIPS payment year. Specifically, we are finalizing to revise the definition of an MVP participant at § 414.1305 to provide that, beginning in the CY 2029 performance period/2031 MIPS payment year, MVP participant means an individual MIPS eligible clinician, single specialty group, multispecialty group that meets the requirements of a small practice, virtual group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

4. QPP Reporting and Data Submission

a. CY 2027 MVP Development and Maintenance

(1) Development of New MIPS Value Pathways (MVPs)

The development of MVPs is informed by the framework established in prior rulemaking (85 FR 84849 through 84856). In the CY 2023 PFS final rule (87 FR 70035 through 70037), we expanded the MVP development process to provide interested parties more opportunities to submit feedback on new candidate MVPs prior to the notice and comment rulemaking process. Consistent with these policies, we posted three MVP candidates for interested parties to review and provide feedback for consideration in the proposed rule. We refer readers to the Quality Payment Program website to review public feedback for each 2027 MVP candidate (*https://qpp.cms.gov/mips/candidate-feedback*).

In alignment with the MVP development process (85 FR 84849 through 84856; 87 FR 70035 through 70037) and feedback received from interested parties, in the CY 2027 PFS proposed rule (91 FR 44475 through 44487) we proposed adopting three new MVPs:

- Diabetic Disease;
- Hospitalist; and
- Hypertension.

We aim to continue developing new MVPs that are relevant and meaningful for MIPS eligible clinicians. The Diabetic Disease and Hypertension MVPs are specifically designed to address the prevention of chronic illnesses by including measures and activities aimed at reducing the incidence and impact of long-term conditions. Disease-specific MVPs allow for more targeted interventions, improved measurement accuracy, and support clinicians in delivering evidence-based care for high—risk populations.

We refer readers to Appendix 3: MVP Inventory, of this final rule for discussion of the proposed new MVPs, the public comments received, and our responses.

We continue to encourage interested parties to use our established pre-rulemaking processes to develop and submit candidate quality and cost measures relevant to their specialty. Furthermore, we continue to develop MVPs based on needs and priorities, as described in the MVP Needs and Priorities document (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip*).

(2) MVP Maintenance Updates to Previously Finalized MVPs

Beginning with the CY 2022 PFS final rule (86 FR 65998 through 66031) and continuing through the CY 2026 PFS final rule (90 FR 50376 through 50405), we have expanded the MVP inventory to include the following 27 MVPs:

- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine;
- Advancing Cancer Care;
- Advancing Care for Heart Disease;
- Advancing Rheumatology Patient Care;
- Complete Ophthalmologic Care;
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes;
- Dermatological Care;
- Diagnostic Radiology;
- Focusing on Women's Health;
- Gastroenterology Care;
- Improving Care for Lower Extremity Joint Repair;
- Interventional Radiology;
- Neuropsychology;
- Optimizing Chronic Disease Management;
- Optimal Care for Kidney Health;
- Pathology;

- Patient Safety and Support of Positive Experiences with Anesthesia;
- Podiatry; and
- Prevention and Treatment of Infectious Disorders Including Hepatitis C and Human Immunodeficiency Virus (HIV);
- Pulmonology Care;
- Quality Care for Patients with Neurological Conditions MVP;
- Quality Care for the Treatment of Ear, Nose, and Throat Disorders;
- Quality Care in Mental Health and Substance Use Disorder; and
- Rehabilitative Support for Musculoskeletal Care;
- Surgical Care;
- Value in Primary Care; and
- Vascular Surgery.

In the CY 2027 PFS proposed rule (91 FR 44487 through 44557), we proposed modifications to 23 previously finalized MVPs with the addition and removal of measures and improvement activities based on the MVP development criteria (85 FR 84849 through 84854). Through these modifications, we can expand upon clinical concepts, advance health and wellness, address maintenance requests from interested parties, and remove measures and activities that would either be replaced by more robust measures or activities or are finalized for removal from their respective MIPS inventory. We also proposed renaming the Rehabilitative Support for Musculoskeletal Care MVP to Rehabilitative Support MVP to better reflect the measures and activities it includes.

Additionally, we proposed modifications to all 27 previously finalized MVPs in alignment with the proposed implementation of MIPS core measures. In the CY 2027 PFS proposed rule (91 FR 44155 through 44159), we proposed modifications to the current MVP quality reporting requirements at § 414.1365 to replace the current requirement for an outcome/high priority measure with one MIPS core measure included in the MVP. We revised the format of the MVP tables in Appendix 3: MVP Inventory to include MIPS core measures for all MVPs.

We refer readers to sections IV.A.4.d.(1) and IV.B.1.b. of this final rule for the proposed policies for MIPS core measures, the public comments received, and our responses. In addition, we refer readers to Appendix 3: MVP Inventory of this final rule for the proposed modifications to the previously finalized MVPs, the public comments received, and our responses.

b. APM Performance Pathway (APP)

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning with the CY 2021 performance period/CY 2023 MIPS payment year. The APP was designed as a reporting and scoring pathway available only to MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM as defined in § 414.1305 (MIPS APM participants) (§ 414.1367(a)). The APP provides a predictable and consistent MIPS reporting option to reduce reporting burden for, and encourage continued APM participation by, these clinicians. We also established in the APP for Shared Savings Program ACOs providing that, beginning with the Shared Savings Program performance year 2021 (CY 2021 performance period/CY 2023 MIPS payment year), ACOs were required to report quality data for purposes of the Shared Savings Program via the APP (42 CFR 425.512(a)(3); 85 FR 84722).

In that same rule, we finalized a quality measure set (85 FR 84860 and 84861) for purposes of quality performance category scoring for the APP. For those MIPS eligible clinicians, groups, or APM Entities for whom a given measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, we established that such measure would be removed from the quality performance category score for such MIPS eligible clinician, group, or APM Entity (85 FR 84861).

In the CY 2025 PFS final rule (89 FR 98562), we finalized a second, optional quality measure set within the APP, called the APP Plus quality measure set, to align with the Universal Foundation measure set. The measure set for CY 2026 performance year includes the current APP quality measures and two additional quality measures from the Adult Universal Foundation measure set. As discussed in the CY 2025 PFS final rule, we intended to incrementally add the remaining three Adult Universal Foundation measures by the CY 2028 performance period/2030 MIPS payment year. We also finalized a 1-year delay to the CY 2026 performance year/CY 2027 MIPS payment year in the incorporation of the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID: 484) measure.

Further, for MIPS eligible clinicians, groups, and APM Entities reporting through the APP, we established in the CY 2021 PFS final rule (85 FR 84907) that we would not apply the quality measure scoring cap at § 414.1380(b)(1)(iv) in the event that a measure in the APP quality measure set is determined to be topped out. Because the APP quality measure set is fixed, we noted that it would not be appropriate to limit the maximum quality performance category score available to APP reporters. Should an APP quality measure be determined to be topped out, we would at that time consider amending the APP quality measure set through future rulemaking, if appropriate.

In the CY 2024 PFS final rule (88 FR 79329), we established the Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) collection type in the APP quality measure set and finalized that the Medicare CQMs collection type would be available to only ACOs participating in the Shared Savings Program.

In the CY 2026 PFS final rule (90 FR 49849 through 49856) we updated quality measures in the original quality measure set and the APP Plus quality measure set, to reflect measures updates specified for the quality performance category.

(2) Updates to Quality Measures in the APP and APP Plus Quality Measure Set

In the CY 2021 PFS final rule, we adopted the original APP quality measure set (85 FR 84860 and 84861). In the CY 2025 PFS final rule, we finalized a phased approach to establish the APP Plus quality measure set over 4 years (89 FR 62024), including by incorporating into the APP Plus quality measure set the measures from the original APP quality measure set.

In the CY 2025 PFS final rule, we finalized a phased approach to establish the APP Plus quality measure set over 4 years (89 FR 62024). As finalized, the APP Plus quality measure set consisted of all the measures that were within the APP quality measure set (five Adult Universal Foundation measures and a separate quality measure) plus one additional measure from the Adult Universal Foundation measure set, with the intention of incrementally incorporating the remaining measures from the Adult Universal Foundation measure set by the CY 2028 performance year/CY 2030 MIPS payment year. We finalized this incremental approach in part to allow for both the eCQM and, for Shared

Savings Program ACOs, Medicare CQM collection types to be developed and become available.

Because the APP is a feature within MIPS and therefore the quality measures used within the APP and APP Plus quality measure sets are all MIPS measures, any proposed updates we apply to MIPS measures also are incorporated into the APP and APP Plus quality measure sets, here accordingly.

As discussed in Table Group D, in Appendix 1, of this final rule, we are finalizing as proposed the adoption of measure specification changes to the following measures that are part of the APP and APP Plus quality measure sets:

- Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001) (eCQMs collection type)
- Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134)
- Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups (Quality ID: 479)

In addition, we are finalizing as proposed the removal of the following measures that, under the policies finalized in the CY 2025 PFS final rule (89 FR 98369 through 98371) had been scheduled to be added to the APP Plus quality measure set for the CY 2027 performance period and for the CY 2028 performance period or the performance period that is 1 year after the eCQM specification becomes available, whichever is later, respectively:

- Initiation and Engagement of Alcohol and Other Drug Dependence Treatment measures (Quality ID: 305)
- Adult Immunization Status (Quality ID: 493)

We proposed the removal of these two measures from the APP Plus quality measure set due to operational issues impacting the development of the collection types that were finalized in the CY 2025 PFS final rule for these two measures. Our policies will address concerns expressed by ACOs with increasing the number of measures in the APP Plus quality measure set each year. ACOs have suggested maintaining a stable measure set as they transition to digital quality measurement. In the CY 2026 PFS dQM RFI, many commenters recommended that we maintain the APP Plus quality measure set as finalized without adding new measures to preserve resources for the transition to digital quality measurement and to consider challenges ACOs face in data aggregations for eCQM/MIPS CQM/Medicare CQM reporting (90 FR 49856).

These changes have been reflected in Table C–BC2. Table C–BC2 also reflects the creation of the new Medicare eCQMs collection type for Shared Savings Program ACOs reporting the APP Plus Quality measure set for performance year 2027 and subsequent performance years, as discussed in section III.G.3.d.(3) of this final rule and Table Group D and DD, in Appendix 1, of this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters recommended several refinements to APP and APP Plus quality measure specifications. With respect to the Screening for Depression and Follow-up Plan measure, commenters supported adding a numerator/denominator exception for patients already screened within the same performance year, and urged CMS to apply this exception across both the CQM and eCQM collection types, noting that repeated screenings across providers within a practice distort performance metrics and create unnecessary documentation burden. Separately, a commenter recommended that CMS revise Medicare CQM specifications to permit clinically appropriate value ranges, rather than requiring a single exact value, for measures assessing attainment of a clinical threshold—consistent with existing eCQM flexibility, such as that used in the Controlling High Blood Pressure measure. Commenters characterized these changes as supporting coordinated, practice-wide care and improved alignment between collection types, while reducing administrative burden and preserving measure integrity.

Response: We appreciate commenters' support for reducing redundant reporting burden associated with the Screening for Depression and Follow-up Plan measures. However, the numerator/denominator exception commenters requested is not within the scope of the changes included in the proposed rule where our proposal considered removal of measures. With respect to the recommendation to permit clinically appropriate value ranges within Medicare CQM specifications, we recognize the goal of aligning Medicare CQM logic with existing eCQM flexibility. We note that Medicare CQM specifications are developed in coordination with measure stewards and are not modified through this rulemaking.

Comment: Several commenters addressed CMS' proposed adoption of measure specification changes to the measures that are part of the APP and APP Plus quality measure sets as discussed in Table Group D, in Appendix 1, of this final rule.

Response: We thank commenters for their feedback and refer readers to Table Group D, in Appendix 1, of this final rule for our full response.

Comment: Several commenters were supportive of the proposal to remove Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) and Adult Immunization Status (Quality ID: 493) from the APP Plus quality measure set. Most commenters cited that the proposal reduces administrative burden, stabilizes the quality measure set during the transition to digital quality measurement and addresses the technical and operational challenges associated with the transition.

Response: We thank the commenters for supporting the removal of these two planned measures from the APP Plus quality measure set.

Comment: Several commenters supported the proposal to remove Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) and Adult Immunization Status (Quality ID: 493) from the APP Plus measure set, but requested clarification to confirm whether these measures would be permanently removed or, and what the future of the APP Plus quality measure set and the long-term quality measure strategy looks like to assist ACOs in planning quality improvement initiatives, clinical workflows, and technology investments.

Response: We thank the commenters for their feedback. CMS would address any future consideration of these measures through future notice and comment rulemaking.

Comment: A few commenters opposed the proposal to remove both Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) and Adult Immunization Status (Quality ID: 493) from the APP Plus measure set citing that these two measures are clinically important and address population health and preventative care domains that should be included. A commenter noted both measures should be included until CMS demonstrates an alternative reporting mechanism that provides a sufficiently actionable signal for substance use treatment engagement and adult immunization, which remain central to Medicare population health. A couple of commenters cited the importance of finding other methods of maintaining accountability for vaccination and substance use treatment if these measures are not retained. Some commenters specifically opposed the removal of Initiation and Engagement of

Substance Use Disorder Treatment (Quality ID: 305) citing removing this measure leaves an important clinical gap for substance use disorder treatment, eliminates a payment incentive to start and retain people in substance use disorder treatment, and works against CMS's behavioral-health and chronic-disease objectives along with reducing accountability for ACOs to provide this care. Some commenters specifically opposed the removal of Adult Immunization Status (Quality ID: 493) citing adult vaccination is an important component of preventive care and population health, and removing the measure eliminates an important incentive for ACOs to assess and improve vaccination coverage. A commenter stated CMS should delay implementation or modify the measure if technical or implementation issues make the previously established date impractical.

Response: We thank the commenters for their feedback. As stated in the CY27 PFS proposed rule (91 FR 44151), we proposed the removal of these two measures from the APP Plus quality measure set due to operational issues impacting the development of the collection types that were finalized in the CY 2025 PFS final rule for these two measures. CMS agrees the clinical concepts of these two measures are important to quality care, their removal from the APP Plus quality measure set does not preclude the quality actions from continuing and they should still continue to be assessed as deemed appropriate by the clinician. CMS believes that this policy would lessen the burden associated with implementing new quality measures as Shared Savings Program ACOs move toward digital quality measurement and FHIR-based reporting.

After consideration of public comments, we are finalizing as proposed the adoption of measure specification changes to the following measures that are part of the APP and APP Plus quality measure sets:

- Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001) (eCQMs collection type)
- Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134)
- Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups (Quality ID: 479)

We are finalizing our policy to the remove the following measures that, under the policies finalized in the CY 2025 PFS final rule (89 FR 98369 through 98371) had been scheduled to be added to the APP Plus quality measure set for the CY 2027 performance period and for the CY 2028 performance period or the performance period that is 1 year after the eCQM specification becomes available, whichever is later, respectively:

- Initiation and Engagement of Alcohol and Other Drug Dependence Treatment measures (Quality ID: 305)
- Adult Immunization Status (Quality ID: 493)

We are finalizing our proposal to remove these two measures from the APP Plus quality measure set as well, as reflected in Table C–BC2.

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TABLE C-BC1: APM PERFORMANCE PATHWAY QUALITY MEASURE SET BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR AND SUBSEQUENT PERFORMANCE PERIODS/MIPS PAYMENT YEARS

#	Measure Title	Collection Type	Submitter Type	Measure Type
001	Diabetes: Glycemic Status Assessment Greater Than 9%	eCQM/MIPS CQM/Part B Claims (all APP reporters)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient Engagement/ Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Outcome

TABLE C-BC2: APP PLUS QUALITY MEASURE SET FOR THE CY 2027 PERFORMANCE PERIOD/CY 2029 MIPS PAYMENT YEAR AND SUBSEQUENT PERFORMANCE PERIODS/MIPS PAYMENT YEARS

QUALITY #	MEASURE TITLE	COLLECTION TYPE	SUBMITTER TYPE	MEASURE TYPE
001	Diabetes: Glycemic Status Assessment Greater Than 9%	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM/Medicare eCQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Intermediate Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM/Medicare eCQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Process
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM /Medicare eCQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Process
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM/Medicare eCQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM/Medicare eCQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient Engagement /Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Outcome

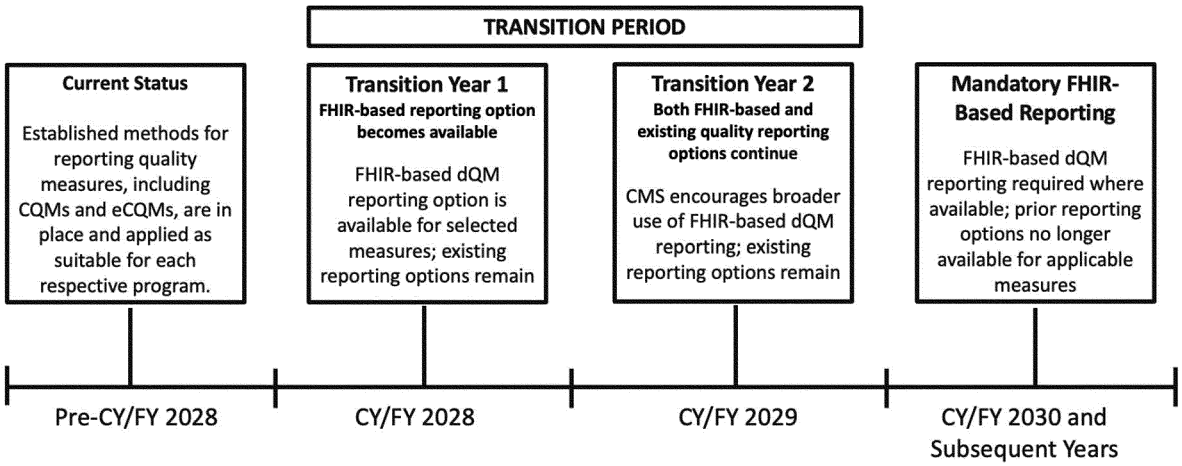
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a. Fast Healthcare Interoperability Resources®-Based Digital Quality Measurement in the Quality Payment Program and Other CMS Quality Programs—Request for Information

We are advancing quality measurement by transitioning existing quality measures and reporting processes to Fast Healthcare Interoperability Resources® (FHIR®)-based digital approaches. Digital quality measures [393] (dQMs) use standardized, interoperable digital data from multiple sources, including electronic health records (EHRs), to enable more comprehensive and timely assessment of care while reducing reporting burden. We continue to collaborate with Federal partners to advance health information technology and digital quality measurement policy, interoperability standards, and quality measurement infrastructure to support the transition to FHIR-based digital quality reporting.

In the CY 2027 PFS proposed rule (91 FR 44143), we discussed a phased transition to FHIR-based digital quality measurement across the Quality Payment Program and other clinician and hospital programs. Figure C–C1 reflects the phased 2-year transition timeline currently under consideration. The 2-year transition would begin in CY/FY 2028 when FHIR-based dQM reporting would coexist with existing CQM/eCQM options, followed by mandatory FHIR-based reporting for transitioned measures starting in CY/FY 2030. To support a seamless transition and implementation, we requested feedback on implementation timelines, readiness barriers, scoring and reporting requirements, and the technical assistance or flexibility needed, particularly for small and rural practices, and operationally complex organizations such as Accountable Care Organizations (ACOs).

Figure C-C1: TIMELINE FOR TRANSITION TO FHIR-BASED QUALITY REPORTING IN CMS QUALITY REPORTING PROGRAMS*



*We note that more specific adoption timelines may vary by measure and program based on feasibility, implementation complexity, and readiness of interested parties. Existing quality collection types for CQMs and eCQMs may include the following, as applicable by program: MIPS CQMs, Medicare CQMs, eCQM reporting via QRDA files, and proposed Medicare eCQMs. An additional timeline, titled "Transition Timeline for FHIR-based Digital Quality Measurement and Reporting," is also available on the QPP Resource Library at https://qpp.cms.gov/resources/resource-library for more context.

We received many comments on this request for information (RFI) and appreciate the feedback which may inform future rulemaking. We did not propose any policies regarding the FHIR-based approaches in the CY 2027 PFS proposed rule, and we are not finalizing any policies regarding the FHIR-based approaches in this final rule; however, we are providing additional details on expected changes under a future transition to FHIR-based quality reporting. For example, in a FHIR-based reporting environment, a FHIR-based dQM may be reported using a measure specification and data requirements that differs from those used under existing CQM or eCQMs. This would be in addition to a change in the submission format that is used to submit an existing CQM or eCQM (for example, replacing Quality Reporting Document Architecture (QRDA) with FHIR). During the transition period, where we may have both dQM and existing CQM and eCQM versions of the same measures available, we intend to establish policies that address the fact that there are various specifications and data elements associated with each method of reporting. Part of these policy considerations would include addressing scoring and public reporting implications.

Additionally, the certification criteria and reporting specifications for FHIR-based dQM requirements may be different than those associated with current eCQM reporting. Any changes to certification criteria and associated changes to digital reporting of quality measures would need to go through notice-and-comment rulemaking by the Office of the National Coordinator for Health IT (ONC) and/or CMS as applicable. Depending on future policy and technical requirements, FHIR-based reporting could impact third-party

[393] Read more about the dQM transition in the Electronic Clinical Quality Improvement (eCQI) Resource Center here: *https://ecqi.healthit.gov/dqm/about-dqms.*

intermediaries, such as Qualified Clinical Data Registries (QCDRs) or qualified registries. However, we would continue to consider standards and other requirements applicable to such reporting options, including the extent to which ONC certification would be required and whether a third-party intermediary may transform data from other systems into the required FHIR-based specification.

Finally, we continue to focus on the broader objective of the digital transition and intend for all future reporting options, including those involving third-party intermediaries, to promote further adoption of FHIR-based standards rather than functioning solely as a conversion of existing measures into a FHIR format. We will continue to further clarify in future rulemaking the requirements applicable to clinicians, QCDRs, qualified registries, and others that may not use certified health IT.

d. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We refer readers to §§ 414.1330 through 414.1340, the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019 through CY 2026 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, 86 FR 65431 through 65445, 87 FR 70047 through 70055, 88 FR 79329 through 79338, and 89 FR 98381 through 98390, and 90 FR 49856 through 49859, respectively) for a description of previously established policies and the statutory basis for policies regarding the quality performance category. In the CY 2027 PFS proposed rule (91 FR 44154), we proposed to:

- Amend the definition of the term ''collection type'' to include the Medicare Electronic Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs).
- Implement the MIPS core measure designations for quality measures in traditional MIPS and MVPs.
- Remove the high priority designation from MIPS quality measures.
- Remove the high priority designation from quality measure retention consideration.
- Replace the requirement to report a high priority measure with the requirement to report a MIPS core measure; and require an attestation process for cases in which a MIPS core measure is not available and applicable.
- Exempt clinicians in small practices from the MIPS core measure requirement and the attestation process.
- Amend the quality performance category data submission criteria at § 414.1335 and § 414.1365 to require MIPS core measure reporting with an attestation process.
- Amend the data submission criteria for the Medicare CQMs collection type.
- Establish the data submission criteria for the Medicare eCQMs collection type.
- Amend the data completeness criteria for the Medicare CQMs collection type.
- Establish data completeness criteria for the Medicare eCQMs collection type.
- Modify the MIPS quality measure set as described in Appendix 1 of this final rule, including the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.

(b) Updating the Definition of Collection Type

In the CY 2027 PFS proposed rule (91 FR 44154 and 44155), we proposed the establishment of a new collection type, the Medicare Electronic Clinical Quality Measures for Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Medicare eCQMs) specific to the APM Performance Pathway (APP); and subsequently, we proposed to amend the definition of the term ''collection type'' to include Medicare eCQMs to account for the new collection type available only to Medicare Shared Savings Program ACOs meeting the reporting requirements of the APP. Specifically, starting with the CY 2027 performance period/2029 MIPS payment year, we proposed to amend the definition of the term ''collection type'' in § 414.1305 to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); Qualified Clinical Data Registry (QCDR) measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs); and Medicare Electronic Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs).

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our response.

Comment: A few commenters supported the proposal to amend the definition of the term ''collection type'' to include the newly established Medicare eCQMs collection type.

Response: We appreciate the support from commenters.

After consideration of public comments, we are finalizing the proposal, as proposed, to amend the definition of the term ''collection type'' in § 414.1305 to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); Qualified Clinical Data Registry (QCDR) measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs); and Medicare Electronic Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs).

(c) Modifying Quality Data Submission Criteria

(i) Designating MIPS Core Measures

In the CY 2026 PFS proposed rule (90 FR 32702), we published a Core Elements Request for Information (RFI) soliciting feedback on how to encourage MVP reporting on key quality measures, or ''core'' measures, that reflect the essential components of care. One goal of MIPS reporting, particularly with the transition to MVPs, is to provide patients with comparative clinician performance data so they can make the most informed decisions about their care. The number of MIPS quality measures available for clinicians to choose from in traditional MIPS reduces the standardization of performance data. While MVPs reduce the number of quality measures for clinicians to choose from, MVPs still provide a degree of measure choice that may not produce sufficient comparative performance data on standardized measures to support patient choice of care. In the Core Elements RFI in the CY 2026 PFS proposed rule (90 FR 37021 and 37022), we sought feedback on a potential reporting requirement in which clinicians reporting an MVP would be required to select and report one quality measure from a subset of ''core'' quality measures in each MVP, which would count as one of the four quality measures required in MVP reporting. MVP reporting requirements for the other performance categories would be unchanged. MIPS core measures would be limited to measures that are most reflective of the care that is unique to each MVP's specialty or medical condition. In response to the Core Elements RFI in the CY 2026 PFS proposed rule (90 FR 32702), commenters shared concerns that MIPS core measures may not be applicable to their scope of care and that a MIPS core measure reporting requirement could add complexity to MVP reporting. We took this commenter feedback into consideration, as discussed in the CY 2027 PFS proposed rule, in our proposal of the MIPS core measures policy and in our proposed modifications to the quality performance category data submission criteria for traditional MIPS and MVPs. Specifically, we proposed to designate certain measures as MIPS core measures. Traditional MIPS reporters would be required to report one MIPS core measure as one of their six required quality measures. MVP reporters would be required to report one MIPS core measure as one of their four required quality measures. Small practices would be exempt from this requirement.

As stated in the CY 2027 PFS proposed rule, one of the goals of implementing MIPS core measures is to provide patients with comparative clinician performance data. This will enable patients to make better assessments of the quality of care provided by requiring clinicians within a given specialty to report on a narrower group of measures. This will also emphasize and increase reporting on select quality measures that are the most reflective of the care central to an applicable specialty, medical condition, or episode of care. In developing the MIPS core measures policy, we evaluated several alternative approaches. First, when considering how to procure more robust comparative performance data, we considered mandating clinicians reporting an MVP be required to report the same MIPS quality measure. This approach was not consistent with section 1848(q)(2)(D)(i) of the Act, nor did it achieve intended policy goals of generating more comparative clinician performance data on key quality measures, since what matters most for high-quality care in one specialty may differ from another. Additionally, cross-cutting quality measures, while applicable to the majority of MIPS eligible clinicians, may not be applicable to all, especially bearing in mind subgroup reporting. Expanding upon this idea, we also examined the possibility of a uniform subset of quality measures that would be consistent across all MVPs, and from which clinicians would be required to report one to two quality measures. While having the same subset of measures provides better coverage of the variety of scopes of care provided by MIPS eligible clinicians, we remain concerned that a uniform subset of quality measures will not sufficiently account for the variety of MIPS eligible clinicians' scopes of care while meaningfully assessing quality performance.

In focusing on the goal of providing patients and clinicians with ''comparative performance data,'' particularly among clinicians practicing within the same clinical specialty or providing care to patients with a specific medical condition, we considered whether to use existing population health measures or to develop new administrative claims-based measures. While these approaches will allow for automatic capture of data, there are still constraints in applicability across MIPS eligible clinicians in addition to resources and feasibility. Given these findings, we determined that the most prudent way to capture meaningful comparative data and provide patients with better insight into the quality of care provided was to create a curated set of core quality measures for each MVP. The list of MIPS core measures was selected because we determined these measures were most reflective of the care central to a clinical specialty or medical condition and will be the measures that the MIPS eligible clinician will be required to report from within that MVP.

For each MVP, we proposed that from the list of MIPS quality measures already assigned to the MVP, we would designate at least one as a MIPS core measure that an MVP reporting clinician would be required to report as one of their four required quality measures because the quality measures within each MVP are measures that are clinically relevant to the MVP's specialty or medical condition, and the proposed MIPS core measures are intended to be most reflective of the care that is central to the MVP's specialty or medical condition. The selection process focused on existing MIPS quality measures and newly proposed quality measures for the CY 2027 performance period/2029 MIPS payment year.

In determining which of the quality measures set forth in an MVP should be designated as a MIPS core measure, we proposed to select a minimum of three MIPS core measures per MVP and proposed to designate more than three measures as MIPS core measures if we determined more than three measures must be selected to reflect the care central to the subspecialties within that MVP.

We proposed that for CY 2027 and future years, selection of the MIPS core measures would be based on the following factors:

- Whether the measure is an outcome-based measure;
- Measure collection type availability and the clinician's ability to meet reporting requirements to the extent practicable. Qualified Clinical Data Registry (QCDR) measures were not considered for MIPS core measure selection to ensure MIPS core measures are broadly available and accessible for all eligible clinicians;
- Measure adoption and current and historic performance rates for each measure, to be in alignment with section 1848(q)(3) of the Act, which states that the Secretary shall consider historical performance standards and opportunity for continued improvement in establishing performance standards; and
- Whether the measure is most reflective of the care that is central to

the clinical focus of the selected MVP, represents best practices essential to the MVP's specialty or medical condition, or addresses important areas for improving care.

We proposed that the MIPS core measure designation would apply to quality measures in both traditional MIPS and MVPs. Establishing a set of unified key quality measures across both reporting pathways promotes alignment, reduced reporting complexity for clinicians reporting both traditional MIPS and MVPs, and is operationally feasible. The proposed MIPS core measure inventory, in other words, the list of all measures from each MVP designated as a MIPS core measure in accordance with the above-mentioned factors, includes over 70 quality measures. These measures represent key aspects of care across a variety of specialties and medical conditions. The MIPS core measure inventory also overlaps with the MIPS quality measures currently designated as high priority measures. Given the proposed removal of the high priority designation for MIPS quality measures, the MIPS core measure inventory will not only support reporting within MVPs but will also be applicable to clinicians reporting via traditional MIPS. Additionally, it would provide sufficient data for benchmarking for the MIPS core measures once we phase out traditional MIPS reporting and transition to full implementation of MVP reporting, as detailed in section IV.A.3.c. of this final rule.

As detailed in section IV.A.4.d.(1)(c)(iii)(B) of this final rule, we proposed that clinicians reporting through the traditional MIPS reporting option would select from the complete inventory of available MIPS core measures for the performance period. Whereas clinicians reporting through the MVP reporting option will select the applicable MIPS core measures from the core measures identified within their chosen MVP. As discussed in section IV.A.4.a.(2) of this final rule, we proposed to revise the format of the MVP tables in Appendix 3: MVP Inventory of this final rule to include MIPS core measures for each previously finalized MVP. We also added a MIPS core measure table to the newly proposed MVPs. Further, we proposed beginning with the CY 2027 performance period/2029 MIPS payment year, to establish a MIPS core measure designation applicable to selected quality measures contained in the MIPS quality measure inventory and the MVP inventory found in the Appendices of this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the MIPS core measure proposals. A commenter stated that the MIPS core measure requirement is an improvement over the current outcome/high priority requirement for meeting the quality performance category.

Response: We thank the commenters for supporting the MIPS core measure proposals.

Comment: A commenter favored a small, clinically meaningful MIPS core measure inventory over a large menu of optional measures and urged CMS to ensure each specialty's MIPS core measures can be reported using data clinicians already captured (including remote monitoring and patient-reported outcomes), without requiring a separate abstraction workflow. A few commenters indicated that CMS should ensure that every MVP includes at least one broadly applicable and clinically relevant MIPS core measure. A commenter recommended expanding the MIPS core measure inventory or retaining a traditional reporting pathway, working with measure stewards to increase relevant measures, and providing a clear crosswalk between current high priority and proposed MIPS core measures. The commenter also requested that CMS explain the rationale for new MIPS core measures, clearly define core measure criteria, ensure appropriateness across specialties and subspecialties, and monitor implementation to support meaningful participation.

Response: We thank the commenters for their feedback. As the goal of MIPS core measures is to focus clinician reporting on more relevant measures, we intentionally kept the MIPS core measure inventory smaller. The MIPS core measures we identified are a subset of measures within each MVP that represents care central to the MVP's clinical specialty or medical condition, and in many cases align with previously identified high-priority measures. These core measures represent the specific central care unique to and aligned with the clinical focus of an MVP. We did not prioritize selecting broadly applicable measures as MIPS core measures because they often do not meet these criteria for a core measure. In accordance with section 1848(q)(3) of the Act and as discussed in section IV.A.4.d.(1)(c)(i) of this final rule, we focused selection of the MIPS core measures on several factors, including whether the measure is an outcome-based measure, measure collection type availability and the clinician's ability to meet reporting requirements to the extent practicable, measure adoption and current and historic performance rates for each measure, and whether the measure is most reflective of the care that is central to the clinical focus of the selected MVP, represents best practices essential to the MVP's specialty or medical condition, or addresses important areas for improving care.

However, not all MIPS core measures will be applicable to all clinicians reporting an MVP; therefore, we established an attestation process if a clinician does not have a MIPS core measure to report. Additionally, many of the selected MIPS core measures are available for reporting in more than one collection type, allowing clinicians to collect and submit quality measure data in the way that best suits their available health technology and clinical documentation processes. The capturing, reporting, and submission of MIPS core measure data is the same as other quality measures and doesn't require separate workflows. Clinicians can choose the most appropriate MIPS core measure for their scope of care and workflow. For MVPs that represent multiple clinician types, settings, or care scopes, we identified additional MIPS core measures ensuring measure availability for those clinicians who choose to report the MVP. We encourage commenters to reach out to measure developers/stewards to develop new measures that will align with current CMS goals and priorities, and fill identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS for submission during the annual Call for Measures (*https://mmshub-impl.cms.gov/sites/default/files/2026-MIPS-Annual-Call-for-Quality-Measures-Fact-Sheet.pdf*). We welcome feedback on all MIPS core measures and encourage commenters to submit this during the annual MVP maintenance review process (*https://qpp.cms.gov/resources/mvp-development-maintenance/maintenance-process*). For more information on MIPS core measures, see section IV.A.4.d.(1)(c)(i) of this final rule.

Comment: A commenter supported the MIPS core measure policy and recommended that CMS align the MIPS core measures with the Core Quality Measures Collaborative (CQMC) and select measures that are consistent with CQMC Core Sets wherever possible to promote alignment with private sector efforts and reduce clinician burden. The commenter requested that CMS work with the Office of the National Coordinator for Health Information

Technology (ONC) and health plans to ensure MIPS core measures are usable across public and private payers and to select MIPS core measures that are patient-centered and meaningful to all interested parties.

Response: We thank the commenter for their support and feedback. We appreciate the feedback on the importance of alignment across programs for consistency and workflow efficiency and note that many of the MIPS core measures are found within CQMC Core Sets. However, there may be programmatic nuances or priorities that do not allow for complete alignment with other programs. We encourage interested parties to submit MIPS core measure suggestions to the MVP maintenance process for future consideration. We also encourage interested parties to engage with measure developers/stewards on further alignment across program measure sets because measure stewards are responsible for measure specification changes and updates. For more details on the MVP Maintenance process, see section IV.A.4.a. of this final rule.

Comment: A commenter supported the MIPS core measures proposal but is concerned that allowing multiple MIPS core measures within an MVP could create variation in reporting and limit meaningful performance comparisons. The commenter also noted this approach might unintentionally exclude sub-specialists whose care is not reflected in the broader MIPS core measures. The commenter asked CMS to monitor the MIPS core measures to ensure they support meaningful performance comparisons and subspecialty engagement. For future policy, the commenter urged CMS to work toward a single MIPS core measure per MVP that is meaningful for all participating specialties and subspecialties.

Response: We thank the commenter for supporting the MIPS core measure proposals and for the suggestions to refine MIPS core measure implementation as we move forward. MVPs are structured in a manner that would not easily allow for identification of a single MIPS core measure, as while MVPs are more narrowly targeted than traditional MIPS, an individual MVP may also span multiple specialties or areas of care related to the MVP's clinical theme. Therefore, we identified a small subset of measures within each MVP that represents care central to the MVP's intent. Not all MIPS core measures will be applicable to all clinicians reporting an MVP; however, to the extent possible, we considered implementation factors such as collection type and setting/clinician type applicability. The intent of the selected set of MIPS core measures is to give a comparable data point for each of the represented specialties or subspecialties that will allow for improved comparison and monitoring across clinician specialties. We will incorporate this new monitoring opportunity in addition to the monitoring and performance comparisons which we already conduct within MIPS. While some MVPs, due to inventory constraints, include broadly applicable measures to ensure adequate coverage and reporting options for clinicians without a specialty specific measure, it is expected that clinicians that are able to report the specialty-specific MIPS core measures would do so, as appropriate, allowing for comparison across that measure's performance.

Comment: A few commenters supported the MIPS core measures policy but were concerned about the new mandatory reporting burdens or costs, stating that MIPS core measures should come from existing MVP measures, be easily reportable, and preserve clinician flexibility. Commenters stated that MVPs should have enough relevant, reportable measures so attestation is rarely needed, instead of relying on attestation to cover measure gaps.

Response: We thank the commenters for their support for MIPS core measures policy. MIPS core measures will be selected from measures available within each MVP. For finalized MVPs, we will designate MIPS core measures from the list of measures previously finalized within the MVP or proposed and finalized within this final rule. For MVPs proposed and finalized in this year's rulemaking, we will designate MIPS core measures from the list of measures proposed and finalized. Four new measures finalized under Table Group A of Appendix 1 of this final rule are being added as MIPS core measures within the applicable MVP (see Tables A.1, A.4, A.7, and A.9 of Appendix 1: MIPS Quality Measures). The norm will be to ensure appropriate coverage of all clinicians reporting the MVP, leading to a more complete data set of quality performance measures across clinicians reporting an MVP; therefore, multiple measures were selected for each MVP to allow flexibility in clinician choice and reduce the need for attestation. We encourage interested parties to submit potential new measures during the annual Call for Measures that will align with current CMS goals and priorities and fill any identified gaps, particularly for those subspecialties with limited measures, allowing meaningful and complete assessment of MIPS eligible clinicians' performance within MVPs.

Comment: A commenter believes that there may be benefit in the MVP transition phase to selecting more Medicare Part B claim measures in the MIPS core measure set until vendors are able to support the Medicare CQMs that are included.

Response: We thank the commenter for their feedback about the transition to MVPs and the data collection types considered for MIPS core measures. We do not believe that it was necessary to prioritize quality measures available for reporting through the Medicare Part B claims collection type for designation as MIPS core measures. This collection type is only available to small practices (83 FR 59752),[394] which would be exempt from MIPS core measure requirements. Moreover, the Medicare CQM collection type is only available to ACOs participating in the Medicare Shared Savings Program and will not be available as a collection type for all the MIPS-eligible clinicians (88 FR 79330 through 79332).

Comment: A few commenters expressed that as CMS develops MVPs and MIPS core measures, the agency should rely on established, standardized, nationally recognized eCQMs and digital quality measures (dQMs) already integrated into clinician workflows. The commenters stated that CMS should continue aligning MIPS core measures with the Universal Foundation and avoid excluding clinically meaningful measures based solely on collection type. Another commenter recommended CMS design required MIPS core measures to rely on standardized United States Core Data for Interoperability (USCDI) and USCDI+ (program-specific extensions of USCDI) data elements, minimizing manual data abstraction or creation, which is especially important as CMS considers transitioning to dQM FHIR.

Response: We thank the commenters for their feedback and appreciate the feedback on the transition to dQM FHIR. Currently, the measure steward, as the proprietor of the measure, determines which collection types will be available for each of their measures without specific requirements for digital measure data element abstraction. Therefore, utilizing criteria, that require an eCQM or dQM collection type, at this time would circumstantially benefit or diminish a measure's inclusion as a

[394] *https://www.federalregister.gov/documents/2018/11/23/2018-24170/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions#page-59752.*

MIPS core measure based on criteria that are not currently required for MIPS quality measures. Additionally, these added requirements for MIPS core measure selection, such as a specific collection type, would further constrain selection options and create a barrier for reporting that is not a MIPS requirement until more measures are converted to dQMs and FHIR-based reporting is mandatory. We accounted for collection type availability for measures selected; however, the final selected measures represent a balance between clinical topic alignment, availability, and applicability, as we can't require use of specific submission criteria.

Comment: Many commenters expressed general concerns about the MIPS core measures policy. Of these commenters, a commenter stated a measure should not be designated as a MIPS core measure merely because it appears broadly relevant at the MVP level. The commenter stated that CMS should confirm that the measure: applies to the clinician's actual scope of practice; is reportable by the intended clinician type; has a benchmark with equitable scoring opportunity; can reasonably meet case minimum; and represents a meaningful aspect of care for the designated specialty or subspecialty. Another commenter stated that a quality measure must possess a benchmark to be classified as a MIPS core measure in an MVP.

Response: We thank the commenters for their feedback. In designating core measures, we balanced choosing measures that most closely represent care central to the MVP topic, while ensuring the availability of the measure collection type and applicability of the setting/clinician type for clinicians that choose to report the MVP, in accordance with the factors we proposed for designation of MIPS core measures. We disagree that only measures with benchmarks should be considered, especially given the current ability to report as multi-specialty groups. Many critical quality actions are represented by specialty specific quality measures which may show low adoption as multispecialty groups focus on capturing data for the more broadly applicable measures. Additionally, we believe that as a designated MIPS core measure, there will be an increase in adoption for the selected measures, allowing for meaningful benchmark creation for quality measures that historically didn't meet reporting requirements. We appreciate the commenters' concern regarding reporting requirements and scoring opportunity and will continue to evaluate measure reporting and policies for future proposals, in addition to the 7-point cap removal policy for MIPS core measures finalized in section IV.B.1.b.(3)(c) of this final rule.

Comment: A few commenters were concerned that the MIPS core measures policy would reduce flexibility and further restrict clinician's ability to select measures that meaningfully reflect their practice. The commenters were further concerned this policy will create a one-size-fits-all model and urged CMS to preserve measure choice, keep core requirements limited, and use broadly applicable measures within physicians' control. A commenter expressed that adding MIPS core measures would add another layer of complexity at a time when CMS is trying to streamline the program and added that physicians should have the flexibility to choose measures that are most relevant to their unique practice. Another commenter stated that MIPS core measures must be clinically relevant, feasible, and applicable across diverse practice settings and requested CMS maintain flexibility when no applicable MIPS core measure exists and regularly reevaluate MIPS core measures to reflect evolving clinical practice. Another commenter stated that surgeons must retain flexibility to select measures relevant to their practices and rather than requiring MIPS core measures, CMS should encourage development of additional measures for specific specialties.

Response: We thank the commenters for their feedback that this change in policy will modify reporting requirements. We note that clinicians will maintain the flexibility to choose the quality measures they report. The MIPS core measures policy will decrease complexity while also increasing flexibility. Reporting a MIPS core measure replaces the requirement to report an outcome/high priority measure, which may not be always best aligned with the MVP topic. For each MVP, we identified a small subset of measures that represent care central to the MVP's specialty or medical condition to continue to allow for flexibility and clinician choice. For some MVPs, such as the Surgical Care MVP, we determined more than three measures must be selected to reflect the care central to the subspecialties able to report the MVP. Additionally, the policy includes an option for self-attestation when the MIPS core measures are not appropriate or applicable to their scope of care, allowing clinicians to choose an alternate measure that is more relevant. We welcome feedback on all MIPS core measures and encourage commenters to submit this during the annual MVP maintenance review process. We also encourage interested parties to submit potential new measures that will align with current CMS goals and priorities and fill these identified gaps to allow meaningful and complete assessment of MIPS eligible clinician's performance within MIPS during the annual Call for Measures.

Comment: Several commenters requested CMS permit QCDR measures to be designated as MIPS core measures.

Response: When developing criteria for selecting MIPS core measures, it was determined that QCDR measures would not be included as MIPS core measures to ensure MIPS core measures are accessible for all eligible clinicians. QCDR measures require additional resources for reporting and therefore may not be a feasible reporting option for some clinicians. As reporting a MIPS core measure is a criterion for meeting quality performance requirements, all measures need to be publicly available and free to use.

Comment: A commenter urged CMS to publish, in the final rule, a complete and clearly identified list of all proposed MIPS core measures, and to establish a transparent process for designating MIPS core measures that include meaningful consultation with the relevant clinical specialty interested parties and the consequence for physician scoring should not be made without the input of the specialties they affect. Similarly, a few commenters requested that CMS publish the list of MIPS core measures each year in rulemaking and seek interested parties' feedback before the list is published. Many specialty societies asked for closer collaboration with CMS on MIPS core measure development and the ability to provide interested parties' feedback. Another commenter requested CMS define a MIPS core measure continuity process before finalizing the designation, noting that high priority status will no longer function as a reason to prevent a measure from being removed. The commenter also stated that the proposed rule did not describe a replacement process for the specialty or MVP that loses its MIPS core measure as a result.

Response: We welcome feedback on all MIPS core measures and encourage commenters to submit this during the annual MVP maintenance review process for consideration in future rulemaking. For more details on the MVP maintenance process, see section IV.A.4.a. of this final rule. MIPS core measure designation factors are outlined in section IV.A.4.d.(1)(c)(i) of this final rule and set the base for consideration criteria during review of each MVP.

While we completed the initial designation of MIPS core measures, this is an element that will be reviewed annually with interested parties' feedback to determine if revisions are warranted. Understanding that some clinicians may not be able to report the selected MIPS core measures, we do allow attestation if a MIPS core measure is not available and applicable. While high priority was a consideration for retaining measures that met removal criteria, many of the other criteria found within 42 CFR 414.1330(c)(2) would be applicable to MIPS core measures as they represent priority areas for quality measure performance data that drives positive outcomes in patients. However, if a MIPS core measure is removed from MIPS for other reasons, such as the measure steward decides to no longer maintain it, another MIPS core measure would be selected as a replacement through the MVP maintenance process and rulemaking.

Comment: Several commenters requested CMS further test the concept of MIPS core measures and urged CMS to delay finalizing MIPS core measures until clinicians have had sufficient time to transition to and gain experience with mandatory MVP reporting. Several commenters requested delaying the MIPS core measures requirement until the CY 2028 MIPS performance period to allow CMS time to refine the MIPS core measure definition and selection process and ensure EHR and registry vendors are ready to support MIPS core measures. Another commenter requested CMS test the MIPS core measures policy through a 2-year informational-only period before applying payment consequences to allow for an adequate transition time and ensure that safeguards are adopted to prevent unnecessary burden. A few clinicians indicated that they need more time to transition to and gain experience with mandatory MVP reporting.

Response: As the MIPS core measures were chosen from quality measures already in MIPS, we do not agree that delaying implementation a year or two would result in meaningful information to change the MIPS core measures policy. Note that although we are finalizing our MIPS core measures policy for the CY 2027 performance period, we are delaying the sunsetting of traditional MIPS by 2 years, which means that MVP-only reporting will begin in the CY 2031 performance/2033 MIPS payment year period instead of the CY 2029 performance period as indicated under section IV.A.3.c. of this final rule. This extra time will allow clinicians more opportunity to begin planning for and reporting MIPS core measures before MVP reporting is required.

Comment: A commenter stated it is critical that at least one of the MIPS core measures in an MVP be considered in relation to one or more of the cost measures.

Response: During identification of MIPS core measures, we considered current and historical submission data to guide applicability and decision-making, working to include appropriate and available measures. Currently there are more specialty specific quality measures available, which are needed to cover as many specialties/subspecialties as possible, and there may not be a complimentary episode-based cost measure available. However, as the goal of MIPS core measures is to target performance data for specific quality actions central to the MVP intent, the link to cost is addressed at the MVP level, rather than to individual quality measures.

Comment: Several commenters expressed concern for limited core measures available for specific specialties. Commenters stated that MIPS core measures add little value when a specialty already has a small, defined set of measures. A commenter stated the primary purpose of an MVP is to measure specialty-specific quality. The commenter stated that if there is only one MIPS core measure available, it does not help with the adoption of the use of MVPs for MIPS reporting. Another commenter stated that the current core set of measures does not meet CMS' stated goal of identifying measures ''most reflective of the care that is unique to each MVP's specialty or medical condition.'' Another commenter said that instead of mandating the reporting of MIPS core measures, CMS should focus its efforts on ensuring that each MVP offers a sufficient number of meaningful measures, including QCDR measures, that appropriately reflect the care delivered by the specialty or subspecialty. A commenter recommended that specialties with few available measures should be exempt from the MIPS core measure requirements. CMS should categorize each measure and report scores by category, which would be more meaningful to patients and avoid incomplete comparisons between clinicians.

Response: We thank the commenters for their comment. In designating MIPS core measures, we balanced alignment of the measure with care central to the MVP topic, while ensuring measure availability for those clinicians who choose to report the MVP. The purpose of MIPS core measures is to capture data that best represents the care unique to the MVP topic, allowing for a targeted set of data that directly compares quality performance for essential care components that patients can readily understand and access for making care provider decisions. While MVPs allow for more meaningful comparisons of performance and connection of quality with cost, varied measure selection for reporting within the MVP leads to varied measure submissions across the MVP, even in MVPs with fewer measures and in cases where new measures are still being developed and may be added to MVPs that have fewer measures in the future. MIPS core measures will provide a more focused performance comparison point across those reporting the MVP. Alignment of MIPS core measures across MVPs was a secondary consideration as appropriate and applicable. MIPS core measures replace the outcome/high priority quality measure requirement while adding flexibility and designating more meaningful measures. Understanding that some clinicians, such as cardiovascular subspecialists, may be unable to report the selected MIPS core measures, we do allow attestation for cases in which a MIPS core measure is not available and applicable. We encourage interested parties to submit potential new measures that will align with current CMS goals and priorities, allowing MIPS eligible clinicians to maximize their potential performance within MIPS during the annual Call for Measures.

Currently, the measures within the MVP are bucketed into clinical groupings, which helps to guide measure reporting choice; however, these also do not always capture all clinicians' individual scope of care. Some MIPS core measures are broadly applicable, seeming to go against the goal of designating measures ''most reflective of the care that is unique to each MVP's specialty or medical condition;'' however, these are not mutually exclusive as the measure may represent a fundamental aspect of care that is unique and unifying across specialties and clinical care topics, such as shared decision-making and risk communication. Additionally, there are certain administration priorities aligned with such unifying concepts, representing important aspects of care that are widely comparable and an important data point for patients deciding on clinicians.

After consideration of public comments, we are finalizing that the measures we proposed to be designated as a MIPS core measure in Appendices

1 and 3 of the CY 2027 PFS proposed rule, in accordance with the methodology we proposed for designating a measure as a MIPS core measure, are finalized as proposed. Finalized designations may be found in the MIPS quality measure inventory and the MVP inventory found in Appendices 1 and 3, respectively, of this final rule. We are also finalizing our considerations for designating a quality measure as a MIPS core measure as proposed. As discussed above, interested parties may submit recommendations for quality measures set forth in an MVP to be designated as a MIPS core measure in accordance with the MVP maintenance process for CMS to consider in future rulemaking. CMS will propose quality measures that meet the factors for a MIPS core measure to be designated as such through rulemaking. We are also finalizing our policy that will designate at least three measures in each MVP as a MIPS core measure.

For the discussion on the policies relating to reporting MIPS core measures for traditional MIPS, specialty measure sets, and the MVP reporting option, please see section IV.A.4.d.(1)(c)(iii)(B) of this final rule.

(ii) Removing High Priority Measure Designation and High Priority Quality Measure Retention Consideration

In the CY 2019 PFS final rule (83 FR 59761), we finalized that beginning with the CY 2019 performance period/2021 MIPS payment year, the term ''high priority measure'' is defined at § 414.1305 as an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. In the CY 2023 PFS final rule (87 FR 70047 through 70049), we finalized an amended definition of the term ''high priority measure'' to include quality measurement pertaining to health equity. In the CY 2026 PFS final rule (90 FR 49857), we finalized at § 414.1305 an amended definition of the term ''high priority measure'' to mean an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure, beginning with the CY 2026 performance period/2028 MIPS payment year.

In the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77785) and subsequent Quality Payment Program and PFS rules (82 FR 53965 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85368, 86 FR 65686 through 65968, 87 FR 70250 through 70633, 88 FR 79556 through 79964, 89 FR 98599 through 98957, and 90 FR 50036 through 50353), we designated certain quality measures as high priority in the MIPS quality measure inventory found in the Appendices of the rules for the applicable performance period to allow MIPS eligible clinicians to easily identify which measures meet the definition of a high priority measure at § 414.1305 and satisfy the reporting requirement. Additionally, in the CY 2022 PFS final rule (86 FR 65998 through 66031) and subsequent PFS rules, we designated high priority quality measures in the MVP inventory found in the Appendices. The Explore Measures and Activities Tool on the QPP website (*https://qpp.cms.gov/reporting-requirements/measures-activities/explore*) also indicates which quality measures are designated as high priority in traditional MIPS and MVP reporting.

Given the implementation of the MIPS core measure designation in section IV.A.4.d.(1)(c)(i) of this final rule, which identifies a subset of measures that reflect the essential components of care specific to a given specialty, medical condition, or episode of care, we proposed to remove the high priority designation from the MIPS quality measure inventory and the MVP inventory. The new MIPS core measures intend to increase reporting on select quality measures that are most reflective of the care central to a particular specialty, medical condition or episode of care, while providing patients with more comparative clinician performance data. We considered maintaining the high priority designation since many of the new MIPS core measures are high priority measures. However, the high priority designation does not appropriately capture a measure's relevance to a specific clinical specialty, medical condition or episode of care. We identify and designate quality measures that reflect agency-wide priorities as high priority in our programs through a myriad of ways such as using the MIPS high priority definition, developing the Universal Foundation, and implementing the Core Quality Measures Collaborative (CQMC). However, the new MIPS core measure designations specifically represent key quality measures that reflect the measure's relevance to a specific clinical specialty, medical condition or episode of care for clinicians and patients for each MVP and essential best practices to the MVP's clinical topic. The significant overlap in the new MIPS core measures with the MIPS high priority measures means we will still largely capture agency-wide priorities but with a greater emphasis on supporting intended MIPS policy goals of providing robust quality measure data relevant to the scope of care for a specialty or medical condition. Additionally, maintaining the high priority measure designation can add complexity and confusion for clinicians given the overlap of the existing high priority measures and the new MIPS core measures. While we acknowledge the overlap in intended goals for high priority measures and MIPS core measures, we anticipate that the new MIPS core measures, with a selection emphasis on outcome-based measures, will provide a more targeted set of measures, focused on more meaningful improvement in the quality of care related to each MVP specialty or medical condition. Therefore, to implement the new MIPS core measure designation as described in section IV.A.4.d.(1)(c)(i) of this final rule, we proposed to remove the high priority designation from the MIPS quality measure and the MVP inventory in Appendices 1 and 3 of this final rule.

Additionally, in the CY 2019 PFS final rule (83 FR 59765) at § 414.1330(c)(2), we revised the approach to remove quality measures to include considerations for retaining MIPS quality measures that otherwise meet the criteria for removal, including ''whether the MIPS quality measure is designated as high priority or not.'' To align with the removal of high priority designation from MIPS quality measures, we will no longer include the use of a high priority measure designation as one of the considerations for retaining a MIPS quality measure. Therefore, we proposed to update the existing quality measure retention consideration at § 414.1330(c)(2)(iv) to state that we will consider whether the quality measure is designated as high priority or not through the CY 2026 performance period/2028 MIPS payment year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to remove the high priority designation for quality measures. A commenter added that it should be assumed that all measures remaining would be considered high priority and supported replacing outcome measures with MIPS core measures.

Response: We thank the commenters for supporting the proposal to remove the high priority measure designation. As we move to a robust, streamlined quality measure inventory, we expect that each measure maintained would meet standards and criteria once associated with high priority measures, essentially resulting in a quality measure inventory that consists of high priority and MIPS core measures.

Comment: A commenter believes that eliminating the high priority designation does not justify replacing it with a MIPS core measure requirement.

Response: We thank the commenter for their comment but disagree. The overall goal of MVPs is to create a small, streamlined set of measures that are reflective of the care given. Identifying MIPS core measures allows for continued choice in measure selection while also supporting the goal of capturing comparable data across clinicians for patient use in care decision making. While we acknowledge the overlap in intended goals for high priority measures and MIPS core measures, we anticipate that the new MIPS core measures, with a selection emphasis on outcome-based measures, will provide a more targeted set of measures, focused on more meaningful improvement in the quality of care related to each MVP specialty or medical condition.

Comment: A few commenters asked CMS to maintain the high priority/outcome designations. A commenter requested maintaining the requirement alongside the core measure designations and allow reporting of either a MIPS core measure or outcome/high priority measure to provide the flexibility needed for subspecialists to report on measures germane to their practice. A commenter believes the three MIPS core measures for its specialty were not a complete representation of the care provided by this specialty and asked for the high priority designation to remain. Another commenter expressed that eliminating these designations would devalue true patient outcome measures and conflict with CMS' goal of clinically relevant, evidence—based performance assessment. Another commenter stated that the high priority designation highlights core quality areas (patient outcomes, care coordination, safety, experience, and appropriate use) that are essential to primary care and expressed concern that removing this designation and its role in measure retention could lead to loss of important primary care measures.

Response: The importance given to patient outcome measures remains regardless of the high priority designation. Currently, over 50 percent of the outcome and patient experience quality measures are designated as MIPS core measures, allowing for the continued reporting of previously selected measures. However, the distribution of outcome and patient experience quality measures across MVPs and within MVPs isn't consistent, leading to potential reporting inequities and inability to meet requirements, but more importantly, potentially missing key aspects of care unique to clinicians reporting an MVP. MIPS core measures, however, are specifically chosen from the MVP measure set to represent these key aspects of care, as opposed to choosing from a set of measures using a historical designation that does not serve the same purpose. While high priority was a consideration for retaining measures that met removal criteria, many of the other criteria found within 42 CFR 414.1330(c)(2) would be applicable to MIPS core measures as they represent priority areas for quality measure performance data that drives positive outcomes in patients. In addition, having adequate coverage for clinicians reporting MVPs is a critical factor taken into consideration when reviewing the measure inventory, and measures would not be removed to the detriment of a specialty (for example, primary care) based on the change in measure designations. All MIPS quality and QCDR measures will continue to be reviewed and assessed for meeting the fully developed and tested criteria, allowing for consistent and reliable implementation in MIPS. We encourage interested parties to develop, or work with measure developers, to submit potential new measures that will align with current CMS goals and priorities and fill these identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS during the annual Call for Measures.

Comment: A commenter recommended that CMS confirm in the final rule that the MIPS core measure designations as finalized in Appendix 1 and Appendix 3 of this final rule are the operative designations for the CY 2027 performance period, and that a measure's core or non-core designation will not be added, removed, or revised through the Explore Measures and Activities Tool or other sub-regulatory channels after the final rule publishes. The rule notes that the high priority designation policy replacement has been communicated through the Explore Measures and Activities Tool in addition to the rule appendices. The commenter asked CMS to state that the core designation will not follow that pattern.

Response: We thank the commenter for this comment. The MIPS core measures list finalized under this final rule are the final designations for the CY 2027 performance period. There will be no further changes to MIPS core measures in CY 2027; however, any resources requiring corrections to align with the CY 2027 finalized MIPS core measures would be allowed to ensure the most accurate information is conveyed. There will be no substantive changes made to the Explore Measures and Activities Tool or other sub-regulatory channels outside of this final rule for CY 2027. Any future updates to MIPS core measures policy, or the list of MIPS core measures, will go through notice-and-comment rulemaking.

After consideration of public comments, we are finalizing the removal of the high priority designation from the MIPS quality measure inventory and the MVP inventory in Appendices 1 and 3 of this final rule, given the implementation of the MIPS core measure designation, as proposed. We are also finalizing updates to the existing quality measure retention consideration at § 414.1330(c)(2)(iv) to state that we would consider whether the quality measure is designated as high priority or not through the CY 2026 performance period/2028 MIPS payment year.

(iii) Implementing Data Submission Requirement for MIPS Core Measures

(A) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77114), we finalized at § 414.1335(a)(1) that for the performance period, a MIPS eligible clinician will report at least six measures including at least one outcome measure. If an applicable outcome measure is not available, a MIPS eligible clinician will be required to report a high priority measure instead. Additionally, in the CY 2022 PFS final rule (86 FR 65412), we finalized at § 414.1365(c)(1), that except as provided in paragraph § 414.1365(c)(1)(i), an MVP participant must select and report, if applicable, 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure), included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii). We were concerned that small practices do not have the same resources to meet the quality reporting requirement of four measures if the MVP does not include four Medicare Part B claims measures. Therefore, we

finalized at § 414.1365(c)(1)(i) that paragraph § 414.1365(c)(1) does not apply to a small practice that reports on an MVP that includes fewer than four Medicare Part B claims measures, provided that the small practice reports each such measure that is applicable.

(B) Update for MIPS Core Measure Data Submission Requirements With Self-Attestation

In conjunction with the removal of the high priority designation for MIPS quality measures, and the new designation of MIPS core measures beginning with the CY 2027 performance period/2029 MIPS payment year, we proposed to remove the current quality measure data submission requirement of one outcome measure (or, if an outcome measure is not available, one high priority measure) for traditional MIPS and MVPs and replace the requirement with a MIPS core measure data submission requirement to emphasize the reporting on the new MIPS core measures. In the CY 2027 PFS proposed rule, we stated the requirement to report an outcome measure (or, if an outcome measure is not available, one high priority measure) would no longer be necessary if the MIPS core measure selection policies were finalized, as the goals of that policy would be met by the new MIPS core measure reporting requirement. Specifically, we proposed that MIPS eligible clinicians reporting via traditional MIPS must submit data on at least six measures, including at least one MIPS core measure. Clinicians reporting a specialty measure set in traditional MIPS must report at least six measures and choose an applicable MIPS core measure, if available, within that specialty measure set. If the set contains fewer than six measures or fewer than six measures within the set apply, they must report on each measure that is applicable. Additionally, to be consistent with the existing reporting requirements for clinicians reporting a specialty measure set, as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77114), if a specialty measure set does not contain a MIPS core measure, clinicians must still report on at least six measures within the specialty set. If the specialty set does not contain a MIPS core measure and contains fewer than six measures, or fewer than six measures within the set apply, they must report on each measure that is applicable within the specialty measure set. An MVP participant must select and report, if applicable, four quality measures, including at least one MIPS core measure. We noted in the proposed rule that clinicians submitting data for the quality performance category in traditional MIPS reporting would choose an applicable MIPS core measure from the full inventory of available MIPS core measures for the performance period. Clinicians reporting an MVP will choose an applicable MIPS core measure from those available in the selected MVP. Each MVP will include a minimum of three MIPS core measures for a clinician to select from. MVPs that encompass multiple specialties or subspecialties may include more than three MIPS core measures to ensure comprehensive coverage for the variety of clinicians reporting that MVP.

Since the new MIPS core measures are identified to reflect the care most central to a clinician specialty, medical condition, or episode of care within each MVP for clinicians and patients, we anticipated that clinicians can report the new MIPS core measures in the selected MVP. We acknowledged that due to the variety of clinician practices, specialties, and subspecialties reporting each MVP, there may be instances in which a clinician does not have an available and applicable MIPS core measure due to the limited inventory of the new MIPS core measures. If an individual eligible clinician, group, subgroup, or APM Entity does not have an available and applicable MIPS core measure that meets the numerator and denominator criteria as specified in the MIPS quality measure inventory for the applicable performance period, either in traditional MIPS or MVP reporting, we proposed to establish a MIPS core measure self-attestation process. Under this process, the clinician would be required in good faith to attest during the data submission period that there was not an available and applicable MIPS core measure for them to report. The clinician would then be required to choose another measure to report in place of the MIPS core measure. A clinician reporting via traditional MIPS can report any other applicable quality measure in the MIPS quality measure inventory. In MVP reporting, a clinician can report any other quality measure in the selected MVP. There may be instances in which a clinician attested to not having an applicable and available MIPS core measure, but new information or changing circumstances later made it so that the clinician does have an applicable and available MIPS core measure to report. To account for these cases, we would allow a clinician to attest that they do not have an applicable and available MIPS core measure and then submit a MIPS core measure. While we considered requiring clinicians without an available and applicable MIPS core measure to report an outcome or high priority measure, we determined that such a requirement would increase complexity for clinicians and would be unnecessary given that MVPs are already a collection of the key quality measures for a specialty, medical condition, or episode of care. We proposed that we would not penalize a MIPS eligible clinician who provides a self-attestation to not having a MIPS core measure to report. We noted in the proposed rule that we may monitor attestations received for the MIPS core measure requirement and may, in future years, conduct random reviews to verify that there were no available and applicable MIPS core measures for reporting. We refer readers to section IV.B.1.b.(1) of this final rule for details on the scoring policies for MIPS core measures.

For traditional MIPS reporting, we proposed at § 414.1335(a)(1)(i) that beginning in the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians, except as provided in paragraphs (a)(1)(ii) and (a)(1)(iii) of this section, submit data on at least six quality measures, including at least one MIPS core measure. If there is not an available and applicable MIPS core measure, a MIPS eligible clinician must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure. If fewer than six measures apply, then the MIPS eligible clinician, group, virtual group, or APM Entity must report on each measure that is applicable.

Additionally, we proposed at § 414.1335(a)(1)(ii) that beginning in the CY 2027 performance period/2029 MIPS payment year, except as provided in paragraph (a)(1)(iii) of this section, a MIPS eligible clinician that reports on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one MIPS core measure. If there is not an available and applicable MIPS core measure, a MIPS eligible clinician must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure within that set. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, report on each measure that is applicable.

For MVP reporting, we proposed at § 414.1365(c)(1) that, beginning in the CY 2027 performance period/2029 MIPS

payment year, except as provided in paragraphs (c)(1)(i) and (c)(1)(ii) of this section, an MVP participant must select and report, if applicable, four quality measures, including one MIPS core measure available in the MVP, excluding the population health measure required under paragraph (c)(4)(ii). If there is not an available and applicable MIPS core measure, an MVP participant must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure within the MVP.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to remove the requirement to report one outcome or high priority measure for traditional MIPS and MVP reporting. A commenter indicated this requirement has been problematic in mandatory MVPs where physicians have fewer measures to choose from and may be unable to identify a relevant outcome or high priority measure. A commenter expressed that replacing the outcome measure requirement with MIPS core measures will solve the issues with established quality measures not receiving benchmarks due to low participation, and clinicians unwilling to elect administrative claims measures (outside of the population health measures) that are available under certain MVPs because they are outcome measures. Another commenter agreed that many clinicians struggle to report outcome measures. Another commenter stated that removing the outcome measure requirement allows clinicians more flexibility to select measures relevant to their practice.

Response: We thank the commenters for supporting the proposal to remove the requirement to report on one outcome or high priority measure for traditional MIPS and MVP reporting.

Comment: Several commenters supported the attestation process for clinicians who have no applicable MIPS core measure to report. A commenter expressed that those with limited measures will also need to use eligible measure applicability (EMA) evaluation. The commenter recommended automatically linking attestation of no MIPS core measure with EMA evaluation to avoid separate processes. Another commenter strongly supported including a straightforward, transparent self-attestation process for physicians who cannot identify an applicable MIPS core measure, emphasizing that it should not create scoring disadvantages or added administrative burden. Another commenter urged CMS to expand flexibility in the attestation process, reduce administrative burden, closely monitor impacts before increasing reliance on MIPS core measures, and use high attestation rates to identify and fix gaps in the MIPS core measure set. Another commenter encouraged CMS to develop adequate guidance on the self-attestation and exemption processes associated with MIPS core measure reporting.

Response: We thank the commenters for supporting the proposed attestation process. We appreciate the commenters' concerns and request for further flexibilities to requirements, such as linking EMA evaluation with the MIPS core measure attestation process or expanding the use of an attestation process for clinicians who are not able to meet program requirements and will continue to monitor the use of the MIPS core measure attestation pathway, MVP measure reporting trends, and interested parties' feedback to determine potential future refinements as we move toward the sunsetting of traditional MIPS. The self-attestation process is completed at the time of submission and is intended to replace the more involved processes associated with current outcome/high priority reporting requirements.

Comment: A commenter requested CMS clarify whether an alternative measure selected, when there is not an available and applicable MIPS core measure, must come from the same MVP, from the broader MIPS quality inventory, or meet specific criteria such as eCQM availability, specialty relevance, denominator applicability, or alignment with the clinician's patient population. Another commenter requested that CMS finalize the MIPS core measure requirement with an exception of permitting an outcome measure of any collection type to satisfy the requirement within an MVP.

Response: We thank the commenters for their suggestions. Clinicians who are unable to report one of the designated MIPS core measures may attest that an applicable core measure was not available to them and then select any other quality measure included within the MVP being reported. In selecting an alternative measure to meet the MIPS core measures requirement, the clinician would need to meet all reporting requirements, and it would be expected that the alternative measure be meaningful to their scope of care. We decline to allow an exception to report any outcome measure. Broadening the requirement to include additional outcome measures than originally identified would be counterintuitive to the goal of establishing a set of unified key quality measures.

Comment: A few commenters requested clarification on the definition of ''available and applicable'' MIPS core measures. A commenter requested CMS define ''applicable'' for purposes of the MIPS core measure self-attestation so that a clinician whose relevant measures are all QCDR outcome measures may attest that no applicable MIPS core measure exists and report an outcome measure in its place. Another commenter requested CMS confirm in sub-regulatory guidance how ''no applicable MIPS core measure'' will be determined and audited for each MVP and specialty measure set.

Response: Clinicians who are unable to report one of the designated MIPS core measures may attest that an applicable MIPS core measure was not available to them and then may select any other quality measure included within the MVP or specialty measure set being reported. There are no specific requirements for this alternative measure beyond current quality measure reporting requirements. As stated in the proposed rule clinicians, in good faith, can attest that they do not have a measure that is available or applicable to them. Additionally, as noted in the proposed rule, we may, in future years, conduct random reviews to verify that there were no available and applicable MIPS core measures for reporting. Measures that are available and applicable would be determined by the alignment of the measure with the clinician's case-mix, scope of care, and ability to implement. See section IV.A.4.d.(1)(c)(i) of this final rule for details on the MIPS core measurement requirement for traditional MIPS and MVP reporting.

Comment: A commenter opposed replacing the outcome/high priority measure requirement with a new MIPS core measure requirement. The commenter stated that practices have already built clinical workflows and EHR reporting modules around the outcome/high priority framework. Adding an entirely new structural requirement introduces administrative confusion and software re-engineering costs without providing a clear benefit to clinical quality or patient outcomes. Another commenter expressed concerned that mandatory MIPS core measure data submission will increase administrative burden and program volatility, contradicting CMS' goal of simplifying MIPS. The commenter urged CMS to avoid rigid requirements and prioritize stability, flexibility, and specialty—specific relevance in MIPS reporting. A commenter stated that

some MVPs do not have enough eCQMs to support full electronic measure submission, much less MIPS core measure reporting. Requiring CQMs or QCDR measures would create significant burden for organizations that currently report only eCQMs.

Response: We thank the commenters for their feedback. The overall goal of MVPs is to create a small, streamlined set of measures that are reflective of the care given. Identifying MIPS core measures allows for continued choice in measure selection while also supporting the goal of capturing comparable data across clinicians for patient use in care decision making. We appreciate the feedback that this change in policy will modify reporting requirements, potentially requiring updates in systems and workflows. However, as the MIPS quality measure inventory is refined annually, this is an inherent circumstance required each year as applicable. Overall, the MIPS core measures policy will decrease complexity while also increasing flexibility. Reporting a MIPS core measure replaces the requirement to report an outcome/high priority measure, which is not always best aligned with the MVP topic. We recognize that the availability and applicability of MIPS core measures may vary, such as when no eCQM MIPS core measures are available in an MVP, which is why we are allowing for self-attestation in these circumstances. We are not requiring a clinician to report a MIPS core measure that is not available or applicable to the clinician. Clinicians who are unable to report one of the designated MIPS core measures may attest that an applicable MIPS core measure was not available to them and then select any other quality measure included within the MVP being reported. Additionally, we will continue to monitor the use of the MIPS core measure attestation pathway, MVP measure reporting trends, and feedback to determine potential future refinements as we move toward the sunsetting of traditional MIPS in the CY 2031 performance period/2033 MIPS payment year as indicated under section IV.A.3.c. of this final rule.

After consideration of public comments, we are finalizing to remove the current quality measure data submission requirement of one outcome measure (or, if an outcome measure is not available, one high priority measure) for traditional MIPS and MVPs and replace the requirement with a MIPS core measure data submission requirement to emphasize the reporting on the finalized MIPS core measures, as proposed.

For traditional MIPS reporting, we are finalizing at § 414.1335(a)(1)(i) as proposed, that beginning in the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians, except as provided in paragraphs (a)(1)(ii) and (a)(1)(iii) of this section, submit data on at least six quality measures, including at least one MIPS core measure. If there is not an available and applicable MIPS core measure, a MIPS eligible clinician must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure. If fewer than six measures apply, then the MIPS eligible clinician, group, virtual group, or APM Entity must report on each measure that is applicable.

Additionally, we are finalizing at § 414.1335(a)(1)(ii) that, as proposed, beginning in the CY 2027 performance period/2029 MIPS payment year, except as provided in paragraph (a)(1)(iii) of this section, a MIPS eligible clinician that reports on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one MIPS core measure. If there is not an available and applicable MIPS core measure, a MIPS eligible clinician must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure within that set. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, report on each measure that is applicable.

For MVP reporting, we are finalizing at § 414.1365(c)(1) that, as proposed, beginning in the CY 2027 performance period/2029 MIPS payment year, except as provided in paragraphs (c)(1)(i) and (c)(1)(ii) of this section, an MVP participant must select and report, if applicable, four quality measures, including one MIPS core measure available in the MVP, excluding the population health measure required under paragraph (c)(4)(ii). If there is not an available and applicable MIPS core measure, an MVP participant must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure within the MVP. We note the sunsetting of traditional MIPS is delayed to the CY 2031 performance period/2033 MIPS payment year, as indicated under section IV.A.3.c. of this final rule.

(C) Exempting Small Practices From MIPS Core Measure Reporting Requirement

We recognized that clinicians in small practices often face challenges in successfully participating in MIPS and MVP reporting due to limited financial, administrative, and health IT resources, when compared to medium and large practices. Historically, we have received feedback from small practices expressing concerns that meeting the MIPS reporting requirements can be challenging due to the limited resources of small practices, and we have implemented policies in MIPS to support clinicians in small practices to address these concerns. For example, in the CY 2022 PFS final rule (86 FR 65412), we finalized at § 414.1365(c)(1)(i) that the requirement to report four quality measures in an MVP does not apply to small practice clinicians reporting under the Medicare Part B claims collection type when the selected MVP contains fewer than four Medicare Part B claims-based quality measures. In addition, in MVPs, small practices reporting via Medicare Part B claims measures are currently exempt from the outcome/high priority reporting requirement if the MVP does not contain at least four Medicare Part B claims measures.

We considered several policy options for small practices with respect to reporting MIPS core measures. Initially, we considered whether to align the reporting requirements for small practices with the new MIPS core measure reporting requirements for clinicians in medium and large practices participating in traditional MIPS and MVP reporting. However, we anticipate that clinicians in small practices may continue to experience challenges with meeting the proposed MIPS core measure reporting requirement due to limited resources, difficulty reaching the case minimum requirement, and the limited inventory of MIPS core measures, particularly the limited inventory of new MIPS core measures available via the Medicare Part B claims collection type, which is only available to small practices. While we also considered exempting small practices from the proposed MIPS core measure reporting requirement only if the selected MVP does not contain at least one MIPS core measure available via the Medicare Part B claims collection type, we remained concerned that such a policy will further limit measure choice for clinicians in small practices and could lead to confusion and unfairness if some MVPs contained Medicare Part B claims MIPS core

measures and other MVPs did not. In recognition of these ongoing challenges, and to streamline reporting requirements for small practices while continuing to support clinicians in small practices, we wanted to provide flexibilities for clinicians in small practices to successfully report the MIPS quality performance category. Therefore, in both traditional MIPS and MVP reporting, we proposed that small practices, as defined under § 414.1305, be exempt from the MIPS core measure data submission requirement. Under this provision, clinicians in small practices will continue to report six quality measures for traditional MIPS or four quality measures as currently required for MVPs. It is important to note that while small practices are not required to report a MIPS core measure, they may choose to do so on a voluntary basis.

Specifically, we proposed at § 414.1335(a)(1)(iii) that beginning with the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians in small practices are not required to submit at least one MIPS core measure or attest to not having an available and applicable MIPS core measure. MIPS eligible clinicians in small practices must submit data on at least six measures, if applicable. Additionally, we proposed at § 414.1365(c)(1)(ii) that beginning with the CY 2027 performance period/2029 MIPS payment year, an MVP participant that meets the requirements of a small practice is not required to submit at least one MIPS core measure or attest to not having an available and applicable MIPS core measure. Except as provided in paragraph (c)(1)(i) of this section, an MVP participant that meets the requirements of a small practice must select and report, if applicable, at least four quality measures included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the small practice exemption from MIPS core measures. One of these commenters cited that practices with fewer than 15 clinicians have fewer administrative and technical resources. The commenter requested this protection be extended to other new reporting mandates. Another commenter encouraged CMS to continue evaluating policies that support successful participation by small practices as reporting requirements evolve. Another commenter supported exempting small practices from the MIPS core measure requirement and asked that CMS consider the unique needs of small and rural anesthesia practices. Another commenter emphasized that small and solo practices still face disproportionate administrative burden and penalty risk under MIPS. An additional commenter requested CMS maintain flexibility for small practices in future years and to monitor whether persistent measure applicability challenges suggest the need for broader refinements to the MIPS core measure framework.

Response: We thank the commenters for supporting the small practice exemption proposal from MIPS core measures. As we develop future MIPS policies, we will continue to consider the impact of these proposals on small practices. We also appreciate the commenter's request for further flexibilities for small practices. We will continue to monitor the use of the MIPS core measure attestation pathway, MVP reporting trends, and feedback to determine potential future policy refinements.

Comment: A commenter stated that the small practice exemption does not address insufficient case volume. Many oncology measures apply only to narrow populations, so small and subspecialized practices often cannot reach benchmarked scores. The commenter recommended that CMS expand MVP measure inventories and confirm the exemption does not disadvantage those practices in scoring or feedback.

Response: We thank the commenter for this comment and note that we will continue to take scoring constraints into consideration as we move forward with MIPS core measures. There may be measures that assess a very limited patient population where it is difficult to produce a benchmark. We believe creating smaller sets of quality measures from which to choose will increase adoption; however, we will continue to monitor this aspect of quality measure scoring for potential policy revisions. For further information about quality measure selection and the MIPS quality measure inventory, please see Appendix 1: MIPS Quality Measures of this final rule. For additional information on quality benchmarks and scoring of MIPS core measures for small practices, please reference section IV.B.1.b.(2) of this final rule.

After consideration of public comments, we are finalizing our proposals to exempt small practices from MIPS core measure reporting requirements. Specifically, we are finalizing at § 414.1335(a)(1)(iii) that, as proposed, beginning with the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians in small practices are not required to submit at least one MIPS core measure or attest to not having an available and applicable MIPS core measure. MIPS eligible clinicians in small practices must submit data on at least six measures, if applicable. Additionally, we are finalizing at § 414.1365(c)(1)(ii) that, as proposed, beginning with the CY 2027 performance period/2029 MIPS payment year, an MVP participant that meets the requirements of a small practice is not required to submit at least one MIPS core measure or attest to not having an available and applicable MIPS core measure. Except as provided in paragraph (c)(1)(i) of this section, an MVP participant that meets the requirements of a small practice must select and report, if applicable, at least four quality measures included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section.

(iv) Modifying the Data Submission Criteria for Medicare CQMs

In the CY 2027 PFS proposed rule (91 FR 44159), we proposed an amendment to the data submission criteria for the Medicare CQMs collection type in § 414.1335(a)(4) by including the availability of Medicare CQMs within the APP Plus measure set, as applicable. Specifically, in § 414.1335(a)(4)(i), we proposed that the data submission criteria pertaining to Medicare CQMs would be met by a MIPS eligible clinician, group, and APM Entity reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set or APP Plus measure set (as applicable) and administering the CAHPS for MIPS Survey as required under the APP.

We are including the availability of Medicare CQMs under the APP Plus measure set to provide various options that would assist Medicare Shared Savings Program ACOs with reporting quality data and transition to the adoption of digital quality measures (dQMs). We encourage Medicare Shared Savings Program ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on their unique composition and technical infrastructure.

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comment we received and our response.

Comment: A commenter supported the proposal to amend the data submission criteria for the Medicare CQMs collection type by including the availability of Medicare CQMs within the APP Plus measure set, as applicable.

Response: We appreciate the support from the commenter.

After consideration of public comment, we are finalizing, as proposed, the amendment to the data submission criteria for the Medicare CQMs collection type in § 414.1335(a)(4) by including the availability of Medicare CQMs within the APP Plus measure set, as applicable. Specifically, in § 414.1335(a)(4)(i), the data submission criteria pertaining to Medicare CQMs will be met by a MIPS eligible clinician, group, and APM Entity reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set or APP Plus measure set (as applicable) and administering the CAHPS for MIPS Survey as required under the APP.

(v) Implementing the Data Submission Criteria for Medicare eCQMs

In the CY 2027 PFS proposed rule (91 FR 44159), we proposed to establish the data submission criteria for the Medicare eCQMs collection type (as proposed under the APP) in § 414.1335(a)(5). Specifically, in § 414.1335(a)(5)(i), we proposed that the data submission criteria pertaining to Medicare eCQMs would be met by a MIPS eligible clinician, group, and APM Entity reporting on the Medicare eCQMs (reporting quality data on beneficiaries eligible for Medicare eCQMs as defined at § 425.20) within the APP Plus measure set (as applicable) and administering the CAHPS for MIPS Survey as required under the APP.

Medicare eCQMs would serve to address concerns discussed in the CY 2027 PFS proposed rule (91 FR 44044 through 44046) by defining a population of beneficiaries that exists within the all payer/all patient eCQM specifications and tethering that population to a Medicare Shared Savings Program ACO's assigned beneficiary population. Medicare Shared Savings Program ACOs have noted challenges with quality data reporting as their list of eligible beneficiaries has often contained beneficiaries for whom the Medicare Shared Savings Program ACO is unable to identify a primary care relationship. Specifically, Medicare eCQMs would address the concern raised by Medicare Shared Savings Program ACOs with a higher proportion of specialty practices and/or multiple EHRs, the broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the Medicare Shared Savings Program ACO. Medicare eCQMs would provide an additional optional collection type for reporting quality data and assist with the transition and adoption of dQMs. Also, we anticipate in future years when FHIR-based reporting becomes mandatory that Medicare Shared Savings Program ACOs would be able to continue to use the FHIR-based digital specifications to report only on their assigned beneficiary population. We encourage Medicare Shared Savings Program ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on their unique composition and technical infrastructure.

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to establish the data submission criteria for the Medicare eCQMs collection type.

Response: We appreciate the support from commenters.

After consideration of public comment, we are finalizing the proposal, as proposed, to establish the data submission criteria for the Medicare eCQMs collection type (under the APP as described in section III.G.3.d.(3) of this final rule) in § 414.1335(a)(5). Specifically, in § 414.1335(a)(5)(i), the data submission criteria pertaining to Medicare eCQMs must be met by a MIPS eligible clinician, group, and APM Entity reporting on the Medicare eCQMs (reporting quality data on beneficiaries eligible for Medicare eCQMs as defined at § 425.20) within the APP Plus measure set (as applicable) and administering the CAHPS for MIPS Survey as required under the APP.

(d) Modifying the Data Completeness Criteria

(i) Modifying the Data Completeness Criteria for Medicare CQMs

As described in the CY 2027 PFS proposed rule (91 FR 44039 through 44044), we are extending the availability of the Medicare CQMs collection type and anticipating the sunsetting of the Medicare CQMs collection type starting with the CY 2030 performance period/2032 MIPS payment year when FHIR-based reporting becomes mandatory. In the CY 2027 PFS proposed rule (91 FR 44159), we proposed an amendment to the data completeness criteria for the Medicare CQMs collection type in § 414.1340(d)(1) by modifying the duration of availability for the Medicare CQMs collection type as a means for meeting data completeness criteria requirements, which would eliminate the specific duration of availability (from the CY 2024 performance period/2026 MIPS payment year to the CY 2028 performance period/2030 MIPS payment year) and extend the duration of the availability of the Medicare CQMs collection type. Such modification would extend the availability of the Medicare CQMs collection type for meeting the data completeness criteria threshold requirements under the APP until CMS identifies the sunsetting of the Medicare CQMs collection type in future rulemaking.

Specifically, in § 414.1340(d), respectively, we proposed the following modification to the data completeness criteria threshold pertaining to the Medicare CQMs collection type:

At paragraph (d)(1), starting with the CY 2024 performance period/2026 MIPS payment year, an APM Entity, specifically a Medicare Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria.

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support of the proposal to amend the data completeness criteria for the Medicare CQMs collection type by extending the availability of the Medicare CQMs collection type.

Response: We appreciate the support from commenters.

Comment: A few commenters expressed concerns regarding difficulties in meeting the data completeness criteria for the Medicare CQMs collection type. They conveyed that there are implementation, interoperability, and data exchange challenges; and requested that CMS continue to monitor the operational impact of meeting the data completeness criteria threshold of at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria.

Response: We recognize that there may be operational complexities in

meeting the data completeness criteria threshold for the Medicare CQMs collection type. We will continue to assess the data completeness criteria threshold for all collection types, including the Medicare CQMs collection type, as we consider future modifications.

After consideration of public comment, we are finalizing the proposal, as proposed, to amend the data completeness criteria for the Medicare CQMs collection type in § 414.1340(d)(1) by modifying the duration of availability for the Medicare CQMs collection type as a means for meeting data completeness criteria requirements, which will eliminate the specific duration of availability (from the CY 2024 performance period/2026 MIPS payment year to the CY 2028 performance period/2030 MIPS payment year) and extend the duration of the availability of the Medicare CQMs collection type.

Specifically, in § 414.1340(d), the data completeness criteria threshold pertaining to the Medicare CQMs collection type will be as follows:

At paragraph (d)(1), starting with the CY 2024 performance period/2026 MIPS payment year, an APM Entity, specifically a Medicare Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria.

(ii) Implementing the Data Completeness Criteria for Medicare eCQMs

As we proposed to establish a new collection type, Medicare eCQMs specific to the APP (91 FR 44048 through 44050) in the CY 2027 PFS proposed rule, we also proposed to establish the data completeness criteria threshold for the Medicare eCQMs collection type (91 FR 44159 and 44160). Specifically, in § 414.1340(e), respectively, we proposed the following data completeness criteria threshold pertaining to the Medicare eCQMs collection type:

At paragraph (e)(1), starting with the CY 2027 performance period/2029 MIPS payment year, an APM Entity, specifically a Medicare Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare eCQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare eCQM, as defined at § 425.20, who meet the measure's denominator criteria.

Also, for the data completeness criteria pertaining to the quality performance category, we proposed a technical amendment to recognize the former paragraph (e) as new paragraph (f) due to the provision that establishes the data completeness criteria for the new collection type, Medicare eCQMs, in § 414.1340(e) as discussed in the CY 2027 PFS proposed rule (91 FR 44160).

We requested public comment on these proposals.

We received public comments on the proposal pertaining to the establishment of the data completeness criteria threshold for the Medicare eCQMs collection type. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to establish the data completeness criteria threshold for the Medicare eCQMs collection type.

Response: We appreciate the support from commenters.

Comment: A commenter expressed concerns regarding difficulties in meeting the data completeness criteria for the Medicare eCQMs collection type. The commenter conveyed that there are implementation, interoperability, and data exchange challenges; and requested that CMS monitor the operational impact of the data completeness criteria threshold of at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare eCQM, as defined at § 425.20, who meet the measure's denominator criteria.

Response: We recognize that there may be operational complexities in meeting the data completeness criteria threshold for the Medicare eCQMs collection type. We will continue to assess the data completeness criteria threshold for all collection types, including the Medicare eCQMs collection type, as we consider future modifications.

After consideration of public comment, we are finalizing the proposal, as proposed, to establish the data completeness criteria threshold for the Medicare eCQMs collection type. Specifically, in § 414.1340(e), respectively, the data completeness criteria threshold pertaining to the Medicare eCQMs collection type is as follows:

At paragraph (e)(1), starting with the CY 2027 performance period/2029 MIPS payment year, an APM Entity, specifically a Medicare Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare eCQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare eCQM, as defined at § 425.20, who meet the measure's denominator criteria.

Also, we did not receive public comment on the proposal regarding a technical amendment to the quality performance category data completeness criteria that recognizes the former paragraph (e) as new paragraph (f) due to the provision that establishes the data completeness criteria for the new collection type, Medicare eCQMs, in § 414.1340(e). Therefore, we are finalizing the proposal as proposed.

(e) Addition of New Quality Measures

(i) Pre-Rulemaking Process

Prior to introducing a new MIPS quality measure in a proposed rule, we received public input on measures through the pre-rulemaking process (referred to as the Pre-Rulemaking Measure Review (PRMR)) established in accordance with section 1890A of the Act. Although section 1848(q)(2)(D)(viii) of the Act provides that the pre-rulemaking process under section 1890A of the Act is not required to apply to the selection of MIPS quality measures, we have found that the pre-rulemaking process provides a comprehensive review of measures from multi-interested party workgroups and have accordingly elected for such measures to be reviewed utilizing the PRMR process (87 FR 70048). Under the established PRMR process (additional information regarding the PRMR process is available at *https://p4qm.org/PRMR*), CMS has contracted with a Consensus-Based Entity (CBE), which is responsible for convening a multi-interested party panel comprised of clinicians, patients, measure experts, and health information technology specialists to provide input on measures CMS is considering for use in Medicare.

The PRMR process begins with CMS' publication of measures under consideration for use in Medicare (the Measures Under Consideration (MUC) List). Each measure on the MUC List is reviewed by one of several committees convened by the CBE for the purpose of providing multi-interested party input to the Secretary. The PRMR process includes opportunities for public comments through a 21-day public comment period, as well as public listening sessions. The CBE posts the compiled comments and listening session inputs received during the public comment period and the listening sessions within 5 days of the close of the public comment period. More details regarding the PRMR process may be found in the PQM

Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review (available at *https://p4qm.org/sites/default/files/2025-07/OP2-PRMR-MSR-Final-Multi-Stakeholder-Group-Guidebook-of-Policies-and-Procedures-508_1.pdf*).

Per the PQM Guidebook, the final vote of the multi-interested party committee convened by the CBE may result in the following disposition of a measure: The committee recommends that this measure be added to the CMS program or the committee does not recommend that this measure be added to the CMS program. A ''does not recommend'' voting result signals continued disagreement among the committee despite being presented with perspectives from public comments and committee member feedback and discussion and highlights the multi-faceted assessments of quality measures. There may be cases in which the CBE does not recommend a measure to move forward to the rulemaking process and eventual implementation but we go forth with proposing a measure. We note that section 1848(q)(2)(D)(iii)(v)(III) of the Act does not preclude the Secretary from proposing and implementing measures that are not endorsed by a CBE as long as the measure is evidence-based.

Quality measures considered for potential implementation in MIPS starting with CY 2027 performance period/2029 MIPS payment year were informed, in part, by the measures included on the 2025 MUC List (available at *https://mmshub.cms.gov/sites/default/files/2025-MUC-List.xlsx*). We refer readers to Table Group A of Appendix 1: MIPS Quality Measures of this final rule for detailed descriptions of the new MIPS quality measures finalized. We noted that we are advancing quality measurement by transitioning existing quality measures and reporting processes to Fast Healthcare Interoperability Resources® (FHIR®)-based digital approaches. We refer readers to section IV.A.4.c. of this final rule, where we sought input on the anticipated transition timeline, key milestones, and implementation considerations for FHIR-based quality reporting.

(ii) Removal of Quality Measures

In the CY 2025 PFS final rule, we codified previously established criteria for the removal of MIPS quality measures from the MIPS quality measure inventory at § 414.1330. In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we established the following criteria for measure removal to include: If the Secretary determines that the MIPS quality measure is no longer meaningful, such as MIPS quality measures that are topped out; and, if a measure steward is no longer able to maintain the quality measure. In the CY 2019 PFS final rule (83 FR 59763), we expanded the criteria for measure removal to include MIPS quality measures that reached an extremely topped-out status (for example, a measure with an average mean performance within the 98th to 100th percentile range). The MIPS quality measure may be proposed for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped-out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors.

Also, in the CY 2019 PFS final rule (83 FR 59764), we established other criteria for measure removal, specifically MIPS quality measures that are: duplicative; not maintained or updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice; and low-bar, standard of care process measures. As described in the CY 2019 PFS final rule (83 FR 59765), we established an approach to incrementally remove process measures where prior to removal, consideration will be given to, but will not be limited to, the following:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the MIPS quality measure addresses a priority area highlighted in the Measure Development Plan: *https://www.cms.gov/medicare/quality/value-based-programs/quality-payment-program/measure-development.*
- Whether the MIPS quality measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the MIPS quality measure is designated as high priority or not.
- Whether the MIPS quality measure has reached extremely topped-out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made.

In the CY 2020 PFS final rule (84 FR 62958 through 62959), we expanded the criteria for measure removal to include MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods and are not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians. For MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods, we noted that we will factor in other considerations (such as, but not limited to, the robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome; and consideration of the MIPS quality measure in developing MVPs) prior to determining whether to remove the MIPS quality measure. We refer readers to section IV.A.4.d.(1)(c)(ii) of this final rule for our provisions regarding removing references to the high priority measure designation from MIPS quality measures and MIPS quality measure retention consideration.

(iii) Inventory of Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding new measures to the list, as appropriate; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77558 through 77816 and 82 FR 53966 through 54174, respectively), and the CY 2019 through CY 2026 PFS final rules (83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, 87 FR 70250 through 70633, 88 FR 79556 through 79964, 89 FR 98599 through 98957, and 90 FR 50036 through 50353, respectively). We are finalizing changes to the MIPS quality measure inventory, as outlined in Appendix 1 of this final rule, including the following: the addition of new measures; updates to specialty sets (that is, creation of new specialty sets; addition and/or removal of measures; and substantive changes to existing measures within specialty sets, as appropriate); removal of existing measures; and substantive changes to existing measures. For the CY 2027 performance period/2029 MIPS

payment year, we are finalizing an inventory of 180 MIPS quality measures.

The new MIPS quality measures that we are finalizing to include in MIPS for the CY 2027 performance period/2029 MIPS payment year and future years can be found in Table Group A of Appendix 1 of this final rule. For the CY 2027 performance period/2029 MIPS payment year, we are finalizing 10 new MIPS quality measures, which include measures focused on patient-reported outcomes and chronic disease management.

On January 14, 2026, we solicited recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for the CY 2027 performance period/2029 MIPS payment year.[395] The recommendations we received were based on the MIPS quality measures finalized in the CY 2026 PFS final rule and the 2025 MUC List. The recommendations included the addition or removal of current MIPS quality measures from existing specialty sets, and/or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agreed with are finalized in this final rule.

We are finalizing modifications to existing specialty sets as described in Table Group B of Appendix 1 of this final rule. Modifications to specialty sets include the addition of new measures and/or existing measures within the MIPS quality measure inventory, removal of measures, and/or substantive changes to previously finalized measures. Specialty and subspecialty sets are not inclusive of every specialty or subspecialty. We develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets as described in Tables Group A and Group B of Appendix 1 of this final rule, we refer readers to Table Group C of Appendix 1 of this final rule for a list of MIPS quality measures finalized for removal and detailed discussion of our rationale for each measure. Of the 20 MIPS quality measures finalized for removal, two MIPS quality measures are extremely topped out, four MIPS quality measures have reached the end of the topped-out lifecycle, three MIPS quality measures are no longer being maintained by the measure steward, eight MIPS quality measures are duplicative of new or current measures, one MIPS quality measure has limited adoption and therefore no benchmark, one MIPS quality measure is a low bar process measure, and one MIPS quality measure lacks robustness. The provision to remove the MIPS quality measures described in Table Group C of Appendix 1 of this final rule will lead to a more parsimonious inventory of meaningful, robust measures in the program.

Further, in Appendix 1 of this final rule, we are finalizing substantive changes to 43 MIPS quality measures, which can be found in Table Group D and Table Group DD of Appendix 1 of this final rule. Of the finalized substantive changes to the 43 MIPS quality measures, two MIPS quality measures are only available for use in relevant MVPs, which can be found in Table Group DD of Appendix 1 of this final rule. We have previously established criteria that will apply when we are considering making substantive changes to a quality measure (81 FR 77137 and 86 FR 65441 through 65442). On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive. The finalized inventory of 180 MIPS quality measures for the CY 2027 performance period/2029 MIPS payment year includes 177 MIPS quality measure available for utilization in traditional MIPS and MVPs, and 3 MIPS quality measures available only for utilization in MVPs (as finalized in the CY 2024 PFS final rule (88 FR 79897 through 77902)).

In summary, in the CY 2027 PFS proposed rule, we proposed to modify the quality performance category measure inventory to include a set of 180 MIPS quality measures for the CY 2027 performance period/2029 MIPS payment year, which includes the following:

- Implementation of 10 new MIPS quality measures including measures focused on patient-reported outcomes and chronic disease management;
- Removal of 20 MIPS quality measures: Two MIPS quality measures that are extremely topped out, four MIPS quality measures that have reached the end of the topped-out measure lifecycle, three MIPS quality measures that are no longer being maintained by the measure steward, eight MIPS quality measures that are duplicative of new or current measures, one MIPS quality measure that has limited adoption and therefore no benchmark, one MIPS quality measure that is a low bar process measure, and one MIPS quality measure lacking robustness, and;
- Substantive changes to 43 current MIPS quality measures.

We refer readers to Table Groups A through DD of Appendix 1 of this final rule for a summary of the new measures finalized, the measures finalized for removal, and the finalized substantive changes, as well as finalized specialty set changes. We received public comments on these proposals. The comments and responses may be found in Appendix 1 of this final rule.

(2) Cost Performance Category

(a) Background

Section 1848(q)(2)(A)(ii) of the Act includes resource use as a performance category under MIPS. We refer to this performance category as the cost performance category. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians are evaluated under all four of the MIPS performance categories, including the cost performance category.

Section 1848(q)(2)(B)(ii) of the Act provides that, for the cost performance category, the measurement of resource use (that is, cost) for such period must be in accordance with section 1848(p)(3) of the Act, using the methodology under section 1848(r) of the Act as appropriate, and, as feasible and applicable, accounting for the cost of drugs under Medicare Part D. Section 1848(p)(3) of the Act provides that costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary that eliminate the effect of geographic adjustments in payment rates, and take into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals) and other factors determined appropriate by the Secretary. Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and Advanced APMs under section 1833(z) of the Act. Specifically, section 1848(r)(2)(H) of the Act provides that, not later than November 1 of each year

[395] Message to the Quality Payment Program listserv on January 14, 2026, entitled ''The Centers for Medicare & Medicaid Services (CMS) is Soliciting Interested Party Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2027 Performance Year of the Merit-based Incentive Payment System (MIPS).''

(beginning with 2018), the Secretary shall, through rulemaking, make revisions to the operational lists of care episode and patient condition codes as the Secretary determines may be appropriate.

We are finalizing the following update to the cost performance category beginning with the CY 2027 performance period/2029 MIPS payment year:

- Update the operational list of care episode and patient condition groups and codes to reflect changes to service and diagnosis codes that define care episodes and patient condition groups, as identified through the annual maintenance of episode-based measures.

For a description of the statutory authority for and existing policies pertaining to the cost performance category, we refer readers to §§ 414.1350 and 414.1380(b)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77162 through 77177), CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), CY 2023 PFS final rule (87 FR 70055 through 70057), CY 2024 PFS final rule (88 FR 79339 through 79349), CY 2025 PFS final rule (89 FR 98390 through 98408), and CY 2026 PFS final rule (90 FR 49859 through 49864).

More details on the provisions in this section, which we invited comments on, are provided in section IV.A.4.d.(2)(b) through section IV.A.4.d.(2)(d) of this final rule.

(b) Selection of Cost Measures

In accordance with our statutory authority as described in section IV.A.4.d.(2)(a) of this final rule and our regulation at § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category.

We consider adoption of cost measures to capture new clinical areas, which furthers our goals to transition from traditional MIPS to MVPs and expands the Medicare spending that is captured by the cost performance category assessment. MVPs require the inclusion of at least one cost measure, so adoption of cost measures for new clinical areas allows us to create new MVPs for clinical areas that do not yet have MVPs or to increase the amount of applicable cost measures in existing MVPs. Additionally, adopting cost measures that assess new clinical areas moves us closer towards the statutory goal of covering 50 percent of costs under Medicare Parts A and B, as specified under section 1848(r)(2)(D)(i)(I) of the Act.

In the CY 2022 PFS final rule (86 FR 65455 through 65459), we established common standards for potential episode-based measures to ensure consistency across episode-based measures being considered for potential use in MIPS. Specifically, the CY 2022 PFS final rule requires that any episode-based measure for the cost performance category include the following: (1) episode definition based on trigger codes that determine the patient cohort; (2) attribution; (3) service assignment; (4) exclusions; and (5) risk adjustment.

Additionally, in the CY 2025 PFS final rule (89 FR 98405), we codified criteria that must be met for a cost measure to be removed from the MIPS cost measure inventory at § 414.1350. Under the criteria, we may remove a cost measure from MIPS based on one or more of the following factors; provided, however, that we may retain a cost measure that meets one or more of the following factors if we determine the benefit of retaining the measure outweighs the benefit of removing it.

- It is not feasible to implement the measure specifications.
- A measure steward is no longer able to maintain the cost measure.
- The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.
- The measure specifications do not reflect current clinical practice or guidelines.
- The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

We did not propose to adopt any new measures for the CY 2027 performance period/2029 MIPS payment year. We also did not propose to remove any measures for the CY 2027 performance period/2029 MIPS payment year.

(c) Inventory of Cost Measures

As discussed previously, we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. There are currently 35 cost measures in the cost performance category for the CY 2026 performance period/2028 MIPS payment year, comprising 33 episode-based measures covering a range of conditions and procedures and 2 population-based measures. Previously finalized MIPS cost measures can be found in the CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), CY 2023 PFS final rule (87 FR 70055 through 70057), CY 2024 PFS final rule (88 FR 79339 through 79349), and CY 2025 PFS final rule (89 FR 98390 through 98408). We refer readers to the CY 2026 PFS proposed rule (90 FR 32718 through 32719) for more context on how we establish the inventory of cost measures, including the pre-rulemaking requirements.

We neither proposed any new MIPS cost measures nor proposed to remove any MIPS cost measures for the CY 2027 performance period/2029 MIPS payment year. We also did not propose substantive changes to any existing MIPS cost measures for the CY 2027 performance period/2029 MIPS payment year.

(d) Provision To Update the Operational List of Care Episode and Patient Condition Groups and Codes

Generally, to calculate MIPS eligible clinicians' performance on cost measures, we use codes from claims data to identify and apply the applicable cost measure's specifications, which govern the attribution, scope, and calculation of the cost measure. We are finalizing our proposed revisions the operational list of care episode and patient condition groups and codes to reflect coding changes that are identified during the annual measure maintenance of implemented cost measures. This section of this final rule provides context on the statutory requirements for care episode and patient condition groups and changes to the operational list.

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and Advanced APMs under section 1833(z) of the Act. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Medicare Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act

require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from interested parties, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list of care episode and patient condition codes as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other interested parties.

For more information about past revisions to the operational list that we made as we developed, proposed, and finalized episode-based measures, we refer readers to the CY 2023 PFS final rule (87 FR 70056 and 70057), CY 2024 PFS final rule (88 FR 79348), and CY 2025 PFS final rule (89 FR 98404). Prior operational lists are available at the QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.*

In accordance with section 1848(r)(2)(H) of the Act, we are revising the operational list beginning with the CY 2027 performance period/2029 MIPS payment year to reflect changes to codes used to identify existing care episode and patient condition groups, based on new information gathered during annual maintenance of MIPS cost measures. We conduct annual maintenance for measures implemented in MIPS to ensure that the codes used for the measure specifications remain up to date. For example, we may update the service or diagnosis codes associated with a cost measure's specifications to retain the intent of the measure when these codes are changed in, added to, or deleted from the applicable code sets. During our annual maintenance review process for MIPS cost measures, we work with the measure developer to identify non-substantive changes to service and diagnosis codes that should be reflected in the operational list of care episode and patient condition groups so that, to the extent feasible, there is alignment between the operational list and measure specifications. More information on the annual maintenance process is available at the CMS Measures Management System (MMS) page at *https://mmshub.cms.gov/measure-lifecycle/measure-use/maintenance/annual-update.*

Our revisions to the operational list are available for review on our QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.* We sought interested party feedback on the service and diagnosis codes used in MIPS care episode and patient condition groups to inform any non-substantive changes to the operational list in tandem with CMS's annual maintenance efforts for the CY 2027 performance period/2029 MIPS payment year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposed updates to the operational list to ensure that the codes are accurate and relevant. The commenters expressed support for our maintenance approach and for our efforts to promote alignment between the operational list with current measure specifications.

Response: We appreciate the commenters support for the updates to the operational list. We agree with the commenters that these revisions encourage accuracy and consistency with the current cost measure specifications.

After consideration of public comments, we are finalizing as proposed to update the operational list of care episode and patient condition groups and codes.

(3) Improvement Activities Performance Category

(a) Background

Section 1848(q)(2)(A)(iii) of the Act includes clinical practice improvement activities as a performance category under MIPS. We refer to this performance category as the improvement activities performance category. As required by section 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians are evaluated under all four of the MIPS performance categories, including the improvement activities performance category.

Section 1848(q)(2)(C)(v)(III) defines the term ''clinical practice improvement activities'' as activities that relevant eligible professional organizations and other relevant interested parties identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

Section 1848(q)(2)(B)(iii) of the Act provides that, for the improvement activities category, the Secretary shall specify subcategories of clinical practice improvement activities, including at least six subcategories as specified in section 1848(q)(2)(B)(iii)(I) through (VI) of the Act. These statutorily enumerated subcategories are: (1) expanded practice access (such as same day appointments for urgent needs and afterhours access to clinician advice); (2) population management (such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry); (3) care coordination (such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth); (4) beneficiary engagement (such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms); (5) patient safety and practice assessment (such as through use of clinical or surgical checklists and practice assessments related to maintaining certification); and (6) participation in an alternative payment model, as defined in section 1833(z)(3)(C) of the Act (section 1848(q)(2)(B)(iii)(I) through (VI) of the Act).

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 Physician Fee Schedule (PFS) final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886), the CY 2022 PFS final rule (86 FR 65462 through 65466), the CY 2023 PFS final rule (87 FR 70057 through 70061), the CY 2024 PFS final rule (88 FR 79350 and 88 FR 79351), CY 2025 PFS final rule (89 FR 98408 through 98413), and CY 2026 PFS final rule (90 FR 49846 through 49868). We also refer readers to § 414.1305 for the relevant definitions of improvement activities and attestation, § 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

We are finalizing various updates to the Improvement Activities Inventory

(the Inventory) beginning with the CY 2027 performance period/2029 MIPS payment year, as described further in section IV.A.4.d.(3)(b)(ii) of this final rule. First, we are finalizing adding six new improvement activities in two performance categories: (1) Care Coordination and (2) Advancing Health and Wellness, our newest subcategory. Second, we are finalizing the modification of five existing improvement activities currently specified for the performance category. Third, we are finalizing the removal of 11 improvement activities currently specified for the performance category.

(b) Improvement Activities Inventory

(i) Annual Call for Activities Background

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the first year of MIPS, we implemented the initial Inventory consisting of approximately 95 activities (81 FR 77817 through 77831). We took several steps to ensure the Inventory was inclusive of activities aligned with statutory and program requirements. As part of this process, we conducted numerous interviews with high performing organizations of all sizes and conducted an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities performance category.

Beginning with the CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659), we introduced an informal process for interested parties to submit new improvement activities or modifications for our consideration and potential inclusion in the comprehensive Inventory. In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), beginning with the CY 2019 performance period/2021 MIPS payment year, we finalized a formal Annual Call for Activities process for the addition of possible new activities and for possible modifications to current activities in the Inventory. This process requires interested parties to submit a nomination form similar to the one we used for the CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659). In order to submit a request for a new activity or a modification to an existing activity, the interested party must submit a nomination form (OMB control # 0938–1314) available at *https://qpp.cms.gov/resources/resource-library* during the Annual Call for Activities.

(ii) Updating the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. For our previously finalized Improvement Activities Inventories, we refer readers to Table H in the CY 2017 Quality Payment Program final rule (81 FR 77817) Appendix, Tables F and G in the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) Appendix, Tables A and B in the CY 2019 PFS final rule (83 FR 60286 through 60303) Appendix 2, Tables A, B, and C in the CY 2020 PFS final rule (84 FR 63514 through 63538) Appendix 2, Tables A, B, and C in the CY 2021 PFS final rule (85 FR 85370 through 85377) Appendix 2, Tables A, B, and C in the CY 2022 PFS final rule (86 FR 65969 through 65997) Appendix 2, Tables A, B, and C in the CY 2023 PFS final rule (87 FR 70633 through 70650) Appendix 2, Tables A, B, and C in the CY 2024 PFS final rule (88 FR 79965 and 88 FR 79977) Appendix 2, Tables A, B, and C in the CY 2025 PFS final rule (89 FR 98958 through 98971) Appendix 2, and Tables A, B, and C in the CY 2026 PFS final rule (90 FR 50354 through 50369) Appendix 2. We also refer readers to the Quality Payment Program website at *https://qpp.cms.gov/* and the Explore Measures and Activities tool at *https://qpp.cms.gov/reporting-requirements/measures-activities/explore?tab=improvementActivities&py=2026for* a complete list of the current improvement activities.

(iii) Adopting New Improvement Activities

We are finalizing our proposal to add six new improvement activities beginning with the CY 2027 performance period/2029 MIPS payment year. We are finalizing our proposal that IA_CC_20 (Use of Data to Improve Practice Workflows) and IA_CC_21 (Understand and Improve Diagnostic Performance) be included in the Care Coordination subcategory. We propose that IA_AHW_2 (Systematic Screening and Intervention for Nutrition and other Health-Impacting, Non-Clinical Issues), IA_AHW_3 (Advance Care Planning Conversations to Support Patient Wellness and Care Preferences), IA_AHW_4 (Clinician Use of Artificial Intelligence (AI) to Improve Patient Care), and IA_AHW_5 (Lifestyle Approaches to Diabetes Remediation) would be included in the Advancing Health and Wellness subcategory.

The first new improvement activity, IA_CC_20, titled ''Use of Data to Improve Practice Workflows,'' would allow MIPS-eligible clinicians to improve integration of evidence-based guidelines into care by developing and refining clinical pathways and workflows. If gaps are identified through data, clinicians will update and implement changes, monitor adoption and outcomes, and reassess performance regularly.

The second new improvement activity, IA_CC_21, titled ''Understand and Improve Diagnostic Performance,'' supports clinicians in improving patient safety by reducing diagnostic safety events and miscommunication through standardized processes for tracking discrepancies, near-misses, and data accuracy. If issues are identified, teams would conduct root-cause analyses, implement corrective actions such as workflow changes or training, and monitor performance regularly to ensure improvement.

The third new improvement activity, IA_AHW_2, titled ''Systematic Screening and Intervention for Nutrition and other Health-Impacting, Non-Clinical Issues,'' would allow MIPS-eligible clinicians to implement standardized screening tools for nutrition, housing, transportation, and financial strain within clinical workflows. If needs are identified, clinicians would initiate referrals to appropriate community resources, track follow-up and resolution, and reassess screening processes and outcomes regularly to improve effectiveness. The fourth new improvement activity, IA_AHW_3, titled ''Advance Care Planning Conversations to Support Patient Wellness and Care Preferences,'' will allow MIPS-eligible clinicians to engage patients and caregivers in advance care planning and end-of-life discussions using structured communication tools while documenting goals of care, symptom management, and patient priorities. If care preferences or needs change, clinicians will update care preferences, coordinate across specialties, and reassess regularly to ensure alignment with the patient's goals and clinical status.

The fifth new activity, IA_AHW_4, titled ''Clinician Use of Artificial Intelligence (AI) to Improve Patient Care,'' would allow MIPS-eligible clinicians to implement and participate in organizational initiatives that improve patient care through the responsible and transparent use of artificial intelligence (AI) in clinical and operational workflows. Clinicians will establish policies for evaluating and monitoring AI tools or participate in

developing and refining AI-enabled resources, such as predictive analytics, clinical decision support, and risk-stratification models, to improve patient outcomes, care-team efficiency, and population health management. Examples may include using AI tools to summarize medical literature for clinical decision-making, assist with documentation (*e.g.,* AI-generated notes with clinician review), support population health management by identifying care gaps, determine patient eligibility for clinical trials, or generate draft responses to patient questions for clinician review.

The sixth new activity, IA_AHW_5, titled ''Lifestyle Approaches to Diabetes Remediation,'' engages clinicians in delivering structured, evidence-based lifestyle interventions for diabetes management, addressing nutrition, physical activity, sleep, stress, and behavior change through programs such as; Lifestyle Empowerment Approach for Diabetes Remission (LEADR) or the Diabetes Self-Management Education and Support (DSMES). Clinicians provide education and coaching, track patient progress, and adjust interventions as needed to improve health outcomes.

See Table F–B1 in Appendix 2 for more information regarding each of these proposed new improvement activities.

We sought public comments on our proposals to add each of these activities to the Inventory beginning with the CY 2027 performance period/2029 MIPS payment year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments in support of finalizing the following new activities: IA_CC_20: Use of Data to Improve Practice Workflows, IA_CC_21: Understand and Improve Diagnostic Performance, IA_AHW_2: Systematic Screening and Intervention for Nutrition and other Health-Impacting, Non-Clinical Issues.

Response: We thank commenters for their support of these new activities.

After consideration of public comments, we are finalizing the four above-listed activities as proposed.

Comment: We received several comments in support of finalizing the IA_AHW_3: Advance Care Planning Conversations to Support Patient Wellness and Care Preferences activity. One commenter recommended encouraging clinicians to assess existing advance care planning (ACP) documents, verifying that patient preferences remain current, and promoting availability and exchange of ACP information across care settings.

Response: We thank commenters for sharing their support and suggestions for this new activity. We appreciate the recommendations; we believe these aspects are already incorporated into the proposed activity description by requiring ''[r]egular review and updates of advance directives or care preferences.''

After consideration of public comments, we are finalizing the IA_AHW_3: Advance Care Planning Conversations to Support Patient Wellness and Care Preferences activity as proposed.

Comment: We received many comments related to the new IA_AHW_4: Clinician Use of Artificial Intelligence (AI) to Improve Patient Care activity. The majority of comments shared support for finalizing the new activity with some offering suggestions on additional protections and/or technologies to include within the activity. Suggestions included more specific requirements for clinical validation and error detection beyond establishing policy and inclusion of specific tools such as digital therapeutics within the activity description. Some commenters opposed the activity and AI in medicine generally. These comments asked to delay the integration of AI into the Improvement Activities Inventory.

Response: We thank commenters for expressing their support, concerns, and suggestions for this activity. At this time of rapid AI development, our goal is to keep this activity broadly applicable. We will revisit these suggestions in the future as we continue to track the progression of AI technology and tools, best practices, and safeguards. We note that the activity requires participating clinicians and organizations to: ''Establish and maintain organizational policies and procedures for AI use in healthcare settings that guide the evaluation, deployment, and monitoring of AI—enabled tools''. We will continue to make modifications and additions to the Improvement Activities Inventory as needed. We note that we offer a range of improvement activities for clinicians to choose from. Additionally, the creation of a new improvement activity does not compel MIPS-eligible clinicians to participate in any particular improvement activity. As AI technology continues to progress and be adopted in healthcare settings, this activity will enable us to encourage its responsible use, while allowing clinicians to attest to policies that include appropriate safeguards. We welcome collaboration with interested parties on this topic as this technology continues to develop and clinicians and facilities develop policies and best practices for its use.

After consideration of public comments, we are finalizing IA_AHW_4: Clinician Use of Artificial Intelligence (AI) to Improve Patient Care activity as proposed.

Comment: Several commenters expressed support for finalizing the new IA_AHW_5: Lifestyle Approaches to Diabetes Remediation activity. Commenters shared how this activity aligns with evidence-based approaches to managing diabetes. Some comments suggested adding more information to the activity description to explain how each resource should be used.

Response: We thank commenters for sharing their support and suggestions for the new IA_AHW_5: Lifestyle Approaches to Diabetes Remediation activity. We have made minor edits to this activity description in response to the comments and will be otherwise finalizing it as proposed.

(iv) Modifying Existing Improvement Activities

We are finalizing our proposal to modify five existing improvement activities beginning with the CY 2027 performance period/2029 MIPS payment year. Taken together, these modifications and removals will reduce duplicative improvement activities and remove activities that are obsolete, in an effort to reduce administrative effort and strengthen the Inventory overall. First, IA_BMH_4 ''Depression screening,'' IA_CC_8 ''Implementation of documentation improvements for practice/process improvements,'' IA_CC_9 ''Implementation of practices/processes for developing regular individual care plans,'' and IA_PM_4 ''Glycemic management services'' will be combined with elements of similar improvement activities in the Inventory to make their descriptions more robust. IA_BMH_4 will be combined with elements from IA_BMH_5 ''Major depressive disorder (MDD) prevention and treatment interventions.'' The description modification involves clinicians using a coordinated, team-based approach to screen for depression, assess suicide risk, and provide evidence-based follow-up care, with ongoing monitoring and documentation to support safe, effective management of patients.

IA_CC_8 will be combined with elements from IA_CC_10 ''Care transition documentation practice improvements,'' IA_CC_11 ''Care transition standard operational improvements,'' and IA_CC_12 ''Care

coordination agreements that promote improvements in patient tracking across settings.'' The description modification promotes proactive, patient-centered care coordination across all settings by improving communication, tracking referrals and transitions, and documenting actions to ensure continuity, reduce fragmentation, and support better outcomes.

IA_CC_9 will be combined with elements from IA_BE_15 ''Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.'' The description modification highlights creating and regularly updating individualized care plans for at-risk patients in collaboration with the patient and their family and/or caregivers. It emphasizes aligning care with the patient's goals, priorities, and desired outcomes while ensuring clear communication and shared understanding.

IA_PM_4 will be combined with elements from IA_PM_19 ''Glycemic Screening Services'' and IA_PM_20 ''Glycemic Referring Services.'' The description modification requires clinicians to attest to screening for abnormal blood glucose, referring eligible patients to prevention programs, and setting individualized glycemic goals that are regularly reassessed. Screening documentation must be at 60 percent of medical records in the first year and 75 percent thereafter.

Second, IA_PSPA_16 ''Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools, including AI-enabled predictive decision-support interventions—and standardized treatment protocols to manage workflow on the care team to meet patient needs,'' will be modified to explicitly incorporate AI-enabled decision support and strengthen oversight requirements, including monitoring, root cause analysis, and mitigation of AI-related risks. The description modification specifies that MIPS-eligible clinicians use interoperable, AI-enabled clinical decision support tools to guide care-team workflows and support evidence-based, patient-centered care, while also implementing safeguards for safe use, ongoing monitoring, and evaluation of tool performance and patient safety.

See Table F–B2 in Appendix 2 for more information regarding each of these proposed modifications to existing improvement activities.

We are sought public comments on our proposals to modify each of these activities currently specified for the Inventory beginning with the CY 2027 performance period/2029 MIPS payment year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comments: We received some comments related to the modification of IA_BMH_4. One comment shared support for finalizing the modification and suggested adding ''evidence-based depression treatment'' to the activity. Another comment shared concern that the combination of two depression-related improvement activities could diminish the visibility of depression management.

Response: We thank commenters for expressing their support, concern, and suggestions for the modification on IA_BMH_4. We believe that language relating to evidence-based depression treatment is already incorporated into the activity description sufficiently through references to the ''[u]se of validated depression screening tools'' and the ''[d]evelopment and execution of evidence—based follow—up plans'' within the activity description. The combination of depression-related improvement activities will not lessen the focus on depression management because the number of improvement activities included in the Inventory does not correlate to the importance of or focus on a particular topic. This modification is aimed at reducing duplicative activities to reduce administrative effort.

After consideration of public comments, we are finalizing this activity modification as proposed.

Comment: We received some comments related to the modification of IA_CC_9. One commenter supports the modification of this activity and its consolidation with IA_BE_15. However, a commenter also expressed concern that beneficiary-engagement activities previously recognized under IA_BE_15 will be excluded if the modification is finalized. Another commenter requested that this activity retain references to family and caregivers.

Response: We thank commenters for expressing their support and concern regarding this activity removal. We do not believe that beneficiary-engagement activities will be diminished under the proposed activity removal. The removal is intended to reduce redundancy in the Inventory and administrative effort for clinicians. Beneficiary engagement remains an important element of the Inventory through multiple activities, including the activity that IA_BE_15 is being combined with, IA_CC_9. IA_CC_9 requires that individualized care plans are ''developed and shared with the beneficiary and family and/or caregiver(s)'' and include their ''goals and priorities, as well as desired outcomes of care.'' Also, fifteen activities will remain in the Inventory in the Beneficiary Engagement subcategory.

After consideration of public comments, we are finalizing this activity modification as proposed.

Comment: We received several comments related to the modification of IA_PSPA_16. All comments shared support for finalizing the modification with some suggesting additional requirements to include within the activity concerning the use of AI in healthcare settings. Suggestions included adding specific tools, documentation, and monitoring requirements to the activity description.

Response: We thank commenters for expressing their support and suggestions for the modification of IA_PSPA_16. We will continue to track the progression of AI technology and tools, best practices, and safeguards. We will propose further modifications to this activity as needed in the future. We welcome collaboration with interested parties on this topic.

After consideration of public comments, we are finalizing this activity modification as proposed.

Comment: We received some comments related to the modification of IA_PM_4, including expressions of support. A specific comment suggested recognizing nutrition-risk and food-access assessments, coordinating glycemic and nutrition intervention, engaging in longitudinal follow up, and making referrals within this activity.

Response: We thank commenters for expressing their support and providing suggestions for this activity modification. We believe that this activity as modified already includes follow up and referral. We will continue to monitor the implementation of this activity, and make further modifications to this activity as needed. We welcome collaboration with interested parties on this topic. We are finalizing this activity as proposed, and will carefully monitor its implementation.

After consideration of public comments, we are finalizing this activity modification as proposed.

We did not receive public comments specifically on the proposed modification to IA_CC_8, and we are finalizing these modifications as proposed.

(v) Removing Existing Improvement Activities

Additionally, we are finalizing our proposal to remove eleven previously finalized improvement activities beginning with the CY 2027

performance period/2029 MIPS payment year: IA_BMH_5 ''MDD prevention and treatment interventions,'' IA_CC_10 ''Care transition documentation practice improvements,'' IA_CC_11 ''Care transition standard operational improvements,'' IA_CC_12 ''Care coordination agreements that promote improvements in patient tracking across settings,'' IA_PSPA_2 ''Participation in MOC Part IV,'' IA_CC_16 ''Primary Care Physician and Behavioral Health Bilateral Electronic Exchange of Information for Shared Patients,'' IA_BE_15 ''Engagement of Patients, Family, and Caregivers in Developing a Plan of Care,'' IA_PM_19 ''Glycemic Screening Services,'' IA_PM_20 ''Glycemic Referring Services,'' IA_EPA_4 ''Additional improvements in access as a result of QIN/QIO TA,'' and IA_PM_2 ''Anticoagulant management improvements.'' We are finalizing the removal of these improvement activities in accordance with our activity removal policy set forth at § 414.1355(d). Specifically, we are finalizing our proposal to remove each of these eleven improvement activities under Removal Factor(s) 1 or 7, which provides that we may remove an improvement activity if we determine it is duplicative of another activity (§ 414.1355(d)(1)) or the activity is obsolete (§ 414.1355(d)(7)).

Our plan to remove IA_BMH_5, IA_CC_10, IA_CC_11, IA_CC_12, IA_BE_15, IA_PM_19, and IA_PM_20 will align with Removal Factor 1, as these activities are similar to other improvement activities in the Inventory and can be considered duplicative. Additionally, our plan to remove IA_PSPA_2, IA_CC_16, IA_EPA_4, and IA_PM_2 will align with Removal Factor 7, as the activities are no longer highly relevant or useful in current clinical practice or policy and can be considered obsolete. Lastly, our plan to remove IA_EPA_4 is also supported by removal Factor 2, as this activity is one of several focused on improvements that can be supported and/or driven by QIN/QIOs. See Table F–B3 in Appendix 2 for more information regarding our plan to remove each of these existing improvement activities.

We are sought public comments on our proposals to remove these activities from the improvement activities performance category beginning with the CY 2027 performance period/2029 MIPS payment year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comments: We received some comments related to the removal of IA_BMH_5. One comment shared support for finalizing the removal. Another comment shared concern that the combination of two depression-related improvement activities could diminish the visibility of depression management.

Response: We thank commenters for expressing their support and concerns regarding the removal of IA_BMH_5. We believe that the combination of depression-related improvement activities will not lessen focus on depression management because the number of improvement activities included in the Inventory does not correlate to the importance of or focus on a particular topic. This removal is aimed at reducing duplicative activities to reduce administrative effort.

After consideration of public comments, we are finalizing this activity removal as proposed.

Comment: We received some comments related to the removal of IA_CC_10, IA_CC_11, and IA_CC_12. One comment shared concern that removing IA_CC_10, IA_CC_11, and IA_CC_12 could inadvertently reduce recognition of the care transition and coordination activities performed by clinicians, particularly infectious disease physicians whose patients regularly move across care settings.

Response: We thank commenters for sharing their concern and emphasizing the importance of care transitions and care coordination for patients with complex conditions. The proposed removals are aimed at reducing duplication within the Inventory while maintaining recognition of the importance of care transitions and care coordination. (See the following existing and modified improvement activities: IA_CC_7, Regular training in care coordination; IA_CC_8, Implementation of Documentation and/or Operational Improvements for Practice/Process Improvements; IA_CC_9, Implementation of Practices/Processes for Developing Regular Individual Care Plans; IA_CC_13, Practice improvements to align with OpenNotes principles; IA_CC_15, PSH Care Coordination; IA_CC_17, Patient Navigator Program; IA_CC_18, Relationship-Centered Communication; and IA_CC_19, Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes. There are also two new activities being finalized for the CY 2027 performance period/2029 MIPS payment year and beyond in this subcategory: IA_CC_20, Use of Data to Improve Practice Workflows; and IA_CC_21, Understand and Improve Diagnostic Performance.) The Improvement Activities Inventory will continue to recognize care transitions, care coordination, and information-sharing practices and give clinicians credit for this work.

After consideration of public comments, we are finalizing this activity removal as proposed.

Comment: We received one comment specifically opposing the removal of IA_PSPA_2, stating that this MOC Part IV activity incentivizes clinician education and practical quality improvement.

Response: We thank the commenter for sharing their opposition of this activity removal. We believe that participating in MOC Part IV is standard and/or required practice and is therefore unlikely to be driving additional meaningful clinical care improvement.

After consideration of public comments, we are finalizing this activity removal as proposed.

Comment: We received some comments specifically related to the removal of IA_CC_16. One comment opposed the removal of this improvement activity, stating that information exchange between primary care and behavioral health providers remains inconsistent and that this activity would continue to incentivize information exchange.

Response: We thank commenters for sharing their concern and emphasizing the importance of information exchange between primary care and behavioral health providers. We agree that information exchange is important, but believe this activity is unlikely to drive additional meaningful clinical care improvement because EHR adoption and data sharing has advanced significantly since the creation of this activity. (Also, please see existing IA_CC_13, Practice improvements to align with OpenNotes principles; and IA_BE_4, Engagement of Patients through Implementation of New Patient Portal.)

After consideration of public comments, we are finalizing this activity removal as proposed.

Comment: We received comments related to the removal of IA_BE_15. One commenter expressed support for the removal of IA_BE_15 and also expressed concern that beneficiary-engagement activities previously recognized under IA_BE_15 may be excluded if the removal is finalized.

Response: We thank commenters for expressing their support and concern regarding this activity removal. We do not believe that beneficiary-engagement activities will be diminished under the proposed activity removal. The removal is intended to reduce redundancy in the Inventory and administrative effort for clinicians. Beneficiary engagement remains an important element of the

Inventory through multiple activities, including the activity that IA_BE_15 is being combined with, IA_CC_9. IA_CC_9 requires that individualized care plans are ''developed and shared with the beneficiary and family and/or caregiver(s)'' and include their ''goals and priorities, as well as desired outcomes of care.'' Also, fifteen activities will remain in the Inventory in the Beneficiary Engagement subcategory.

After consideration of public comments, we are finalizing this activity removal as proposed.

Comment: We received some comments related to the removal of IA_PM_2. One commenter opposed the removal of IA_PM_2 and recommended maintaining the activity within the inventory.

Response: We thank commenters for their feedback. However, this activity no longer reflects most common current anticoagulation practice. To ensure improvement activities remain broadly clinically relevant, we will finalize the removal of this activity. We will continue to consider opportunities to develop future activities that reflect current approaches to anticoagulation management.

After consideration of public comments, we are finalizing the removal of IA_PM_2 as proposed.

We did not receive public comments specifically on the removal of IA_PM_19, IA_PM_20, or IA_EPA_4; we are finalizing these removals as proposed.

(4) MIPS Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A)(iv) of the Act includes the meaningful use of certified electronic health record (EHR) technology (CEHRT) as a performance category under MIPS. We refer to this performance category as the MIPS Promoting Interoperability performance category (formerly the advancing care information performance category).

Section 1848(q)(2)(B)(iv) of the Act provides that the requirements established under section 1848(o)(2) of the Act for determining whether a MIPS eligible clinician is a meaningful EHR user also applies to our assessment of a MIPS eligible clinician's performance on measures and activities with respect to the MIPS Promoting Interoperability performance category. Section 1848(o)(2)(D) of the Act generally provides that the requirements for being a meaningful EHR user under section 1848(o)(2) of the Act continue to apply for purposes of MIPS.

Under section 1848(o)(2)(A) of the Act, a MIPS eligible clinician must meet three requirements related to the meaningful use of CEHRT during a performance period for a MIPS payment year. Specifically, under section 1848(o)(2)(A) of the Act, the MIPS eligible clinician must: (1) demonstrate to the satisfaction of the Secretary the use of CEHRT in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary; (2) demonstrate to the satisfaction of the Secretary that their CEHRT is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for electronic exchange of health information to improve the quality of care, such as promoting care coordination, and demonstrates (through a process specified by the Secretary), that they have not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the CEHRT; and (3) use CEHRT to submit information on clinical quality measures and such other measures as selected by the Secretary.

For previously established policies regarding the MIPS Promoting Interoperability performance category, we refer readers to §§ 414.1305 (includes definitions pertaining to the MIPS Promoting Interoperability performance category), 414.1375 (MIPS Promoting Interoperability performance category provisions), and 414.1380(b)(4) (includes scoring provisions pertaining to the MIPS Promoting Interoperability performance category); and the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820), CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), CY 2022 PFS final rule (86 FR 65466 through 65490), CY 2023 PFS final rule (87 FR 70060 through 70087), CY 2024 PFS final rule (88 FR 79307 through 79312 and 79351 through 79365), the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking final rule (89 FR 54662 through 54718), CY 2025 PFS final rule (89 FR 98413 through 98427), and CY 2026 PFS final rule (90 FR 49868 through 49902).

In the CY 2027 PFS proposed rule, we proposed to—

- Modify the definition of CEHRT to align with ONC Health IT Certification Program proposed updates relevant to the MIPS Promoting Interoperability performance category;
- Remove the ONC Direct Review and ONC-Authorized Certification Bodies (ACB) Surveillance attestations;
- Remove the Security Risk Analysis measure;
- Adopt the Electronic Prior Authorization for Prescription Drugs measure; and
- Modify the previously adopted Electronic Prior Authorization measure.

(b) Modifying the Definition of Certified Electronic Health Record Technology in the MIPS Promoting Interoperability Performance Category

(i) Background

In accordance with § 414.1375(b)(1), to earn a performance category score for the MIPS Promoting Interoperability performance category, a MIPS eligible clinician must be a meaningful EHR user for MIPS and use CEHRT during the performance period, as both terms are defined in § 414.1305. In the CY 2025 PFS final rule, we discussed previously finalized modifications related to the definition of CEHRT for the Quality Payment Program, including for the MIPS Promoting Interoperability performance category at § 414.1305 (89 FR 98414 and 98415). Currently, we define CEHRT, for purposes of MIPS, as EHR technology (which could include multiple technologies) certified under the Office of National Coordinator for Health Information Technology's (ONC) Health Information Technology (IT) Certification Program that meets the Base EHR definition at 45 CFR 170.102 and certified as meeting additional ONC health IT certification criteria as adopted and updated in 45 CFR 170.315 as enumerated in paragraph (2)(i) of the definition of CEHRT at § 414.1305, including as necessary to report on applicable measures specified for the MIPS Promoting Interoperability performance category. In the CY 2027 PFS proposed rule, Table C–G 8 (91 FR 44197 and 44198) outlined the measures for the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year and the associated ONC health IT certification criteria set forth at 45 CFR 170.315 impacting the definition of CEHRT, as applicable.

In the Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI–5) proposed rule (90 FR 60970 through 61034) published in the **Federal Register** [396] on December 29,

[396] ASTP/ONC is now referred to as ONC, pursuant to a notice published in the **Federal Register** on April 1, 2026 (91 FR 16204). Although, at the time of specific references noted herein, ONC

Continued

2025, ONC proposed a wide-ranging set of updates to the ONC Health IT Certification Program. The HTI–5 proposed rule focuses on deregulatory actions in 45 CFR part 170 (Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology) and 45 CFR part 171 (Information Blocking). The HTI–5 proposed rule seeks to reduce burden, offer flexibility to developers and providers, and support innovation through the removal and revision of certain certification criteria and regulatory provisions. The following summarizes proposals in the HTI–5 proposed rule that are relevant to MIPS eligible clinicians.

was either referenced as ASTP/ONC or as ONC; for clarity, all references in this final rule are noted as ONC.

In the HTI–5 proposed rule, ONC identified 34 certification criteria for removal and 7 certification criteria for revision. ONC stated that removing or revising these criteria would reduce burden and costs for health IT developers and clinicians, partly due to the decreased necessity to maintain ongoing conformance with certification requirements (90 FR 60973).

In the CY 2027 PFS proposed rule, Table C–G 1 (91 FR 44168) summarized the impact the proposed modifications to remove and revise the ONC health IT certification criteria may have on MIPS eligible clinicians reporting the MIPS Promoting Interoperability performance category. Also, Table C–G 1 described how the criteria subject to HTI–5 proposals are incorporated into the definition of CEHRT in § 414.1305. In addition to the ONC health IT certification criteria included in the definition of CEHRT in § 414.1305, the definition includes EHR technology certified under the ONC Health IT Certification Program that meets the Base EHR definition at 45 CFR 170.102 and technology certified to the health IT certification criteria necessary to report on applicable measures specified for the MIPS Promoting Interoperability performance category.

In this final rule, we updated Table C–G 1 to reflect policies subsequently finalized in the Health Data, Technology, and Interoperability: ONC Deregulatory Actions to Unleash Prosperity (HTI–5) final rule (91 FR 67916 through 67998),[397] which was published in the **Federal Register** on October 28, 2026.

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[397] The Health Data, Technology, and Interoperability: ONC Deregulatory Actions to Unleash Prosperity (HTI–5) final rule was published in the **Federal Register** on October 28, 2026, *see: https://www.govinfo.gov/content/pkg/FR-2026-10-28/pdf/2026-21943.pdf*.

TABLE C-G 1 HTI-5 PROPOSED AND FINALIZED POLICIES TO REMOVE AND REVISE ONC HEALTH IT CERTIFICATION CRITERIA THAT IMPACT THE CEHRT DEFINITION FOR THE MIPS PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY

ONC Health IT Certification Criteria as Defined in the Following Sections of Title 45 CFR 170.315	HTI-5 Proposed Rule Action	HTI-5 Final Rule Action	Effective Date	Relevance to the CEHRT Definition for the MIPS Promoting Interoperability Performance Category
Patient Demographics and Observations - (a)(5)	Revise	Revision Not Finalized*	N/A	Specified in Base EHR definition.
Implantable Device List - (a)(14)	Remove	Removal Not Finalized**	N/A	Specified in Base EHR definition.
Decision Support Interventions - (b)(11)	Revise	Revised	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Direct Project - (h)(1)	Remove	Removed	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Direct Project, Edge Protocol, and XDR/XDM - (h)(2)	Remove	Removed	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Family Health History - (a)(12)	Remove	Removed	Effective January 1, 2027.	Specified in CEHRT definition.
Patient Health Information Capture - (e)(3)	Remove	Removed	Effective January 1, 2027.	Specified in CEHRT definition.
Automated Numerator Recording - (g)(1)	Remove	Removed	Effective January 1, 2027.	Specified in CEHRT definition.
Automated Measure Calculation – (g)(2)	Remove	Removed	Effective January 1, 2027.	Specified in CEHRT definition.
Clinical Quality Measures – Report – (c)(3)	Revise	Revised	Effective January 1, 2027.	Specified in CEHRT definition.
Clinical Quality Measures – Filter – (c)(4)	Remove	Removed	Effective January 1, 2027	Specified in CEHRT definition
Transitions of Care - (b)(1)	Revise	Finalized with Modification - Revised***	Effective January 1, 2030.	Specified criterion for the Support Electronic Referral Loops by Sending Health Information, Support Electronic Referral Loops by Receiving and Reconciling Health Information, Health Information Exchange Bi-Directional Exchange, and Enabling Exchange Under TEFCA measures.
Clinical Information Reconciliation and Incorporation - (b)(2)	Remove	Removal Not Finalized - Revised**	Effective date of HTI-5 final rule.	Specified criterion for the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.
View, Download, and Transmit to 3rd Party - (e)(1)	Revise	Revised	Effective date of HTI-5 final rule.	Specified criterion for the Provide Patients Electronic Access to Their Health Information measure.
Transmission to cancer registries – (f)(4)	Remove	Removal Not Finalized**	N/A	Specified criterion for the Public Health Registry Reporting measure.
Transmission to public health agencies – Electronic Case Reporting - (f)(5)	Revise	Revision Not Finalized**	N/A	Specified criterion for the Electronic Case Reporting measure.
Transmission to public health agencies – Health Care Surveys - (f)(7)	Remove	Removal Not Finalized**	N/A	Specified criterion for the Public Health Registry Reporting measure.

ONC Health IT Certification Criteria as Defined in the Following Sections of Title 45 CFR 170.315	HTI-5 Proposed Rule Action	HTI-5 Final Rule Action	Effective Date	Relevance to the CEHRT Definition for the MIPS Promoting Interoperability Performance Category
Application access — patient selection - (g)(7)	Remove	Removed	Effective January 1, 2027.	Specified criterion for the Provide Patients Electronic Access to Their Health Information and Health Information Exchange Bi-Directional Exchange measures.
Application Access – All Data Request - (g)(9)	Remove	Removed	Effective January 1, 2027.	Specified criterion for the Provide Patients Electronic Access to Their Health Information and Health Information Exchange Bi-Directional Exchange measures.

* Please note that such policy proposal from the HTI-5 proposed rule was not discussed in the HTI-5 final rule and may, in the future, be included in a subsequent final rule or as a revised proposal in a subsequent proposed rule.

** Such policy proposal was not finalized in the HTI-5 final rule.

*** Such policy proposal was finalized with modification in the HTI-5 final rule.

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In the CY 2027 PFS proposed rule (91 FR 44168), we noted that proposed changes in the HTI–5 proposed rule would affect ONC health IT certification criteria included in the definition of CEHRT in 42 CFR 414.1305, which applies to the MIPS Promoting Interoperability performance category in several ways. First, several ONC proposals either revise or remove certain ONC Health IT Certification Program certification criteria included within the Base EHR definition at 45 CFR 170.102, which is incorporated into the definition of CEHRT at § 414.1305. Removal of these criteria from the ONC Health IT Certification Program and the Base EHR definition would therefore remove the requirement that a MIPS eligible clinician must use CEHRT that includes health IT certified to the removed criteria. Specifically, ONC proposed to remove the following ONC health IT certification criteria from the Base EHR definition at: 45 CFR 170.315(a)(14)—''implantable device list'' (90 FR 60983 through 60984), 45 CFR 170.315(h)(1)—''transport methods and other protocols—direct project'' (90 FR 60998 and 60999), and 45 CFR 170.315(h)(2)—''transport methods and other protocols—Direct Project, Edge Protocol, and XDR/XDM'' (90 FR 60999). ONC also proposed to revise the following criteria referenced in the Base EHR definition: 45 CFR 170.315(b)(1)—''transitions of care'' (90 FR 60984), 45 CFR 170.315(a)(5)—''patient demographics and observations'' (90 FR 60980 through 60982) and 45 CFR 170.315(b)(11)—''decision support interventions'' (90 FR 60986 through 60987).

Also, ONC proposed to remove the following five ONC health IT certification criteria specified in the text of the definition of CEHRT at § 414.1305. Specifically, ONC proposed to remove: 45 CFR 170.315(a)(12)—''family health history,'' 45 CFR 170.315(e)(3)—''patient health information capture,'' 45 CFR 170.315(g)(1)—''automated numerator recording,'' 45 CFR 170.315(g)(2)—''automated measure calculation,'' and 45 CFR 170.315(c)(4)—''clinical quality measures—filter'' (90 FR 60982 and 60983; 60991 and 60992; 60994 and 60995; and 60988, respectively). Also, ONC proposed to revise 45 CFR 170.315(c)(3)—''clinical quality measures—report'' (90 FR 60988). Such ONC health IT certification criteria are discussed further in section IV.A.4.d.(4)(b)(ii) of this final rule.

In addition, in the CY 2027 PFS proposed rule (91 FR 44169), we noted that ONC proposed to remove and/or revise other ONC health IT certification criteria that directly support certain MIPS Promoting Interoperability performance category measures. For example, ONC proposed to revise the ''transitions of care'' criterion in 45 CFR 170.315(b)(1), which supports the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures and remove the ''clinical information reconciliation and incorporation'' criterion in 45 CFR 170.315(b)(2), which supports the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (90 FR 60984). In addition, of the four ONC health IT certification criteria that are identified as supporting the Provide Patients Electronic Access to Their Health Information measure: 45 CFR 170.315(e)(1), 45 CFR 170.315(g)(7), 45 CFR 170.315(g)(9), and 45 CFR 170.315(g)(10), we noted that three were impacted by the proposals in the HTI–5 proposed rule. ONC proposed to revise 45 CFR 170.315(e)(1) (90 FR 60990 through 60991) and remove 45 CFR 170.315(g)(7) and 45 CFR 170.315(g)(9) (90 FR 60997 and 60998). In the CY 2027 PFS proposed rule (91 FR 44169), we noted that MIPS eligible clinicians would only need to implement the remaining heath IT certification criteria identified for the Provide Patients Electronic Access to Their Health Information measure (the revised 45 CFR 170.315(e)(1) and unaltered 45 CFR 170.315(g)(10)), if ONC finalizes such proposals. In the CY 2027 PFS proposed rule (91 FR 44169), we noted that similarly, for the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures, MIPS eligible clinicians would only need to implement the remaining ONC health IT certification criteria if applicable ONC health IT certification criteria proposed for removal in the HTI–5 proposed rule are finalized as proposed. In the CY 2027 PFS proposed rule, Table C–G 8 (91 FR 44197 and 44198) contained a complete list of the MIPS Promoting Interoperability performance category measures, and the applicable ONC health IT certification criteria, including the impact to individual ONC health IT certification criteria if the proposals in the HTI–5 proposed rule are finalized.

Regarding the Public Health Registry Reporting measure, ONC proposed to remove both ONC health IT certification criteria that support the measure: 45 CFR 170.315(f)(4)—''transmission to cancer registries'' and 45 CFR 170.315(f)(7)—''transmission to public health agencies—health care surveys''

(90 FR 60992 through 60994). In the CY 2027 PFS proposed rule (91 FR 44169), we noted that if the proposed removal of the ONC health IT certification criteria is finalized as proposed in the HTI–5 proposed rule, there would be no specific ONC health IT certification criteria identified for this measure. Consistent with existing policy, a MIPS eligible clinician would still be able to use any available data exchange standard specified in 45 CFR part 170 subpart B to meet the measure requirements. For example, the transmission could be in the form of a Consolidated Clinical Document Architecture (C–CDA) as adopted in 45 CFR 170.205(a)(4), or Quality Reporting Document Architecture (QRDA) as adopted in 45 CFR 170.205(h)(2).

Regarding the Electronic Case Reporting measure, ONC proposed to revise the following health IT certification criterion that supports the measure: at 45 CFR 170.315(f)(5)—''transmission to public health agencies—electronic case reporting'' (90 FR 60992 through 60993). Such ONC proposal would update the ONC health IT certification criterion to focus on functional, rather than standards-based requirements. While ONC's proposal, if finalized, would revise the requirements for health IT products certified to this ONC health IT certification criterion, MIPS eligible clinicians would continue to need to use health IT certified to this criterion to report the Electronic Case Reporting measure.

Also, in the CY 2027 PFS proposed rule (91 FR 44169), we noted that ONC proposed to remove certain ONC health IT certification criteria such as 45 CFR 170.315(g)(3)—''safety-enhanced design,'' 45 CFR 170.315(g)(4)—''quality management system,'' (90 FR 60995 through 60997), and a series of criteria related to privacy and security functionality in 45 CFR 170.315(d)(1) through (13) (90 FR 60988 through 60990), most of which are included in the Health IT Module certification requirements at 45 CFR 170.550. Such ONC health IT certification criteria represent capabilities commonly found in certified health IT products used by MIPS eligible clinicians. Furthermore, in the CY 2027 PFS proposed rule (91 FR 44169), we noted that the ONC proposed removal of such health IT certification criteria from the ONC Health IT Certification Program would not affect a MIPS eligible clinician's obligation to ensure the privacy and safety of patient electronic health information under the Health Insurance Portability and Accountability Act of 1996 and other applicable laws. In the CY 2027 PFS proposed rule, we referred readers to Table C–G 8 (91 FR 44197 and 44198) for a complete list of ONC health IT certification criteria that support each MIPS Promoting Interoperability performance category measure, including ONC health IT certification criteria ONC proposed to remove and/or revise. We noted that, in most cases, the ONC health IT certification criteria that support measure reporting would remain part of the ONC Health IT Certification Program. For additional information regarding ONC's proposals in the HTI–5 proposed rule, we referred readers to the HTI–5 proposed rule (90 FR 60970 through 61034).

The HTI–5 final rule (91 FR 67916 through 67998) was published in the **Federal Register** on October 28, 2026. Some of the proposals in the HTI–5 proposed rule were not finalized or were finalized with modification in the HTI–5 final rule. Specifically, the following proposals were not finalized or were finalized with modification in the HTI–5 final rule.

- ''Patient demographics and observations''—45 CFR 170.315(a)(5): The proposal to revise such criterion was not finalized. Please note that such proposal from the HTI–5 proposal rule was not discussed in the HTI–5 final rule and may, in the future, be included in a subsequent final rule or as a revised proposal in a subsequent proposed rule.
- ''Implantable device list''—45 CFR 170.315(a)(14): The proposal to remove such criterion was not finalized (91 FR 67930).
- ''Transitions of care''—45 CFR 170.315(b)(1): The proposal to revise such criterion was finalized with modification (91 FR 67931).
- ''Clinical information reconciliation and incorporation''—45 CFR 170.315(b)(2): The proposal to remove such criterion was not finalized, and the criterion was revised (91 FR 67934).
- ''Decision support interventions''—45 CFR 170.315 (b)(11): The proposal to revise such criterion was finalized with modification (91 FR 67941).
- ''Transmission to cancer registries''—45 CFR 170.315(f)(4): The proposal to remove such criterion was not (91 FR 67951).
- ''Transmission to public health agencies—Electronic Case Reporting''—45 CFR 170.315(f)(5): The proposal to revise such criterion was not finalized (91 FR 67953).
- ''Transmission to public health agencies—Health Care Surveys''—45 CFR 170.315(f)(7): The proposal to remove such criterion was not finalized (91 FR 67956).

(ii) Modifying the Definition of Certified Electronic Health Record Technology in the MIPS Promoting Interoperability Performance Category

Beginning with the CY 2019 performance period and subsequent performance periods, the definition of CEHRT for the MIPS Promoting Interoperability performance category in § 414.1305 requires the use of EHR technology certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to specific ONC health IT certification criteria as adopted and updated in 45 CFR 170.315. In paragraph (2)(i) of the definition of CEHRT, the definition further specifies that EHR technology must be certified to criteria for ''family health history'' (45 CFR 170.315(a)(12)) and ''patient health information capture'' (45 CFR 170.315(e)(3)). In paragraph (2)(ii) of the definition of CEHRT, the definition specifies that EHR technology must be certified to ONC health IT certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category. Paragraph (2)(ii)(A) of the definition of CEHRT includes the applicable measure calculation certification criteria at 45 CFR 170.315(g)(1) or (2) for all ONC health IT certification criteria that support an objective with a percentage-based measure. Paragraph (2)(ii)(B) includes clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) and optionally (c)(4).

In the CY 2027 PFS proposed rule (91 FR 44169 through 44171), we proposed to amend the definition of CEHRT (specified as ''Certified electronic health record technology (CEHRT)'') in § 414.1305, by modifying paragraphs (2)(i), (2)(ii)(A), and (2)(ii)(B) to align with the applicable ONC proposals to remove and revise certain ONC health IT certification criteria as proposed in the HTI–5 proposed rule. Specifically, we proposed to remove references to the following ONC health IT certification criteria for the CY 2027 performance period/2029 MIPS payment year:

- ''Family health history''—45 CFR 170.315(a)(12);
- ''Patient health information capture''—45 CFR 170.315(e)(3);
- ''Automated numerator recording''—45 CFR 170.315(g)(1);

• ''Automated measure calculation''—45 CFR 170.315(g)(2); and

• ''Clinical quality measures—filter''—45 CFR 170.315(c)(4) (91 FR 44169 through 44171).

We noted that if the ONC proposals to remove such ONC health IT certification criteria are finalized as proposed, the ONC health IT certification criteria at 45 CFR 170.315(a)(12), 45 CFR 170.315(e)(3), 45 CFR 170.315(g)(1), and 45 CFR 170.315(g)(2) would no longer be required and ONC health IT certification criteria at 45 CFR 170.315(c)(4) would no longer be included as an optional criterion to meet the definition of CEHRT, effective January 1, 2027. As part of the proposed modification to the definition of CEHRT, in the CY 2027 PFS proposed rule (91 FR 44170), we also specified a limited timeframe, from CY 2019 through CY 2026, for the following ONC health IT certification criteria to be included in the definition of CEHRT; ''family health history'' (45 CFR 170.315(a)(12)), ''patient health information capture'' (45 CFR 170.315(e)(3)), ''automated numerator recording'' (45 CFR 170.315(g)(1)), ''automated measure calculation'' (45 CFR 170.315(g)(2), and ''clinical quality measures'' (45 CFR 170.315(c)(4)). Additionally, as part of the proposed modification to the definition of CEHRT, we noted in the CY 2027 PFS proposed rule (91 FR 44170) that we would modify the reference to the ''clinical quality measures—report'' (45 CFR 170.315(c)(3)) ONC health IT certification criterion from ''(c)(3)(i) and (ii)'' to (c)(3), which would align with the proposed revisions in the HTI–5 proposed rule to modify (c)(3) to include the provision of (c)(3)(i), and remove subparagraphs (c)(3)(i) and (c)(3)(ii). Lastly, we proposed to amend the definition of CEHRT in § 414.1305 by modifying paragraphs 2(i), (2)(i)(A), and (2)(i)(B) (91 FR 44169 through 44171).

We noted in the CY 2027 PFS proposed rule (91 FR 44170) that while such proposed modifications are consistent with the proposals in the HTI–5 proposed rule (90 FR 60970 through 61034), the proposal to modify the definition of CEHRT is not contingent upon the final actions from ONC regarding its proposals to remove and revise ONC health IT certification criteria as proposed in the HTI–5 proposed rule.

In the CY 2027 PFS proposed rule (91 FR 44170), we noted that the longstanding presence of the ONC health IT certification criteria for ''family health history'' at 45 CFR 170.315(a)(12) and ''patient health information capture'' at 45 CFR 170.315(e)(3) in the ONC Health IT Certification Program (adopted in 2015 at 80 FR 62624 and 80 FR 62661 and 62662, respectively) and the incorporation of such criteria into the MIPS Promoting Interoperability performance category requirements mean functionality reflected in such ONC health IT certification criteria is likely to be fully embedded in certified health IT and is widely available for use by MIPS eligible clinicians. Furthermore, ONC anticipates that health IT developers would continue to retain such capabilities in their Health IT Modules despite the absence of ONC health IT certification criteria for such functionalities (90 FR 60982 and 60991). Such ONC health IT certification criteria are not identified as supporting any specific measures within the MIPS Promoting Interoperability performance category and as a result, we do not anticipate any modifications to the measure specifications due to the removal of such ONC health IT certification criteria from the definition.

We further noted that if the ONC health IT certification criteria needed for measure calculation (''automated numerator recording'' and ''automated measure calculation'' ONC health IT certification criteria in 45 CFR 170.315(g)(1) and 45 CFR 170.315(g)(2)) are finalized for removal, then EHR technology used by MIPS eligible clinicians would not need to be certified to such two ONC health IT certification criteria in order to meet the requirement for MIPS eligible clinicians to use CEHRT; however, we anticipate that health IT developers seeking to support customers participating in the MIPS Promoting Interoperability performance category will continue to support the functionality of these criteria by reporting of numerators and denominators for certain MIPS Promoting Interoperability performance category measures, including the e-Prescribing measure and Provide Patients Electronic Access to Their Health Information measure. Removing the requirements for ONC health IT certification criteria at 45 CFR 170.315(g)(1) and 45 CFR 170.315(g)(2) from the definition of CEHRT in § 414.1305 would reduce administrative burden for health IT developers associated with testing and certifying to such functionality without impacting reporting requirements for the MIPS Promoting Interoperability performance category.

Additionally, for the optional ONC health IT certification criterion pertaining to ''clinical quality measures—filter'' in 45 CFR 170.315(c)(4), we indicated in the CY 2027 PFS proposed rule (91 FR 44170) that we do not believe that such ONC health IT certification criterion is a meaningful addition to the definition of CEHRT for health care providers. The optional designation for such ONC health IT certification criterion has led to limited uptake of health IT certified to the criterion, while health care providers and health IT developers have indicated that this functionality is available in EHRs without relying on a regulatory requirement. Also, ONC stated that it anticipates that health IT systems would continue to retain the clinical quality measure filtering functionality despite the absence of the ONC health IT certification criterion for such functionality (90 FR 60988).

As described in the CY 2027 PFS proposed rule, we proposed to amend the definition of CEHRT, specified as ''Certified electronic health record technology (CEHRT)'' in § 414.1305, by modifying paragraphs (2)(i), (2)(i)(A), and (2)(i)(B) (91 FR 44170 through 44171). Specifically:

• In paragraph (2)(i), we proposed to remove for CY 2027 and subsequent years, the certification criteria for ''family health history'' (as adopted and updated at 45 CFR 170.315(a)(12)) and ''patient health information capture'' (as adopted and updated at 45 CFR 170.315(e)(3));

• In paragraph (2)(ii)(A), we proposed to remove for CY 2027 and subsequent years, the ONC health IT certification criteria for ''automated numerator recording'' (as adopted and updated at 45 CFR 170.315(g)(1)) and ''automated measure calculation'' (as adopted and updated at 45 CFR 170.315(g)(2)); and

• In paragraph (2)(ii)(B), we proposed to remove for CY 2027 and subsequent years, the ONC health IT certification criterion for ''clinical quality measures—filter'' (as adopted and updated at 45 CFR 170.315(c)(4)) (91 FR 44169 through 44172).

The proposed revised text would read as follows:

''Certified electronic health record technology (CEHRT) [. . .]

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315-

(i) For CY 2019 through CY 2026, at 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3)

(patient health information capture); and

(ii) Necessary to report on applicable objectives and measures specified for MIPS including the following:

(A) For CY 2019 through CY 2026, the applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3), and for CY 2019 through CY 2026, optionally (c)(4), and can be electronically accepted by CMS.''

In the CY 2027 PFS proposed rule (91 FR 44171), we noted that the proposed modifications would be effective on January 1, 2027, which aligns with the effective date of ONC's proposal to remove such ONC health IT certification criteria from the Code of Federal Regulations as proposed in the HTI–5 proposed rule. With the proposed modifications to the definition of CEHRT, a MIPS eligible clinician's EHR technology would no longer be required to meet the ONC health IT certification criteria at 45 CFR 170.315(a)(12), (e)(3), (g)(1), or (g)(2), the ONC health IT certification criteria at 45 CFR 170.315(c)(4) would no longer be included as optional in paragraph (2)(ii)(B), and paragraph (2)(ii)(B) would reference the entirety of the certification criterion at 45 CFR 170.315(c)(3) in the definition of CEHRT at 42 CFR 414.1305. All other remaining ONC health IT certification criteria included in the definition of CEHRT would continue to be a requirement for a MIPS eligible clinician's EHR technology. In the CY 2027 PFS proposed rule (91 FR 44171), we noted that there is a similar proposal to remove certain ONC health IT certification criteria from the definition of CEHRT for the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) in the ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; and Other Policy Changes'' (FY 2027 IPPS/LTCH PPS) proposed rule (91 FR 19620 through 19621).

We requested public comment on the proposal to modify the definition of CEHRT.

We received public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to modify the definition of CEHRT in the MIPS Promoting Interoperability performance category to align with the applicable ONC health IT certification criteria proposed for removal and revisions in the HTI–5 proposed rule. Several of such commenters supported that the modifications to the definition of CEHRT would ensure consistency and alignment between agencies. A few commenters supported that these modifications would remove outdated or duplicative requirements when functionalities have become embedded in the health IT infrastructure. A commenter indicated that streamlining the definition of CEHRT can reduce administrative burden while allowing CMS and ONC to focus certification requirements on capabilities that meaningfully advance interoperability and patient care.

Response: We appreciate the support from commenters.

Comment: Several commenters did not support the proposal to modify the definition of CEHRT in the MIPS Promoting Interoperability performance category to align with the applicable ONC health IT certification criteria that are proposed to be removed and revised in the HTI–5 proposed rule. A few commenters did not support the proposal to remove the references in the definition of CEHRT to the health IT certification criteria for ''automated numerator recording'' at 45 CFR 170.315(g)(1) and ''automated measure calculation'' at 45 CFR 170.315(g)(2) from the definition of CEHRT. A few commenters opposed removing such health IT certification criteria because CMS still requires measures (such as ''Provide Patients Electronic Access'') that depend on the capabilities associated with the health IT certification criteria. A few commenters stated that removal of these criteria without a clearly defined plan for measure calculation may introduce inconsistency, data errors, inaccurate scores, cost and administrative burden, and increased audit risk for MIPS eligible clinicians, particularly smaller and less resourced practices. A commenter requested that CMS coordinate closely with ONC to develop standardized calculation guidance, updated specifications, and a cohesive transition strategy. A commenter recommended that if CMS were to finalize removal of such health IT certification criteria, CMS should also remove the corresponding mandatory reporting requirements for MIPS eligible clinicians. Another commenter recommended that CMS should commit to not establishing future measures requiring numerator and denominator data.

Response: Health IT developers seeking to support customers participating in the MIPS Promoting Interoperability performance category will still need to support reporting of numerators and denominators for certain measures, including the Electronic Prescribing measure and Providing Patients Electronic Access to Their Health Information measure. However, ONC has stated that removing the health IT certification criteria at 45 CFR 170.315(g)(1) and 45 CFR 170.315(g)(2) would reduce administrative burden for health IT developers associated with testing and certifying such functionality without impacting reporting requirements for the MIPS Promoting Interoperability performance category. Thus, we do not agree with the concerns from commenters regarding potential burden from CMS continuing to require measures that require the capabilities associated with the ''automated numerator recording'' and ''automated measure calculation'' certification criteria.

In regard to concerns from commenters pertaining to calculation errors and accountability, we note that the proposed revisions to the definition of CEHRT do not affect current functionality; we have not proposed changes to measures with numerator and denominator calculations that would prompt configuration changes. Therefore, we recommend that MIPS eligible clinicians work closely with their vendors to ensure that current functionality is retained. Also, we note that MIPS eligible clinicians already have a responsibility to ensure the accuracy of their reported values. Using EHR technology certified to particular ONC health IT certification criteria is not sufficient to meet the responsibility to ensure accuracy of reported values due to the risk of local configuration errors.

Additionally, we note that while this functionality originally helped to ensure standardized approaches to reporting, health IT developers have gained time and experience with measures under the program since the certification criteria in § 170.315(g)(1) and § 170.315(g)(2) were added to the definition of CEHRT. We believe that health IT developers will continue to ensure that patients or actions included in a measure's numerator are recorded in a fashion that supports accurate calculation to meet CMS requirements without needing to

certify their health IT products to § 170.315(g)(1) or § 170.315(g)(2). MIPS eligible clinicians may continue to use a separate, non-certified system such as when supported by a qualified registry, a QCDR, or other third-party intermediary to calculate numerators and denominators and to generate reports on the measures. We will continue to work closely with ONC to ensure consistency in specifications and accuracy in reporting methodologies, and we intend to include details in this respect in future measure specification documents.

Lastly, we do not agree with commenters requesting CMS to remove measures that require numerator and denominator data or limit the addition of such measures in the future given that such measures assess important aspects of interoperability.

Comment: A few commenters did not support the proposal to remove the ''family health history,'' ''patient health information capture,'' and ''clinical quality measures—filter'' ONC health IT certification criteria from the definition of CEHRT; the commenters indicated that there is no guarantee such functionalities would continue to be offered within health IT products. The commenters expressed concern that the removal of such ONC health IT certification criteria supporting such measures or reporting requirements could potentially result in inconsistent CEHRT performance or risks to patient safety.

Response: We believe that the longstanding presence of the ''family health history'' health IT certification criterion at 45 CFR 170.315(a)(12) and ''patient health information capture'' health IT certification criterion at 45 CFR 170.315(e)(3) in the ONC Health IT Certification Program and their incorporation into the MIPS Promoting Interoperability performance category requirements means that the functionality reflected in these criteria is already embedded in certified health IT and is widely available and used by MIPS eligible clinicians. In conjunction with ONC, we believe that the functionality associated with the ''clinical quality measures—filter'' health IT certification criterion at 45 CFR 170.315(c)(4) is not likely to be removed from health IT systems (90 FR 60988).

In conjunction with ONC, we anticipate that removing the ''family health history'' ONC health IT certification criterion will have minimal impact on data consistency or patient safety because, as noted by ONC, it is expected that many developers of certified health IT will continue to conform to the Systematized Nomenclature of Medicine—Clinical Terms® (SNOMED CT) US Edition standard and the functionality to code family health history with such standard would likely remain in certified health IT adopted by hospitals and physicians (90 FR 60982). Moreover, we believe that updates to the United States Core Data for Interoperability (USCDI) in USCDI v6 demonstrate ONC's commitment to the exchange of family health history information using the SNOMED CT US Edition standard.[398] We note that while USCDI v6 has not been adopted in regulation at this time, it may be considered for adoption in future rulemaking. Of note, USCDI v6 has been approved by the National Coordinator for use under the Standards Version Advancement Process (SVAP), which means health IT developers may voluntarily incorporate this standard into Certified Health IT Modules.[399]

Regarding the patient health information capture criterion, the capabilities described in the criterion are widely implemented and used in health IT at this time, as noted by ONC (90 FR 60991) and we believe these capabilities will remain in health IT products even if the corresponding criterion is removed from the definition of CEHRT. ONC noted that removing the criterion from the Certification Program could spur greater development and innovation in this area and specified that there are other certification criteria that support patient engagement, such as the ''view, download, and transmit to 3rd party'' and ''standardized API for patient and population services'' ONC health IT certification criteria (90 FR 60991). ONC has seen developers integrate the functionality in the patient health information capture certification criterion as part of other patient engagement features, such as patient portals.

Regarding the ''clinical quality measures—filter'' ONC health IT certification criterion, the optional designation within the definition of CEHRT for the MIPS Promoting Interoperability performance category has led to limited ONC certification to the health IT certification criterion. However, as noted by ONC (91 FR 60988), health IT systems have widely adopted these capabilities and we believe that systems will continue to retain the functionality without the ONC health IT certification criterion for such functionality and without the optional designation within the definition of CEHRT.

Accordingly, we anticipate that the functionalities of the ''family health history data,'' ''patient health information capture,'' and ''clinical quality measures—filter'' ONC health IT certification criteria will remain available to clinicians through their health IT without the presence of health IT certification criteria in the definition of CEHRT; and thus, we believe that the definition of CEHRT does not need to include such ONC health IT certification criteria. We will continue to monitor and analyze feedback from clinician users to ascertain whether health IT developers are continuing to support these capabilities within their products.

Comment: A few commenters recommended that CMS delay the modification of the definition of CEHRT. A few other commenters recommended that CMS wait until ONC finalizes the HTI–5 proposed rule prior to modifying the definition of CEHRT to support consistency and predictability in compliance across HHS programs. A few commenters recommended that CMS coordinate with ONC to ensure providers have sufficient time to implement changes (including workflow redesign, testing, and implementation) and recommended that both CMS and ONC provide 24 months for transitioning certification criteria after updates are made.

Response: We thank commenters for their recommendations; however, we do not agree with commenters regarding a delay in modifying the definition of CEHRT. The proposed modifications are consistent with the timelines outlined in the HTI–5 proposed rule and HTI–5 final rule (90 FR 60970 through 61034; and 91 FR 67916 through 67998). In the CY 2027 PFS proposed rule (91 FR 44170), we stated that we do not believe that finalizing, as proposed, the modifications to the definition of CEHRT are contingent upon the final actions from ONC regarding its proposals to remove and revise health IT certification criteria as proposed in the HTI–5 proposed rule. As identified in Table C–G 1 of this final rule, ONC finalized, as proposed, its proposals in the HTI–5 final rule with respect to health IT certification criteria in 45 CFR 170.315(a)(12), (e)(3), (g)(1), (g)(2), (c)(3), and (c)(4) (91 FR 67928, 91 FR 67950, 91 FR 67957, 91 FR 67958, 91 FR 67944, and 91 FR 67945, respectively). Regarding concerns that MIPS eligible clinicians would not have sufficient time for implementation, we reiterate

[398] *See https://isp.healthit.gov/sites/default/files/2026-07/2026%20Standards%20for%20Approval_508.pdf.*

[399] *See https://isp.healthit.gov/united-states-core-data-interoperability-uscdi#uscdi-v6.*

that the proposed modifications to the definition of CEHRT have the effect of removing, rather than adding, requirements with respect to the definition of CEHRT. Therefore, we do not expect any new implementation requirements to arise from these proposed removals that would require additional time for health IT developers and their customers to achieve compliance.

Comment: A commenter requested additional clarification from CMS regarding which certification requirements are expected to change, the anticipated timeline for implementation, and which actions eligible clinicians and organizations will need to take to remain compliant.

Response: For a summary of the changes to the ONC health IT certification criteria proposed in the HTI–5 proposed rule and policies finalized in the HTI–5 final rule, we refer readers to Table C–G 1 of this final rule. The modifications to the definition of CEHRT for the MIPS Promoting Interoperability performance category will be effective as of the published date of this final rule. We encourage MIPS eligible clinicians to work closely with their vendors to ensure that the necessary functionalities are retained to meet remaining MIPS requirements.

Comment: A commenter requested for CMS to ensure that the proposed modifications to the definition of CEHRT would not shift new implementation burden onto MIPS eligible clinicians in rural and low-resourced areas.

Response: We recognize the potential challenges that may be faced by smaller and under-resourced MIPS eligible clinicians and are committed to continuing to receive feedback and explore ways to offer support where possible. We will continue to work closely with ONC to ensure consistency, flexibility, and stability of our policies, and to closely monitor for any unintended consequences to MIPS eligible clinicians participating in the MIPS Promoting Interoperability performance category.

Comment: A few commenters requested CMS to coordinate with ONC on implementation of ONC health IT certification criteria. A few commenters encouraged coordination to ensure certified EHR technology can facilitate the transition to digital quality measurement. Because some practices may still need to support the underlying functionality of the certification criteria, a few commenters recommended coordination across CMS programs and with ONC so that MIPS eligible clinicians and health IT developers receive consistent and clear guidance on what functionalities remain necessary for MIPS reporting as well as to ensure standardized calculation guidance, updated specifications, and a cohesive transition strategy.

Response: We will continue to work closely with ONC and across CMS programs to ensure consistency in specifications and accuracy in reporting methodologies, to identify opportunities for technical support that will facilitate the transition away from ONC certification of these functionalities, and to help ensure that any changes to CEHRT-related requirements are clearly communicated in a manner that supports readiness among health IT developers and MIPS eligible clinicians. We will also continue to work closely with ONC to align health IT regulations where applicable, reduce administrative burden when feasible, incentivize the reliable exchange of data, and minimize any unintentional consequences of these changes.

Comment: A few commenters recommended that CMS and ONC establish ongoing monitoring to identify whether health IT developers discontinue the functions associated with the removed certification criteria, impose new costs, or shift implementation and workflow burden to MIPS eligible clinicians in other ways. A commenter only supported the removal of the ''family health history'' and ''patient health information capture'' health IT certification criteria from the definition of CEHRT if CMS and ONC first establish enforceable safeguards ensuring the capabilities remain available to MIPS eligible clinicians.

Response: We note that ONC expects that health IT developers will continue to retain these capabilities in their Health IT Modules despite the absence of certification criteria (90 FR 60982, 60988, 60991,60994, 60995) as the functionalities are already fully embedded in certified health IT and are widely available and used by MIPS eligible clinicians. We understand commenters' concerns regarding the potential for health IT vendors to monetize or reduce support for these important capabilities and encourage MIPS eligible clinicians to consider these capabilities when reviewing their EHR technology purchase options with health IT vendors and during contract negotiations. Also, we note that if the main effect of the policy is to decrease the certification and testing burden of health IT developers, the removal of the references to these criteria in the definition of CEHRT by itself should not cause health IT developers to make changes to their products or otherwise expend development resources that could result in added costs for customers. Nevertheless, we agree that ongoing monitoring of the effects of the removal of these criteria is necessary, and we will continue to work with ONC to do so.

Regarding concerns pertaining to the modifications to the definition of CEHRT that may shift burden to MIPS eligible clinicians, we note that the removal of health IT certification criteria from the definition of CEHRT decreases CEHRT requirements for MIPS eligible clinicians. We believe that the underlying functionalities of the removed health IT certification criteria will continue to exist within EHR systems.

After consideration of public comment, we are finalizing, as proposed, the proposal to amend the definition of CEHRT, specified as ''Certified electronic health record technology (CEHRT)'' in § 414.1305, by modifying paragraphs (2)(i), (2)(i)(A), and (2)(i)(B). The finalized, as proposed, revised text will read as follows:

''Certified electronic health record technology (CEHRT) [. . .]

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315-

(i) For CY 2019 through CY 2026, at 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) Necessary to report on applicable objectives and measures specified for MIPS including the following:

(A) For CY 2019 through CY 2026, the applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3), and for CY 2019 through CY 2026, optionally (c)(4), and can be electronically accepted by CMS.''

We note that there is a similar finalized, as proposed, policy to remove certain ONC health IT certification criteria from the definition of CEHRT for the Medicare Promoting Interoperability

Program for eligible hospitals and critical access hospitals (CAHs) in the FY 2027 IPPS/LTCH PPS final rule (91 FR 50029 through 50035).

(c) Removing ONC Direct Review and ONC-Authorized Certification Bodies (ACB) Surveillance Attestations

(i) Background

In the CY 2017 Quality Payment Program final rule, we finalized policies to support MIPS eligible clinicians in ONC health IT surveillance and direct review activities through requiring two attestations, specifically, the ONC Direct Review attestation and the ONC-Authorized Certification Bodies (ACB) Surveillance attestation (81 FR 77019 through 77028). The purpose of ONC surveillance and direct review is to provide greater assurance that health IT meets certification requirements not only in a controlled testing environment, but also when used by health care providers in actual production environments (80 FR 62707). When such attestations were finalized as requirements for the MIPS Promoting Interoperability performance category (formerly the advancing care information performance category) in the CY 2017 Quality Payment Program final rule, we intended for the attestations to complement and strengthen recent updates to ONC's ability to perform surveillance and direct review activities.

Specifically, in October 2015, ONC finalized the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications final rule, which added requirements for ONC–ACBs to conduct more frequent and more rigorous surveillance of certified technology and capabilities in the field (80 FR 62707). Additionally, in October 2016, ONC published the ONC Health IT Certification Program: Enhanced Oversight and Accountability final rule, which established regulatory processes to facilitate ONC's direct review and evaluation of the performance of certified health IT in certain circumstances (81 FR 72406 through 72407). In the CY 2017 Quality Payment Program final rule, we determined that surveillance and direct review activities provided greater assurance to health care providers that their certified EHR technology would perform in a manner that meets their expectations, but that such surveillance and direct review would not be effective unless health care providers cooperated with such activities, including by granting access to and assisting ONC–ACBs and ONC to observe the performance of production systems (81 FR 77020).

In § 414.1375(b)(3)(i)(A), we require an attestation that acknowledges the requirement to cooperate in good faith with ONC direct review of his or her health IT certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received. A MIPS eligible clinician must attest that he or she, if requested, cooperated in good faith with ONC direct review of his or her health IT certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the MIPS eligible clinician in the field. Also, we specified at § 414.1375(b)(3)(i)(B) an optional attestation that acknowledges the option to cooperate in good faith with ONC–ACB surveillance of his or her health IT certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received. A MIPS eligible clinician may attest that he or she, if requested, cooperated in good faith with ONC–ACB surveillance of his or her health IT certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the MIPS eligible clinician in the field.

The ONC Direct Review attestation is a required element of the MIPS Promoting Interoperability performance category. Submitting a ''Yes'' response is the only means to fulfill the requirement of the attestation. If a MIPS eligible clinician submits a ''No'' response or does not submit any attestation for the ONC Direct Review attestation, the MIPS eligible clinician will receive a score of zero for the MIPS Promoting Interoperability performance category. The ONC–ACB Surveillance attestation is optional. A MIPS eligible clinician can submit a ''Yes'' or ''No'' response or not submit any attestation for the ONC–ACB Surveillance attestation, which would not impact a MIPS eligible clinician's score for the MIPS Promoting Interoperability performance category. In the CY 2027 PFS proposed rule, we referred readers to the discussion regarding the scoring implications for the proposal to remove the required ONC Direct Review attestation and optional ONC–ACB Surveillance attestation (91 FR 44191).

(ii) Removing the ONC Direct Review and ONC–ACB Surveillance Attestations Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

In the CY 2027 PFS proposed rule, we proposed to remove the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation in § 414.1375(b)(3)(i)(A) and (B), respectively, beginning with the CY 2026 performance period/2028 MIPS payment year to reduce administrative burden (91 FR 44172). For the CY 2026 performance period, we noted in the CY 2027 PFS proposed rule that MIPS eligible clinicians would not be reporting on such attestations until the applicable submission period, which starts on January 1, 2027 (91 FR 44172). Given that the two attestations are reported during the applicable submission period, we determined that it would be feasible for CMS to implement and operationalize such modifications to the MIPS Promoting Interoperability performance category requirements prior to the start of the submission period associated with the CY 2026 performance period. As noted in the CY 2027 PFS proposed rule, we continue to recognize the importance of ONC direct review and ONC–ACB surveillance activities and consider such mechanisms important for mitigating issues with health IT products that may pose serious risks to public health or safety, and we continue to collaborate with ONC to support the ONC Health IT Certification Program (91 FR 44172). As stated in the CY 2017 Quality Payment Program final rule (81 FR 77020), efforts to strengthen surveillance and direct review of certified health IT are critical to the success of HHS programs and initiatives that require the use of certified health IT to improve health care quality and the efficient delivery of care. In the CY 2027 PFS proposed rule, we noted that we do not anticipate a change in commitment from ONC and the ONC–ACBs toward such goals (91 FR 44172).

While ONC–ACB surveillance and ONC direct review activities remain important to being a user of certified health IT, we no longer consider the administrative step of attesting to cooperating and/or participating in such activities to be necessary. Since 2016 (1 year prior to the enactment of MACRA, in which the MIPS Promoting Interoperability performance category replaced the Medicare EHR Incentive

Program for eligible professionals), the ONC–ACB surveillance and ONC direct review activities and processes have become known to MIPS eligible clinicians and as a result, the value of participation has become evident without dependence on an ongoing need to conduct annual attestations. Therefore, the administrative burden associated with such attestations outweighs their value compared to when they were originally adopted.

The proposal to remove the required ONC Direct Review attestation and optional ONC–ACB Surveillance attestation aligns with the goals of reducing administrative burden while simultaneously focusing on high-value, outcome-oriented measures. Specifically, the removal of such attestations from the MIPS Promoting Interoperability performance category requirements provides an opportunity to reduce the number of discrete manual steps and reporting fields required for successful adherence to reporting requirements without diminishing the integrity or central goals of the MIPS Promoting Interoperability performance category. Although we proposed to remove such attestations, we strongly encouraged MIPS eligible clinicians to continue participating in the surveillance and direct review processes when assistance is requested by ONC or an ONC–ACB. In the CY 2027 PFS proposed rule, we noted that CMS would continue to support surveillance and direct review activities, as appropriate (91 FR 44172).

In the CY 2027 PFS proposed rule, we proposed to amend § 414.1375(b)(3)(i) by modifying the requirements to include a specific allotted timeframe (CY 2017 performance period/2019 MIPS payment year through CY 2025 performance period/2027 MIPS payment year) for requiring the reporting of attestations pertaining to the ONC Direct Review attestation and ONC–ACB Surveillance attestation (91 FR 44172). Specifically, we proposed to amend § 414.1375(b)(3)(i) as follows: ''Supporting providers with the performance of CEHRT (SPPC). To engage in activities related to supporting providers with the performance of CEHRT beginning with the 2019 MIPS payment year through the 2027 MIPS payment year, the MIPS eligible clinician—. . .'' We proposed to remove the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation beginning with the CY 2026 performance period/2028 MIPS payment year to reduce burden. Additionally, in the CY 2027 PFS proposed rule (91 FR 44172) we noted that if the proposal to remove the ONC Direct Review attestation and ONC–ACB Surveillance attestation is finalized as proposed, for the CY 2026 performance period/2028 MIPS payment year, MIPS eligible clinicians would not, in the case of the ONC Direct Review attestation, be required to report on such attestation, and in the case of the ONC–ACB Surveillance attestation, have the option of reporting on such attestation during the applicable submission period (January 1, 2027, through March 1, 2027). We noted that the removal of such attestations would not affect a MIPS eligible clinician's score for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year, respectively. In the CY 2027 PFS proposed rule (91 FR 44172), we noted that the proposals to remove the ONC Direct Review attestation and optional ONC–ACB Surveillance attestation align with the same policies for the Medicare Promoting Interoperability Program as proposed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19621 through 19622).

We requested public comment on this proposal.

We received public comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to remove the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation beginning with the CY 2026 performance period/2028 MIPS payment year. Many of these commenters suggested that removal of these attestations would reduce burden and eliminate measures of limited value, and a few commenters noted that this reduced burden will allow more time and resources for MIPS eligible clinicians to dedicate to patient care and meaningful interoperability efforts. A commenter noted that this removal would align with the same finalized policy in the FY 2027 IPPS/LTCH PPS final rule.

Response: We appreciate the support from commenters.

Comment: A few commenters provided recommendations about the removal of the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation beginning with the CY 2026 performance period/2028 MIPS payment year. A few commenters recommended CMS maintain strong interoperability oversight, encourage voluntary cooperation with ONC review activities, give vendors time to update scoring tools, and clarify how third-party intermediaries should handle attestations already collected for the CY 2026 performance period/2028 MIPS payment year without requiring retroactive changes.

Response: We will continue to work with ONC to support direct review and surveillance activities. Please note that although we proposed to remove these attestations, we strongly encourage MIPS eligible clinicians to continue participating in these activities when requested. We recognize that MIPS eligible clinicians may have already been preparing to submit data for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year, which previously included the submission of an attestation for the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation. Also, we recognize that the proposal to removal the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation for the CY 2026 performance period/2028 MIPS payment year conflicts with the previously established policy that required MIPS eligible clinicians to submit an attestation for the required ONC Direct Review attestation and when applicable, the submission of an attestation for the optional ONC–ACB Surveillance attestation. However, we believe that the removal of the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation starting with the CY 2026 performance period/2028 MIPS payment year reduces the requirements and burden under MIPS Promoting Interoperability performance category. To facilitate understanding and minimize potential confusion regarding the requirements for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year, we intend to update the CY 2026 MIPS Promoting Interoperability performance category, disseminate a listserv announcing the reduction in requirements, and implement a technical function in the Quality Payment Program system alerting submitters that attestations pertaining to the ONC Direct Review attestation and ONC–ACB Surveillance attestation cannot be included in a submitted file for the CY 2026 performance period/2028 MIPS payment year if the submission includes such attestations.

As finalized, these attestations would no longer be required for the CY 2026 performance period/2028 MIPS payment year. We believe that the removal of the ONC Direct Review attestation and ONC–ACB Surveillance

attestation would not cause any harm or create undue burden for MIPS eligible clinicians who have already prepared for the submission of such attestations or already collected data for such attestations for the CY 2026 performance period/2028 MIPS payment year. To prepare the submission file for the CY 2026 performance period/2028 MIPS payment year that will be submitted to meet the reporting requirements, the file will need to exclude the ONC Direct Review attestation and ONC–ACB Surveillance attestation; otherwise, an alert will be prompted by the Quality Payment Program system indicating that a file submission cannot include the ONC Direct Review attestation and the ONC–ACB Surveillance attestation, in which the file will need to be resubmitted without such attestations. For MIPS eligible clinicians who manually report data in the Quality Payment Program System, they will not be able to submit a response for the ONC Direct Review attestation or the ONC–ACB Surveillance attestation given that the Quality Payment Program system will not include options to select the ONC Direct Review attestation or the ONC–ACB Surveillance attestation.

Comment: A commenter, while noting their support for removal, also shared their belief that removal will not meaningfully reduce compliance obligations and would require updating infrastructure to align with updated requirements.

Response: CMS acknowledges there is burden in meeting these reporting requirements, and as a result, CMS decided to remove the burden associated with the MIPS Promoting Interoperability performance category measures. However, we recognize that some MIPS eligible clinicians may have already prepared for the submission of such attestations or already collected data for such attestations. To prepare the submission file for the CY 2026 performance period/2028 MIPS payment year that will be submitted to meet the reporting requirements, the file will need to exclude the ONC Direct Review attestation and ONC–ACB Surveillance attestation; otherwise, an alert will be prompted by the Quality Payment Program system indicating that a file submission cannot include the ONC Direct Review attestation and the ONC–ACB Surveillance attestation, in which the file will need to be resubmitted without such attestations. For MIPS eligible clinicians who manually report data in the Quality Payment Program System, they will not be able to submit a response for the ONC Direct Review attestation or the ONC–ACB Surveillance attestation given that the Quality Payment Program system will not include options to select the ONC Direct Review attestation or the ONC–ACB Surveillance attestation.

Comment: A commenter noted their support for the proposed removal of the ONC Direct Review and ONC–ACB Surveillance attestations but requested that CMS state the effective date for removal of the attestations, including identifying both the performance period affected and the submission period in which the change takes effect.

Response: We appreciate the support from the commenter. We note that the effective date for removal of the ONC Direct Review and ONC–ACB Surveillance attestations would be the date of publication of the CY 2027 PFS final rule, and would be in effect for the remaining portion of the CY 2026 performance period/2028 MIPS payment year. The data submission period for the CY 2026 performance period/2028 MIPS payment year is January 1, 2027, through March 31, 2027.

After consideration of public comment, we are finalizing, as proposed, the proposal to remove the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation in § 414.1375(b)(3)(i)(A) and (B), respectively, beginning with the CY 2026 performance period/2028 MIPS payment year. We note that the finalized, as proposed, policy to remove the ONC Direct Review attestation and optional ONC–ACB Surveillance attestation aligns with the same finalized, as proposed, policy for the Medicare Promoting Interoperability Program as proposed in the FY 2027 IPPS/LTCH PPS final rule (91 FR 50036).

We refer readers to Table C–G 2, Table C–G 3, and Table C–G 6 in sections IV.A.4.d.(4)(g)(i) and IV.A.4.d.(4)(g)(ii)(D) of this final rule for information regarding the reporting requirements and scoring methodology of the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year. The CY 2025 performance period/2027 MIPS payment year will be the last performance period/MIPS payment year in which the ONC required Direct Review attestation and optional ONC–ACB Surveillance attestation will be included under the MIPS Promoting Interoperability performance category.

(d) Removing Security Risk Analysis Measure

(i) Background

The HIPAA Security Rule [400] (45 CFR part 160 and subparts A and C of part 164) contains, among other things, the administrative safeguards that covered entities and business associates (45 CFR 164.308) must implement, such as the standard and implementation specifications for security management processes. Among such safeguards are implementation specifications that require covered entities and business associates to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information (ePHI) that is created, received, used or maintained by a covered entity or its business associate (45 CFR 164.308(a)(1)(ii)(A)). Safeguards also include implementing security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with the general requirements of the HIPAA Security Rule at 45 CFR 164.306(a).

Ensuring the privacy and security of ePHI is essential for demonstrating meaningful use of CEHRT (90 FR 49871). Since 2010, we adopted and maintained the Security Risk Analysis measure based on the HIPAA Security Rule risk analysis requirement in 45 CFR 164.308(a)(1)(ii)(A) for the Medicare EHR Incentive Program for Eligible Professionals,[401] the predecessor to the MIPS Promoting Interoperability performance category.[402] In the CY 2017 Quality Payment Program final rule (81 FR 77219 through 77220), we adopted the Protect Patient Health Information objective for the MIPS Promoting Interoperability performance category and included the Security Risk Analysis measure within this objective. We

[400] On January 6, 2025, the U.S. Department of Health and Human Services published the HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information proposed rule (90 FR 898). The proposed rule has not been finalized as of the publication of this final rule.

[401] Medicare and Medicaid Programs: Electronic Health Record Incentive Program final rule (75 FR 44368 and 44369); established at 42 CFR 495.6(d)(15)(ii).

[402] Section 101(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) sunset the Medicare EHR Incentive Program for Eligible Professionals, set forth at section 1848(o) of the Act. As discussed previously, section 1848(o)(2) of the Act has been incorporated into the MIPS Promoting Interoperability performance category's requirements via section 1848(q)(2)(B)(iv) of the Act. *See* CY 2017 Quality Payment Program final rule (81 FR 77018 and 77019) for more information regarding the sunsetting of the Medicare EHR Incentive Program for Eligible Professionals.

subsequently modified this measure in the CY 2019 PFS final rule (83 FR 59789 through 59790) and the CY 2026 PFS final rule (90 FR 49870 through 49874).

As described in the CY 2026 PFS final rule, the MIPS Promoting Interoperability Security Risk Analysis measure requires MIPS eligible clinicians to attest ''Yes'' to having conducted security risk management and attest ''Yes'' to having conducted or reviewed a security risk analysis as required by the HIPAA Security Rule (90 FR 49870 through 49874).

(ii) Removing the Security Risk Analysis Measure Beginning With the CY 2027 Performance Period/2029 MIPS Payment Year

In the CY 2027 PFS proposed rule, we proposed to remove the Security Risk Analysis measure beginning with the CY 2027 performance period/2029 MIPS payment year to reduce reporting burden (91 FR 44172 through 44174). The HIPAA Security Rule (45 CFR part 160 and subparts A and C of part 164) contains, among other requirements, the administrative safeguards that covered entities and business associates (45 CFR 164.308) must implement, such as the standard and implementation specifications for security risk analysis and risk management processes. The administrative safeguards also require implementation of security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with the general requirements of the HIPAA Security Rule at 45 CFR 164.306.

Given that MIPS eligible clinicians are covered entities under the HIPAA Security Rule and the requirements of the Security Risk Analysis measure derive from the HIPAA Security Rule requirements, removal of the Security Risk Analysis measure will not weaken any cybersecurity requirements for MIPS eligible clinicians. When the Security Risk Analysis measure was adopted in the CY 2017 Quality Payment Program final rule, we determined that requiring an attestation regarding certain HIPAA Security Rule requirements promoted awareness of these requirements among MIPS eligible clinicians (81 FR 77219 through 77220).

However, as discussed in the CY 2027 PFS proposed rule (91 FR 44172 through 44174), we considered the ongoing applicability of the measure given its longstanding presence in the MIPS Promoting Interoperability performance category and the established awareness of HIPAA Security Rule requirements among MIPS eligible clinicians. In the assessment of whether it remained appropriate to maintain the Security Risk Analysis measure in the MIPS Promoting Interoperability performance category, we considered the extent to which the measure continues to advance the measure's intended goals relative to the costs associated with the continued use of the measure. As asserted in the CY 2027 PFS proposed rule (91 FR 44173), we believe that such costs include not only the burden associated with reporting the requisite attestations, but also the costs associated with administering and maintaining the measure within the MIPS Promoting Interoperability performance category. Such costs may include, but are not limited to the following: clinician burden associated with information collection and submission; clinician burden associated with complying with overlapping programmatic and regulatory requirements, including the HIPAA Security Rule; and CMS resources associated with oversight, maintenance, education, and operational support for the measure. In the case of the Security Risk Analysis measure, due to the underlying security risk analysis and risk management activities are already required under the HIPAA Security Rule, we noted in the CY 2027 PFS proposed rule (91 FR 44173) that it may be unnecessarily costly and of limited incremental benefit to retain this measure where its continued inclusion no longer meaningfully advances the objectives of the MIPS Promoting Interoperability performance category beyond the separate regulatory requirements that already apply. For such reasons, we believe removal of the Security Risk Analysis measure at this juncture would balance the goals of reducing unnecessary administrative burden, maintaining a parsimonious and meaningful measure set, and preserving the focus of the MIPS Promoting Interoperability performance category on high-value measures that more directly support program objectives. We rely on our federal partner, the HHS Office for Civil Rights, to administer and enforce compliance with the HIPAA Security Rule requirements that MIPS eligible clinicians may otherwise be subject to.

The proposal aligns with our goals of reducing administrative burden while simultaneously focusing on high-value, outcome-oriented measures. Specifically, the removal of the Security Risk Analysis measure from the MIPS Promoting Interoperability performance category provides an opportunity to reduce the number of discrete manual steps and reporting fields required for successful adherence to reporting requirements without diminishing the integrity or central goals of the MIPS Promoting Interoperability performance category. Although we proposed to remove the Security Risk Analysis measure, we reminded MIPS eligible clinicians to continue to conduct security risk analysis and security risk management to safeguard ePHI as required under the HIPAA Security Rule (91 FR 44173). We anticipate that MIPS eligible clinicians will continue to conduct security risk analysis and security risk management activities to comply with the requirements pertaining to the security of ePHI that is created, received, used, or maintained by a covered entity or its business associate in accordance with the HIPAA Security Rule.

Retirement of the Security Risk Analysis measure from the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year would reduce burden by removing the attestation requirement and supporting a more parsimonious and outcomes-oriented measure set. Specifically, in the CY 2027 PFS proposed rule, we proposed at § 414.1375(b)(2)(ii)(A) to specify a limited timeframe, through the 2028 MIPS payment year for which a MIPS eligible clinician would be required to report that they completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs (91 FR 44174).

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to remove the Security Risk Analysis measure beginning with the CY 2027 performance period/2029 MIPS payment year. Many of these commenters supported removal of the Security Risk Analysis measure because they believed it would reduce administrative burden and remove duplicative requirements as MIPS eligible clinicians are already bound by other privacy and security statutes and regulations such as the HIPAA Security Rule to perform security risk analysis. A few commenters also believed that removal of the Security Risk Analysis measure would allow providers to have more time and resources to focus on patient care and meaningful interoperability efforts. A commenter recommended that CMS continue

providing the 'reminder' in QPP educational materials that MIPS eligible clinicians must safeguard electronic patient health information as required under the HIPAA Security Rule.

Response: We appreciate the support from commenters. We will consider the feedback on communicating MIPS eligible clinicians' obligations to safeguard electronic patient health information.

Comment: A few commenters recommended the removal of the Security Risk Analysis measure to be sooner than the proposed CY2027 performance period/2029 MIPS payment year, but starting with the CY 2026 performance period/2028 MIPS payment year to accelerate reduction of burden and program simplification.

Response: We do not agree with the commenters suggestion to remove the Security Risk Analysis measure starting with the CY 2026 performance period/ 2028 MIPS payment year. With the CY 2026 performance period already underway, MIPS eligible clinicians are currently completing or have completed the actions required for the Security Risk Analysis measure given that requirements must be completed during the year in which the performance period occurs, unlike the ONC Direct Review and ONC–ACB Surveillance attestations, which do not always require specific actions to have already been completed during the performance period when attesting to participate in applicable ONC-related activities. Thus, we believe that removing the Security Risk Analysis measure starting with the CY 2027 performance period/2029 MIPS payment year is appropriate.

Comment: Many commenters requested clarification and confirmation that removing the Security Risk Analysis measure and relying on use of CEHRT does not remove clinicians' obligations to perform security risk analysis and risk management activities to support strong cybersecurity practices and meet obligations under the HIPAA Security Rule on emerging generative AI technologies. A commenter expressed the opinion that removing the measure does not meaningfully reduce MIPS eligible clinicians' burden.

Response: We acknowledge that MIPS eligible clinicians will still need to meet the requirements in the HIPAA Security Rule. However, requiring MIPS eligible clinicians to report the Security Risk Analysis measure provides little incremental benefit compared to the associated costs and, therefore, we have decided to remove the requirement that MIPS eligible clinicians report the Security Risk Analysis measure. While MIPS eligible clinicians will continue to have the underlying obligation to assess security risk based on the requirements in the HIPAA Security Rule, we believe that removing the Security Risk Analysis measure from the MIPS Promoting Interoperability performance category reduces burden by eliminating MIPS-specific reporting and attestation requirements.

Comment: A few commenters requested that CMS align requirements across other programs, coordinate with other agencies on security risk analysis including U.S. Department of Health and Human Services, Office for Civil Rights and ONC, and monitor requirements of the HIPAA Security Rule.

Response: We strive to align program requirements across applicable federal programs, if appropriate. Also, we intend to continue our efforts to coordinate with other CMS programs and federal offices and agencies involved in cybersecurity and security risk assessment and mitigation.

Comment: A few commenters expressed the view that CMS should limit the year-to-year measure changes, which may create confusion and add administrative burden, and provide sufficient advance notice before changing or removing a security measure to allow MIPS eligible clinicians time to adjust their processes.

Response: While we agree that minimizing annual measures updates provides stability to MIPS eligible clinicians, we must also balance stability with being responsive to emerging technologies, including generative AI and agentic tools integrated into EHRs that process ePHI, are posing new security concerns and must be continuously monitored. We will continue to work across federal programs and with other federal agencies and will, to the best of our ability, provide as much advance notice as possible before changes take effect.

Comment: A few commenters opposed the proposal to remove the Security Risk Analysis measure due to increasing cybersecurity incidents in the healthcare industry, the delay in finalizing the new HIPAA Security Rule, and the lack of specificity in the HIPAA requirements around the frequency of performing a security risk analysis. A commenter shared a belief that the benefits of maintaining the Security Risk Analysis measure outweigh the burdens of reporting. Another commenter recommended revisiting removal once the HIPAA Security Rule is finalized and considering working with ONC to develop an alternative mechanism for MIPS eligible clinicians to report variations in expected operations of CEHRT to perform secure health information exchange, especially in the absence of ONC health IT certification criteria that validate functionality critical to CEHRT.

Response: We are aware of emerging cybersecurity concerns and will rely on MIPS eligible clinicians meeting the requirements of the HIPAA Security Rule, without the additional MIPS Promoting Interoperability performance category security analysis measure. Removal of the Security Risk Analysis measure from the MIPS Promoting Interoperability performance category does not remove the underlying security obligations applicable to MIPS eligible clinicians under the HIPAA Security Rule and such requirements continue to apply independent of MIPS requirements, regardless of whether updates to the HIPAA Security Rule are finalized. Additionally, while some commenters expressed concern that HIPAA does not provide specificity around the frequency of performing a security risk analysis, we note that risk analysis is an ongoing process and that retaining the MIPS measure would not address frequency as the measure is a simple annual attestation. We continue to believe that removing the measure reduces unnecessary MIPS reporting, documentation, and audit burden while preserving existing security obligations under HIPAA. We will continue to monitor to determine if additional requirements in this area are needed to supplement other federal regulatory requirements, and if necessary, will discuss in future rulemaking.

After consideration of public comment, we are finalizing, as proposed, the proposal to remove the Security Risk Analysis measure beginning with the CY 2027 performance period/2029 MIPS payment year.

We refer readers to Table C–G 2, Table C–G 4, Table C–G 6, and Table C–G 8 in sections IV.A.4.d.(4)(g)(i), IV.A.4.d.(4)(g)(ii)(D), and IV.A.4.d.(4)(g)(iv) of this final rule for more information regarding the reporting requirements and scoring methodology of the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year, which includes the finalization of the proposal as proposed to remove the Security Risk Analysis measure.

Also, we refer readers to section IV.A.4.d.(4)(g)(ii)(B) of this final rule for the discussion regarding the scoring implications associated with the removal of the Security Risk Analysis measure.

(e) Adopting a New Electronic Prior Authorization for Prescription Drugs Measure Beginning With the CY 2028 Performance Period/2030 MIPS Payment Year

(i) Background

Under section 1848(o)(2)(A) of the Act, the MIPS Promoting Interoperability performance category assesses whether MIPS eligible clinicians use CEHRT in a meaningful manner. By statute, such demonstration includes the use of electronic prescribing as determined to be appropriate by the Secretary. The MIPS Promoting Interoperability performance category has therefore included measures related to electronic prescribing since its inception (75 FR 44337; and 81 FR 77229 through 77237). Separately from the MIPS Promoting Interoperability performance category, we have also advanced the adoption of electronic prescribing through authority under section 1860D–4(e) of the Act, which requires that prescriptions for covered Medicare Part D drugs transmitted electronically comply with a uniform transaction standard specified by CMS. Under the same authority under section 1860D–4(e) of the Act, we also generally require that Schedule II, III, IV, and V controlled substances under Medicare Part D and Medicare Advantage prescription drug plans be prescribed electronically in accordance with an electronic prescription drug program. That required standard includes transactions for the electronic prior authorization of Part D-covered drugs prescribed to Part D-eligible individuals (85 FR 86827 through 86832 and 89 FR 51242 through 51247).

Historically, the ONC Health IT Certification Program and the Part D Program have maintained complementary policies of aligning ONC health IT certification criteria and associated standards related to electronic prescribing, medication history, and electronic prior authorization for prescriptions (89 FR 51257). In successive rules supporting the ONC Health IT Certification Program, ONC has adopted the National Council for Prescription Drugs Program (NCPDP) SCRIPT standard as the required exchange standard for the electronic prescribing certification criterion at 45 CFR 170.315(b)(3). In the ''Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications'' final rule (89 FR 51242 through 51247), the Part D Program finalized at § 423.160(b)(1) the requirement that Part D sponsors, prescribers and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, must comply with the standard in 45 CFR 170.205(b). Taken in conjunction with the standards and expiration date adopted by ONC in the same rule (89 FR 51258 through 51259), § 423.160(b)(1) will require Part D sponsors, prescribers and dispensers to use NCPDP SCRIPT standard version 2023011, which ONC adopted at 45 CFR 170.205(b)(2), beginning January 1, 2028, and expire NCPDP SCRIPT standard version 2017071, which ONC previously adopted at 45 CFR 170.205(b)(1) as of January 1, 2028. The NCPDP SCRIPT standard version 2023011 includes enhancements to support electronic prescribing and transmission of prescription-related and electronic prior authorization information.

On April 14, 2026, the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges'' (2026 CMS Interoperability Standards and Prior Authorization for Drugs) proposed rule was published and introduced proposals that require Medicare Advantage organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plans offered on the Federally-facilitated Exchanges (collectively ''impacted payers'') to support certain exchange standards for the electronic prior authorization of prescription drugs (91 FR 19890 through 20062). We proposed that, beginning on October 1, 2027, impacted payers be required to support electronic prior authorization for all drugs that require prior authorization. Two separate sets of standards were proposed for payers to facilitate electronic prior authorization for drugs: three NCPDP standards (NCPDP SCRIPT Standard,© NCPDP Formulary and Benefit (F&B) Standard,© and NCPDP Real-Time Prescription Benefit (RTPB) Standard©) for prescription drugs covered under a pharmacy benefit; and six Fast Healthcare Interoperability Resources® (FHIR®) standards including the HL7 FHIR Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide (IG), the HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) IG, the HL7 FHIR Da Vinci—Prior Authorization Support (PAS) IG) for prescription drugs covered under a medical benefit.

Concurrent with other CMS efforts to promote standards-based electronic prior authorization, the MIPS Promoting Interoperability performance category has placed increasing emphasis on prior authorization through its adoption of the Electronic Prior Authorization measure (89 FR 8909 through 8927) as established in the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program'' (2024 CMS Interoperability and Prior Authorization) final rule. In the CY 2027 PFS proposed rule, we noted that the Electronic Prior Authorization measure assesses MIPS eligible clinicians on the use of a Prior Authorization application programming interface (API) to request prior authorization for medical items and services (91 FR 44174 and 44175). However, we noted that the measure does not assess the use of electronic prior authorization for prescription drugs, in part because the Prior Authorization API requirements finalized in the 2024 CMS Interoperability and Prior Authorization final rule excluded prescription drugs (89 FR 8918).

(ii) Adopting Electronic Prior Authorization for Prescription Drugs Measure

Across the healthcare industry, a majority of prior authorizations for prescription drugs covered under a pharmacy benefit remain a separate manual process outside of the EHR workflow, not connected to e-prescribing, and could cause major points of friction and delay in the prescribing and prior authorization workflow. In 2023, approximately 38 percent of prescription drug prior authorizations were fully electronic and 15 percent were fully manual, indicating continuing capacity for

improvement in the domain.[403] This current level of adoption of electronic prior authorization for prescription drugs contributes to a reliance on payer portals and manual processes, including processes based on phone, or fax, which are entirely outside the EHR and that may delay patients' access to needed medications, increase administrative complexity for clinicians and staff, and undermine the efficiency and clinical value of electronic prescribing. As more payers support standardized electronic prior authorization, we have determined that measuring the use of prior authorization for prescription drugs will be a valuable addition to our assessment of meaningful use of CEHRT under the MIPS Promoting Interoperability performance category. Standards-based electronic prior authorization should improve timeliness and transparency of medication access by facilitating information-gathering and tracking of prior authorization status within clinician EHR workflows to support care coordination and help close the prescriber-to-dispenser loop. Thus, we believe that incorporating electronic prior authorization for prescription drugs is an appropriate aspect of demonstrating meaningful use of CEHRT by MIPS eligible clinicians.

Action in this area is further supported by longstanding efforts to promote standards adoption for prescription-related transactions under the Part D Program and the ONC Health IT Certification Program. As previously noted, CMS and ONC have maintained complementary policies aligning electronic prescribing and prescription-related standards at 42 CFR 423.160(b)(1) for Part D transactions and 45 CFR 170.315(b)(3) for the ONC Health IT Certification Program. Health IT developers also have experience with the underlying transaction standards because of their use in Part D transactions. Therefore, we believe that MIPS eligible clinicians and their health IT vendors have a foundation to implement the functionality for a new measure and thus, we proposed the adoption of a new measure, Electronic Prior Authorization for Prescription Drugs, in the CY 2027 PFS proposed rule (91 FR 44174 through 44176).

We proposed to adopt the new measure, Electronic Prior Authorization for Prescription Drugs, for the MIPS Promoting Interoperability performance category beginning with the CY 2028 performance period/2030 MIPS payment year (91 FR 44176). As noted in the CY 2027 PFS proposed rule, we intend for the new Electronic Prior Authorization for Prescription Drugs measure to be included in the Health Information Exchange objective for the MIPS Promoting Interoperability performance category to emphasize the role of prior authorization in promoting care coordination and collocate the new measure in the same objective as the previously adopted Electronic Prior Authorization measure (91 FR 44175). The new Electronic Prior Authorization for Prescription Drugs measure aims to assess a MIPS eligible clinician's utilization of standards-based electronic prior authorization. In the CY 2027 PFS proposed rule, we proposed for the specifications of the Electronic Prior Authorization for Prescription Drugs measure to be as follows (91 FR 44175):

- *Measure Description:* For at least one prescription drug ordered by the MIPS eligible clinician during the performance period for which prior authorization is required, the prior authorization is requested electronically using CEHRT.
- *Reporting Requirements:* ''Yes''/''No'' response.
- *Exclusion:* Any MIPS eligible clinician who—

++ Does not prescribe drugs that require prior authorization during the applicable performance period;

++ Only prescribes drugs requiring prior authorization where the payer does not support the specified electronic prior authorization standard during the applicable performance period; or

++ Prescribes fewer than 100 permissible prescription drugs during the performance period.

We noted in the CY 2027 PFS proposed rule that the last exclusion matches an exclusion in the Electronic Prescribing measure (91 FR 44175). For this exclusion, ''permissible prescriptions'' means all drugs that meet the current definition of a prescription as ordered by a MIPS eligible clinician to dispense a drug that would not be dispensed without such order. ''Permissible prescriptions'' may include electronic prescriptions of controlled substances where creation of an electronic prescription for the medication is feasible using CEHRT and where allowable by state and local law. Additionally, for purposes of this exclusion, permissible prescriptions include any prescription, not only those requiring prior authorization. To successfully report this measure, MIPS eligible clinicians must submit a ''Yes'' response, in which they are affirmatively attesting to having requested prior authorization electronically using CEHRT for at least one prescription drug ordered by the MIPS eligible clinician during the performance period or (if applicable) claim an exclusion. We expect that once a MIPS eligible clinician has the capability of requesting prior authorization electronically, MIPS eligible clinician will do so more frequently, though we did not propose to measure frequency of use at this time with this initial version of the measure. The new measure will apply to prescription drugs covered under a pharmacy benefit, as functionally defined by whether prior authorization can be requested for the drug can be authorized using the NCPDP SCRIPT standard.

The proposal to use CEHRT for the measure would require use of health IT certified to the ONC health IT certification criteria at 45 CFR 170.315(b)(3)—''Electronic prescribing'' and at 45 CFR 170.315(b)(4)—''Real-time prescription benefit'' to support any electronic prior authorization requests used to satisfy this measure. Use of both ''electronic prescribing'' and ''real-time prescription benefit'' ONC health IT certification criteria ensures that MIPS eligible clinicians use standards-based capabilities within their health IT systems to successfully complete the measure. Beginning January 1, 2028, the specified standards within the certification criteria in 45 CFR 170.315(b)(3) and 45 CFR 170.315(b)(4) will be the same versions of the NCPDP SCRIPT Standard and NCPDP RTPB Standard, respectively, required for Medicare Part D sponsors and to be required for other impacted payers in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 19925 through 19927). For purposes of the new Electronic Prior Authorization for Prescription Drugs measure, ''requested electronically'' means initiating and submitting an electronic prior authorization request from within CEHRT using health IT certified under 45 CFR 170.315(b)(3) and 45 CFR 170.315(b)(4). Using health IT certified to the ''real-time prescription benefit'' ONC health IT certification criterion in 45 CFR 170.315(b)(4) allows a MIPS eligible clinician to ascertain the patient-specific out-of-pocket cost of a prescription drug, the cost of suitable alternatives, compare prescription costs at different pharmacies, and learn whether prior authorization for a specific prescription drug is required.

The 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule also proposed that impacted payers support the NCPDP

[403] For more information, *see: https://www.caqh.org/hubfs/Issue%20Briefs/CAQH_Insights_NCPDP_SCRIPT_Issue_Brief.pdf.*

F&B standard (91 FR 19925 and 19926). We are not including this standard as part of required CEHRT for this measure at this juncture. However, we believe that the NCPDP F&B standard complements the NCPDP SCRIPT and RTPB standards certification criteria for Health IT Modules in 45 CFR 170.315(b)(3) and 45 CFR 170.315(b)(4), respectively, and we encourage MIPS eligible clinicians to use the F&B standard functions within their EHRs as part of an electronic prior authorization workflow as well.

We noted in the CY 2027 PFS proposed rule that adoption of the new Electronic Prior Authorization for Prescription Drugs measure is not contingent upon the finalization of the proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 44176). We also noted that the new Electronic Prior Authorization for Prescription Drugs measure includes an exclusion for cases in which no applicable payer supports the specified electronic prior authorization standard (91 FR 44176).

Electronic prior authorization requests for prescription drugs covered under a pharmacy benefit, which would leverage the NCPDP SCRIPT Standard and NCPDP RTPB Standard, are often for those prescription drugs dispensed at a retail pharmacy. We recognize that other prescription drugs may be covered under a medical benefit and are usually administered or dispensed by a medical provider in a health care setting. Those drugs covered under a medical benefit generally use FHIR-based electronic prior authorization processes, such as those supported by the Da Vinci CRD, DTR, and PAS implementation guides finalized under ONC health IT certification criteria, and therefore, are not in scope for the new Electronic Prior Authorization for Prescription Drugs measure. A MIPS eligible clinician that only needs prior authorization for prescription drugs covered under a medical benefit and not a pharmacy benefit would be eligible to claim an exclusion for not ordering an applicable prescription drug during the performance period.

For purposes of the new Electronic Prior Authorization for Prescription Drugs measure, ''one prescription drug ordered by the MIPS eligible clinician'' includes a new prescription and, where applicable, a prescription renewal or refill request that generates a prior authorization requirement at the time of prescribing. A prescription drug ''for which prior authorization is required'' is one for which the applicable payer rules indicate a prior authorization requirement at the point of prescribing for the patient and plan. In the CY 2027 PFS proposed rule, we indicated that we believe the NCPDP F&B Standard would help inform MIPS eligible clinicians when a prior authorization is required or not, even if not a mandate of the Electronic Prior Authorization for Prescription Drugs measure. We recognized that coverage for certain prescription drugs may fall under either the pharmacy or medical benefit and would continue to consider future policies to reduce workflow fragmentation across prior authorization approaches (91 FR 44176). In the CY 2027 PFS proposed rule, we requested public comment with a Request for Information (RFI) on the potential to expand the scope of the Electronic Prior Authorization measure to include prescription drugs covered under a medical benefit (91 FR 44182).

In the CY 2027 PFS proposed rule, we proposed that the Electronic Prior Authorization for Prescription Drugs measure would require an attestation of ''Yes'' or ''No'' response from a MIPS eligible clinician (*91 FR 44175 and 44176*). Beginning with the CY 2028 performance period/2030 MIPS payment year, a MIPS eligible clinician would be required to submit a ''Yes'' response for the measure or claim an applicable exclusion in order to earn a score for the MIPS Promoting Interoperability performance category. If a MIPS eligible clinician submits a ''No'' response for the measure, fails to submit any attestation, or does not claim an applicable exclusion for the Electronic Prior Authorization for Prescription Drugs measure, the MIPS eligible clinician would receive a score of zero for the MIPS Promoting Interoperability performance category (weighted at 25 percent of the MIPS final score), and would not be considered a meaningful EHR user for purposes of the MIPS Promoting Interoperability performance category for an applicable performance period.

In the CY 2027 PFS proposed rule, we proposed that the measure would initially require an attestation of a ''Yes'' or ''No'' response to allow MIPS eligible clinicians to gain familiarity with electronic prior authorization for prescription drugs and measure reporting (91 FR 44175 and 44176). We anticipate a future conversion of the Electronic Prior Authorization for Prescription Drugs measure to numerator/denominator reporting once standardized data capture and reporting have further progressed. We noted that we would monitor the measure's feasibility and consider updates, including volume-based thresholds or rate-based scoring, to ensure the measure reflects meaningful use at scale (91 FR 44176).

We requested public comment on the proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to add the new Electronic Prior Authorization for Prescription Drugs measure as a required measure in the MIPS Promoting Interoperability performance category beginning with the CY 2028 performance period/2030 MIPS payment year. Several commenters highlighted the potential for standardized electronic prior authorization for prescription drugs to reduce administrative burden and delays and to improve patients' timely access to needed medications. A few commenters noted that electronic prior authorization for prescription drugs could improve care coordination, efficiency, and patient experience. A commenter noted that the new measure would align with the adoption of NCPDP SCRIPT standards supporting electronic prior authorization.

Response: We appreciate the support from commenters regarding the proposal to establish the new Electronic Prior Authorization for Prescription Drugs measure. We agree with commenters that use of standards-based electronic prior authorization for prescription drugs covered under a pharmacy benefit has the potential to reduce administrative burden and delays, support more timely patient access to needed medications, and improve care coordination and workflow efficiency. We believe the proposed new measure would help advance adoption of interoperable electronic prior authorization capabilities among MIPS eligible clinicians and other entities involved in the prescription-drug prior authorization process.

Comment: Many commenters did not support the proposal to establish the new Electronic Prior Authorization for Prescription Drugs measure as a required measure beginning with the CY 2028 performance period/2030 MIPS payment year. Several commenters expressed concern that the Electronic Prior Authorization for Prescription Drugs measure could become mandatory before standardized electronic prior authorization capabilities and workflows are sufficiently mature and have demonstrated meaningful value for MIPS eligible clinicians and patients. The commenters indicated that premature implementation of the

Electronic Prior Authorization for Prescription Drugs measure could result in additional administrative and financial burden. A few commenters questioned the need for a mandatory measure, noting that MIPS eligible clinicians already have incentives to adopt electronic prior authorization due to its potential to streamline prior authorization workflows and reduce associated administrative burden.

Response: We appreciate the feedback regarding the readiness of electronic prior authorization capabilities and workflows for prescription drugs, as well as the potential burden associated with implementing a new required measure. While we recognize the potential burden associated with the new required measure, we believe that the benefits of the measure outweigh the potential burdens and that finalizing, as proposed, to adopt the Electronic Prior Authorization for Prescription Drugs measure will advance use of standards-based electronic prior authorization for prescription drugs covered under a pharmacy benefit, which has the potential to reduce reliance on manual and portal-based processes and support more timely and transparent prior authorization workflows. Also, we believe that MIPS eligible clinicians and health IT vendors will have sufficient time to build an infrastructure, test, and prepare for the implementation of the Electronic Prior Authorization for Prescription Drugs measure requirements during the entirety of CY 2027 and the permissibility of continuing preparation into CY 2028. We intend for the adoption of the Electronic Prior Authorization for Prescription Drugs measure as a required measure beginning with the CY 2028 performance period/2030 MIPS payment year to strike an appropriate balance between providing stakeholders time to prepare for implementation and advancing broader adoption of electronic prior authorization for prescription drugs in a timely manner. The proposed start date allows a meaningful period for continued development, testing, and workflow integration while also supporting the objectives of the MIPS Promoting Interoperability performance category to advance interoperable, standards-based electronic exchange.

MIPS eligible clinicians and health IT developers will have a foundation for implementation through the NCPDP SCRIPT and Real-Time Prescription Benefit (RTPB) standards. CMS previously finalized requirements for Medicare Part D sponsors, prescribers, and dispensers to use specified NCPDP SCRIPT standards when electronically transmitting prescriptions, including for electronic prior authorization transactions, as well as requirements for Part D sponsors to implement a real-time benefit tool using the RTPB standard (42 CFR 423.160).

In addition, the measure includes an exclusion for MIPS eligible clinicians for whom no applicable payer supports the specified electronic prior authorization standard. The measure is structured as an attestation measure and merely requires a MIPS eligible clinician to electronically request prior authorization for one applicable prescription drug during the performance period to satisfy the measure. While MIPS eligible clinicians may already have business and clinical incentives to use electronic prior authorization for prescription drugs, we do not believe those incentives alone have been sufficient to drive widespread, consistent adoption of standards-based electronic prior authorization workflows and we believe that a measure under the MIPS Promoting Interoperability performance category will encourage further uptake.

Comment: Many commenters recommended delaying or phasing implementation of the Electronic Prior Authorization for Prescription Drugs measure. Other commenters requested the Electronic Prior Authorization for Prescription Drugs measure be optional and eligible for bonus points for the CY 2028 performance period/2030 MIPS payment year to encourage early adoption and implementation experience and then transition the Electronic Prior Authorization for Prescription Drugs measure to be required beginning with CY 2029 performance period/2031 MIPS payment period or other future performance period. A few commenters noted that allowing for an optional reporting period prior to requiring the measure would be consistent with phased approaches used to introduce other Promoting Interoperability measures in previous years. Several commenters specifically requested delaying mandatory reporting until the CY 2029 performance period/2031 MIPS payment period at the earliest. Commenters generally noted that a delayed or phased approach would provide additional time for payers, health IT developers, and MIPS eligible clinicians to implement and test electronic prior authorization capabilities, integrate them into clinical workflows, and gain implementation experience before mandatory measure reporting begins. A few commenters recommended that CMS consider the timing of payer implementation requirements when determining when to require the Electronic Prior Authorization for Prescription Drugs measure, expressing concern that payers and health IT developers may not have sufficient time to implement and test the necessary capabilities. A commenter recommended that this new measure remains voluntary during the transition year if CMS finalizes policies to increase the performance threshold or require MVP participation in the same performance year.

Response: We intend for the adoption of the Electronic Prior Authorization for Prescription Drugs measure as a required measure beginning with the CY 2028 performance period/2030 MIPS payment year to strike an appropriate balance between providing stakeholders time to prepare for implementation and advancing broader adoption of electronic prior authorization for prescription drugs in a timely manner. The proposed start date allows a meaningful period for continued development, testing, and workflow integration while also supporting the objectives of the MIPS Promoting Interoperability performance category to advance interoperable, standards-based electronic exchange.

While we have previously used phased approaches (for example, establishing an initial optional reporting period prior to requiring a measure) when introducing new measures or policies, we do not believe an initial optional reporting period is necessary for the Electronic Prior Authorization for Prescription Drugs measure and we note that an optional approach could lead to uneven adoption and slow progress toward more standardized use of electronic prior authorization processes for prescription drugs. Establishing the Electronic Prior Authorization for Prescription Drugs measure as required beginning with the CY 2028 performance period/2030 MIPS payment year will promote more consistent implementation across stakeholders and encourage movement away from manual prior authorization processes. We believe adoption of the Electronic Prior Authorization for Prescription Drugs measure can incentivize adoption of practices that reduce inefficiency and potential delays in patient access to medications.

We do not believe it is necessary to delay implementation of the new Electronic Prior Authorization for Prescription Drugs measure beyond the CY 2028 performance period/2030 MIPS payment year to align with payer compliance dates proposed in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed

rule (91 FR 19890). We note the proposed October 1, 2027, compliance date for impacted payers to support electronic prior authorization for prescription drugs precedes the implementation of the new measure beginning with the CY 2028 performance period/2030 MIPS payment year. However, adoption of this measure is not contingent on finalization of the proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule. The new Electronic Prior Authorization for Prescription Drugs measure promotes the use of existing electronic prior authorization workflows for prescription drugs, which are already supported through established standards and are not dependent on the FHIR-based Prior Authorization API requirements for medical items and services. CMS also has previously existing requirements for Part D sponsors, prescribers, and dispensers to use specified NCPDP SCRIPT standards for electronic prescription drug prior authorization (42 CFR 423.160). These requirements build upon previously established electronic prior authorization standards and provide a standards-based foundation for implementation of this measure.

Additionally, this measure is intended to align with the implementation of the Electronic Prior Authorization measure relating to medical services and items as it becomes a required measure beginning with the CY 2028 performance period/2030 MIPS payment year. The simultaneous and in tandem implementation of the new Electronic Prior Authorization for Prescription Drugs measure and the Electronic Prior Authorization measure as required measures will encourage expansive adoption of electronic prior authorization.

We note that the MIPS performance threshold has been finalized with no increases until CY 2028 performance period/2030 MIPS payment year (90 FR 49918). Additionally, we refer readers to section IV.A.3.c. of this final rule for discussion of the proposed policy regarding the sunset of traditional MIPS, which has been finalized with a modification to delay implementation. Regardless, potential changes to the MIPS performance threshold, MVP participation policies and other policies, are separate policy topics that do not, in our view, justify making the Electronic Prior Authorization for Prescription Drugs measure optional.

Comment: Many commenters expressed concerns about ecosystem readiness to support the Electronic Prior Authorization for Prescription Drugs measure. Several commenters noted that standardized electronic prior authorization capabilities and workflows for prescription drugs are not yet widely available or sufficiently mature, with functionality varying across payers, health IT developers, and clinical practice settings. Several commenters noted that MIPS eligible clinicians' ability to successfully use electronic prior authorization for prescription drugs depends on the readiness and functionality of payers, health IT developers, pharmacy benefit managers, pharmacies, and other entities outside of their control. Several commenters also stressed that availability of electronic prior authorization functionality alone does not automatically demonstrate readiness and highlighted the need for functionality to be fully operational, integrated into clinical workflows, and tested end-to-end across participating entities. Several commenters recommended that CMS assess and monitor payer, health IT developer, and MIPS eligible clinician readiness to inform implementation of the measure. Commenters also noted that inconsistent adoption across the ecosystem could require MIPS eligible clinicians to maintain multiple workflows. A few commenters additionally raised concerns about the affordability of available technology, implementation costs, and differences in readiness across practice settings (such as small, independent, rural, and safety-net practices). A commenter recommended that CMS accompany the measure with enforceable expectations for health insurance plans and pharmacy benefit managers such as response timeframes and patient protections.

Response: We believe the previously established Medicare Part D requirements for use of specified NCPDP SCRIPT and RTPB standards for electronic prescribing and prescription-related transactions that support electronic prior authorization (42 CFR 423.160) provide a reasonable foundation for implementation beginning with the CY 2028 performance period. The measure's limited attestation requirement further supports implementation by requiring only one qualifying electronic prior authorization request during the performance period. Additionally, this measure, as proposed, includes exclusions that provide flexibility for MIPS eligible clinicians who may face challenges meeting the measure's requirements, including accommodation for where an applicable payer does not support the specified electronic prior authorization standard.

By requiring the Electronic Prior Authorization for Prescription Drugs measure, we intend to promote coordinated readiness across stakeholders to ensure that workflows become operational. Establishing the Electronic Prior Authorization for Prescription Drugs measure will encourage continued progress toward broader implementation and workflow integration across the ecosystem. Over time, increased use of standardized electronic prior authorization has the potential to reduce reliance on fragmented and duplicative workflows and better support interoperability goals. We will continue to work to align with ONC and other agencies regarding requirements for health IT developers, health insurance plans, and pharmacy benefit managers. We intend to assess implementation experience, and broader industry progress as the Electronic Prior Authorization for Prescription Drugs measure is implemented, and we will consider whether future refinements are warranted through rulemaking.

Additionally, we acknowledge the concerns from commenters regarding the affordability of available technology, implementation costs, and the spectrum of readiness across practice settings such as small, independent, rural, and safety-net practices. We intend to monitor the availability of technology, implementation challenges, and readiness across various practice settings, including small, independent, rural, and safety-net practices.

Comment: Several commenters emphasized the importance of aligning CEHRT requirements for the Electronic Prior Authorization for Prescription Drugs measure with broader CMS and HHS interoperability and prior authorization policies, including aligning clinician and payer requirements around common underlying standards to support consistent implementation across clinicians, payers, and health IT developers. A few commenters recommended for CMS to maintain consistency across programs, including the MIPS Promoting Interoperability performance category and Medicare Promoting Interoperability Program, to minimize differences in measure requirements, specifications, and implementation timelines, and prevent clinicians from being subject to different electronic prior authorization requirements across programs. Some commenters specifically requested for the proposal to align with ONC-certified health IT and standards-based

functionality. A commenter requested that CMS finalize the underlying standards requirements in related rulemaking before adopting the Electronic Prior Authorization for Prescription Drugs measure. A commenter recommended preserving established NCPDP standards for pharmacy-benefit transactions while promoting interoperability with emerging FHIR-based standards, emphasizing the importance of a coordinated approach that avoids disrupting established workflows as standards and program requirements evolve.

Response: We agree with the comment regarding the alignment with ONC-certified health IT and applicable standards-based functionality as it is important to support successful implementation and to minimize avoidable differences in technical and operational expectations across the industry. We recognize the importance of promoting consistency across CMS programs, where appropriate, to reduce burden. The NCPDP SCRIPT and Real-Time Prescription Benefit standards supporting the health IT certification criteria specified for the new Electronic Prior Authorization for Prescription Drugs measure align with standards required for Medicare Part D sponsors (42 CFR 423.160) and proposed for adoption by other impacted payers under the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 19925 through 19927), supporting consistent standards-based electronic prior authorization capabilities across MIPS eligible clinicians, health IT developers, and payers.

However, we note that differences across programs may sometimes reflect distinct statutory authorities, program structures, or policy objectives. We agree that established standards, such as NCPDP standards, play an important role in current workflows and at the same time recognize the growing importance of newer approaches such as FHIR-based standards. We intend to continue seeking alignment across CMS programs and with broader federal interoperability efforts, to the extent feasible, as implementation proceeds.

Comment: Several commenters recommended expanding or strengthening the proposed exclusions and other protections for MIPS eligible clinicians who are unable to successfully report the Electronic Prior Authorization for Prescription Drugs measure due to circumstances outside their control. A few commenters recommended that such protections account for circumstances in which required electronic prior authorization capabilities are unavailable, nonfunctional, or not operationally implemented or integrated due to payer or health IT developer readiness limitations. A few commenters also raised concerns about the burden and practical challenges associated with determining and documenting whether a MIPS eligible clinician qualifies for an exclusion and recommended simplifying this process, such as through standardized reasons for not being able to meet the measure successfully or CMS-provided information on payer support for applicable electronic prior authorization standards.

Response: We note that the policies already available under the MIPS Promoting Interoperability performance category, including existing exclusion policies where applicable, and the significant hardship exception for the MIPS Promoting Interoperability performance category, provide important safeguards for MIPS eligible clinicians who are unable to meet requirements due to circumstances beyond their control. These policies are intended to provide flexibility in cases where a MIPS eligible clinician cannot reasonably comply with the MIPS Promoting Interoperability performance category requirements. We do not believe it would be practical to base exclusions on a CMS-maintained list of payer support for applicable electronic prior authorization standards because payer readiness may vary over time and across products, markets, and vendors. We believe that the current MIPS exclusion framework provides a more consistent approach. We intend to assess implementation experience, payer and health IT readiness, technological advancements, and the availability of ONC-certified health IT as this measure is operationalized, including issues related to the availability and functionality of electronic prior authorization capabilities.

Comment: Commenters provided mixed feedback on the proposed attestation based measure design for the Electronic Prior Authorization for Prescription Drugs measure. Several commenters supported the proposed attestation-based format for the initial measure design, noting that a percentage or frequency-based measure could potentially penalize MIPS eligible clinicians for payer limitations outside their control, particularly when their patient populations are covered by payers that do not yet fully support electronic prior authorization. Several commenters recommended that CMS transition to a numerator/denominator, performance-based approach as electronic prior authorization adoption and measure reporting capabilities mature. These commenters stated that a performance-based approach could better measure routine, integrated use of electronic prior authorization across applicable prescribing workflows. A commenter encouraged CMS to adopt numerator/denominator reporting as soon as feasible.

Response: We appreciate commenters' feedback on the proposed Electronic Prior Authorization for Prescription Drugs measure design. Beginning with an initial attestation based approach is appropriate because it allows MIPS eligible clinicians to gain familiarity with electronic prior authorization for prescription drugs and measure reporting while standardized data capture and reporting capabilities continue to develop. We also recognize that MIPS eligible clinicians may encounter variation in payer support for electronic prior authorization. The Electronic Prior Authorization for Prescription Drugs measure includes an exclusion for MIPS eligible clinicians who only prescribe drugs requiring prior authorization from payers that do not support the specified electronic prior authorization standard during the applicable performance period.

As implementation of the Electronic Prior Authorization for Prescription Drugs measure matures and more consistent data are available to support reliable performance measurement, we will continue to assess whether updating to a numerator/denominator-based approach is feasible and appropriate in future rulemaking.

Comment: Several commenters requested additional clarification regarding the technical requirements for the Electronic Prior Authorization for Prescription Drugs measure. For example, commenters requested clarification regarding the technical capabilities and transactions that would satisfy the Electronic Prior Authorization for Prescription Drugs measure, including whether conforming electronic prior authorization functionality delivered through a connected application would qualify and the minimum criteria for a qualifying electronic prior authorization transaction. Another commenter recommended clarifying the respective roles of NCPDP SCRIPT and Real-Time Prescription Benefit (RTPB) standards in facilitating electronic prior authorization and specifying which certified health IT capabilities are necessary to satisfy the measure. A commenter requested clarification

distinguishing electronic prior authorization for prescription drugs covered under the pharmacy benefit from those covered under the medical benefit. Another commenter recommended that CMS develop standardized calculation guidance and testing tools to promote consistent measure implementation and reporting across health IT vendors. A commenter requested that CMS publish the complete specification for the measure.

Response: We appreciate the feedback from commenters requesting clarification regarding the technical requirements for the Electronic Prior Authorization for Prescription Drugs measure. To meet the measure, a MIPS eligible clinician must initiate and submit an electronic prior authorization request from within CEHRT using health IT certified to the ''electronic prescribing'' and ''real-time prescription benefit'' criteria at 45 CFR 170.315(b)(3) and 45 CFR 170.315(b)(4). With regard to the request for clarification about electronic prior authorization functionality delivered through a connected application, we note that MIPS eligible clinicians adopt and use certified health IT from different health IT developers to meet the CEHRT definition, and may use applications connected to their primary EHR system as long as those applications are certified to the relevant ONC certification criteria required for the measure at 45 CFR 170.315(b)(3) and (b)(4).

The Real-Time Prescription Benefit (RTPB) functionality described in the certification criterion at 45 CFR 170.315(b)(4) may help a MIPS eligible clinician determine whether prior authorization is required for a particular prescription drug, but RTPB functionality alone does not satisfy the measure. The measure action requires the electronic submission of a prior authorization request using the applicable NCPDP SCRIPT transaction. Specifically, as we stated in the CY 2027 PFS proposed rule (91 FR 44176), for purposes of the new Electronic Prior Authorization for Prescription Drugs measure, ''requested electronically'' means initiating and submitting an electronic prior authorization request from within CEHRT using health IT certified under 45 CFR 170.315(b)(3) and 45 CFR 170.315(b)(4). Thus, we require the use of health IT certified to the ONC health IT certification criteria at 45 CFR 170.315(b)(3)—''Electronic prescribing'' and at 45 CFR 170.315(b)(4)—''Real-time prescription benefit'' to support any electronic prior authorization requests used to satisfy this measure.

Furthermore, we note that for every qualifying request, health IT certified to the RTPB functionality at 45 CFR 170.315(b)(4) must be used to check for a coverage requirement and then use health IT certified to the ONC health IT certification criteria at 45 CFR 170.315(b)(3)—''Electronic prescribing'' must be used to submit the request. We recognize that such actions may not be conducted in every circumstance in which a MIPS eligible clinician may seek prior authorization and note that the measure provides such flexibility as a result of requiring that for at least one prescription drug ordered by the MIPS eligible clinician during the performance period for which prior authorization is required, the prior authorization is requested electronically using CEHRT.

Regarding the commenter requesting clarification on distinguishing electronic prior authorization for prescription drugs covered under the pharmacy benefit from those covered under the medical benefit, we clarify that the electronic prior authorization processes outlined in this section of the final rule applies to prescription drugs covered under a pharmacy benefit and does not apply to prescription drugs covered under a medical benefit, which generally use different electronic prior authorization workflows.

We recognize the importance of clear implementation guidance regarding the technical capabilities and transactions that satisfy the measure. We will provide educational and guidance resources, as appropriate and feasible, to clarify implementation details. The measure specifications for the new Electronic Prior Authorization for Prescription drugs measure will be available on the QPP website at *https://qpp.cms.gov/reporting-requirements/measures-activities/explore*.

Comment: A commenter recommended that when implementing the new Electronic Prior Authorization for Prescription Drugs measure, CMS should require continued monitoring of denials, appeals, and treatment abandonment to measure whether patients are able to get needed care and medications in a timely manner.

Response: The Electronic Prior Authorization for Prescription Drugs measure in the MIPS Promoting Interoperability performance category is intended to assess whether MIPS eligible clinicians are using electronic prior authorization functionality for prescription drugs, rather than to measure payer decision-making, appeal outcomes, or patient medication adherence or abandonment. Data on denials, appeals, and treatment abandonment may not be consistently available to clinicians or captured in certified health IT in a standardized and reliable manner for purposes of MIPS reporting. In addition, these outcomes may be influenced by factors outside the clinician's control. Thus, we do not believe it is appropriate to require monitoring of denials, appeals, and treatment abandonment as a part of the Electronic Prior Authorization for Prescription Drugs measure at this time.

After consideration of public comment, we are finalizing, as proposed, the proposal to adopt the Electronic Prior Authorization for Prescription Drugs measure beginning with the CY 2028 performance period/2030 MIPS payment year.

We refer readers to Table C–G 2, Table C–G 5, Table C–G 6, and Table C–G 8 in sections IV.A.4.d.(4)(g)(i), IV.A.4.d.(4)(g)(ii)(D), and IV.A.4.d.(4)(g)(iv) of this final rule for information regarding the reporting requirements and scoring methodology of the MIPS Promoting Interoperability performance category.

(f) Modifying the Electronic Prior Authorization Measure

(i) Background

In the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we adopted the Electronic Prior Authorization measure under the Health Information Exchange objective in the MIPS Promoting Interoperability performance category. We finalized that MIPS eligible clinicians will be required to attest to the Electronic Prior Authorization measure beginning with the CY 2027 performance period/2029 MIPS payment year (89 FR 8910); and subsequently, once the measure will become effective as a required measure in the MIPS Promoting Interoperability performance category, MIPS eligible clinicians would be required to satisfactorily report on the measure (and meet the other reporting requirements) in order to earn a score for the MIPS Promoting Interoperability performance category. For purposes of the Electronic Prior Authorization measure, a prior authorization request would need to be made using a Prior Authorization API using data from CEHRT to submit a ''Yes'' response for the measure, unless a MIPS eligible clinician claims an applicable exclusion. We finalized the following measure description for the Electronic Prior Authorization measure (89 FR 8916):

For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the

performance period, the prior authorization is requested electronically from a Prior Authorization API using data from CEHRT.

Exclusions: Any MIPS eligible clinician who:

- Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance period; or
- Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets CMS's Prior Authorization API requirements during the applicable performance period.

In addition to becoming a required measure beginning with the CY 2027 performance period/2029 MIPS payment year, we finalized that the Electronic Prior Authorization measure will not be scored (that is, not assigned points for successful completion) for the CY 2027 performance period/2029 MIPS payment year (89 FR 8910 through 8915). For the MIPS Promoting Interoperability performance category, satisfactory performance on the Electronic Prior Authorization measure can be demonstrated only by submitting a ''Yes'' response to affirmatively attest to the measure or by claiming an applicable exclusion. MIPS eligible clinicians who submit a ''No'' response, fail to submit any attestation response, or do not claim an applicable exclusion for the Electronic Prior Authorization measure will receive a score of zero for the MIPS Promoting Interoperability performance category (weighted at 25 percent of the MIPS final score), and will not be considered a meaningful EHR user for purposes of the MIPS Promoting Interoperability performance category for the applicable performance period (89 FR 8910 through 8915).

Also, the 2024 CMS Interoperability and Prior Authorization final rule finalized that Medicare Advantage plans, state Medicaid Fee-for-service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plans (QHP) issuers on the Federally-Facilitated Exchange (collectively referred to as ''impacted payers'') must implement and maintain a Prior Authorization API beginning in CY 2027. The compliance date is January 1, 2027, for MA organizations and state Medicaid and CHIP FFS programs; by the first rating period beginning on or after January 1, 2027, for Medicaid managed care plans and CHIP managed care entities; and for plan years beginning on or after January 1, 2027, for individual market QHP issuers on the FFEs (89 FR 8759 through 8760). In the 2024 CMS Interoperability and Prior Authorization final rule, we recommended, rather than required, specific FHIR Implementation Guides (IGs) to support the APIs (89 FR 8937).

In the Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule (HTI–4 final rule), which was published as part of the FY 2026 IPPS/LTCH PPS final rule (90 FR 37164 through 37182), ONC finalized the following three ONC health IT certification criteria for electronic prior authorization:

- ''Provider prior authorization API—coverage requirements discovery'' in 45 CFR 170.315(g)(31).
- ''Provider prior authorization API—documentation templates and rules'' in 45 CFR 170.315(g)(32).
- ''Provider prior authorization API—prior authorization support'' in 45 CFR 170.315(g)(33).

These certification criteria are based on three IGs developed by the HL7 Da Vinci project which ONC adopted in the HTI–4 final rule [404] at 45 CFR 170.215(j)(1), (2), and (3)—

- HL7® FHIR® Da Vinci—Coverage Requirements Discovery (CRD) IG;
- HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) IG; and
- HL7 FHIR Da Vinci—Prior Authorization Support (PAS) IG.

Together, these ONC health IT certification criteria can enable electronic prior authorization for healthcare providers. We refer readers to the HTI–4 final rule (90 FR 37162 through 37175) for more information regarding ONC's finalized certification criteria at 45 CFR 170.315(g)(31) through (33) and section XI.B.4.b. of the HTI–4 final rule (90 FR 36541 through 36542) for a summary of all ONC finalized policies.

In the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, we proposed to require impacted payers to implement and maintain Prior Authorization APIs that conform to the CRD, DTR, and PAS IGs adopted by ONC on behalf of the Secretary at 45 CFR 170.215(j)(1), (2), and (3). We proposed compliance dates for impacted payers to conform to the proposed standards and IGs beginning October 1, 2027 (however, impacted payers must still implement Prior Authorization APIs beginning in CY 2027). Finally, in section II.J.6. of the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 20002 and 20003), ONC proposed to adopt updated versions of the CRD, DTR, and PAS IGs. If finalized, such proposed updated versions will enable payers and health IT developers to implement Prior Authorization APIs and Health IT Modules conforming to the finalized ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) to utilize the latest versions of these specifications.

The 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule includes proposals for impacted payers to implement and maintain Prior Authorization APIs using the CRD, DTR, and PAS IGs. Those proposals, along with the proposals ONC finalized in the HTI–4 final rule to adopt the CRD, DTR, and PAS IGs and establish electronic prior authorization certification criteria for health IT developers, collectively support the Electronic Prior Authorization measure for MIPS eligible clinicians and advance interoperability by applying consistent standards across HHS programs. We refer readers to the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule and the HTI–4 final rule (90 FR 37169 through 37171) for more information regarding the three ONC health IT certification criteria to support electronic prior authorization at 45 CFR 170.315(g)(31), (32), and (33).

(ii) Modifying the Electronic Prior Authorization Measure for the CY 2027 Performance Period/2029 MIPS Payment Year

In the CY 2027 PFS proposed rule, we proposed amendments to the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year by modifying the measure description (91 FR 44176 through 44178). Specifically, we proposed that the new measure description would be: For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT.

For the proposed modification to the measure description, we proposed amending the phrase from ''using data from CEHRT'' to ''using CEHRT'' to clarify that MIPS eligible clinicians must use certified Health IT Modules where necessary to support the electronic prior authorization processes specified in this measure (91 FR 44176 through 44178). When we adopted the

[404] In the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, ONC has proposed updated versions of such Implementation Guides (91 FR 19910 and 19911).

Electronic Prior Authorization measure in the 2024 CMS Interoperability and Prior Authorization final rule, we did not identify specific ONC health IT certification criteria required to complete the actions specified in the measure (89 FR 8910 through 8915). We stated that gathering structured data from CEHRT would be achievable without additional certification criteria (89 FR 8925) that had not been proposed or finalized at the time of the 2024 CMS Interoperability and Prior Authorization final rule. The proposed update to the measure description to require that a prior authorization be requested electronically ''using CEHRT'' is consistent with the availability of certified Health IT Modules that must be used to complete the action specified in the Electronic Prior Authorization measure. At this juncture, we did not propose to include the exclusion criteria that were finalized when the Electronic Prior Authorization measure was adopted (89 FR 8916). In the CY 2027 PFS proposed rule (91 FR 44178), we proposed to amend the Electronic Prior Authorization measure by modifying the measure description for the CY 2027 performance period/2029 MIPS payment year aligned with the same proposal for the Medicare Promoting Interoperability Program as proposed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19626).

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the modifications to the Electronic Prior Authorization measure for the CY 2027 performance period/ 2029 MIPS payment year. A commenter expressed the belief that the broader adoption of interoperable, standards based electronic prior authorization has the potential to reduce reliance on manual processes that disrupt clinical workflows and unnecessarily delay patient care. A few commenters supported CMS's efforts to clarify and update the measure, including the proposed change from requiring electronic prior authorization ''using data from CEHRT'' to ''using CEHRT.'' A few commenters indicated that the modified measure language would more clearly establish the role of certified health IT in successfully meeting the Electronic Prior Authorization measure and support alignment with standards-based electronic prior authorization capabilities.

Response: We appreciate the support from commenters. We agree with commenters that the use of CEHRT and the alignment with ONC health IT certification criteria will help establish a consistent technical foundation for the measure, support broader adoption of standards-based electronic prior authorization, and improve interoperability across MIPS eligible clinicians, EHRs, health IT vendors, and payers.

Comment: A few commenters raised concerns regarding changing the measure language from ''using data from CEHRT'' to ''using CEHRT.'' Commenters stated that electronic prior authorization workflows may rely on multiple systems, including EHRs, revenue cycle systems, payer portals, clearinghouses, and other connected applications. Commenters expressed concern that a narrow ''using CEHRT'' requirement could constrain practical software implementation options and increase burden. Commenters also noted that payer and health IT readiness to support standards-based electronic prior authorization remains variable, which could further limit the ability of MIPS eligible clinicians to satisfy the measure using CEHRT.

A few commenters recommended retaining the current ''using data from CEHRT'' language or clarifying that MIPS eligible clinicians may use conforming electronic prior authorization technology to meet the measure, whether embedded within CEHRT or provided through other systems or applications integrated into clinician workflows, such as revenue cycle systems, payer portals, and clearinghouses.

Response: We acknowledge the concerns from commenters regarding the proposed change in the measure description from specifying ''using data from CEHRT'' to ''using CEHRT.'' We recognize that electronic prior authorization workflows may involve multiple systems, entities, and technology solutions. Our intent is not to prohibit the use of standards-based intermediaries or other interoperable tools that support the electronic prior authorization workflow. Rather, the measure is intended to ensure that MIPS eligible clinicians conduct the measure action using standards-based health IT functionality certified to ONC's electronic prior authorization certification criteria. We note that different types of health IT products may obtain certification under the ONC Health IT Certification program and that nothing prohibits eligible clinicians from using certified Health IT Modules from different health IT developers in assembling technology meeting the CEHRT definition to support participation in the Promoting Interoperability performance category. Moreover, our proposal does not prohibit intermediaries from supporting electronic prior authorization exchange in other ways separate from the capabilities reflected in the electronic prior authorization certification criteria. As discussed in sections IV.A.4.d.(4)(f)(v) and IV.B.1.d. of this final rule, we are finalizing, as proposed, the proposal to make the Electronic Prior Authorization measure an optional measure and eligible for 10 bonus points for the CY 2027 performance period/2029 MIPS payment year, during which MIPS eligible clinicians may use one or more Health IT Modules certified to the applicable electronic prior authorization certification criteria, as necessary to fulfill the measure action. This final policy provides additional flexibility during initial implementation and assists in addressing concerns from commenters regarding implementation lead time, interface testing, and payer readiness.

Comment: Several commenters requested clarification or modifications to the technical specifications for the Electronic Prior Authorization measure. A few commenters recommended that CMS more clearly define what constitutes a qualifying electronic prior authorization transaction. A commenter expressed concern that the proposed measure language could be interpreted inconsistently across implementers because it does not clearly distinguish among initiation of an electronic workflow, successful submission of a standards-based electronic prior authorization transaction, portal-based processes, and requested clarification regarding the acceptable source(s) for a request that can initiate the workflow for a qualifying electronic prior authorization transaction.

A few commenters specifically recommended that a successfully completed transaction count regardless of whether the payer determines that prior authorization is required and, for the CY 2027 performance period/2029 MIPS payment year, that a successfully submitted request count even if a payer response is not received. A commenter also requested that CMS clarify whether conforming electronic prior authorization functionality delivered through an application connected to CEHRT, rather than embedded within CEHRT itself, may satisfy the measure.

Response: We appreciate the feedback from commenters, specifically the request for clarification regarding what constitutes a successful electronic prior authorization action for purposes of the

measure. For a prior authorization request for a medical item or service to qualify for the measure, the need for prior authorization must be established. Therefore, if a MIPS eligible clinician uses CEHRT to query a payer's Prior Authorization API and the payer responds that prior authorization is not required, the transaction would not satisfy the measure.

According to the Da Vinci IGs, the eligible clinician that queries a payer's Prior Authorization API will receive a response to the prior authorization request such as: *covered = not-covered* (that is, no coverage or possibility of coverage); *pa-needed = no-auth* (that is, service is covered and does not require prior authorization); *pa-needed = satisfied* (that is, prior authorization required, conditions evaluated, and authorization can be bypassed); *conditional* (that is, the payer cannot yet determine coverage, prior authorization, or documentation requirements); and *pa-needed = auth-needed* (that is, a prior authorization request is required, so the workflow can proceed through DTR and PAS until it is ultimately complete, having been approved or denied). To attest ''Yes'' for the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year, the electronic prior authorization request must result in a satisfied, approved, or denied request; submission of a request without receipt of a payer response would not be sufficient. For the CY 2027 performance period/2029 MIPS payment year, a MIPS eligible clinician may use one or any subset of the Health IT Modules certified to the electronic prior authorization certification criteria at 45 CFR 170.315(g)(31), (32), and (33), as necessary to complete a qualifying transaction. This approach accommodates variation in electronic prior authorization workflows based on the medical item or service and the payer's documentation requirements. A MIPS eligible clinician needs to only successfully complete one qualifying electronic prior authorization request for at least one medical item or service during the performance period to attest ''Yes'' for the measure. We will provide educational and guidance resources, as appropriate and feasible, to clarify qualifying workflows and implementation details.

With respect to the request for clarification about electronic prior authorization functionality delivered through an application connected to CEHRT, we recognize that electronic prior authorization workflows often involve multiple systems and entities, including EHRs, revenue cycle systems, payer systems, clearinghouses, health information exchanges, standards-based intermediaries, and other interoperable technology solutions. MIPS eligible clinicians may use health IT from more than one health IT developer, including applications connected to a primary EHR system, to meet CEHRT requirements to support electronic prior authorization exchange as long as the health IT applications are certified to at least one of the relevant ONC certification criteria required for the measure at 45 CFR 170.315(g)(31), (32), and (33) for the CY 2027 performance period/2029 MIPS payment year.

After consideration of public comment, we are finalizing, as proposed, the proposal to modify the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year by updating the measure description to amend the phrase from ''using data from CEHRT'' to ''using CEHRT'' to require that MIPS eligible clinicians must use certified Health IT Modules where necessary to support the electronic prior authorization processes specified for this measure. We note that the finalized, as proposed, policy that amends the Electronic Prior Authorization measure by modifying the measure description for the CY 2027 performance period/2029 MIPS payment year aligns with the same finalized, as proposed, policy for the Medicare Promoting Interoperability Program as finalized in the FY 2027 IPPS/LTCH PPS final rule (91 FR 50043 through 50047)

(iii) Modifying the Electronic Prior Authorization Measure Beginning With the CY 2028 Performance Period/2030 MIPS Payment Year

In the CY 2027 PFS proposed rule, we proposed amendments to the Electronic Prior Authorization measure description beginning with the CY 2028 performance period/2030 MIPS payment year to include a complete set of actions necessary to support robust prior authorization and require use of Health IT modules certified to the ONC health IT certification criteria at 45 CFR 170.315(g)(31),[405] (32),[406] and (33) [407] as part of the measure requirements (91 FR 44178). We proposed updating the measure in order to take a step-wise approach to the certified health IT capabilities necessary to complete the measure and ensure that MIPS eligible clinicians continue to progress towards adoption of capabilities necessary to fully support electronic prior authorization.

Specifically, in the CY 2027 PFS proposed rule (91 FR 44178) we proposed modifying the measure description as follows beginning with the CY 2028 performance period/2030 MIPS payment year: For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the MIPS eligible clinician uses CEHRT to electronically request and receive coverage requirements, request and populate prior authorization documentation using templates and rules, submit the prior authorization request, and receive the payer response through a provider Prior Authorization API (91 FR 44178).

We proposed modifying the measure description in the CY 2027 PFS proposed rule (91 FR 44178) to explicitly delineate the requirement to use technology certified to each of the relevant ONC health IT certification criteria for the Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year. We proposed modifying the measure description to specify the following actions required for meeting the requirement of the measure: ''electronically request and receive coverage requirements,'' ''request and populate prior authorization documentation using templates and rules,'' ''submit the prior authorization request,'' and ''receive the payer response'' (does not require the approval of the prior authorization request by the payer, but does require that the MIPS eligible clinician receive a prior authorization decision or determination response from the payer) to reflect the specific capabilities supported by Health IT Modules certified to the ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) (91 FR 44178). We noted that we would interpret this requirement to mean that each of these specific actions should occur within the same prior authorization request (91 FR 44178).

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for advancing the Electronic Prior Authorization measure toward a more complete, standards-

[405] *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-C/section-170.315#p-170.315(g)(31).*

[406] *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-C/section-170.315#p-170.315(g)(32).*

[407] *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-C/section-170.315#p-170.315(g)(33).*

based electronic prior authorization workflow beginning with the CY 2028 performance period/2030 MIPS payment year, including use of FHIR-enabled Health IT Modules certified to ONC's electronic prior authorization certification criteria. A few commenters suggested that alignment with standardized, certified electronic prior authorization capabilities would advance interoperability and electronic prior authorization adoption, support care coordination, and reduce administrative burden.

Response: We thank commenters for their support. We agree that the proposed modifications will advance a more complete, standards-based electronic prior authorization workflow by requiring certified health IT functionality that enables a complete set of actions necessary to support robust electronic prior authorization. We believe this approach will support broader adoption and improve interoperability.

Comment: Several commenters raised concerns with the modification to the Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year to require completion of the specified electronic prior authorization workflow for at least one medical item or service, excluding drugs. A commenter expressed concerns that the measure holds clinicians accountable for the responsiveness of a payer to a prior authorization request, which is outside of the clinician's control. Several commenters noted that the proposed workflow includes electronic prior authorization functionality supported by the ONC certification criteria for determining coverage requirements, assembling required documentation, submitting the prior authorization request, and receiving a payer response. A few commenters stated that although MIPS eligible clinicians may need to have the capabilities supporting the complete electronic prior authorization workflow available, not every prior authorization request requires use of every capability. Commenters noted that, depending on the circumstances of a particular request, one or more steps may not be necessary to resolve the authorization. For example, an initial coverage requirements exchange may determine that prior authorization is not required or that additional documentation is unnecessary.

Several commenters, therefore, recommended that CMS not require every component of the specified workflow for a given request to satisfy the measure but instead allow MIPS eligible clinicians to use the certified electronic prior authorization capabilities necessary to successfully complete the particular request. Several commenters cautioned that requiring transactions that are not necessary to resolve a particular prior authorization request could add administrative burden to a process that electronic prior authorization is intended to streamline.

Response: We recognize that individual prior authorization requests may not require every electronic prior authorization capability in all circumstances and that payers may not respond electronically to every prior authorization request made by clinicians. We note that to satisfy the Electronic Prior Authorization measure, a MIPS eligible clinician would attest ''Yes'' to completing the specified actions for at least one qualifying prior authorization request during the performance period. Successfully meeting the Electronic Prior Authorization measure does not require completion of the specified workflow for every prior authorization request. This approach appropriately advances adoption of the capabilities necessary to support robust, standards-based electronic prior authorization while limiting the reporting requirement to at least one qualifying request.

Comment: Several commenters requested clarification regarding the proposed requirement, beginning with the CY 2028 performance period/2030 MIPS payment year, for MIPS eligible clinicians to electronically request and receive coverage requirements, request and populate prior authorization documentation using templates and rules, submit the prior authorization request, and receive the payer response within the same qualifying prior authorization request. Commenters indicated that the actions necessary to complete a given prior authorization request may vary depending on the circumstances of the request and the payer's coverage and documentation requirements.

Several commenters therefore recommended that CMS allow MIPS eligible clinicians to complete only the electronic prior authorization actions necessary to resolve a given prior authorization request, rather than requiring each of the specified actions within the same request. A commenter specifically recommended that requesting and populating prior authorization documentation using templates and rules be required only when the payer requires additional documentation, noting that this action may not be necessary when the payer can complete the authorization without additional documentation.

Response: We recognize that electronic prior authorization workflows may vary depending on the medical item or service and the payer's coverage and documentation requirements. However, the modifications to the Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year are intended to advance the measure from the flexibility provided for the CY 2027 performance period/2029 MIPS payment year toward a more complete electronic prior authorization workflow.

To satisfy the Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year, a MIPS eligible clinician must use CEHRT to electronically request and receive coverage requirements; request and populate prior authorization documentation using templates and rules; submit the prior authorization request; and receive the payer response through a provider Prior Authorization API, with each of these actions occurring within the same qualifying prior authorization request. We note that the Electronic Prior Authorization measure requires a MIPS eligible clinician to attest ''Yes'' based on at least one qualifying prior authorization request during the performance period; it does not require completion of the specified workflow for every prior authorization request. We recognize that only a subset of prior authorization requests may require the use of all capabilities and that clinicians will continue to conduct prior authorization requests that do not require the complete set of capabilities, consistent with the documentation needs associated with a given prior authorization request.

Accordingly, we disagree with recommendations from commenters that would require only those actions that may be necessary for a particular request, including the recommendation to require the documentation templates and rules action only when additional documentation is otherwise needed. Requiring the specified actions within at least one qualifying request will advance adoption of the capabilities necessary to support a complete, standards-based electronic prior authorization workflow. As noted previously, our intent is to pursue a stepwise expansion of electronic prior authorization capabilities in 2028. The revised measure would enable meeting this goal by ensuring eligible clinicians demonstrate the adoption of these

capabilities for at least one prior authorization.

Comment: Several commenters expressed concerns regarding whether MIPS eligible clinicians, payers, and health IT vendors would be sufficiently ready to support the proposed modifications to the Electronic Prior Authorization measure that begin with the CY 2028 performance period/2030 MIPS payment year. These commenters highlighted the variability in payer, EHR, and health IT vendor readiness as a particular concern given that MIPS eligible clinicians depend on them to support electronic prior authorization transactions. Commenters stated that successful implementation of standardized electronic prior authorization capabilities would require coordination, integration, and testing across MIPS eligible clinicians, health IT developers, payers, and other intermediaries.

A commenter stated that, based on discussions with electronic prior authorization stakeholders, only functionality for coverage requirements determination is expected to be available in the CY 2027 performance period/2029 MIPS payment year, with end-to-end electronic prior authorization not expected to become available until at least the CY 2028 performance period/2030 MIPS payment year. The commenter cautioned that availability of the technology does not necessarily equate to operational readiness, noting that EHR developers, payers, and intermediaries would need to test end-to-end functionality throughout CY 2028 performance period/2030 MIPS payment year and that fully operational end-to-end electronic prior authorization may therefore not be realized until the CY 2029 performance period/2031 MIPS payment year at the earliest. Another commenter similarly noted that current implementation efforts are concentrated on coverage requirements discovery and that integrated use of the capabilities needed to support the complete electronic prior authorization workflow remains uncommon. Several commenters recommended that CMS monitor implementation and readiness of electronic prior authorization and adjust the measure requirements or implementation timeline, as needed, based on demonstrated readiness.

Response: We appreciate the feedback from commenters. In regard to commenters' concerns about ecosystem readiness to support the proposed CY 2028 performance period/2030 MIPS payment year requirement for MIPS eligible clinicians to use functionality represented by all three specified ONC electronic prior authorization certification criteria for the Electronic Prior Authorization measure. We recognize that successful implementation will require coordination among MIPS eligible clinicians, health IT developers, payers, and other partners, as well as time for development, certification, testing, integration, and workflow redesign. As discussed in sections IV.A.4.d.(4)(f)(v) and IV.B.1.d. of this final rule, we are finalizing, as proposed, the proposal to make the Electronic Prior Authorization measure an optional measure and eligible for bonus points for the CY 2027 performance period/2029 MIPS payment year. As discussed in section IV.A.4.d.(4)(f)(v) of this final rule, we are also finalizing, as proposed, the proposal to modify the Electronic Prior Authorization measure by requiring a MIPS eligible clinician to use CEHRT to electronically request and receive coverage requirements, request and populate prior authorization documentation using templates and rules, submit the prior authorization request, and receive the payer response through a provider prior authorization API beginning with the CY 2028 performance period/2030 MIPS payment year. We believe that such step-wise approach will allow participants additional time to gain implementation experience and advance operational readiness. We intend to assess implementation experience and coordinate with ONC and across CMS as standards, certified health IT capabilities, and payer-facing requirements continue to mature.

We further note that under the revised measure starting in the CY 2028 performance period/2030 MIPS payment year, we would continue to require the completion of only one prior authorization request consistent with the use of capabilities identified in the revised measure language. Eligible clinicians and health IT developers that need a longer period during CY 2028 to adopt and deploy technology within clinical workflows could continue testing and rollout activities during the CY 2028 performance period/2030 MIPS payment year and successfully complete an action satisfying the measure at the end of the performance period. Additionally, this measure, as proposed, includes exclusions that provide flexibility for MIPS eligible clinicians who may face challenges meeting the measure's requirements, including accommodation for where an applicable payer does not support the specified electronic prior authorization standard.

After consideration of public comment, we are finalizing, as proposed, the proposal to modify the Electronic Prior Authorization measure by requiring a MIPS eligible clinician to use CEHRT to electronically request and receive coverage requirements, request and populate prior authorization documentation using templates and rules, submit the prior authorization request, and receive the payer response through a provider prior authorization API beginning with the CY 2028 performance period/2030 MIPS payment year.

(iv) ONC Health IT Certification Criteria To Support the Electronic Prior Authorization Measure

In the CY 2027 PFS proposed rule, we proposed to require that an electronic prior authorization must be requested using CEHRT to satisfy the Electronic Prior Authorization measure (91 FR 44178 through 44180). We are requiring MIPS eligible clinicians to use Health IT Modules certified to the ONC health IT certification criteria in 45 CFR 170.315(g)(31), (32), and/or (33) as finalized in the HTI–4 final rule. Specifically, for the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians would be required to use CEHRT for electronic prior authorization requests that includes the utilization of one, or more than one, Health IT Modules certified to the ONC health IT certification criteria in 45 CFR 170.315(g)(31), (32), or (33) as necessary to meet the requirements of the Electronic Prior Authorization measure. Beginning with the CY 2028 performance period/2030 MIPS payment year, MIPS eligible clinicians would be required to use CEHRT for electronic prior authorization requests that includes the utilization of Health IT Modules certified to all three of the ONC health IT certification criteria in 45 CFR 170.315(g)(31), (32), and (33) to meet the requirements of the Electronic Prior Authorization measure. Using certified health IT to support these electronic prior authorization transactions ensures that MIPS eligible clinicians have standards-based capabilities within their health IT systems to interact with Prior Authorization APIs impacted payers are required to implement and maintain.

In the CY 2027 PFS proposed rule, we discussed how the three ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) are based on the HL7 Da Vinci CRD, DTR, and PAS IGs, and address different parts of the electronic prior authorization workflow (91 FR 44178). The ''provider

prior authorization API—coverage requirements discovery'' in 45 CFR 170.315(g)(31) enables a healthcare provider to request information from payers about coverage requirements. Where further information is needed to support a prior authorization request, the ''provider prior authorization API—documentation templates and rules'' criterion in 45 CFR 170.315(g)(32) provides a mechanism for providers to assemble the documentation needed to support a prior authorization request according to a payer's requirements. Lastly, the ''provider prior authorization API—prior authorization support'' in 45 CFR 170.315(g)(33) enables submission of prior authorization requests from health IT systems as well as to check the status of a previously submitted request. By finalizing each component of the workflow as a separate ONC health IT certification criterion, ONC sought to support a more dynamic health IT marketplace in which a health IT developer could develop Health IT Modules demonstrating conformance to all three IGs or focus on a specific element or elements (90 FR 37167 through 37169).

In the CY 2027 PFS proposed rule, we proposed to modify the Electronic Prior Authorization measure such that a MIPS eligible clinician could submit a ''Yes'' response, in which they are affirmatively attesting to the measure, if a ''prior authorization is requested electronically through a Prior Authorization API using CEHRT'' for the CY 2027 performance period/2029 MIPS payment year (91 FR 44178 through 44180). Different prior authorization scenarios that allow a MIPS eligible clinician to successfully attest to the measure for the CY 2027 performance period/2029 MIPS payment year may require the functionality of one, or more than one, Health IT Modules certified to the criteria in 45 CFR 170.315(g)(31), (32), and (33). For instance, a MIPS eligible clinician could successfully report on the measure for the CY 2027 performance period/2029 MIPS payment year using CEHRT that includes a Health IT Module that is only certified to the ''provider prior authorization API—coverage requirements discovery'' criterion in 45 CFR 170.315(g)(31), but not to the ONC health IT certification criteria at 45 CFR 170.315(g)(32) or (33).

Consider an example, from the CY 2027 proposed rule, in which a patient is a Medicare Advantage (MA) enrollee who has stable coronary artery disease and new exertional dyspnea (feeling shortness of breath during physical exertion) (91 FR 44179). The patient's cardiologist wants to order an outpatient transthoracic echocardiogram (TTE) to assess left ventricular function and valvular disease. When the cardiologist places an order for a TTE in the EHR, a Health IT Module certified to the ''provider prior authorization API—coverage requirements discovery'' criterion (45 CFR 170.315(g)(31)) automatically sends a real-time query to the patient's MA plan endpoint to determine whether prior authorization is required for the requested service (the TTE) and, if so, what documentation is needed. In this example, the MA plan returns a CRD response (via CDS Hooks ''card'') indicating that prior authorization is necessary and has been approved under the beneficiary's plan benefits and network status, including information such as the prior authorization number and assumed billing codes.

In this first example, the prior authorization request is satisfied using only the capabilities represented with the ''provider prior authorization API—coverage requirements discovery'' (45 CFR 170.315(g)(31)). The MIPS eligible clinician submitted a query for prior authorization, the payer responded that prior authorization was required, the prior authorization was approved without the need for further documentation, and the MIPS eligible clinician received a response indicating this approval from the payer through the payer's Prior Authorization API. In this case, the receipt of an approval indicates that the MIPS eligible clinician effectively submitted a request for prior authorization, consistent with the requirements of the Electronic Prior Authorization measure. Conversely, if the MIPS eligible clinician receives a response that no prior authorization is required, that query would not fulfill the requirements of the measure. Also, we considered whether the allowance of using CEHRT to conduct a check to determine if an item or service requires prior authorization should be able to satisfy the measure when the MIPS eligible clinician successfully submits a prior authorization coverage requirements determination query, regardless of whether the payer's response indicates that prior authorization is required. We requested comment on whether such additional flexibility would benefit MIPS eligible clinicians.

In the CY 2027 PFS proposed rule, we noted that based on feedback we have received from implementers about their likely approach to phasing in electronic prior authorization capabilities, we expect that the use of health IT certified to the ''provider prior authorization API—coverage requirements discovery'' (45 CFR 170.315(g)(31)), as described in the example above, may be a common approach for the CY 2027 performance period/2029 MIPS payment year (91 FR 44179). However, we noted that under the approach to use certified Health IT Modules for the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year as described in the CY 2027 PFS proposed rule, there could be additional scenarios that would qualify for the measure in which a MIPS eligible clinician uses only the Health IT Modules certified to the criteria in 45 CFR 170.315(g)(32) or (g)(33) as part of the workflow for submitting a prior authorization request (91 FR 44179).

For the following second example, the case illustrates a prior authorization workflow that would meet the requirements of the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year and also meet the more stringent requirements for the measure beginning with the CY 2028 performance period/2030 MIPS payment year, as described in the CY 2027 PFS proposed rule, when all three certified Health IT Modules in 45 CFR 170.315(g)(31), (32) and (33) would be required (91 FR 44179). The initial prior authorization query from a MIPS eligible clinician to a payer could result in a response indicating the need for additional information before a determination as to whether prior authorization is approved or denied can be provided, based on the coverage requirements identified. Additional certified Health IT Modules supporting additional elements of the electronic prior authorization workflow would then need to be used to submit the prior authorization request after collecting the necessary documentation and receive the decision.

The CY 2027 PFS proposed rule considered another example, in which the patient is an MA enrollee who has been diagnosed with metastatic colorectal cancer (91 FR 44179 through 44180). The patient's oncologist has ordered a PET–CT scan and immunotherapy infusion. The oncologist places the order for a PET–CT scan and immunotherapy infusion in the EHR, which is certified to the ''provider prior authorization API—coverage requirements discovery'' criterion (45 CFR 170.315(g)(31)) and automatically queries the patient's MA plan's FHIR API. The EHR receives a response via CDS Hooks card indicating that prior authorization is required for both services and describes coverage criteria and documentation needs.

Because the EHR is also certified to 45 CFR 170.315(g)(32), the certified health IT enables the oncologist to complete prior authorization following the DTR IG. An embedded Substitutable Medical Applications and Reusable Technologies (SMART) on FHIR app fetches the payer's specific documentation template and rules for oncology prior authorizations. For the PET–CT, the payer's documentation rules ask for the cancer staging information and previous imaging results; the immunotherapy, the payer's documentation rules require the patient's biomarker (for example, PD–L1 expression) status, prior treatment history, and recent lab results. Much of this information can be auto-populated because the embedded DTR app uses Clinical Quality Language (CQL) logic and FHIR queries to pull the patient's latest CT scan report and lab results from her medical record, and it confirms her cancer diagnosis and stage from the problem list. The oncologist answers a few additional questions (such as confirming the patient has no contraindications and that a required biomarker test was positive). By the end of this step, the EHR has compiled all necessary supporting documentation for the prior authorization, ensuring the request will be complete.

Next, the oncologist's office submits the prior authorization request electronically using the capabilities under the ''provider prior authorization API-prior authorization support'' criterion (45 CFR 170.315(g)(33)) to bundle the request and documentation and send it to the MA plan's prior authorization endpoint. This bundle is transmitted via a FHIR RESTful interaction to the payer, as defined by the PAS IG. The EHR's certified Health IT Module ensures the request conforms to the required FHIR structure and sends it securely. Because all required information was provided up front and matched the plan's coverage criteria, the MA plan's system could potentially automatically adjudicate and approve the requests in near real-time. If that happened, the oncologist could now schedule the patient's therapy without delay, confident that the services are covered.

Both examples result in a prior authorization request that would meet the modification to Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year because in each case, the MIPS eligible clinician requests prior authorization electronically using CEHRT. However, each example utilized different combinations of Health IT Modules certified to electronic prior authorization certification criteria in 45 CFR 170.315(g)(31), (32), and (33). In the first example, the MIPS eligible clinician used a single Health IT Module certified to the ''provider prior authorization API—coverage requirements discovery'' criterion (45 CFR 170.315(g)(31)) to complete actions necessary to successfully attest ''Yes'' to the Electronic Prior Authorization measure. In the second example, the MIPS eligible clinician used Health IT Modules certified to all three of the electronic prior authorization certification criteria to complete all actions for the MIPS eligible clinician to successfully attest ''Yes'' to the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year.

Consistent with the hypothetical examples, we note that a MIPS eligible clinician will be able to successfully attest ''Yes'' to the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year using only those certified Health IT Modules necessary to meet the requirements of the measure. MIPS eligible clinicians will not be required to adopt additional Health IT Modules certified to the applicable certification criteria if they are not needed for the purposes of successfully reporting the Electronic Prior Authorization measure. We expect that the ability to utilize different combinations of certified Health IT Modules to meet the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year will afford MIPS eligible clinicians and health IT developers flexibility in how they deploy, adopt, and use different aspects of certified health IT functionality for electronic prior authorization.

In the CY 2027 PFS proposed rule we proposed to modify the Electronic Prior Authorization measure language beginning with the CY 2028 performance period/2030 MIPS payment year to state that a MIPS eligible clinician must use CEHRT to ''electronically request and receive coverage requirements, request and populate prior authorization documentation using templates and rules, submit the prior authorization request, and receive the payer response through a provider prior authorization API'' (91 FR 44180). In order for a MIPS eligible clinician to attest ''Yes'' to the Electronic Prior Authorization measure, health IT Modules certified to all three criteria at 45 CFR 170.315(g)(31), (32), and (33) would be required, consistent with the actions associated with the proposed modifications to the measure, which require capabilities corresponding to each of the three ONC Health IT certification criteria . Only the second example described above, in which a prior authorization request is submitted after obtaining additional documentation necessary for the request and utilizing health IT certified to the complete set of ONC health IT certification criteria for electronic prior authorization, would meet the requirements of the measure for the CY 2028 performance period/2030 MIPS payment year.

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for the proposal to update the Electronic Prior Authorization measure to require use of specific FHIR-enabled Health IT Modules certified to ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and/or (33) to support electronic prior authorization transactions for medical items and services, excluding drugs. The commenters supported alignment of the measure with the specified ONC health IT certification criteria, which are based on the HL7 Da Vinci Coverage Requirements Discovery (CRD), Documentation Templates and Rules (DTR), and Prior Authorization Support (PAS) implementation guides and support different aspects of an electronic prior authorization workflow. Commenters stated that use of standardized, certified functionality could support interoperable electronic prior authorization workflows and reduce administrative burden.

A commenter specifically supported requiring the complete electronic prior authorization workflow supported by CRD, DTR, and PAS. A few commenters also supported the proposed implementation flexibility provided under the proposed CY 2027 performance period/2029 MIPS payment year measure specifications, under which MIPS eligible clinicians could use one or more certified Health IT Modules as necessary to support the applicable electronic prior authorization workflow.

Response: We appreciate the support from commenters. We agree with commenters that aligning the Electronic Prior Authorization measure with ONC's electronic prior authorization certification criteria will promote use of standardized, interoperable functionality that supports electronic prior authorization workflows. Also, we

agree with commenters that allowing MIPS eligible clinicians, for the CY 2027 performance period/CY 2029 MIPS payment year, to use one or more certified Health IT Modules as necessary to complete a qualifying electronic prior authorization request provides appropriate implementation flexibility as these capabilities continue to mature and become integrated into clinical workflows.

Comment: Several commenters raised concerns or requested clarification regarding the proposed requirement for MIPS eligible clinicians to use CEHRT that includes Health IT Modules certified to the ONC electronic prior authorization certification criteria at 45 CFR 170.315(g)(31), (32), and (33). Commenters discussed the role of the three certification criteria as the technical foundation for the Electronic Prior Authorization measure, noting that the criteria correspond to the CRD, DTR, and PAS implementation guides and support different components of the electronic prior authorization workflow.

Several commenters requested clarification regarding how the certified functionality would be used or interpreted for purposes of satisfying the measure, including whether the measure may be satisfied using CRD, DTR, PAS, or a combination of these capabilities. A few commenters specifically recommended that a CRD response, indicating prior authorization is not required, should qualify as a successful transaction rather than requiring subsequent DTR or PAS functionality; the commenters noted that electronically determining prior authorization is not required provides useful information and can avoid unnecessary documentation, payer portal checks, phone calls, and other administrative processes. A commenter requested clarification regarding whether conforming electronic prior authorization functionality delivered through an application connected to CEHRT, rather than embedded within CEHRT itself, may satisfy the measure. Another commenter requested clarification regarding what constitutes a ''decision or determination response,'' including whether payer responses requiring further interaction outside the electronic workflow, such as a peer-to-peer review or referral to a delegated benefit manager, may satisfy the measure.

Response: The ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) support different components of an electronic prior authorization workflow, including coverage requirements discovery, documentation templates and rules, and prior authorization support. For the CY 2027 performance period/2029 MIPS payment year, a MIPS eligible clinician could use one or more certified Health IT Modules, as necessary to complete a qualifying prior authorization request. Beginning with the CY 2028 performance period/2030 MIPS payment year, clinicians would be required to use health IT that is certified to all three certification criteria to complete the actions specified in the measure within the same qualifying prior authorization request.

We disagree with commenters that a coverage requirement response indicating that prior authorization is not required should independently satisfy the Electronic Prior Authorization measure. A medical item or service that the payer determines does not require prior authorization is not within the scope of the measure because no prior authorization request is required or submitted. Although electronically determining whether prior authorization is required is an important component of the electronic prior authorization workflow, such a response would not satisfy the Electronic Prior Authorization measure for the CY 2028 performance period/2030 MIPS payment year due to the documentation and prior authorization submission actions specified in the measure would not occur.

With respect to how the certified functionality may be implemented, the intent is not to prohibit the use of applications, intermediaries, or other interoperable tools that are integrated with CEHRT and support the electronic prior authorization workflow. Rather, the Electronic Prior Authorization measure is intended to ensure that MIPS eligible clinicians have access to, and use, standards-based health IT functionality certified to ONC's electronic prior authorization health IT certification criteria to complete the required measure actions. Such approach supports a consistent technical foundation for electronic prior authorization within clinician workflows, while allowing Health IT Modules certified to the relevant criteria to be deployed in configurations that meet the operational needs of a MIPS eligible clinician.

Also, we clarify that receipt of a payer response does not require approval of the prior authorization request. A qualifying request may result in an approval or denial, provided that the MIPS eligible clinician completes the applicable measure requirements and receives the payer's decision or determination response through the provider Prior Authorization API. Where the payer's response indicates that additional documentation or other electronic action is needed before a decision can be made, the MIPS eligible clinician would need to complete the applicable workflow actions for the request to satisfy the measure. We will provide educational and guidance resources, as appropriate and feasible, to support consistent implementation and reporting.

Comment: Several commenters raised concerns about ecosystem readiness to support the proposed use of FHIR-enabled Health IT Modules certified to the ONC health IT certification criteria for the Electronic Prior Authorization measure. Specific concerns included ongoing interoperability challenges, limited payer readiness to support FHIR-based prior authorization, and EHR developers that are still building, testing, and refining connectivity to payer Prior Authorization APIs at scale. A commenter requested further guidance on how clinicians and EHR developers would identify and connect to payer API endpoints and raised concerns that some payers may continue to rely on existing portal-based processes rather than transition to API-enabled exchange.

A few commenters specifically raised concerns about the maturity of the CRD, DTR, and PAS capabilities needed to support the proposed certified health IT requirements. A commenter, based on their assessment of the current state of implementation, reported that implementation efforts remain largely concentrated on CRD and that integrated use of CRD, DTR, and PAS across payers, EHR developers, and provider workflows remains uncommon. The commenter questioned whether widespread, integrated use of all three capabilities would be achievable across medical groups by the CY 2028 performance period/2030 MIPS payment year and cited recent industry implementation activity focused primarily on CRD rather than full deployment of all three capabilities. A few commenters emphasized that successful implementation depends on factors including payer conformance, EHR developer readiness, workflow integration, testing, and operational support.

Several commenters recommended that CMS account for ecosystem readiness in implementing the certified health IT requirements. A commenter recommended using the CY 2027 performance period/2029 MIPS payment year as a transition period to evaluate real-world readiness and provide educational resources and technical assistance to support

implementation, while another encouraged CMS and ONC to coordinate implementation timelines and requirements for EHR developers to support feasibility for clinicians. Some commenters also recommended that CMS allow additional time for implementation of the certified health IT requirements and align implementation timelines with the availability and readiness of the required functionality.

Response: We appreciate commenters' concerns regarding the readiness of the health IT ecosystem to support standards-based electronic prior authorization. We recognize that successful implementation of the Electronic Prior Authorization measure depends on coordination among MIPS eligible clinicians, health IT developers, payers, intermediaries, and other partners, as well as on technical development, testing, workflow integration, training, and operational support.

The proposed phased approach appropriately balances these considerations with the goal of advancing interoperable electronic prior authorization. For the CY 2027 performance period/2029 MIPS payment year, we are finalizing our proposal to make the Electronic Prior Authorization measure optional and eligible for bonus points, allowing MIPS eligible clinicians and their health IT developers additional flexibility to implement, test, and gain experience with certified electronic prior authorization capabilities before the measure would be required beginning with the CY 2028 performance period/2030 MIPS payment year. For the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians could use one or more certified Health IT Modules, as necessary to complete a qualifying electronic prior authorization request.

We acknowledge commenters' concerns regarding the maturity of integrated CRD, DTR, and PAS capabilities and agree that ongoing coordination among CMS, ONC, payers, health IT developers, and clinicians will be important. We intend to assess implementation experience and consider recommendations from commenters as we develop educational and guidance resources, as appropriate and feasible. The measure is intended to advance the availability and use of standards-based, certified electronic prior authorization functionality through CEHRT, while supporting a transition away from fragmented and manual prior authorization processes.

Comment: Several commenters highlighted the importance of alignment between CMS Promoting Interoperability requirements and related ONC health IT certification policies. Commenters recommended continued CMS and ONC coordination to ensure consistent or parallel implementation timelines, certification criteria, and requirements for EHR vendors so that certified health IT supports MIPS eligible clinicians and ACOs in meeting electronic prior authorization reporting requirements. A commenter expressed appreciation for CMS's efforts to align Promoting Interoperability requirements with ONC health IT certification criteria.

Response: We appreciate the support from commenters regarding the continued alignment between CMS Promoting Interoperability requirements and ONC health IT certification policies. We agree with commenters that aligning the Electronic Prior Authorization measure with the ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) supports a consistent technical foundation for standards-based electronic prior authorization and we will continue to coordinate with ONC and across other CMS programs, as appropriate, to promote consistency in implementation.

Comment: A commenter recommended applying a consistent approach to electronic prior authorization requirements under the Promoting Interoperability Program.

Response: We believe that, although use of technology certified to all three criteria may not be required to satisfy the Electronic Prior Authorization measure in the CY 2027 performance period/2029 MIPS payment year, it is important for eligible clinicians to rapidly gain experience with use of technology certified to all three ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) in advance of the implementation of the revised measure in 2028 requiring technology supporting the all of the components of an electronic prior authorization workflow. We will continue to work across CMS programs to help ensure that over time and as appropriate, there are consistent electronic prior authorization measure requirements.

After consideration of public comment, we are finalizing, as proposed, the proposal to require MIPS eligible clinicians to use CEHRT that includes Health IT Modules certified to the ONC Health IT certification criteria at 45 CFR 170.315(g)(31), (32), and/or (33), as applicable, to satisfy the Electronic Prior Authorization measure. Specifically in the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians would be required to use CEHRT for electronic prior authorization requests that includes the utilization of one, or more than one, Health IT Modules certified to the ONC health IT certification criteria necessary for the measure as finalized the CY 2027 performance period/2029 MIPS payment year. Beginning with the CY 2028 performance period/2030 MIPS payment year, MIPS eligible clinicians would be required to use CEHRT for electronic prior authorization requests that includes Health IT Modules certified to all three ONC Health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) consistent with the revised measure finalized for the CY 2028 performance period/2030 MIPS payment year.

(v) Modifying the Electronic Prior Authorization Measure to an Optional Measure for the CY 2027 Performance Period/2029 MIPS Payment Year

In the CY 2027 PFS proposed rule (91 FR 44180 and 44181), we proposed to amend the previously finalized requirement that required MIPS eligible clinicians to report the Electronic Prior Authorization measure in order to be considered a meaningful EHR user for the CY 2027 performance period/2029 MIPS payment year (89 FR 8916 through 8919). Subsequent to the Electronic Prior Authorization measure being established, we proposed in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule to require that impacted payers implement and maintain Prior Authorization APIs that use HL7 FHIR and conform to the HL7 FHIR Da Vinci CRD, DTR, and PAS implementation guides, as adopted by ONC, with compliance generally beginning October 1, 2027 (91 FR 19910 through 19911). In the CY 2027 PFS proposed rule (91 FR 44180), it was noted that we expect additional implementation complexity for MIPS eligible clinicians, who are downstream from impacted payers and health IT developers who would be required to implement such API standards version requirements in CY 2027 if the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule is finalized as proposed (91 FR 19910 through 19911). As a result, we believe that MIPS eligible clinicians may need additional time and flexibility before requiring the Electronic Prior Authorization measure to account for such changes to the underlying transaction standards occurring in CY 2027. First, we recognize that MIPS eligible clinicians and health IT developers would need

additional time for procurement, integration, and testing to operationalize standards-based electronic prior authorization capabilities that support the Electronic Prior Authorization measure (91 FR 44180). Second, interested parties have indicated that achieving widespread implementation and routine use of these capabilities in CY 2027 may be challenging, particularly for small, rural, and otherwise under-resourced MIPS eligible clinicians (91 FR 44180). Third, there may be additional implementation complexity for MIPS eligible clinicians because the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule includes proposals to update the versions of underlying transaction standards within the relevant ONC health IT certification criteria (91 FR 44180). For such reasons, a year of optional reporting would both incentivize adoption of Health IT Modules certified to ONC criteria for electronic prior authorization through bonus points and offer flexibility to those MIPS eligible clinicians that could benefit from additional time to test, implement, and deploy the CEHRT functionality that is required to support the Electronic Prior Authorization measure. In the CY 2027 PFS proposed rule (91 FR 44180), we note that we do not believe that finalization of this proposal is contingent on finalization of proposals in the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule because health care providers, payers, and health IT developers have already begun to adopt and test standards-based electronic prior authorization capabilities, and we expect standards adoption, conformance testing, and validation for the relevant Health IT Modules to continue.[408]

Therefore, in the CY 2027 PFS proposed rule (91 FR 44180 and 44181), we proposed to modify the Electronic Prior Authorization measure, with the proposed measure updates, to be an optional measure. The measure would be eligible for 10 bonus points for MIPS eligible clinicians who submit a ''Yes'' response for the measure indicating that they have requested a prior authorization electronically using CEHRT from a payer's Prior Authorization API for at least one medical item or service (excluding drugs) ordered within the CY 2027 performance period. To account for the Electronic Prior Authorization measure being an optional measure for the CY 2027 performance period/2029 MIPS payment year with an allocation of 10 bonus points, we proposed to modify the scoring methodology for optional measures under the MIPS Promoting Interoperability performance category as described in the CY 2027 PFS proposed rule (91 FR 44205 and 44206). Under the proposal to modify the Electronic Prior Authorization measure from a required measure to an optional measure, a MIPS eligible clinician who submits a ''No'' response would not have an affected score for the MIPS Promoting Interoperability performance category, and their response would not impact the MIPS eligible clinician being considered a meaningful EHR user for the CY 2027 performance period/2029 MIPS payment year.

Such modification would change the policy adopted for the Electronic Prior Authorization measure as finalized in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8911). As described in the CY 2027 PFS proposed rule, the optional reporting of the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year may be particularly beneficial for MIPS eligible clinicians in small, rural, or otherwise under-resourced clinical practice settings navigating new measure requirements while minimizing and balancing operational and reporting burden and demand (91 FR 44181). Under the proposal to amend the Electronic Prior Authorization measure by modifying the measure from a required measure to an optional measure, exclusions would not be available for the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year because there would be no negative consequences for MIPS eligible clinicians who do not report on the optional measure (91 FR 41881). Given the allocated timeframe for MIPS eligible clinicians to become familiar with the Electronic Prior Authorization measure since the CY 2024 performance period as provided in the 2024 CMS Interoperability and Prior Authorization final rule, we believe that proposing to amend the Electronic Prior Authorization measure by modifying it from being a required measure to being as an optional bonus measure solely for the CY 2027 performance period/2029 MIPS payment year will provide MIPS eligible clinicians sufficient time to adopt and begin utilizing the certified health IT necessary to successfully report the Electronic Prior Authorization measure.

In the CY 2027 PFS proposed rule (91 FR 44181), we noted that the proposal to amend the Electronic Prior Authorization measure by modifying the measure requirement from being a required measure to an optional measure for the CY 2027 performance period/2029 MIPS payment year aligned with the same proposal for the Medicare Promoting Interoperability Program as proposed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19625).

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to modify the Electronic Prior Authorization measure to be optional for the CY 2027 performance period/2029 MIPS payment year. Many commenters expressed appreciation that making the Electronic Prior Authorization measure optional for the CY 2027 performance period/2029 MIPS payment year would allow additional time and flexibility to ensure payer, health IT developer, and physician readiness, including testing and operationalizing electronic prior authorization workflows. A few commenters specifically supported making the measure eligible for bonus points during the CY 2027 performance period, noting that the incentive could encourage early adoption of electronic prior authorization. A commenter stated that the bonus opportunity would further strengthen incentives for clinicians to use electronic prior authorization tools associated with the 2024 CMS Interoperability and Prior Authorization final rule.

A few commenters supported the phased implementation approach, noting its alignment with previously implemented Promoting Interoperability measures and the Electronic Prior Authorization measure proposed for the Medicare Promoting Interoperability Program in the FY 2027 IPPS/LTCH PPS proposed rule. A few commenters also stated that optional reporting would provide time for practices to prepare for implementation of the modified measure requirements, particularly small, rural, and other under-resourced practices. A few commenters noted that the optional reporting approach could reduce reporting burden while providing practices additional time to implement evolving interoperability requirements.

Response: We appreciate the support from commenters regarding the proposal to make the Electronic Prior Authorization measure optional and

[408] For example, CMS has announced early adopters advancing electronic prior authorization solutions; *see https://www.cms.gov/newsroom/press-releases/cms-announces-early-adopters-advance-solutions-electronic-prior-authorization-accelerating-momentum.*

eligible for bonus points for the CY 2027 performance period/2029 MIPS payment year. We agree with commenters that the phased approach would provide MIPS eligible clinicians, payers, and health IT developers additional flexibility and incentive implementation, testing, and operationalization of electronic prior authorization capabilities and workflows before the modified measure requirements would apply beginning with the CY 2028 performance period/2030 MIPS payment year.

Also, we agree with commenters that the optional reporting period may be particularly beneficial for small, rural, and other under-resourced practices by providing additional time to prepare for evolving interoperability requirements while encouraging early adoption of standards-based electronic prior authorization.

Comment: Several commenters expressed concerns about ecosystem readiness during the CY 2027 performance period to support the Electronic Prior Authorization measure. A few commenters noted that MIPS eligible clinicians depend on factors outside their control, including payer API readiness, availability of certified health IT, vendor implementation timelines, and integration of electronic prior authorization functionality into provider workflows. A few commenters also raised concerns about alignment between provider-side and payer standards and the resulting challenges for workflow integration across the industry.

Commenters noted that these dependencies may require additional implementation time and supported flexibility during the CY 2027 performance period to allow clinicians, payers, and health IT developers to gain experience and advance operational readiness. A few commenters specifically emphasized the need for additional flexibility for small, rural, and under-resourced practices as electronic prior authorization capabilities continue to mature.

Response: We recognize that successful implementation of electronic prior authorization depends on alignment among MIPS eligible clinicians, health IT developers, and payers. We intend for the implementation of the Electronic Prior Authorization measure to encourage continued progress toward broader implementation and workflow integration across the ecosystem. With regard to concerns about readiness, we note that one year of reporting the Electronic Prior Authorization measure as an optional bonus measure provides sufficient time for MIPS eligible clinicians, including small, rural, and under-resource practices, to successfully deploy and test EHR upgrades by working with vendors, and to address any current challenges to electronic prior authorization implementation. The optional bonus year will also provide MIPS eligible clinicians with the opportunity to gain experience with and become familiar with the Electronic Prior Authorization measure without facing a penalty.

Comment: A few commenters recommended extending the optional reporting period beyond the CY 2027 performance period/2029 MIPS payment year or delaying mandatory reporting until CY 2029 performance period/2031 MIPS payment year or later, to allow adequate time for configuration, testing, training, and maturation of electronic prior authorization workflows across MIPS eligible clinicians, payers, EHR developers, and clearinghouses, and to allow practices and providers to become familiar with the Electronic Prior Authorization measure. Several commenters recommended that CMS assess payer, health IT developer, and MIPS eligible clinician readiness to inform implementation of the measure.

A few commenters also recommended aligning the implementation timeline for the Electronic Prior Authorization measure for medical items and services with the proposed Electronic Prior Authorization for Prescription Drugs measure, noting that aligned timelines could allow EHR implementation activities for the two measures to occur concurrently.

Response: We appreciate feedback from commenters regarding the implementation timeline. We believe that making the measure an optional measure and eligible for 10 bonus points for the CY 2027 performance period/2029 MIPS payment year provides appropriate implementation flexibility before the measure becomes required beginning with the CY 2028 performance period/2030 MIPS payment year. We intend to assess implementation experience, payer and health IT readiness, technological advancements, and the availability of ONC-certified health IT as the measure is implemented. Also, we recognize the benefits of aligning implementation activities with the proposed Electronic Prior Authorization for Prescription Drugs measure, which is reflected in our final policies because the Electronic Prior Authorization for Prescription Drugs measure would also be required beginning in the CY 2028 performance period/2030 MIPS payment year.

After consideration of public comment, we are finalizing, as proposed, the proposal to modify the Electronic Prior Authorization measure to be an optional measure and eligible for 10 bonus points for the CY 2027 performance period/2029 MIPS payment year.

We refer readers to Tables C–G 2, C–G 4, C–G 6, and C–G 8 in sections IV.A.4.d.(4)(g)(i), IV.A.4.d.(4)(g)(ii)(D), and IV.A.4.d.(4)(g)(iv) of this final rule for information regarding the reporting requirements and scoring methodology of the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year. We note that the finalized, as proposed, policy to amend the Electronic Prior Authorization measure by modifying the measure from being a required measure to an optional measure and eligible for 10 bonus points for the CY 2027 performance period/2029 MIPS payment year aligns with the same finalized, as proposed, policy for the Medicare Promoting Interoperability Program as finalized in the FY 2027 IPPS/LTCH PPS final rule (91 FR 50052).

(vi) Requiring the Electronic Prior Authorization Measure Beginning With the CY 2028 Performance Period/2030 MIPS Payment Year

When the Electronic Prior Authorization measure was adopted in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we finalized that for a MIPS eligible clinician to satisfactorily meet the requirements of the measure, they would be required to affirmatively attest or claim an applicable exclusion for the Electronic Prior Authorization measure beginning with the CY 2027 performance period/2029 MIPS payment year (89 FR 8910). If a MIPS eligible clinician submits a ''No'' response, fails to submit any attestation, or does not claim an applicable exclusion for the Electronic Prior Authorization measure, the MIPS eligible clinician would receive a score of zero for the MIPS Promoting Interoperability performance category (weighted at 25 percent of the MIPS final score) and would not be considered a meaningful EHR user for purposes of the MIPS Promoting Interoperability performance category for the applicable performance period (89 FR 8911).

In the CY 2027 PFS proposed rule, we proposed to amend the Electronic Prior Authorization measure by modifying the measure to require MIPS eligible clinicians to report the Electronic Prior Authorization measure beginning with

the CY 2028 performance period/2030 MIPS payment year (91 FR 44181 and 44182). Specifically, beginning with the CY 2028 performance period/2030 MIPS payment year, we proposed that a MIPS eligible clinician must use CEHRT to electronically request and receive coverage requirements, request and populate prior authorization documentation using templates and rules, submit the prior authorization request, and receive the payer response through a Prior Authorization API for at least one medical item or service (excluding drugs) ordered within the applicable performance period. A MIPS eligible clinician would submit a ''Yes'' response, or alternatively claim an applicable exclusion, to satisfy the requirements of the Electronic Prior Authorization measure. In each case, the Electronic Prior Authorization measure would not affect the total score for the MIPS Promoting Interoperability performance category. If a MIPS eligible clinician submits a ''No'' response, fails to submit any attestation, or does not claim an applicable exclusion for the Electronic Prior Authorization measure, the MIPS eligible clinician would receive a score of zero for the MIPS Promoting Interoperability performance category (weighted at 25 percent of the MIPS final score) and would not be considered a meaningful EHR user for purposes of the MIPS Promoting Interoperability performance category for the applicable performance period (89 FR 8911). As noted in the CY 2027 PFS proposed rule (91 FR 44181), the proposal reflects the measure reporting requirements that were first adopted for the Electronic Prior Authorization measure as described in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8911), but modifies the measure to being a required measure for the MIPS Promoting Interoperability performance category beginning with the CY 2028 performance period/2030 MIPS payment year instead of beginning with the CY 2027 performance period/2029 MIPS payment year as originally finalized.

As described in the CY 2027 PFS proposed rule (91 FR 44181 and 44182), the measure exclusions originally adopted in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8923 and 8924 would be available to MIPS eligible clinicians for the CY 2028 performance period/2030 MIPS payment year and subsequent years. The available exclusions would be for any MIPS eligible clinician who: (1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance period; or (2) Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets CMS's Prior Authorization API requirements during the applicable performance period. A MIPS eligible clinician would also be able to claim the first exclusion if none of its prior authorization requests required the functionality described in the certification criteria at 45 CFR 170.315(g)(31), (32) and (33) for electronic prior authorization, which correspond to the elements of the revised measure language for the CY 2028 performance period/2030 MIPS payment year. For instance, if no prior authorization request submitted by a MIPS eligible clinician during the performance period required gathering and submitting additional documentation to support the request, which is supported by health IT certified to the criteria in 45 CFR 170.315(g)(32) and 45 CFR 170.315(g)(33), then no prior authorization request that MIPS eligible clinician performed would fulfill the measure and the MIPS eligible clinician will be able to claim an exclusion. More broadly, if the MIPS eligible clinician is unable to use CEHRT to effectively exchange information and submit a prior authorization request with any payer from which they are seeking an authorization, we believe that would be sufficient for a MIPS eligible clinician to claim that the payer does not have a functioning Prior Authorization API for the purpose of the reporting and exclusion eligibility.

In the CY 2027 PFS proposed rule, we noted that CMS's specified payer Prior Authorization API requirements include conformance to the three IGs underlying the ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) (91 FR 44182). Therefore, a MIPS eligible clinician could claim the second exclusion if all their requests are with payers that do not support all three FHIR IGs.

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to require the Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year, with some commenters specifically supporting the phased approach of allowing optional reporting for the CY 2027 performance period/2029 MIPS payment year before transitioning to mandatory reporting for the CY 2028 performance period/2030 MIPS payment year. Commenters noted that making the measure required could help drive adoption of standardized electronic prior authorization capabilities, complement impacted payers' implementation and maintenance of Prior Authorization APIs under the 2024 CMS Interoperability and Prior Authorization final rule (CMS–0057–F), reduce administrative burden and delays, and streamline the prior authorization experience for patients, MIPS eligible clinicians, and payers.

Response: We appreciate the support from commenters. We agree with commenters that making the Electronic Prior Authorization measure optional for the CY 2027 performance period/2029 MIPS payment year before requiring it beginning with the CY 2028 performance period/2030 MIPS payment year provides an appropriate phased approach to advance adoption of standards-based electronic prior authorization. We believe requiring the measure beginning with the CY 2028 performance period/2030 MIPS payment year will support MIPS eligible clinicians' use of the Prior Authorization APIs that applicable payers must implement and maintain, promote broader adoption and interoperability, and help reduce administrative burden. We discuss comments regarding the scoring implications of the measure in section IV.A.4.d.(4)(g)(ii) of this final rule.

Comment: Many commenters either opposed making the Electronic Prior Authorization measure mandatory beginning with the CY 2028 performance period/2030 MIPS payment year or recommended delaying mandatory reporting until the CY 2029 performance period/2031 MIPS payment year or later. Commenters stated that the proposed timeline would not provide sufficient lead time for payers, EHR developers and other health IT vendors, MIPS eligible clinicians, and other stakeholders to implement, test, integrate, and operationalize reliable end-to-end electronic prior authorization capabilities. A few commenters expressed concern that changing measure specifications for the Electronic Prior Authorization measure while making it a mandatory measure and adding a new Electronic Prior Authorization for Prescription Drugs measure in the CY 2028 performance period/2030 MIPS payment year may add operational and technical burden for clinicians, specifically as a result of

having to update developer workflows. Commenters emphasized the importance of sufficient lead time to establish ecosystem readiness, particularly given variation in payer and vendor readiness and the ongoing development and uneven availability of standards-based, FHIR-based electronic prior authorization functionality.

Several commenters recommended extending optional reporting of the Electronic Prior Authorization measure beyond the CY 2027 performance period/2029 MIPS payment year. Several commenters requested that CMS use the period of optional reporting to evaluate real-world implementation and ecosystem readiness before transitioning to mandatory reporting. A commenter specifically recommended that CMS assess the number of impacted payers operating a conformant prior authorization API as a measure of ecosystem readiness. Several commenters expressed concern that MIPS eligible clinicians could be held accountable for technology, interoperability, payer, or vendor limitations outside their control. A few commenters noted that implementation challenges may be particularly significant for small, rural, and other resource constrained practices.

Response: We recognize that successful implementation depends on coordination across the healthcare ecosystem, including the availability and deployment of certified health IT and payer support for electronic prior authorization transactions. However, we believe that making the Electronic Prior Authorization measure optional and eligible for bonus points for the CY 2027 performance period/2029 MIPS payment year provides an appropriate transition to required reporting beginning with the CY 2028 performance period/2030 MIPS payment year. The optional reporting year provides MIPS eligible clinicians, including small, rural, and other resource-constrained practices, an opportunity to gain experience with the measure, work with health IT developers to deploy and test necessary capabilities, and address implementation challenges without a negative effect on their Promoting Interoperability performance category score. Additionally, we believe the modifications to the Electronic Prior Authorization measure and the implementation of the Electronic Prior Authorization for Prescription Drugs measure are appropriate and necessary to advance more consistent electronic prior authorization processes across care settings. We expect these concurrent measure additions will promote greater standardization and interoperability over time, which would ultimately reduce manual processes, duplicative work, and administrative burden on clinicians.

We intend to assess implementation experience, payer and health IT readiness, technological advancements, and the availability of ONC-certified health IT as the measure is implemented. Requiring the measure beginning with the CY 2028 performance period/2030 MIPS payment year will support MIPS eligible clinicians' use of the Prior Authorization APIs that applicable payers must implement and maintain and advance broader adoption of standards-based electronic prior authorization.

Comment: Several commenters recommended that implementation of the mandatory Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year be aligned across applicable CMS programs and coordinated with related payer requirements. Commenters specifically requested consistency in measure requirements and implementation timelines across clinician and hospital programs and for clinician requirements to be appropriately sequenced with payer Prior Authorization API obligations.

Response: We appreciate feedback from commenters regarding alignment of Electronic Prior Authorization requirements across CMS programs and related payer requirements. We agree that the alignment of applicable requirements among MIPS eligible clinicians, eligible hospitals and CAHs, health IT developers, and payers is important to support consistent, standards-based electronic prior authorization workflows. We recognize that the proposed policy in the CY 2027 PFS proposed rule and the finalized, as proposed, policy in this final rule that requires MIPS eligible clinicians to use CEHRT for electronic prior authorization requests that includes the utilization of Health IT Modules certified to all three of the ONC health IT certification criteria in 45 CFR 170.315(g)(31), (32), and (33) to meet the requirements of the Electronic Prior Authorization measure starting with the CY 2028 performance period/2030 MIPS payment year differs from the finalized, as proposed, policy in the FY 2027 IPPS/LTCH PPS final rule pertaining to the Electronic Prior Authorization measure requirements applicable to eligible hospitals and CAHs. In the FY 2027 IPPS/LTCH PPS final rule (91 FR 50047), we stated that we are strongly considering returning to rulemaking in the FY 2028 IPPS.LTCH PPS proposal rule in order to align the Electronic Prior Authorization measure requirements to match the proposed requirements for MIPS eligible clinicians in the CY 2027 PFS proposed rule, which proposed to require the use of functionality found in each of the three ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) for CY 2028. Also, we note that the requirements for the Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year align with related CMS and ONC policies; particularly, the Electronic Prior Authorization measure requires the same electronic prior authorization standards established by related CMS and ONC policies, including the ONC health IT certification criteria and payer Prior Authorization API requirements. We will continue to coordinate across CMS programs and with ONC to promote consistency in requirements and implementation timelines as electronic prior authorization capabilities mature.

After consideration of public comment, we are finalizing, as proposed, the proposal to require MIPS eligible clinicians to report the Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year.

We refer readers to Table C–G 2, Table C–G 5, Table C–G 6, and Table C–G 8 in sections IV.A.4.d.(4)(g)(i), IV.A.4.d.(4)(g)(ii)(D), and IV.A.4.d.(4)(g)(iv) of this final rule for information regarding the reporting requirements and scoring methodology of the MIPS Promoting Interoperability performance category beginning with the CY 2028 performance period/2030 MIPS payment year. We note that the finalized, as proposed, policy to amend the Electronic Prior Authorization measure by modifying the measure to be a required measure beginning with CY 2028 performance period/2030 MIPS payment year aligns with the same finalized, as proposed, policy for the Medicare Promoting Interoperability Program as finalized in the FY 2027 IPPS/LTCH PPS final rule (91 FR 50054). As noted in the FY 2027 IPPS/LTCH PPS final rule, we are strongly considering proposals in the FY 2028 IPPS/LTCH PPS final rule to align the Electronic Prior Authorization measure with the revisions we are finalizing for the MIPS Promoting Interoperability performance category (91 FR 50044 through 50047).

(vii) Request for Information on Future Potential Performance-Based Measure of Electronic Prior Authorization

In the CY 2027 PFS proposed rule, we solicited comments on potential future updates we could make to the Electronic Prior Authorization measures, including the Electronic Prior Authorization measure and the Electronic Prior Authorization for Prescription Drugs measure, to incentivize MIPS eligible clinicians to use CEHRT for electronic prior authorization for a more substantial set of the electronic prior authorization requests that they submit over the course of a performance period and corresponding MIPS payment year (91 FR 44182). Specifically, we sought feedback on barriers and challenges that MIPS eligible clinicians in small, rural, or otherwise under-resourced practice settings might face when reporting performance-based electronic prior authorization measures; what alternative approaches should be considered to support use of electronic prior authorization; and how we can further strengthen the Electronic Prior Authorization measures in a manner that incentivizes progress while avoiding undue administrative complexity and implementation challenges for MIPS eligible clinicians (91 FR 44182).

We received many comments on this RFI, and thank commenters for their feedback. Although we will not be addressing the comments received in response to the RFI in this final rule, we value the input received and will take into consideration the feedback as we assess changes to the Electronic Prior Authorization measure included in the MIPS Promoting Interoperability performance category.

(g) Modifying Requirements and Scoring Policies for the MIPS Promoting Interoperability Performance Category

(i) Modifying Objectives and Measures

In the CY 2027 PFS proposed rule, we proposed updates to requirements and scoring policies for different performance periods (91 FR 44182 through 44198). For reference, Table C–G 2 in the CY 2027 PFS proposed rule (91 FR 44184 through 44190) and in section IV.A.4.d.(4)(g)(i) of this final rule sets forth the objectives and measures for the MIPS Promoting Interoperability performance category that are required for the CY 2026 performance period/2028 MIPS payment year, CY 2027 performance period/2029 MIPS payment year, the CY 2028 performance period/2030 MIPS payment year, and subsequent years. In the CY 2027 PFS proposed rule (91 FR 44184 through 44190) and in this final rule, Table C–G 2 reflects modifications to previously established objectives and measures, including:

- For the CY 2026 performance period/2028 MIPS payment year: Removal of the ONC Direct Review and ONC–ACB Surveillance attestations.
- For the CY 2027 performance period/2029 MIPS payment year: Removal of the Security Risk Analysis measure; and modification to the existing Electronic Prior Authorization measure that makes the measure optional and eligible for 10 bonus points.
- For the CY 2028 performance period/2030 MIPS payment year: Modification to the existing Electronic Prior Authorization measure that makes the measure required and unscored; and addition of the new Electronic Prior Authorization for Prescription Drugs measure to the Health Information Exchange objective.

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TABLE C-G 2: OBJECTIVES AND MEASURES FOR THE MIPS PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR, CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR, THE CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR, AND SUBSEQUENT YEARS

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing – At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
Electronic Prescribing	Query of PDMP – For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	Any MIPS eligible clinician who: 1. Is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; OR 2. Does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period.
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning care or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition of care or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from other healthcare providers into their EHR using the functions of CEHRT	Support Electronic Referral Loops by Sending Health Information – For at least one transition of care or referral, the MIPS eligible clinician that transitions care of a patient or refers their patient to another setting of care or healthcare provider: 1. Creates a summary of care using CEHRT; AND 2. Electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically.	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician.	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.
Health Information	Support Electronic	Number of	Number of electronic	Any MIPS eligible clinician

Objective	Measure	Numerator	Denominator	Exclusion
Exchange (HIE)	Referral Loops by Receiving and Reconciling Health Information – For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: 1. Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; 2. Medication allergy – Review of the patient's known medication allergies; and 3. Current Problem List – Review of the patient's current and active diagnoses.	summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange (HIE)	Health Information Exchange Bi-Directional Exchange – Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition of care or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy. Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs and not engaging in exclusionary behavior	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.			
Health Information Exchange	Enabling Exchange Under TEFCA – MIPS eligible clinicians attest to the following. Statement 1: I participate as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition of care or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy. Statement 2: I use the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A
Health Information Exchange	Electronic Prior Authorization for Prescription Drugs (CY 2028 and subsequent performance periods) – For at least one prescription written by the MIPS eligible clinician during the	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	Any MIPS eligible clinician who: 1. Does not write a prescription that requires prior authorization during the applicable performance period; or 2. only writes prescriptions requiring prior authorization where the payer does not support the specified electronic prior

Objective	Measure	Numerator	Denominator	Exclusion
	performance period for which prior authorization is required, the prior authorization is requested electronically using CEHRT.*			authorization standard during the applicable performance period; or 3 writes fewer than 100 permissible prescriptions during the performance period.*
Health Information Exchange	Electronic Prior Authorization (CY 2027 performance period *only*) – For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT.**	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None**
Health Information Exchange	Electronic Prior Authorization (CY 2028 and subsequent performance periods) – For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the MIPS eligible clinician uses CEHRT to electronically discover applicable coverage requirements, complete required documentation, submit the prior authorization request, and receive the payer response through a Prior Authorization API.*	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	Any MIPS eligible clinician who: 1. Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance period; OR 2. Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets CMS's specified Prior Authorization API requirements.*
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information – For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized	Number of patients (or patient authorized representatives) in the denominator who are provided timely access to health information to view online, download, and	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	representative) is provided timely access to view online, download, and transmit his or her health information; AND 2. The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	transmit to a third-party and to access using an application of their choice that is configured to meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting – The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	The MIPS eligible clinician: 1. Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2. Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the definition of CEHRT at the start of the performance period; OR 3. Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Electronic Case Reporting – The MIPS eligible clinician is in active engagement with a PHA to electronically submit	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	The MIPS eligible clinician: 1. Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system

Objective	Measure	Numerator	Denominator	Exclusion
	case reporting of reportable conditions.			during the performance period; OR 2. Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the definition of CEHRT at the start of the performance period; OR 3. Operates in a jurisdiction where no PHA has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Public Health Registry Reporting (Optional) – The MIPS eligible clinician is in active engagement with a PHA to submit data to public health registries.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting (Optional) – The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting (Optional) – The MIPS eligible clinician is in active engagement with a PHA to submit syndromic surveillance data from an urgent care setting.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Public Health Reporting Using TEFCA (Optional)* – The MIPS eligible clinician: 1. Is participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website); 2.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None

Objective	Measure	Numerator	Denominator	Exclusion
	Is not suspended from participating in TEFCA exchange; 3. Submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; 4. Is in active engagement Option 2 (validated data production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; AND 5. Uses the functions of CEHRT to exchange with the PHA.			
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or maintained by CEHRT through the implementation of appropriate technical, administrative, and physical safeguards. Protect Patient Health Information	High Priority Practices SAFER Guide – Beginning with the CY 2024 performance period/2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the High Priority Practices SAFER Guide measure using the 2025 High Priority Practices SAFER Guide during the year in which the performance period occurs.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None

* Reflects modifications proposed in the CY 2027 PFS proposed rule and finalized, as proposed, in this final rule that apply to the CY 2028 performance period/2030 MIPS payment year and subsequent years.

** Reflects modifications proposed in the CY 2027 PFS proposed rule (91 FR 44184 through 44190) and finalized, as proposed, in this final rule that apply to the CY 2027 performance period/2029 MIPS payment year.

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(ii) Modifying Scoring Methodology

For reference, Tables C–G 3, C–G 4, and C–G 5 in the CY 2027 PFS proposed rule (91 FR 44192 through 44194) and this final rule set forth the scoring methodology for the MIPS Promoting Interoperability performance category for CY 2026 performance period/2028 MIPS payment year, the CY 2027 performance period/2029 MIPS payment year, and the CY 2028 performance period/2030 MIPS payment year and subsequent years. In the CY 2027 PFS proposed rule, we discussed the removal of certain attestations and measures, addition of certain measures, and modifications/updates to certain measures for the MIPS Promoting Interoperability

performance category (91 FR 44171 and 44182).

In the CY 2027 PFS proposed rule, we referred readers to the discussion regarding the modifications to the scoring methodology that account for the Electronic Prior Authorization measure being changed to an optional measure with an allocation of 10 bonus points for the CY 2027 performance period/2029 MIPS payment year (91 FR 44191 and 44192). Also, we noted that there are no implications to the scoring methodology for the proposed modifications to the definition of CEHRT (91 FR 44191).

In the CY 2027 PFS proposed rule, we discussed the scoring implications for the proposed modifications to the following attestations and measures within the MIPS Promoting Interoperability performance category (91 FR 44191 and 44192):

- Removal of the ONC Direct Review and ONC–ACB Surveillance attestations;
- Removal of the Security Risk Analysis measure;
- Addition of the new Electronic Prior Authorization for Prescription Drugs measure; and
- Modifications to the Electronic Prior Authorization measure.

(A) Modifying Scoring for the ONC Direct Review and ONC–ACB Surveillance Attestations

As discussed in the CY 2027 PFS proposed rule, we proposed to remove the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation beginning with the CY 2026 performance period/CY 2028 MIPS payment year (91 FR 44171 and 44172). Subsequently, in the CY 2027 PFS proposed rule, we proposed to remove the scoring policies related to the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation beginning with the CY 2026 performance period/CY 2028 MIPS payment year (91 FR 44191).

Prior to the proposal to remove the required ONC Direct Review attestation and optional ONC–ACB Surveillance attestation, to earn a score for the MIPS Promoting Interoperability performance category for inclusion in the MIPS final score, a MIPS eligible clinician must be a meaningful EHR user for MIPS and submit a ''Yes'' response attesting to engaging in activities supporting providers with performance of CEHRT, including acknowledging the requirement to cooperate in good faith with ONC Direct Review. For the optional ONC–ACB Surveillance attestation, a MIPS eligible clinicians could attest ''Yes,'' ''No,'' or not submit an attestation (81 FR 77019 through 77027).

In accordance with the proposal to remove the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation, the ONC Direct Review attestation would no longer be required to earn a score for the MIPS Promoting Interoperability performance category and the optional ONC–ACB Surveillance attestation would no longer be available beginning with the CY 2026 performance period/CY 2028 MIPS payment year (91 FR 44191). Since we did not provide measure points for the required ONC Direct Review attestation and optional ONC–ACB Surveillance attestation, the removal of the attestation requirements and scoring policies beginning with the CY 2026 performance period/2028 MIPS payment year would not necessitate a redistribution of measure points within the MIPS Promoting Interoperability performance category.

In the CY 2027 PFS proposed rule, we referred readers to Table C–G 3 for more information regarding the scoring methodology for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/ 2028 MIPS payment year (91 FR 44190 through 44192).

We requested public comment on this proposal.

We did not receive public comment on the proposal, and therefore, we are finalizing, as proposed, the proposal to remove scoring policies related to the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation beginning with the CY 2026 performance period/CY 2028 MIPS payment year. We refer readers to Table C–G 3 in section IV.A.4.d.(4)(g)(ii)(D) of this final rule for more information regarding the scoring methodology for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/ 2028 MIPS payment year, which does not include the ONC Direct Review attestation or optional ONC–ACB Surveillance attestation

(B) Modifying Scoring for the Security Risk Analysis Measure

As discussed in the CY 2027 PFS proposed rule, we proposed to remove the Security Risk Analysis measure beginning with the CY 2027 performance period/2029 MIPS payment year (91 FR 44173 and 44174). Subsequently, in the CY 2027 PFS proposed rule, we proposed to remove scoring policies related to the Security Risk Analysis Measure beginning with the CY 2027 performance period/CY 2029 MIPS payment year (91 FR 44191). We noted that the Security Risk Analysis measure is a required measure within the Protect Patient Health Information objective; however, the measure is not scored or does not contribute to the MIPS Promoting Interoperability performance category score as long as a MIPS eligible clinician affirmatively attests to meeting the requirements of the measure. While an attestation of a ''Yes'' response from a MIPS eligible clinician does not garner points within the Protect Patient Health Information objective or contribute to a MIPS eligible clinician's MIPS Promoting Interoperability performance category score, an attestation of a ''No'' response from a MIPS eligible clinician demonstrates that the MIPS eligible clinician did not complete the actions included in the measure as required by § 414.1375(b)(2)(ii)(A) and did not satisfy the definition of a meaningful EHR user at § 414.1305. Therefore, if the MIPS eligible clinician submits a ''No'' response for the Security Risk Analysis measure, the MIPS eligible clinician would earn a score of zero for the MIPS Promoting Interoperability performance category in accordance with § 414.1375(b)(2) (91 FR 44191).

In the CY 2027 PFS proposed rule, we noted that in accordance with the proposal to remove the Security Risk Analysis measure, such measure would no longer be required to earn a score for the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/CY 2029 MIPS payment year (91 FR 44191). Since we did not provide measure points for the Security Risk Analysis measure, the removal of the measure requirement and scoring policies beginning with the CY 2027 performance period/2029 MIPS payment year would not necessitate a redistribution of measure points within the MIPS Promoting Interoperability performance category. In the CY 2027 PFS proposed rule, we referred readers to Table C–G 4 for more information regarding the scoring methodology for the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year, which would no longer include the Security Risk Analysis measure (91 FR 44191 and 44193).

We requested public comment on this proposal.

We did not receive public comment on the proposal, and therefore, we are finalizing, as proposed, the proposal to remove the scoring policy for the Security Risk Analysis measure beginning with the CY 2027 performance period/2029 MIPS payment year. We refer readers to

section IV.A.4.d.(4)(d) of this final rule for the discussion regarding the finalization of the proposal, as proposed, to remove the Security Risk Analysis measure. Also, we refer readers to Table C–G 4 in section IV.A.4.d.(4)(g)(ii)(D) this final rule for more information regarding the scoring methodology for the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year, which does not include the Security Risk Analysis measure.

(C) Modifying Scoring for the New Electronic Prior Authorization for Prescription Drugs Measure

As discussed in the CY 2027 PFS proposed rule, we proposed to adopt and implement the new attestation-based Electronic Prior Authorization for Prescription Drugs measure beginning with the CY 2028 performance period/2030 MIPS payment year (91 FR 44175 and 44176). Subsequently, in the CY 2027 PFS proposed rule, we proposed to establish the scoring methodology for the Electronic Prior Authorization for Prescription Drugs measure, in which the measure would be included as a requirement under the Health Information Exchange objective and would not be scored or contribute to the MIPS Promoting Interoperability performance category beginning with the CY 2028 performance period/2030 MIPS payment year as long as a MIPS eligible clinician submits a ''Yes'' response attesting to meeting the requirements of the measure or claims an applicable exclusion (91 FR 44191). As a result, the measure would not affect the total score for the MIPS Promoting Interoperability performance category. If a MIPS eligible clinician submits a ''No'' response for the attestation-based measure, fails to submit an attestation for the measure, or fails to claim an applicable exclusion, then the MIPS eligible clinician would receive a score of zero for the MIPS Promoting Interoperability performance category (currently weighted at 25 percent of the MIPS final score), and would not be considered a meaningful EHR user for MIPS for the applicable performance period (91 FR 44191).

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our response.

Comment: Many commenters did not support the proposed scoring methodology for the Electronic Prior Authorization for Prescription Drugs measure and expressed concerns regarding the scoring methodology for the Electronic Prior Authorization for Prescription Drugs measure, specifically, the provision that would consequently cause a MIPS eligible clinician to receive a score of zero for the entire Promoting Interoperability performance category if a MIPS eligible clinician attests ''No'' for the measure, fails to report the measure, or does not claim an applicable exclusion. The commenters described such consequence as disproportionate, particularly when successful reporting for the measure may depend on readiness factors that are outside the control of MIPS eligible clinicians. A few commenters supported the proposal to not assign points for the proposed Electronic Prior Authorization for Prescription Drugs measure, while a few commenters recommended changing the proposed scoring approach, including assigning points to the measure once it becomes required, in which the failure to meet the measure requirements would result in the loss of measure points rather than receiving a score of zero for the entire Promoting Interoperability performance category. A few commenters recommended that CMS make the Electronic Prior Authorization for Prescription Drugs measure optional and eligible for bonus points during the initial implementation of the measure to encourage early adoption.

Response: We appreciate the feedback from commenters regarding the proposed scoring methodology for the Electronic Prior Authorization for Prescription Drugs measure beginning with the CY 2028 performance period/2030 MIPS payment year. We recognize that successful use of standards-based electronic prior authorization depends on coordination among MIPS eligible clinicians, payers, health IT developers, intermediaries, and other entities, and that some implementation challenges may be outside the control of individual MIPS eligible clinicians. However, we believe that requiring an attestation of a ''Yes'' response for meeting the measure requirements or allowing for an applicable exclusion to be claimed, which would result in the measure not being scored or contributing to the MIPS Promoting Interoperability performance category score beginning with the CY 2028 performance period/2030 MIPS payment year, is an appropriate scoring approach to encourage adoption of electronic prior authorization for prescription drugs, which provides valuable information in assessing meaningful use of CEHRT under the MIPS Promoting Interoperability performance category. Additionally, as we aim to provide consistency and reduce complexity in scoring, such approach aligns with the scoring methodology for other required measures in the MIPS Promoting Interoperability performance category in which a MIPS eligible clinician who does not affirmatively attest (submission of a ''Yes'' response) to meeting the requirements of a required measure or claim an applicable exclusion receives a score of zero for the MIPS Promoting Interoperability performance category.

We intend to assess implementation experience, payer and health IT readiness, technological advancements, and the availability of ONC-certified health IT as the measure is implemented.

After consideration of public comment, we are finalizing, as proposed, the proposal to establish the scoring methodology for the Electronic Prior Authorization for Prescription Drugs measure, in which the measure would be included as a requirement under the Health Information Exchange objective. Beginning with the CY 2028 performance period/2030 MIPS payment year, a MIPS eligible clinician will be required to affirmatively attest (submission of a ''Yes'' response) to meeting the requirements the Electronic Prior Authorization for Prescription Drugs measure or claim an applicable exclusion. For MIPS eligible clinicians affirmatively attesting to meeting the Electronic Prior Authorization measure requirements or claiming an applicable exclusion, the measure will not affect the total score for the MIPS Promoting Interoperability performance category. If a MIPS eligible clinician submits a ''No'' response for the attestation-based measure, fails to submit an attestation for the measure, or fails to claim an applicable exclusion, then the MIPS eligible clinician will receive a score of zero for the MIPS Promoting Interoperability performance category and will not be considered a meaningful EHR user for MIPS for the applicable performance period. We refer readers to Table C–G 5 in section IV.A.4.d.(4)(g)(ii)(D) of this final rule for more information regarding the scoring methodology for the MIPS Promoting Interoperability performance category for the CY 2028 performance period/2030 MIPS payment year and subsequent years.

(D) Modifying Scoring for the Electronic Prior Authorization Measure

When we adopted the Electronic Prior Authorization measure in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we

finalized that MIPS eligible clinicians would report the measure as an unscored attestation for the CY 2027 performance period (89 FR 8910); however, we did not specify the measure's scoring methodology for subsequent years because we determined that it will be more appropriate to determine the measure's scoring methodology closer in time to the measure's effective date.

In the CY 2027 PFS proposed rule, we proposed to modify the Electronic Prior Authorization measure by making the measure optional and eligible for 10 bonus points for MIPS eligible clinicians who submit a ''Yes'' response attesting to meeting the requirements of the measure for the CY 2027 performance period/2029 MIPS payment year (91 FR 44176 through 44181). Allocating 10 bonus points is an appropriate and effective incentive to promote the adoption and use of certified technology for requesting electronic prior authorizations among MIPS eligible clinicians. To account for the allocation of bonus points specific to the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year, we proposed to amend § 414.1380(b)(4)(ii)(C) by adding a new provision at § 414.1380(b)(4)(ii)(C)(4). In the CY 2027 PFS proposed rule, we referred readers to the proposal (91 FR 44205 and 44206) that establishes the allocation of 10 bonus points to the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year in § 414.1380(b)(4)(ii)(C)(4), respectively, for MIPS eligible clinicians who affirmatively attest to meeting the requirements of the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year.

Also, as described in the CY 2027 PFS proposed rule, we proposed to require the reporting of the Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year. We refer readers to section IV.A.4.d.(4)(f) of this final rule for discussion of finalization of the Electronic Prior Authorization measure. Similar to the Electronic Prior Authorization measure's original scoring methodology as adopted in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), the Electronic Prior Authorization measure would not be scored or contribute to the MIPS Promoting Interoperability performance category score as long as a MIPS eligible clinician affirmatively attests (submission of a ''Yes'' response) to meeting the requirements of the measure or claims an applicable exclusion beginning with the CY 2028 performance period. If a MIPS eligible clinician submits a ''No'' response for the attestation, fails to submit an attestation for the measure, or fails to claim an applicable exclusion, then the MIPS eligible clinician would receive a score of zero for the MIPS Promoting Interoperability performance category and would not be considered a meaningful EHR user for MIPS for the applicable performance period. Such scoring methodology would provide additional time for MIPS eligible clinicians to adjust to the new electronic prior authorization workflow using Prior Authorization APIs without undue focus on scoring implications in the MIPS Promoting Interoperability performance category. As noted in the CY 2027 PFS proposed rule, we anticipate that the Electronic Prior Authorization measure would retain its importance as an aspect of health information exchange (91 FR 44192).

We requested public comment on these proposals.

We received public comment on the proposals. The following is a summary of the comments we received and our response.

Comment: Many commenters supported the proposed scoring methodology for the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year, in which the measure would be an optional measure and eligible for 10 bonus points.

Response: We appreciate the support from commenters.

Comment: Several commenters did not support the proposed scoring methodology for the Electronic Prior Authorization measure and raised concerns regarding the proposed scoring consequences associated with making the Electronic Prior Authorization measure mandatory beginning with the CY 2028 performance period/2030 MIPS payment year. Several commenters characterized the proposed scoring methodology for the CY 2028 performance period/2030 MIPS payment year and subsequent years as disproportionate, noting that a MIPS eligible clinician who does not affirmatively attest (submission of a ''Yes'' response) to meeting the requirements of the measure or claim an applicable exclusion would receive a zero score for the entire MIPS Promoting Interoperability performance category, even though the measure itself does not have assigned points. Commenters indicated that MIPS eligible clinicians could face substantial consequences under MIPS due to technical limitations, payer or vendor failures, interoperability issues, or other circumstances outside their control.

Some commenters recommended for CMS to assign the measure a specific number of points and apply a proportionate scoring consequence when the measure is not met, which would be consistent with the scoring of other measures in the MIPS Promoting Interoperability performance category. A commenter recommended for CMS to phase in scoring or initially treat the measure as an attestation-only requirement that would not result in a zero score for the entire Promoting Interoperability performance category if the measure is not successfully met.

A few commenters requested that the Electronic Prior Authorization measure continue to be an optional measure and eligible for 10 bonus points for the CY 2028 performance period/2030 MIPS payment year to encourage adoption while implementation and ecosystem readiness are further evaluated. A commenter recommended that CMS monitor implementation of standardized electronic prior authorization functionality and adjust scoring if widespread limitations are identified.

Response: We appreciate the feedback from commenters. We recognize that successful use of standards-based electronic prior authorization depends on coordination among MIPS eligible clinicians, payers, health IT developers, intermediaries, and other entities; and some implementation challenges may be outside the control of individual MIPS eligible clinicians. However, we believe that making the Electronic Prior Authorization measure as an optional measure and eligible for 10 bonus points for the CY 2027 performance period/2029 MIPS payment year provides a transition period for MIPS eligible clinicians to implement and test the measure without negative scoring consequences. Also, we believe that the scoring methodology for the Electronic Prior Authorization measure is appropriate when the measure becomes required beginning with the CY 2028 performance period/2030 MIPS payment year to encourage adoption of electronic prior authorization for prescription drugs, which provides valuable information in assessing meaningful use of CEHRT under the MIPS Promoting Interoperability performance category. With regard to the commenters that recommended CMS assign the Electronic Prior Authorization measure a specific number of points, we note that a points based scoring methodology for the Electronic Prior Authorization measure

would be inconsistent with our scoring approach for other required, non-scored measures in the MIPS Promoting Interoperability performance category. Therefore, as we aim to provide consistency and reduce complexity in scoring, such approach aligns with the scoring methodology for other required measures in the MIPS Promoting Interoperability performance category, in which the Electronic Prior Authorization measure would not be scored or contribute to the MIPS Promoting Interoperability performance category score as long as a MIPS eligible clinician affirmatively attests (submission of a ''Yes'' response) to meeting the requirements of the measure or claims an applicable exclusion. Conversely, if a MIPS eligible clinician submits a ''No'' response for the attestation-based measure, fails to submit an attestation for the measure, or fails to claim an applicable exclusion, then the MIPS eligible clinician will receive a score of zero for the MIPS Promoting Interoperability performance category and will not be considered a meaningful EHR user under MIPS for the applicable performance period.

We intend to assess implementation experience, payer and health IT readiness, technological advancements, and the availability of ONC-certified health IT as the measure is implemented.

After consideration of public comment, we are finalizing, as proposed, the proposal to establish the scoring methodology of the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year, in which the measure will be an optional measure and eligible for 10 bonus points. Also, we are finalizing, as proposed, the proposal to establish the scoring methodology for the Electronic Prior Authorization measure as it becomes a required measure beginning with the CY 2028 performance period/2030 MIPS payment year, in which the measure will not be scored or contribute to the MIPS Promoting Interoperability performance category score as long as a MIPS eligible clinician affirmatively attests (submission of a ''Yes'' response) to meeting the requirements of the measure or claims an applicable exclusion. Conversely, if a MIPS eligible clinician submits a ''No'' response for the attestation-based measure, fails to submit an attestation for the measure, or fails to claim an applicable exclusion, then the MIPS eligible clinician will receive a score of zero for the MIPS Promoting Interoperability performance category and will not be considered a meaningful EHR user under MIPS for the applicable performance period. We refer readers to Table C–G–4 and Table C–G 5 in section IV.A.4.d.(4)(g)(ii)(D) this final rule for more information regarding the scoring methodology for the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year and CY 2028 performance period/2030 MIPS payment year and subsequent years.

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TABLE C-G 3: SCORING METHODOLOGY FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange Under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting • Public Health Reporting Using TEFCA	5 points (*bonus*)	Optional
Protect Patient Health Information	Security Risk Analysis	Not scored*	Required
	High Priority Practices SAFER Guide	Not scored*	Required
No Associated Objective: Attestation Requirements**	Actions to Limit or Restrict the Compatibility of CEHRT	Not scored*	Required

* Required measures and attestations that are not scored and do not have associated points. Failure to fulfill such requirements will result in a score of zero for the MIPS Promoting Interoperability performance category.

**Attestation Requirements: As described in section IV.A.4.d.(4)(c)(ii) of this final rule, the removal of the required ONC-Direct Review attestation and the optional ONC-ACB Surveillance attestation is applicable starting with the CY 2026 performance period/2028 MIPS payment year.

TABLE C-G 4: SCORING METHODOLOGY FOR THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange Under TEFCA	30 points	
	Electronic Prior Authorization*	10 points (*bonus*)	Optional
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting • Public Health Reporting Using TEFCA	5 points (*bonus*)	Optional
Protect Patient Health Information**	High Priority Practices SAFER Guide	Not scored***	Required
No Associated Objective: Attestation Requirements****	Actions to Limit or Restrict the Compatibility of CEHRT	Not scored***	Required

* As described in sections IV.A.4.d.(4)(f)(v) and IV.A.4.d.(4)(f)(vi) of this final rule, the Electronic Prior Authorization measure is optional and eligible for 10 bonus points for the CY 2027 performance period/2029 MIPS payment year; and required and not scored starting with the CY 2028 performance period/2030 MIPS payment year.

** As described in section IV.A.4.d.(4)(d)(ii) of this final rule, the removal of the Security Risk Analysis measure is applicable starting with the CY 2027 performance period/2029 MIPS payment year.

*** Required measures and attestations that are not scored and do not have associated points. Failure to fulfill such requirements will result in a score of zero for the MIPS Promoting Interoperability performance category.

**** Attestation Requirements: As described in section IV.A.4.d.(4)(c)(ii) of this final rule, the removal of the required ONC-Direct Review attestation and the optional ONC-ACB Surveillance attestation is applicable starting with the CY 2026 performance period/2028 MIPS payment year.

TABLE C-G 5: SCORING METHODOLOGY FOR THE CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR AND SUBSEQUENT YEARS

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange Under TEFCA	30 points	
	Electronic Prior Authorization*	Not scored**	Required
	Electronic Prior Authorization for Prescription Drugs***	Not scored**	Required
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting • Public Health Reporting Using TEFCA	5 points (*bonus*)	Optional
Protect Patient Health Information****	High Priority Practices SAFER Guide	Not scored**	Required
No Associated Objective: Attestation Requirements*****	Actions to Limit or Restrict the Compatibility of CEHRT	Not scored***	Required

* As described in section IV.A.4.d.(4)(f)(vi) of this final rule, the Electronic Prior Authorization measure is required and not scored starting with the CY 2028 performance period/2030 MIPS payment year. We note that in section IV.A.4.d.(4)(f)(v) of this final rule, the Electronic Prior Authorization measure is optional and eligible for 10 bonus points for the CY 2027 performance period/2029 MIPS payment year.

** Required measures and attestations that are not scored and do not have associated points. Failure to fulfill such requirements will result in a score of zero for the MIPS Promoting Interoperability performance category.

*** As described in section IV.A.4.d.(4)(e)(ii) of this final rule, the newly adopted Electronic Prior Authorization for Prescription Drugs measure is required and not scored starting with the CY 2028 performance period/2030 MIPS payment year.

**** As described in section IV.A.4.d.(4)(d)(ii) of this final rule, the removal of the Security Risk Analysis measure is applicable starting with the CY 2027 performance period/2029 MIPS payment year.

*****Attestation Requirements: As described in section IV.A.4.d.(4)(c)(ii) of this final rule, the removal of the required ONC-Direct Review attestation and the optional ONC-ACB Surveillance attestation is applicable starting with the CY 2026 performance period/2028 MIPS payment year.

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The proposals in this final rule include modifications that are effective for the CY 2026 performance period/2028 MIPS payment year, CY 2027 performance period/2029 MIPS payment year, and CY 2028 performance period/2030 MIPS payment year. Table C–G 6 summarizes the required measures and attestations for each of the three aforementioned performance periods.

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TABLE C-G 6: SUMMARY OF REQUIREMENTS FOR THE MIPS PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR, CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR, CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR, AND SUBSEQUENT YEARS

Objective	Measure	2026 Performance Period	2027 Performance Period	2028 Performance Period and Subsequent Years
Electronic Prescribing	e-Prescribing	Required (10 points)	Required (10 points)	Required (10 points)
	Query of PDMP	Required (10 points)	Required (10 points)	Required (10 points)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	Required (30 points for selected option)	Required (30 points for selected option)	Required (30 points for selected option)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information			
	-OR-			
	Health Information Exchange Bi-Directional Exchange			
	-OR-			
	Enabling Exchange Under TEFCA			
	Electronic Prior Authorization	---	Optional (10 bonus points)	Required (not scored)*
	Electronic Prior Authorization for Prescription Drugs	---	---	Required (not scored)*
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	Required (25 points)	Required (25 points)	Required (25 points)
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	Required (25 points)	Required (25 points)	Required (25 points)
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting • Public Health Reporting Using TEFCA	Optional (5 bonus points)	Optional (5 bonus points)	Optional (5 bonus points)
Protect Patient Health Information	Security Risk Analysis	Required (not scored)*	---	---
	High Priority Practices SAFER Guide	Required (not scored)*	Required (not scored)*	Required (not scored)*
No Associated Objective: Attestation Requirements	Actions to Limit or Restrict the Compatibility of CEHRT	Required (not scored)*	Required (not scored)*	Required (not scored)*

* Required measures and attestations that are not scored and do not have associated points. Failure to fulfill such requirements will result in a score of zero for the MIPS Promoting Interoperability performance category.

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(iii) Exclusion Redistribution

In the CY 2027 PFS proposed rule (91 FR 44196) and this final rule, we note that many required measures have exclusions associated with them as set forth in Table C–G 7. If a MIPS eligible clinician determines that an exclusion for a particular measure is applicable, then the MIPS eligible clinician may claim the applicable exclusion when reporting their data. The maximum available points, as shown in Table C–G 7, do not include the points that would be redistributed if a MIPS eligible clinician claims an exclusion for a specific measure. Table C–G 7 sets forth how points will be redistributed among the objectives and measures specified for the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year in the event a MIPS eligible clinician claims an exclusion for a given measure.

TABLE C-G 7: EXCLUSION REDISTRIBUTION FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange (HIE)	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange Under TEFCA	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following two measures: • Electronic Case Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to Their Health Information measure

(iv) ONC Health IT Certification Criteria

In the CY 2027 PFS proposed rule (91 FR 44197 and 44198) and this final rule, Table C–G 8 sets forth the objectives and measures for the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year and subsequent years, and the associated ONC health IT certification criteria set forth at 45 CFR 170.315, as applicable as of the publication of this final rule. Also, Table C–G 8 summarizes the changes to the relevant ONC Health IT certification criteria proposed in the HTI–5 proposed rule (90 FR 60970 through 61034) and finalized in the HTI–5 final rule (91 FR 67916 through 67998). We refer readers to section IV.A.4.d.(4)(b)(ii) of this final rule for discussion of and amendments to the definition of CEHRT at § 414.1305.

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TABLE C-G 8: MIPS PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY OBJECTIVES AND MEASURES, AND ONC HEALTH IT CERTIFICATION CRITERIA

Objective	Measure	Certification Criteria (CY 2027 Performance Period/2029 MIPS Payment Year and Subsequent Years) in Title 45 of the CFR	HTI-5 Proposed Actions	HTI-5 Final Actions
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing	N/A	N/A
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing	N/A	N/A
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	§ 170.315(b)(1) Transitions of care	Revise	Finalized with Modification - Revised
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	§ 170.315(b)(1) Transitions of care	Revise	Revised
		§ 170.315(b)(2) Clinical information reconciliation and incorporation	Remove	Removal Not Finalized - Revised
Health Information Exchange (alternative)	Health Information Exchange Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:		
		§ 170.315(b)(1) Transitions of care	Revise	Finalized with Modification - Revised
		§ 170.315(b)(2) Clinical information reconciliation and incorporation	Remove	Removal Not Finalized – Revised
		§ 170.315(g)(7) Application access — patient selection	Remove	Removed
		§ 170.315(g)(9) Application access — all data request	Remove	Removed
		§ 170.315(g)(10) Standardized API for patient and population services	N/A	N/A
Health Information Exchange (alternative)	Enabling Exchange Under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:		
		§ 170.315(b)(1) Transitions of care	Revise	Finalized with Modification - Revised
		§ 170.315(b)(2) Clinical information reconciliation and incorporation	Remove	Removal Not Finalized – Revised
		§ 170.315(g)(7) Application access — patient selection	Remove	Removed
		§ 170.315(g)(9) Application access — all data request	Remove	Removed
		§ 170.315(g)(10) Standardized API for patient and population services	N/A	N/A
Health Information Exchange	Electronic Prior Authorization*	Certified health IT capabilities that may support the actions of this measure		
		170.315(g)(31) Provider prior authorization API —	N/A	N/A

Objective	Measure	Certification Criteria (CY 2027 Performance Period/2029 MIPS Payment Year and Subsequent Years) in Title 45 of the CFR	HTI-5 Proposed Actions	HTI-5 Final Actions
		coverage requirements discovery*		
		170.315(g)(32) Provider prior authorization API — documentation templates and rules*	N/A	N/A
		170.315(g)(33) Provider prior authorization API — prior authorization support*	N/A	N/A
Health Information Exchange	Electronic Prior Authorization for Prescription Drugs**	170.315(b)(3) Electronic prescribing**	N/A	N/A
		170.315(b)(4) Real-time prescription benefit**	N/A	N/A
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	§ 170.315(e)(1) View, download, and transmit to 3rd party	Revise	Revised
		§ 170.315(g)(7) Application access — patient selection	Remove	Removed
		§ 170.315(g)(9) Application access — all data request	Remove	Removed
		§ 170.315(g)(10) Standardized API for patient and population services	N/A	N/A
Public Health and Clinical Data Exchange	Immunization Registry Reporting	§ 170.315(f)(1) Transmission to immunization registries	N/A	N/A
	Syndromic Surveillance Reporting (Optional)	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance	N/A	N/A
	Electronic Case Reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting	Revise	Revision Not Finalized
	Public Health Registry Reporting (Optional)	§ 170.315(f)(4) Transmission to cancer registries	Remove	Removal Not Finalized
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys	Remove	Removal Not Finalized
	Clinical Data Registry Reporting (Optional)	No ONC health IT certification criteria at this juncture.	N/A	N/A
	Public Health Reporting Using TEFCA (Optional)	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:		
		§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting	Revise	Revision Not Finalized
Protect Patient Health Information	Security Risk Analysis	The requirements are a part of CEHRT specific to each certification criterion.	N/A	N/A
	High Priority Practices SAFER Guide	No ONC health IT certification criteria at this juncture.	N/A	N/A

* As described in sections IV.A.4.d.(4)(f)(v) and IV.A.4.d.(4)(f)(vi) of this final rule, the Electronic Prior Authorization measure is optional and eligible for 10 bonus points for the CY 2027 performance period/2029 MIPS payment year; and required and not scored starting with the CY 2028 performance period/2030 MIPS payment year.

** As described in section IV.A.4.d.(4)(e)(ii) of this final rule, the newly adopted Electronic Prior Authorization for Prescription Drugs measure is required and not scored starting with the CY 2028 performance period/2030 MIPS payment year.

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B. MIPS Final Score Methodology

1. Performance Category Scores

a. Background

Sections 1848(q)(1)(A)(i) and (ii) and (5)(A) of the Act provide, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act requires us to use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures and activities that must be specified under the quality performance category. The statute does not specify the number of quality measures on which a MIPS eligible clinician must report, nor does it specify the amount or type of information that a MIPS eligible clinician must report on each quality measure.

In the CY 2027 PFS proposed rule (91 FR 44198 through 44207), we proposed scoring policies consistent with the MIPS core measure reporting requirement proposed in the CY 2027 PFS proposed rule (91 FR 44157 through 44159). Additionally, we proposed policies building on the current scoring policies for topped out quality measures. Moreover, we proposed policies to modify the benchmarks for Medicare CQMs and apply flat benchmarks to Medicare eCQMs that are consistent with the proposed Medicare eCQM collection type in section III.G.3.d.(3) of this final rule. In this section, we also proposed policy to update scoring for the Electronic Prior Authorization measure in the Promoting Interoperability performance category. Lastly, we also included a request for information (RFI) on the future direction of MVP scoring policies. Specifically, we proposed to:

- Establish a policy for scoring MIPS core measures;
- Apply the defined topped out benchmark for certain topped out measures for clinicians impacted by limited measure choice;
- Apply the defined topped out benchmark for topped out MIPS core measures;
- Modify the publishing location of topped out measures impacted by limited measure choice and scored according to the defined topped out benchmark;
- Modify the flat benchmarking methodology for the Medicare CQMs collection type;
- Establish a flat benchmarking methodology for the Medicare eCQMs collection type;
- Modify the Electronic Prior Authorization measure from a required measure to an optional measure under the Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year.

and

- Modify § 414.1380(b)(3)(i) to clarify and maintain that, for MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent.

Additionally, we discussed the impact of the MIPS core measure scoring for small practices and explained that we would apply the historical benchmark if a measure is no longer topped out. We noted that the proposed policies for scoring the MIPS quality performance category would apply to both traditional MIPS and MVP scoring.

b. Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measures and Administrative Claims Measures

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules, the CY 2020, CY 2021, CY 2022, CY 2023, CY 2024, CY 2025, and CY 2026 PFS final rules (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913, 86 FR 65490 through 65509, 87 FR 70088 through 70091, 88 FR 79368 and 79369, 89 FR 98427 through 98439, and 90 FR 49903 through 49914), and § 414.1380(b)(1) for our current policies regarding, among other things, quality measure benchmarks, calculating total measure achievement points, calculating the quality performance category score, including achievement and improvement points, the small practice bonus, and scoring flexibilities. In the CY 2026 PFS final rule (90 FR 49903 through 49914), we finalized policies for scoring topped out measures impacted by limited measure choice and the scoring methodology for administrative claims-based quality measures at § 414.1380(b)(1)(i) and (b)(1)(ii)(D).

(1) Scoring of MIPS Core Measures

Section 1848(q)(5)(B)(i) of the Act requires the Secretary to treat any MIPS eligible clinician who fails to report on a required measure or activity as achieving the lowest potential score applicable to the measure or activity. In the CY 2017 Quality Payment Program final rule (81 FR 77291), we finalized at § 414.1380(b)(1) that MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335, on which no data is submitted in accordance with § 414.1325. In the CY 2022 PFS final rule (86 FR 65421), we finalized that scoring the required quality measures in an MVP is consistent with traditional MIPS scoring policies described under § 414.1380(b)(1).

In section IV.A.4.d.(1)(c)(iii)(B) of this final rule, we are finalizing that MIPS eligible clinicians will need to report a MIPS core measure, as one of their six required quality measures in traditional MIPS or one of their four required quality measures in MVP reporting. The MIPS core measure requirement will replace the existing outcome or high priority measure requirement for clinicians participating in traditional MIPS and MVP reporting. We also are finalizing an attestation requirement, during data submission, for clinicians who do not have an available and applicable MIPS core measure. Additionally, we are finalizing in that section that the MIPS core measure reporting requirement will not apply to clinicians in small practices. We refer readers to section IV.A.4.d.(1)(c)(iii) of this final rule for details on the MIPS core measure reporting requirement, the attestation process, and exemption of small practices from the MIPS core measure reporting requirement that we are finalizing in this final rule. We refer readers to Appendix 1: MIPS Quality Measures and Appendix 3: MVP Inventory of this final rule for details on the MIPS core measures inventory for the CY 2027 performance period/2029 MIPS payment year.

Beginning in the CY 2027 performance period/2029 MIPS payment year, for scoring the quality performance category for clinicians that are not part of small practices, we will include the MIPS core measure we are finalizing in this rule as one of the six required quality measures for clinicians participating in traditional MIPS or one of the four required quality measures for clinicians participating in MVP reporting. As discussed in section IV.A.4.d.(1)(c)(iii)(B) of this final rule, clinicians who attest to not having an applicable and available MIPS core measure will still need to report enough measures to meet the required number of six quality measures in traditional MIPS or four quality measures in MVP

reporting. For clinicians who attest to not having an applicable and available MIPS core measure, we will use the highest scoring six or four quality measures, respectively, to determine the quality performance category score. As discussed in section IV.A.4.d.(1)(c)(iii)(B) of this final rule, there may be instances in which a clinician attested to not having an applicable and available MIPS core measure, but new information or changing circumstances later made it so that the clinician does have an applicable and available MIPS core measure to report. To account for these cases, if an attestation is submitted during data submission and a MIPS core measure is also reported, we will score the MIPS core measure as one of the six required quality measures in traditional MIPS reporting or one of the four required quality measures in MVP reporting. If a MIPS eligible clinician submits data for more than one MIPS core measure, we will use the highest scoring MIPS core measure as one of the six or four quality measures, and the remaining scored measures will consist of either the five highest scoring quality measures or the three highest scoring measures, as applicable, in traditional MIPS and MVP reporting.

In section IV.A.4.d.(1)(c)(ii) of this final rule, we are finalizing our proposal to remove the current quality measure data submission requirement of one outcome measure (or, if an outcome measure is not available, one high priority measure) for traditional MIPS and MVP reporting and replace the requirement with a MIPS core measure data submission requirement. As discussed in section IV.A.4.d.(1)(c)(i) of this final rule, one of the factors considered for the MIPS core measure selection included an emphasis on whether the measure is an outcome-based measure. We refer readers to section IV.A.4.d.(1)(c)(i) of this final rule for additional details on the designation of MIPS core measures. In the CY 2027 PFS proposed rule (91 FR 44199 and 44200), we proposed to assign zero measure achievement points for one quality measure if clinicians reporting traditional MIPS or MVP do not submit a MIPS core measure and do not attest during data submission that they do not have an available and applicable MIPS core measure. This proposal is consistent with the existing rule under § 414.1380(b)(1)(i). Under the existing policy under § 414.1380(b)(1)(i), MIPS eligible clinicians who submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the measures with the greatest number of measure achievement points. Therefore, we did not propose any changes to the regulatory text for this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the proposal to keep the scoring methodology consistent in the transition to MIPS core measures. A commenter supported using the highest scoring MIPS core measure for clinicians who submit more than one MIPS core measure.

Response: We thank the commenters for their support.

Comment: Several commenters requested that CMS not score zero points during the initial MIPS core measure implementation period to allow time for clinicians to update workflows to support the attestation and evaluate the applicability and burden associated with MIPS core measure reporting before incorporating such measures into scoring methodologies. A commenter requested that CMS provide information and notice as part of the annual performance feedback for clinicians who did not meet the MIPS core measure data submission requirement and are assigned zero measure achievement points.

Response: We appreciate commenters' concerns that clinicians may need to assess the applicability of the MIPS core measures, update workflows, and become familiar with the process for indicating that a required MIPS core measure is not available or applicable. However, assigning zero measure achievement points when a required MIPS core measure is applicable, but the data submission requirement is not satisfied, is necessary to ensure that the MIPS core measure data submission requirement is meaningful and applied consistently across MIPS eligible clinicians. Additionally, we believe that clinician workflows will be able to support this policy because it is consistent with the existing policy under § 414.1380(b)(1) that MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335, on which no data is submitted in accordance with § 414.1325. As discussed in section IV.A.4.d.(1)(c)(i) of this final rule, the MIPS core measure inventory includes outcome measures or measures previously identified as high priority, and the MIPS core measure data submission requirement will replace the existing data submission requirement to report an outcome or high priority measure. Where a MIPS core measure is not available or applicable, clinicians may attest as such using the process defined in section IV.A.4.d.(1)(c)(iii)(B) of this final rule.

We also appreciate the commenters' interest in having an opportunity to evaluate the burden associated with MIPS core measure reporting and to gain experience with the applicable attestation requirements. We will continue to monitor implementation of the MIPS core measure data submission requirements, including clinician experience with the attestation process, reporting burden, and available submission and performance data. We refer readers to sections V.B.7.b.(1) and V.B.7.c.(1) for the discussion that we are not adjusting our burden estimates due to this policy.

Comment: A few commenters did not support the proposal to assign zero achievement points if no MIPS core measure or attestation is submitted. A commenter expressed concern with the proposal since eCQM MIPS core measures are not available for every MVP.

Response: Assigning zero measure achievement points when an applicable MIPS core measure is required but the data submission requirement is not satisfied is necessary to ensure that the MIPS core measure data submission requirement is meaningful and applied consistently across MIPS eligible clinicians. Without a scoring policy for not meeting the MIPS core measure data submission requirement, the requirement would have limited effect in promoting consistent reporting of MIPS core measures.

We recognize that the availability and applicability of MIPS core measures may vary, such as when no eCQM MIPS core measures are available in an MVP, which is why the data submission requirement as described in section IV.A.4.d.(1)(c)(iii)(B) of this final rule, does not require a clinician to report a MIPS core measure that is not available or applicable to the clinician. The clinician may attest to that circumstance and would not be assigned zero measure achievement points solely because the MIPS core measure was not available or applicable.

Comment: A commenter requested confirmation that an attestation stating that no applicable MIPS core measure exists would not result in the assignment of zero achievement points. A commenter suggested that CMS should not assign zero achievement points for not reporting a MIPS core measure until CMS has established clear applicability guidance and provided clinicians with an opportunity to correct

a submission if a measure applicability determination is not accepted. A commenter requested that CMS ensure that MIPS core measure scoring reflects the diversity and complexity of practices while supporting meaningful comparisons across clinicians.

Response: We agree that clear information regarding the applicability of MIPS core measures is important to support accurate reporting and scoring. As described in section IV.A.4.d.(1)(c)(iii)(B) of this final rule, when a MIPS core measure is not available or applicable, a MIPS eligible clinician may attest that the measure is not available or applicable. A MIPS eligible clinician who submits such an attestation that they do not have an available and applicable MIPS core measure would not be assigned zero measure achievement points for one quality measure in traditional MIPS or MVP as long as they report enough measures to meet the required number of six quality measures or a complete specialty measure set in traditional MIPS or four quality measures in MVP reporting. We recognize the importance of providing clinicians with sufficient information to understand the MIPS core measure data submission requirements, including the circumstances under which a MIPS core measure may be considered not available or applicable, as discussed in section IV.A.4.d.(1)(c)(iii)(B) of this final rule. We will continue to provide guidance and resources, as appropriate, to support clinicians in understanding and satisfying these requirements. After consideration of public comments, we are finalizing as proposed to assign zero measure achievement points for one quality measure if clinicians reporting traditional MIPS or MVP do not submit a MIPS core measure and do not attest during data submission that they do not have an available and applicable MIPS core measure. A MIPS eligible clinician who submits an attestation that they do not have an available and applicable MIPS core measure would not be assigned zero measure achievement points for one quality measure in traditional MIPS or MVP reporting as long as they report enough measures to meet the required number of six quality measures or a complete specialty measure set in traditional MIPS or four quality measures in MVP reporting. This policy is consistent with the existing § 414.1380(b)(1)(i).

(2) Small Practice Scoring Exemption Clarification for MIPS Core Measures

Historically, we have heard from clinicians in small practices that they face unique challenges to successfully participate in MIPS. To further support clinicians in small practices, who often have limited resources to successfully participate in MIPS, we implemented policies to provide them with more flexibilities. For example, as described under § 414.1380(b)(1)(v)(C), beginning with the CY 2019 performance period/2021 MIPS payment year, MIPS eligible clinicians in small practices receive six measure bonus points if they submit data to MIPS on at least one quality measure. To continue the existing flexibilities and further support clinicians in small practices, we are finalizing in section IV.A.4.d.(1)(c)(iii)(C) of this final rule, that small practice clinicians participating in both traditional MIPS and MVP reporting would be exempt from the MIPS core measure reporting requirement. Under this exemption, clinicians in small practices are not required to submit a MIPS core measure and will not need to attest during data submission if they do not have an available and applicable MIPS core measure. The existing regulation text under § 414.1380(b)(1)(i) states that MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 for which no data is submitted in accordance with § 414.1325. Consistent with the existing regulation at § 414.1380(b)(1)(i) and given the finalization of the proposal to exempt small practices from the MIPS core measure requirement in section IV.A.4.d.(1)(c)(iii)(C) of this final rule, we will not assign zero measure achievement points for one MIPS core measure if clinicians in small practices do not submit data for such measure in traditional MIPS and MVP reporting. If a small practice chooses to submit data on a MIPS core measure, we will include the MIPS core measure in the quality performance category score only if the MIPS core measure is one of the six highest scoring measures in traditional MIPS or one of the four highest scoring measures in MVP reporting, in accordance with the existing regulation under § 414.1380(b)(1)(i). We refer readers to Appendix 1: MIPS Quality Measures and Appendix 3: MVP Inventory of this final rule for details on the MIPS core measures inventory for the CY 2027 performance period/2029 MIPS payment year.

We received public comments on the proposal that small practice clinicians participating in both traditional MIPS and MVP reporting would be exempt from the MIPS core measure reporting requirement. We refer readers to section IV.A.4.d.(1)(c)(iii)(C) of this final rule for discussion of the public comments received.

(3) Scoring Topped Out Measures

(a) Background on Scoring Topped Out Measures

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules (81 FR 77282 through 77287, 82 FR 53721 through 53727, and 83 FR 59761 through 59765), the CY 2023, CY 2025, and CY 2026 PFS final rules (88 FR 70090 and 70091, 89 FR 98428 through 98435, and 90 FR 49902 through 49908), and § 414.1380(b)(1)(iv) for established topped out measure scoring policies.

Topped out measures are measures for which measure performance is considered so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (81 FR 77136). Section 1848(q)(3)(B) of the Act requires that in establishing performance standards with respect to measures and activities, we consider, among other things, the opportunity for continued improvement. Topped out measures do not provide an opportunity for continued improvement, nor do payment adjustments based on topped out measures incentivize clinicians to improve their care. As a result, we finalized policies in the CY 2018 Quality Payment Program final rule (82 FR 53723 through 53727) to identify and cap the scoring potential of topped out measures. Additionally, we established policies for the removal of topped out measures, such as establishing the topped out measure lifecycle, to continue to drive quality improvement in areas where such improvement is possible and necessary. The topped out measure lifecycle is described in the CY 2018 Quality Payment Program final rule (82 FR 53721 through 53727). We established at § 414.1380(b)(1)(iv)(B) that we will cap scoring for topped out measures at 7 measure achievement points in the second consecutive year that the measure benchmark is identified as topped out. If a measure has been identified as topped out for three consecutive years after being originally identified through the benchmarks, such measure may then be proposed for removal through notice-and-comment rulemaking (83 FR 59761). This timeline, however, is not fixed. We noted our concern that removal of topped out measures may leave clinicians with fewer than six applicable measures to report and that such removal in those instances will impact some specialties more than

others (82 FR 53721). We stated that consideration for ensuring available applicable measures would be made when considering measure removals (83 FR 59763).

In the CY 2018 Quality Payment Program final rule (82 FR 53727), we established the topped out scoring cap to encourage MIPS eligible clinicians to submit measures that are not topped out. However, we created an exemption to this policy in the CY 2025 PFS final rule (89 FR 98428 through 98435) for certain topped out measures that are frequently used by certain specialties impacted by limited measure choice (89 FR 98428 through 98435). To address scoring scenarios in which limited measure choice compels clinicians to report topped out measures with scoring caps, we finalized in the CY 2025 PFS final rule (89 FR 98428 through 98435) at § 414.1380(b)(1)(iv)(C) that beginning with the CY 2025 performance period/2027 MIPS payment year, topped out measures frequently used by certain specialties reporting specialty measure sets that are impacted by limited measure choice, as specified in accordance with § 414.1380(b)(1)(ii)(E), are not subject to the 7-point scoring cap. In the CY 2025 PFS final rule, we finalized at § 414.1380(b)(1)(ii)(E) that beginning with the CY 2025 performance period/2027 MIPS payment year, we will annually publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice. Measures included in the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period, in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

In the CY 2026 PFS final rule (90 FR 49904 through 49908), we modified our approach for identifying the list of measures impacted by limited measure choice and subject to defined topped out measure benchmarks. We finalized that each specialty measure set and MVP is reviewed by collection type to identify if the prevalence of topped out measures within such a set of measures hinders a clinician's ability to successfully participate in the MIPS quality performance category. To make such a determination, we finalized a policy stating that we will analyze the ability of clinicians reporting the specialty measure sets and MVPs to reasonably achieve 75 percent of available quality achievement points based upon the measures available to them and program requirements. Specifically, at the collection type level, each measure is assigned points based upon the current benchmarking data: new measures receive 7 or 5 points based on year in the program, measures with benchmarks are given points based upon the highest decile achievable with a less than perfect score (less than 100 percent or greater than 0 percent for inverse measures), and measures with no available historic benchmark are given 0 points. All measure set points are added together to get an output of scoring potential; the Medicare Part B claims collection type measure sets have an additional 6 points added to the output to account for the small practice bonus. The sum of quality achievement points for each specialty measure set and MVP are then compared to the analysis threshold of 75 percent of available quality achievement points, based on the number of available measures. Any specialty measure sets or MVPs that are unable to meet or exceed the analysis threshold are flagged as ''at-risk.'' Additional factors that we take into consideration include whether the topped out measure is considered a cross-cutting measure or is a broadly applicable measure, which we consider to be a measure included in three or more specialty sets or MVPs. We also consider whether the specialty measure set or MVP contains more than ten measures, by collection type (90 FR 49904 through 49908).

(b) Measures Impacted by Limited Measure Choice To Be Subject to Defined Topped Out Benchmark for the CY 2027 Performance Period/2029 MIPS Payment Year

Table C–H1 of this final rule contains the list of measures that meet the criteria for topped out measures impacted by limited measure choice in specialty measure sets and MVPs as finalized in the CY 2026 PFS final rule (90 FR 49904 through 49908), and for which we proposed, in the CY 2027 PFS proposed rule (91 FR 44201 through 44203), to apply the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year.

TABLE C-H1: TOPPED OUT MEASURES IMPACTED BY LIMITED MEASURE CHOICE AND SUBJECT TO DEFINED TOPPED OUT MEASURE BENCHMARKS FOR THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Measure ID	Collection Type	Measure Title
127	MIPS CQM	Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention - Evaluation of Footwear
144	MIPS CQM	Oncology: Medical and Radiation - Plan of Care for Pain
145	Medicare Part B Claims, MIPS CQM	Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy
249	Medicare Part B Claims, MIPS CQM	Barrett's Esophagus
250	Medicare Part B Claims, MIPS CQM	Radical Prostatectomy Pathology Reporting
351	MIPS CQM	Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation
360	MIPS CQM	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies
364	MIPS CQM	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines
395	Medicare Part B Claims, MIPS CQM	Lung Cancer Reporting (Biopsy/Cytology Specimens)
396	MIPS CQM	Lung Cancer Reporting (Resection Specimens)
397	Medicare Part B Claims, MIPS CQM	Melanoma Reporting
405	MIPS CQM	Appropriate Follow-up Imaging for Incidental Abdominal Lesions
406	Medicare Part B Claims, MIPS CQM	Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients
440	MIPS CQM	Skin Cancer: Biopsy Reporting Time - Pathologist to Clinician
477	MIPS CQM	Multimodal Pain Management

We discussed in the CY 2027 PFS proposed rule (91 FR 44201 through 44203) that we considered proposing measures 143: Oncology: Medical and Radiation—Pain Intensity Quantified (eCQM and MIPS CQM), 320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patient (Medicare Part B Claims and MIPS CQM), and 350: Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (MIPS CQM) to be subject to the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year since the measures met the criteria for topped out measures in specialty measure sets or MVPs impacted by limited measure choice according to the methodology finalized in the CY 2026 PFS final rule (90 FR 49904 through 49908). However, we did not propose these measures for the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year because we proposed to remove these measures from the MIPS quality performance category measure inventory for the CY 2027 performance period/2029 MIPS payment year in the CY 2027 PFS proposed rule (91 FR 44161 and 44162). We proposed that if we do not finalize the removal of these measures from the MIPS quality performance category inventory for the CY 2027 performance period/2029 MIPS payment year, we would score these measures with the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year. Since we are finalizing measures 143: Oncology: Medical and Radiation—Pain Intensity Quantified (eCQM and MIPS CQM), 320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patient (Medicare Part B Claims and MIPS CQM), and 350: Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical)

Therapy (MIPS for removal in section IV.A.4.d.(1)(e)(ii) of this final rule, the measures will not be subject to the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year. We had also proposed to score measures 430: Prevention of Post-Operative Nausea and Vomiting (PONV)—Combination Therapy and 463: Prevention of Post-Operative Vomiting (POV)—Combination Therapy (Pediatrics) to be scored according to the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year. However, because those measures are finalized for removal in Table Group C of Appendix 1 of this final rule, the measures will not be subject to the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed list of measures subject to the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year. Commenters expressed their belief that the defined topped out measure benchmark will provide scoring relief for clinicians who feel compelled to report topped out measures with the 7-point scoring cap due to limited measure choice.

Response: We thank commenters for their support.

Comment: Several commenters suggested CMS expand the criteria for measures impacted by limited measure choice and apply the defined topped out measure benchmark to additional topped out measures, including measures that do not meet the previously finalized criteria for topped out measures impacted by limited measure choice. Several commenters suggested CMS apply the defined topped out measure benchmark to all topped out measures. Commenters cited their belief that limiting the application of the defined topped out measure benchmark to a subset of topped out measures impacted by limited measure choice adds complexity, creates inequitable scoring opportunities across specialties, and does not fairly reward high performance on topped out measures. A commenter recommended that QCDR measures should be included in the defined topped out measure benchmark policy.

Response: The defined topped out measure benchmark is applied to measures impacted by limited measure choice, as determined by criteria finalized in the CY 2025 PFS final rule (89 FR 98432 through 98435) and CY 2026 PFS final rule (90 FR 49904 through 49908), using an analysis of the ability of clinicians reporting the specialty measure set or MVP to reasonably achieve 75 percent of available quality achievement points based upon the measures available to them and program requirements and factors such as whether the topped out measure is considered a cross-cutting or broadly applicable measure. These criteria were previously finalized in order to focus the application of the defined topped out measure benchmark to cases in which clinicians are unable to report sufficient non-topped out measures to successfully participate in the MIPS quality performance category, while maintaining the 7-point topped out measure scoring cap to continue to encourage MIPS eligible clinicians to submit measures that are not topped out in cases where there is not limited measure choice. We believe that encouraging clinicians to report non-topped out measures outweighs the complexity of only scoring some topped out measures using the defined topped out measure benchmark, and applying the defined topped out measure benchmark to all topped out measures may lead to increased reporting of topped out measures and increased quality performance category scores and the overall final scores. Because topped out measures do not provide an opportunity for continued improvement, nor do payment adjustments based on topped out measures incentivize clinicians to improve their care, we continue to believe the 7-point topped out measure scoring cap is appropriate. We will continue to monitor the impact of the topped out measure scoring cap and conduct future assessments to determine whether the criteria should be updated. In section IV.B.1.a.(3)(c) of this final rule, we are finalizing MIPS core measures in their second or more consecutive year of being topped out will also be scored using the defined topped out benchmark, which will provide additional scoring relief for clinicians reporting topped out MIPS core measures. QCDR measures are not included in the defined topped out measure benchmark policy since they are governed by policy at § 414.1400(b)(4)(iii)(C) stating that CMS may revoke a measure's second year approval if identified as topped out.

Comment: A commenter requested that CMS not omit the ninth decile in the defined topped out measure benchmark because they believed it would result in more consistent and fair scoring.

Response: We clarify that the defined topped out measure benchmark does not omit any decile. In the CY 2025 PFS final rule (89 FR 98429 through 98432), we discussed that we proposed to remove the ninth decile for the defined topped out measure benchmark, however, that policy was not finalized. We finalized the defined topped out measure benchmark to include the ninth decile, which corresponds to a performance rate from 99 to 99.9 percent.

Comment: A commenter recommended that CMS set a 2-year timeframe for reevaluating measures selected for the list of topped out measures impacted by limited measure choice.

Response: We do not apply the defined topped out measure benchmarks for a 2-year timeframe because measure performance varies each year, and thus a measure's topped out status may change each year.

After consideration of public comments, we are finalizing as proposed the list of topped out measures impacted by limited measure choice and subject to the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year.

(c) Scoring Topped Out MIPS Core Measures According to Defined Topped Out Benchmark

In the CY 2027 PFS proposed rule (91 FR 44157 and 44158), we proposed that MIPS eligible clinicians would need to report a MIPS core measure as one of their six required quality measures in traditional MIPS or one of their four required quality measures in MVP reporting, beginning in the CY 2027 performance period/2029 MIPS payment year. We refer readers to Appendix 1: MIPS Quality Measures and Appendix 3: MVP Inventory of this final rule for the MIPS core measure inventory. There were 19 proposed MIPS core measures that are topped out and subject to the 7-point topped out measure scoring cap for the CY 2026 performance period/2028 MIPS payment year. To address scoring scenarios in which limited measure choice compels clinicians to report topped out measures with scoring caps, we finalized the defined topped out benchmark in the CY 2025 PFS final rule (89 FR 98428 through 98435). The defined topped out benchmark removes the 7-point scoring cap for topped out measures and scores them from 1 to 10 measure achievement points according

to a benchmark calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

The prevalence of topped out MIPS core measures, combined with the limited measure choice associated with MIPS core measures, could result in a clinician being compelled to report a topped out MIPS core measure as one of their six required quality measures in traditional MIPS or one of their four required quality measures in MVP reporting. Given the combination of limited measure choice and the 7-point scoring cap for topped out measures, we are concerned that the application of the 7-point scoring cap to topped out MIPS core measures would penalize clinicians for complying with the MIPS core measure reporting requirement. Therefore, we proposed in the CY 2027 PFS proposed rule (91 FR 44203) that MIPS core measures in their second or more consecutive year of being topped out would not be subject to the 7-point topped out measure scoring cap, and instead the measures would be scored from 1 to 10 measure achievement points according to the defined topped out benchmark.

Subsequently, we proposed to create the scoring methodology for MIPS core measures that are topped out. Thus, we proposed to amend and codify at § 414.1380(b)(1)(ii) by establishing a new provision at § 414.1380(b)(1)(ii)(H), which would establish the scoring (1 to 10 measure achievement points) for MIPS core measures that have benchmarks identified as topped out for 2 or more consecutive years. Specifically, we proposed to establish and codify at § 414.1380(b)(1)(ii)(H), which would determine the following: Beginning in the CY 2027 performance period/2029 MIPS payment year, MIPS core measures, which are required under § 414.1335(a)(1)(i) and (ii), for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years, are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year. Also, we proposed for MIPS core measures not to be subject to the 7-point topped out measure scoring cap. Specifically, we proposed to amend and codify at § 414.1380(b)(1)(iv) by establishing a new provision at § 414.1380(b)(1)(iv)(D), which would determine the following: Beginning with the CY 2027 performance period/2029 MIPS payment year, MIPS core measures, which are required under § 414.1335(a)(1)(i) and (ii), are not subject to the 7 measure achievement point cap specified at § 414.1380(b)(1)(iv)(B).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for the proposal that MIPS core measures in their second or more consecutive year of being topped out would not be subject to the 7-point topped out measure scoring cap, and instead the measures would be scored from 1 to 10 measure achievement points according to the defined topped out benchmark. Commenters expressed their belief that the 7-point topped out scoring cap would unfairly limit scoring opportunities for MIPS core measures because of the MIPS core measure reporting requirement, as discussed in section IV.A.4.d.(1)(c)(iii)(B) of this final rule.

Response: We thank commenters for their support.

Comment: A few commenters requested clarification regarding whether the proposal to score MIPS core measures in their second or more consecutive year of being topped out according to the defined topped out benchmark would apply to all measures designated as MIPS core measures, even, for example, when reported via an MVP in which the measure is not a MIPS core measure for that MVP, but the measure is a MIPS core measure in another MVP. A commenter also requested clarification regarding whether the topped out MIPS core measure would be scored with the defined topped out measure benchmark if a clinician reports more than one MIPS core measure.

Response: The defined topped out measure benchmark will be applied to all measures designated as MIPS core measures that are in their second or more consecutive year of being topped out. The defined topped out measure benchmark will be applied every time the measure is reported, even if the measure is not designated as a MIPS core measure in the MVP being reported, and even if a clinician has additionally reported other MIPS core measures.

Comment: A commenter expressed concern that scoring MIPS core measures in their second or more consecutive year of being topped out from 1 to 10 measure achievement points according to the defined topped out benchmark would not adequately address the scoring limitations of topped out MIPS core measures, citing their belief that the heavily skewed distribution of topped out measure performance limits a clinician's ability to earn a high score if their performance rate is below 100 percent.

Response: The defined topped out measure benchmark, as described in the CY 2025 PFS final rule (89 FR 98429), is intended to address the heavily skewed performance distribution of topped out measures. Specifically, the defined topped out benchmark aims, for clinicians with limited measure availability, to continue to account for high performance without capping the scoring potential at 7 point for exceptional performers and offers better scoring opportunities for those performing higher than the median score in the distribution. . A performance rate of 97 percent corresponds to a score equivalent to 10 percent of the performance threshold. For example, if the performance threshold is 75, a performance rate of 97 percent would earn 7.5 measure achievement points. A clinician with a performance rate of 98–99 percent would earn 8–9 measure achievement points, which rewards clinicians with high performance.

After consideration of public comments, we are finalizing as proposed that MIPS core measures in their second or more consecutive year of being topped out would not be subject to the 7-point topped out measure scoring cap, and instead the measures would be scored from 1 to 10 measure achievement points according to the defined topped out benchmark.

(d) Clarification Regarding Scoring Non-Topped Out Measures According to Historical Benchmark

In the CY 2025 PFS final rule (89 FR 98428 through 98435), we finalized at § 414.1380(b)(1)(ii)(E) that beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice on an annual basis. Measures included in the list will be scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year. The measures are identified using a methodology finalized in the CY 2026

PFS final rule (90 FR 49904 through 49908), which analyzes whether the prevalence of topped out measures within a specialty measure set or an MVP hinders a clinician's ability to successfully participate in the MIPS quality performance category. Using current benchmarking data, the analysis evaluates the ability of clinicians to reasonably achieve 75 percent of available quality achievement points given the measures available to them and program requirements.

At the time of the internal analysis to inform the list of measures impacted by limited measure choice, the most current benchmarking data is for the performance period prior to that which the defined topped out measure benchmark would be applied. For example, we analyzed CY 2026 benchmarks to inform the list of measures impacted by limited measure choice for the CY 2027 performance period/2029 MIPS payment year. Therefore, there are instances in which a measure is finalized to be scored according to the defined topped out benchmark for a given performance period, but it is later determined that the historic baseline period benchmark for that measure is not topped out for that performance period. This was the case for Medicare Part B Claims Measure 141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20 percent OR Documentation of a Plan of Care for the CY 2026 performance period/2028 MIPS payment year. In the CY 2026 PFS final rule (90 FR 49906 through 49908), we finalized Medicare Part B Claims Measure 141 to be scored according to the defined topped out measure benchmark for the CY 2026 performance period/2028 MIPS payment year based on an analysis of the CY 2025 performance period/2027 MIPS payment year benchmarks, the most recently available benchmarks at the time of the analysis. However, the subsequently released benchmarks for the CY 2026 performance period/2028 MIPS payment year indicated that the baseline period benchmark for Medicare Part B Claims Measure 141 was not topped out. Given the topped out measure lifecycle, as finalized in the CY 2018 Quality Payment Program final rule (82 FR 53721 through 53727), Medicare Part B Claims Measure 141 would not be capped at 7 measure achievement points for the CY 2026 performance period/2028 MIPS payment year since it was not topped out.

If a measure is not topped out, it no longer meets the criteria for the removal of the 7 measure achievement point cap. We clarify that if a measure previously finalized for removing the 7-point cap is no longer topped out, it will be scored using its historical benchmark instead of the topped out measure benchmark.

(e) Modify Location for Publishing List of Measures Subject to Defined Topped Out Benchmark

In the CY 2025 PFS final rule (89 FR 98428 through 98435), we finalized at § 414.1380(b)(1)(ii)(E) to state that beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice on a yearly basis. Measures included in the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year. In the CY 2026 PFS final rule (90 FR 49904 through 49908), we finalized the methodology to identify topped out measures impacted by limited measure choice. We analyzed whether the prevalence of topped out measures with a 7-point cap within a specialty measure set or an MVP hinders a clinician's ability to successfully participate in the MIPS quality performance category. This analysis was based on the most current benchmarking data available at that time. We finalized in the CY 2018 Quality Payment Program final rule that MIPS eligible clinicians will know the quality performance category measure benchmarks in advance of the performance period, when possible (81 FR 77271 and 77272), and that the benchmarks will be posted on the Quality Payment Program website (81 FR 77139).

Given the benchmark availability timeline, the list of topped out measures scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark published in the **Federal Register** for a performance period may not accurately indicate whether a measure is topped out for that performance period. For example, as discussed in the CY 2027 PFS proposed rule (91 FR 44203 and 44204), a measure previously determined to be topped out and scored from 1 to 10 points for the CY 2026 performance period/2028 MIPS payment year based on data using the CY 2025 performance period benchmarks was later found not to be topped out based on the updated CY 2026 benchmarks. This occurs because, during the time of analysis to identify measures impacted by limited measure choice, only the most recent benchmarks from the prior performance period are available. For example, we analyzed CY 2026 performance period benchmarks to inform topped out measures impacted by limited measure choice for the CY 2027 performance period/2029 MIPS payment year.

We are concerned that publishing the list of topped out measures impacted by limited measure choice and scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark in the **Federal Register**, prior to the benchmark information for that performance period being available, can lead to confusion. To avoid confusion for clinicians, we proposed in the CY 2027 PFS proposed rule (91 FR 44204) that, beginning in the CY 2027 performance period/2029 MIPS payment year, we would publish the list of topped out measures impacted by limited measure choice and scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark on the Quality Payment Program website at *https://qpp.cms.gov.* Specifically, we proposed to remove the phrase ''in the **Federal Register**'' under § 414.1380(b)(1)(ii)(E).

Further, we noted in the CY 2027 PFS proposed rule (91 FR 44204) that the measures included in this list would still be identified using the previously finalized methodology for determining topped out measures impacted by limited measure choice in specialty measure sets and MVPs, as finalized in the CY 2026 PFS final rule (90 FR 49904 through 49908). By publishing the list of topped out measures impacted by limited measure choice on the Quality Payment Program website, we would be able to update the list, once the benchmark information for that performance period becomes available, to remove measures that are not topped out for that performance period, consistent with the topped out measure lifecycle finalized in the CY 2018 Quality Payment Program final rule (82 FR 53721 through 53727). We refer readers to section IV.B.1.b.(3)(d) of this final rule for our discussion that measures previously finalized to be scored using the defined topped out benchmark will instead be scored using the baseline period benchmark if updated benchmark data show the measure is not topped out for that performance period.

As discussed in the CY 2027 PFS proposed rule (91 FR 44204), we would publish the list of topped out measures impacted by limited measure choice and

scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark on the Quality Payment Program website no later than the publication of the proposed rule for that CY performance period/MIPS payment year. This timeline would provide interested parties with sufficient opportunity to review and provide comments on the list of measures during the public comment period for that proposed rule. This would mean that a list of measures subject to the defined topped out measure benchmark for a given performance year would be published three times: once following the publication of that year's proposed rule, once with the final rule, and once again when the benchmarks for that performance year are published. Once the list of topped out measures impacted by limited measure choice and scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark is published with the final rule, the only changes to the list would be the removal of a measure because it is no longer topped out based on most current benchmarks published in the performance period, consistent with the topped out measure lifecycle finalized in the CY 2018 Quality Payment Program final rule (82 FR 53721 through 53727).

Thus, we proposed to amend § 414.1380(b)(1)(ii)(E) by removing the phrase ''in the **Federal Register**''. Also, we proposed a technical amendment in § 414.1380(b)(1)(ii)(E) for grammar purposes, which would modify the beginning of the second sentence in § 414.1380(b)(1)(ii)(E) from ''. . . measure included in the list . . .'' to ''measure included on the list . . .''.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to publish the list of topped out measures impacted by limited measure choice and scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark on the Quality Payment Program website, expressing their belief that the policy would increase transparency and external party engagement.

Response: We thank the commenters for their support.

Comment: A commenter suggested that the proposed rule should publish the list of measures to be scored with the defined topped out measure benchmark prospectively within the rule or other annual updates ahead of the respective performance year and not on the Quality Payment Program website. The commenter expressed their belief that this would assist with planning and workflow efforts and not result in last-minute changes.

Response: The proposal to publish the list of measures to be scored with the defined topped out measure benchmark on the Quality Payment Program website is intended to provide accurate and timely information to provide opportunities for clinicians to develop planning and workflow efforts and mitigate last-minute changes. We will publish the list of topped out measures impacted by limited measure choice and scored according to the defined topped out measure benchmark no later than the publication of the proposed rule for the respective performance year. Maintaining the list of measures on the Quality Payment Program website will provide clinicians with the most up to date benchmark information as benchmark data becomes available for the respective performance year.

After consideration of public comments, we are finalizing that beginning in the CY 2027 performance period/2029 MIPS payment year, we will publish the list of topped out measures impacted by limited measure choice and scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark on the Quality Payment Program website at *https://qpp.cms.gov* with the proposed rule, final rule, and publication of benchmarks for a given performance year. Once published, the only revisions to the list would be the removal of measures that are no longer topped out or those finalized for removal by notice and comment rulemaking. These measures will still be identified by our methodology previously established for determining topped out measures impacted by limited measure choice in specialty measure sets and MVPs, as finalized in the CY 2026 PFS final rule (90 FR 49904 through 49908).

In order to improve the clarity of the regulation text, we are modifying our proposed amendment to § 414.1380(b)(1)(ii)(E). Rather than removing the phrase ''in the **Federal Register**'' from § 414.1380(b)(1)(ii)(E), we are finalizing that we will specify that beginning for the CY 2025 and 2026 performance periods/2027 and 2028 MIPS payment years, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice, and beginning in the CY 2027 performance period/2029 MIPS payment year, remove the phrase ''in the **Federal Register**'' and replace it with ''on the QPP website''. We are also finalizing as proposed the technical amendment in § 414.1380(b)(1)(ii)(E) for grammar purposes, which will modify the beginning of the second sentence in § 414.1380(b)(1)(ii)(E) from ''. . . measure included in the list . . .'' to ''measure included on the list . . .''. The revised § 414.1380(b)(1)(ii)(E) will state: For the CY 2025 and 2026 performance periods/2027 and 2028 MIPS payment years, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice on a yearly basis. Beginning with the CY 2027 performance period/2029 MIPS payment year, CMS will publish a list of topped out measures determined to be impacted by limited measure choice on the QPP website. Measures included on the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

c. Scoring the Quality Performance Category for Medicare Shared Savings Program ACOs

(1) Use Flat Benchmarks To Score Medicare Shared Savings Program ACOs Reporting Medicare CQMs

In the CY 2025 PFS final rule (89 FR 98117), we finalized our proposal to establish new benchmarks for scoring Medicare Shared Savings Program ACOs on the Medicare CQMs under MIPS in alignment with MIPS benchmarking policies. As historical Medicare CQM data would not be available, we finalized that for performance years 2024 and 2025, we will score Medicare CQMs using performance period benchmarks. We also finalized that, for performance year 2026 and subsequent performance years, when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii), we would score Medicare CQMs using historical benchmarks. In the CY 2025 PFS final rule, we also finalized our proposal to add § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type would be scored using flat benchmarks for their first two performance periods in MIPS (89 FR 98120).

As described in the CY 2027 PFS proposed rule (91 FR 44205), we proposed to modify § 414.1380(b)(1)(ii)(F) by removing the applicability of the first two performance periods to the use of flat benchmarks and extending the use of flat benchmarks to score all Medicare CQMs for performance year 2025 and subsequent performance years. Also, we proposed to retroactively apply flat benchmarks to Quality Measure ID: 001 (Diabetes: Glycemic Status Assessment Greater Than 9%), Quality Measure ID: 134 (Preventive Care and Screening: Screening for Depression and Follow-up Plan), and Quality Measure ID: 236 (Controlling High Blood Pressure), if reported via the Medicare CQMs collection type for performance year 2026.

Specifically, we proposed to amend and codify at § 414.1380(b)(1)(ii)(F), by converting such section to a title section entitled ''Medicare CQMs collection type benchmarks'' and establishing § 414.1380(b)(1)(ii)(F)(*1*) and (*2*). In § 414.1380(b)(1)(ii)(F)(*1*), we proposed that for the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQMs collection type would utilize flat benchmarks for their first two performance periods in MIPS. In § 414.1380(b)(1)(ii)(F)(*2*), we proposed to retroactively apply the utilization of flat benchmarks for the Medicare CQMs collection type beginning with the CY 2026 performance period/2028 MIPS payment year. Specifically, we proposed that beginning with the CY 2026 performance period/2028 MIPS payment year, measures of the Medicare CQMs collection type would utilize flat benchmarks. We refer readers to the CY 2027 PFS proposed rule (91 FR 44039 through 44044) for further discussion regarding the extension of applying the utilization of flat benchmarks for the Medicare CQMs collection type, including discussion about the retroactive use of flat benchmarks for the Medicare CQMs collection type for the CY 2026 performance period/2028 MIPS payment year.

We requested public comment on these proposals.

We received public comments on the proposals. The following is a summary of the comments we received and our responses. However, we note that additional comments and responses pertaining to the extension and retroactive application of utilizing flat benchmarks for the Medicare CQMs collection type are discussed in section III.G.3.c. of this final rule.

Comment: Many commenters supported the utilization of flat benchmarks to assess performance for the Medicare CQM collection type for the CY 2027 performance period and subsequent performance periods. The commenters stated that the extension of flat benchmarks provides increased predictability, transparency, and stability during the transition to digital quality measurement.

Response: We appreciate the support from commenters; and agree with commenters. As discussed in the CY 2027 PFS proposed rule (91 FR 44039 through 44044), the extension of utilizing flat benchmarks for the Medicare CQMs collection type provides continuity and supports the transition to digital quality measurement (91 FR 44039 through 44044). In the CY 2025 PFS final rule, we indicated that the use of flat benchmarks would allow Medicare Shared Savings Program ACOs with high scores to earn maximum or near maximum achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years (89 FR 98118). The use of flat benchmarks helps to ensure that Medicare Shared Savings Program ACOs with high performance on a measure are not penalized as low performers (89 FR 98118).

Comment: Many commenters supported the proposal to retroactively apply the flat benchmark to assess performance on Quality Measure ID: 001 (Diabetes: Glycemic Status Assessment Greater Than 9%), Quality Measure ID: 134 (Preventive Care and Screening: Screening for Depression and Follow-up Plan), and Quality Measure ID: 236 (Controlling High Blood Pressure) for the CY 2026 performance period. Several commenters stated that the retroactive application of flat benchmarks improves benchmarking transparency, reduces reporting uncertainty, and promotes scoring consistency.

Response: We agree with commenters and appreciate the support.

Comment: A commenter expressed concern regarding the application of flat benchmarks to Quality Measure ID: 001 (Diabetes: Glycemic Status Assessment Greater Than 9%) and Quality Measure ID: 236 (Controlling High Blood Pressure), conveying that such measures are influenced by patient complexity, risk factors, and resource constraints. The commenter stated that flat benchmarks may not reflect such differences and could unintentionally disadvantage clinicians caring for high-risk or underserved populations.

Response: As described in the CY 2027 PFS proposed rule (91 FR 44039), we analyzed performance year 2024 data on Shared Savings Program ACOs that reported all three Medicare CQMs (Quality Measure ID: 001 (Diabetes: Glycemic Status Assessment Greater Than 9%), Quality Measure ID: 134 (Preventive Care and Screening: Screening for Depression and Follow-up Plan), and Quality Measure ID: 236 (Controlling High Blood Pressure)) in the APP quality measure set, which had performance-based benchmarks, and compared performance year 2024 quality scores to simulated quality scores using flat benchmarks for the three Medicare CQMs. The analysis showed that the use of flat benchmarks was estimated to increase average quality scores by 11 percentage points; thus, increasing the likelihood that Shared Savings Program ACOs would meet the quality performance standard for sharing in savings at the maximum rate under its track. The analysis illustrated that the use of performance-based benchmarks, if flat benchmarks are not used, could lead to Medicare Shared Savings Program ACOs forgoing shared savings that might otherwise have been available for reinvestment. As such, applying flat benchmarks would afford the Medicare Shared Savings Program ACOs with increased shared savings the opportunity to devote greater resources to providing better quality of care to Medicare beneficiaries over time and improving care coordination that benefits the Medicare beneficiaries served by the Medicare Shared Savings Program ACOs. For further discussion, we refer readers to section III.G.3.c. of this final rule.

Comment: A few commenters requested CMS to periodically reassess the appropriateness of flat benchmarks and evaluate whether observed performance changes reflect improvements in care or differences in data captured and reporting methods. A commenter requested that CMS monitor performance to ensure that benchmarks appropriately distinguish high performers while avoiding unintended consequences for organizations serving medically complex, rural, or socially at-risk populations.

Response: We will continue to monitor the uptake of Medicare CQMs by Medicare Shared Savings Program ACOs and the appropriateness of the flat benchmarks, and evaluate how quality of care or care improvements are assessed and rewarded as a result of using flat benchmarks.

After consideration of public comments, we are finalizing the following proposals, as proposed.

- Modify § 414.1380(b)(1)(ii)(F) by removing the applicability of the first two performance periods to the use of

flat benchmarks and extending the use of flat benchmarks to score all Medicare CQMs for performance year 2026 and subsequent performance years.

- Retroactively apply flat benchmarks to Quality Measure ID: 001 (Diabetes: Glycemic Status Assessment Greater Than 9%), Quality Measure ID: 134 (Preventive Care and Screening: Screening for Depression and Follow-up Plan), and Quality Measure ID: 236 (Controlling High Blood Pressure), if reported via the Medicare CQMs collection type for performance year 2026.
- Specifically, amend and codify at § 414.1380(b)(1)(ii)(F) by converting such section to a title section entitled ''Medicare CQMs collection type benchmarks'' and establish § 414.1380(b)(1)(ii)(F)(*1*) and (*2*).

++ In § 414.1380(b)(1)(ii)(F)(*1*), we establish that for the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQMs collection type use flat benchmarks for their first two performance periods in MIPS.

++ In § 414.1380(b)(1)(ii)(F)(*2*), we are retroactively applying the utilization of flat benchmarks for the Medicare CQMs collection type beginning with the CY 2026 performance period/2028 MIPS payment year. Specifically, beginning with the CY 2026 performance period/2028 MIPS payment year, measures of the Medicare CQMs collection type use flat benchmarks.

(2) Use Flat Benchmarks To Score Medicare Shared Savings Program ACOs Reporting Medicare eCQMs

As described in the CY 2027 PFS proposed rule (91 FR 44205), we proposed to develop a policy that establishes the utilization of flat benchmarks for measures of the newly proposed Medicare eCQMs collection type reported by Medicare Shared Savings Program ACOs. As a result, Medicare eCQMs would be scored using flat benchmarks beginning with the 2027 performance period. To effectuate such proposal under MIPS for purposes of assessing and scoring performance for the quality performance category, we proposed to add § 414.1380(b)(1)(ii)(G) to establish a new provision specific to benchmarks for measures of the Medicare eCQMs collection type, entitled ''Medicare eCQMs collection type benchmarks.'' Subsequently, we proposed to add § 414.1380(b)(1)(ii)(G)(1), which establishes the utilization of flat benchmarks under the Medicare eCQMs collection type benchmarks provision established at § 414.1380(b)(1)(ii)(G). Specifically, we proposed in § 414.1380(b)(1)(ii)(G)(1) to establish that beginning with the CY 2027 performance period/2029 MIPS payment year, measures of the Medicare eCQMs collection type would utilize flat benchmarks.

We requested public comment on this proposal.

We received public comments on the proposal. The following is a summary of the comments we received and our responses. However, please note that additional comments and responses pertaining to the utilization of flat benchmarks for the Medicare eCQMs collection type are discussed in section III.G.3.d.(3) of this final rule.

Comment: Several commenters supported the proposal to develop a policy that establishes the utilization of flat benchmarks for measures of the new Medicare eCQMs collection type reported by Medicare Shared Savings Program ACOs. The commenters indicated that the utilization of flat benchmarks provides a consistent, predictable, and transparent scoring methodology.

Response: We appreciate the support from commenters. We refer readers to section III.G.3.d.(3) of this final rule for further discussion and additional comments/responses regarding the implementation and reporting requirements of the Medicare eCQMs collection type within the APP Plus measure set.

Comment: A few commenters expressed concern regarding the reporting of Medicare eCQMs, which could be associated with lower performance rates compared to the reporting of Medicare CQMs.

Response: We appreciate the feedback from commenters regarding the concern about potentially lower performance rates for eCQMs compared with reported CQM rates. For further discussion, we refer readers to section III.G.3.d.(3) of this final rule.

After consideration of public comment, we are finalizing the proposal, as proposed, to add § 414.1380(b)(1)(ii)(G), which establishes a new provision specific to benchmarks for measures of the Medicare eCQMs collection type, entitled ''Medicare eCQMs collection type benchmarks,'' and add § 414.1380(b)(1)(ii)(G)(1), which establishes the utilization of flat benchmarks under the Medicare eCQMs collection benchmarks provision established at § 414.1380(b)(1)(ii)(G). Specifically, in § 414.1380(b)(1)(ii)(G)(1), we establish that beginning with the CY 2027 performance period/2029 MIPS payment year, measures of the Medicare eCQMs collection type use flat benchmarks.

d. Scoring the Promoting Interoperability Performance Category

(1) Modify the Scoring of the Electronic Prior Authorization Measure for CY 2027 Performance Period/2029 MIPS Payment Year

In the CY 2027 PFS proposed rule (91 FR 44177 and 44178), we proposed to modify the Electronic Prior Authorization measure by changing the measure from a required measure to an optional measure and eligible for 10 bonus points when MIPS eligible clinicians affirmatively attest (''Yes'' response) to meeting the requirements of the measure for the CY 2027 performance period/2029 MIPS payment year. We believed that the allocation of 10 bonus points is an appropriate and effective incentive to promote the adoption and use of certified technology for requesting electronic prior authorizations among MIPS eligible clinicians. To account for the allocation of bonus points specific to the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year, we noted that the scoring methodology for optional measures available for bonus points needed to be amended.

In § 414.1380(b)(4)(ii)(C)(3), the optional measures available for reporting are not identified or categorized by objective; however, the applicable optional measures available in the MIPS Promoting Interoperability performance category as of the CY 2026 performance period (Syndromic Surveillance Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Public Health Reporting Using TEFCA) are all under the Public Health and Clinical Data Exchange objective. When reporting one, more than one, or all such optional measures, the total number of bonus points that could be earned is five bonus points. To distinguish between such optional measures that are available under the Public Health and Clinical Data Exchange objective and the Electronic Prior Authorization measure as an optional measure for the CY 2027 performance period/2029 MIPS payment year that is under the Health Information Exchange objective and has an allocation of 10 bonus points, we proposed to modify the scoring methodology to account for the optional measures available under each applicable objective within the MIPS Promoting Interoperability performance category.

We proposed to modify the scoring methodology for optional measures to reflect an allocation of a total of five bonus points when reporting one, more than one, or all optional measures (Syndromic Surveillance Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Public Health Reporting Using TEFCA) available under the Public Health and Clinical Data Exchange objective and an allocation of a total of 10 bonus points when reporting the optional Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year available under the Health Information Exchange objective.

Thus, we proposed to amend § 414.1380(b)(4)(ii)(C)(*3*) by modifying the provision to identify the MIPS Promoting Interoperability performance category objective, specifically the Public Health and Clinical Data Exchange objective, in which the applicable optional measures are available to earn a total of five bonus points when reporting one, more than one, or all optional measures. Specifically, we proposed to amend § 414.1380(b)(4)(ii)(C)(*3*) by modifying the provision to indicate that the total number of bonus points available to be earned when reporting one optional measure, more than one optional measure, or all optional measures under the Public Health and Clinical Data Exchange objective is a total of five bonus points beginning with the CY 2026 performance period/2028 MIPS payment year. Additionally, we proposed to establish a new provision at § 414.1380(b)(4)(ii)(C)(*4*) to account for the Electronic Prior Authorization measure being an optional measure under the Health Information Exchange objective and having an allocation of a total of 10 bonus points for the CY 2027 performance period/2029 MIPS payment year. Specifically, we proposed to establish § 414.1380(b)(4)(ii)(C)(*4*), which would determine that the total number of bonus points available to be earned when reporting the Electronic Prior Authorization optional measure is a total of 10 bonus points for the CY 2027 performance period/2029 MIPS payment year. The establishment of such provision (only applicable to the CY 2027 performance period/2029 MIPS payment year) would enable a MIPS eligible clinician to earn 10 bonus points for affirmatively attesting that they requested a prior authorization electronically from a payer's Prior Authorization API using data from CEHRT for at least one medical item or service (excluding drugs) ordered within the CY 2027 performance period/2029 MIPS payment year.

We requested public comment on this proposal.

We received public comment on the proposal. The following is a summary of the comments we received and our response.

Comment: Some commenters supported the proposal to enable a MIPS eligible clinician to earn 10 bonus points for affirmatively attesting that they requested a prior authorization electronically from a payer's Prior Authorization API using data from CEHRT for at least one medical item or service (excluding drugs) ordered within the CY 2027 performance period/2029 MIPS payment year. The commenters conveyed that such approach provides a transition period for MIPS eligible clinicians to prepare for implementation and meeting the requirements of the measure before the measure becomes required beginning with the CY 2028 performance period/2030 MIPS payment year. A commenter expressed support for the Electronic Prior Authorization measure not being required for the CY 2027 performance period, which would not negatively impact MIPS eligible clinicians who do not report the optional measure.

Response: We appreciate the support from commenters.

After consideration of public comment, we are finalizing the proposal, as proposed, to modify the scoring methodology for optional measures to reflect an allocation of a total of five bonus points when reporting one, more than one, or all optional measures (Syndromic Surveillance Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Public Health Reporting Using TEFCA) available under the Public Health and Clinical Data Exchange objective and an allocation of a total of 10 bonus points when reporting the optional Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year available under the Health Information Exchange objective.

Specifically, we are:

- Amending § 414.1380(b)(4)(ii)(C)(*3*) by modifying the provision to indicate that the total number of bonus points available to be earned when reporting one optional measure, more than one optional measure, or all optional measures under the Public Health and Clinical Data Exchange objective is a total of five bonus points beginning with the CY 2026 performance period/2028 MIPS payment year.
- Establishing a new provision at § 414.1380(b)(4)(ii)(C)(*4*), which determines that the total number of bonus points available to be earned when reporting the Electronic Prior Authorization optional measure is a total of 10 bonus points for the CY 2027 performance period/2029 MIPS payment year. The establishment of such provision (only applicable to the CY 2027 performance period/2029 MIPS payment year) enables a MIPS eligible clinician to earn 10 bonus points for affirmatively attesting that they requested a prior authorization electronically using CEHRT to send a request through a payer's Prior Authorization API for at least one medical item or service (excluding drugs) ordered within the CY 2027 performance period/2029 MIPS payment year.

e. MVP Scoring Request for Information

As we move toward the full implementation of MVPs, we are exploring scoring policies that consider commenter feedback and align with the intended goals of MVPs. Specifically, we are exploring an MVP scoring methodology and policies to fairly evaluate and reward MVP participants for delivering high-quality and low-cost care by comparing clinician performance with others reporting the same MVP. As we consider policy options for MVP scoring, we sought comments on questions in the CY 2027 PFS proposed rule (91 FR 44206 through 44207) to inform further discussion and considerations for the future of MVP scoring. We received many comments in response to this request for information and appreciate all the input received. We will consider the feedback shared with CMS in future rulemaking.

f. Scoring the Improvement Activities Performance Category for APMs

In the CY 2017 Quality Payment Program final rule (81 FR 77008 through 77012), we established policies for scoring the improvement activities performance category, including criteria for weighting and attestation. In that same rule, we also established special scoring provisions for MIPS eligible clinicians participating in Alternative Payment Models (APMs), recognizing that such clinicians are often already engaged in activities aligned with MIPS improvement activities through their APM participation. Specifically, we finalized a policy under § 414.1380(b)(3)(i) to assign a minimum score for the improvement activities performance category for MIPS eligible clinicians participating in APMs (81 FR 77096). We explained that this approach was intended to reduce reporting

burden while acknowledging that APM participants are typically undertaking practice improvement efforts consistent with the goals of the improvement activities performance category.

We have maintained this policy in subsequent rulemaking, specifically the CY 2021 PFS final rule (85 FR 84472), we attempted to ensure that scoring this category did not inadvertently harm participants. However, in doing so we introduced scenarios where IA scores for some APM participants would not be awarded credit as established in section 1848(q) of the Act.

We proposed to revise § 414.1380(b)(3)(i) to clarify and maintain that, for MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent. This revision is consistent with the policy we established in the CY 2017 Quality Payment Program.

We requested public comment on this proposal.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

C. Third-Party Intermediaries General Requirements

1. Background

We refer readers to 42 CFR 414.1305,414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84926 through 84947), the CY 2022 PFS final rule (86 FR 65538 through 65550), CY 2023 PFS final rule (87 70102 FR through 70109), the CY 2024 PFS final rule (88 FR 79381 through 79394), the CY 2025 PFS final rule (89 FR 98459), and the CY 2026 PFS final rule (90 FR 49920) for our previously established policies regarding third-party intermediaries.

In this section of the final rule, we update our requirements for third-party intermediaries related to conditions for approval for Qualified Clinical Data Registries (QCDRs) and qualified registries, remove the additional requirements for health IT vendors, and update our remedial action/termination policies. Specifically, we proposed the following in the CY 2027 PFS proposed rule (91 FR 44207 through 44211):

- Additional Requirements for Health IT Vendors:

++ Clarifying that additional requirements for health IT vendors do not apply beginning with the CY 2025 performance period/2027 MIPS payment year, because beginning in the CY 2025 performance period/2027 MIPS payment year health IT vendors are no longer allowed to submit MIPS data as a third-party intermediary,

- Conditions for Approval:

++ Clarifying that performance feedback reports from QCDRs and qualified registries to clinicians would be provided based on participation level (for example, individual, group, subgroup, virtual group, or APM entity).

++ Updating two existing policies, in which (1) a third-party intermediary with fewer than 10 Quality Payment Program participants submitting MIPS data must audit all Quality Payment Program participants and (2) a third-party intermediary submitting data for Quality Payment Program participants with fewer than 5 patient records must audit all patient records.

++ Updating the policy in which third-party intermediaries that do not submit data for one year are required to submit a self-nomination participation plan.

++ Modifying the qualified postings' policy in which changes to the information submitted should not be done after the qualified posting is publicly posted on the Quality Payment Program website (*https://qpp.cms.gov/*).

++ Revising existing policies to specify a QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one MIPS core measure to align with the proposed removal of high-priority designation from MIPS quality measures and the MIPS core measure reporting requirements in section IV.A.4.d.(1)(c) of this final rule.

- Remedial Action and Termination of Third-party Intermediaries:

++ Clarifying that if a third-party intermediary does not submit data for one year, they would be required to provide documentation and would be terminated if documentation cannot be provided and/or the documentation shows that they would not be submitting data for the given MIPS performance period.

We received public comments on each of these proposals and discuss further details later in the sections.

2. Further Clarify in Regulation Text That Health IT Vendors Can Not Submit Data Beginning With the CY 2025 Performance Period/2027 MIPS Payment Year and That Preexisting Requirements for Health IT Vendors No Longer Apply

In the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382), we established the category of health IT vendors as a type of third-party intermediary in the Quality Payment Program. In the CY 2019 PFS final rule, we codified the definition of a health IT vendor as an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's Certified Electronic Health Record Technology (CEHRT) (83 FR 59907). In the CY 2022 PFS final rule (86 FR 65541), we finalized a reorganization of the regulatory text governing third-party intermediaries to improve clarity and readability. In that revised text, we established general requirements at § 414.1400(a), additional requirements for QCDRs and qualified registries at § 414.1400(b), and additional requirements for health IT vendors at § 414.1400(c).

The CY 2024 PFS final rule removed health IT vendors from the category of third-party intermediaries in the Quality Payment Program beginning in the CY 2025 performance period/2027 MIPS payment year at § 414.1400(a)(1)(iii) (88 FR 79390 and 79391). We noted that the removal of health IT vendors from the definition of third-party intermediary would not preclude the vendors from assisting MIPS eligible clinicians with reporting under the program by providing their technology for clinicians to directly report under MIPS. We also noted that removing the category of health IT vendor as a distinct type of third-party intermediary created a clearer distinction between (1) vendors that are submitting data to CMS for the purposes of MIPS and must meet the requirements of a qualified registry or QCDR, and (2) vendors that work with clinicians through the sale and support of health IT permitting the clinician or group to submit the data.

We recognize that § 414.1400(c)(1) outlines additional requirements for health IT vendors submitting data for the MIPS performance category beginning with the CY 2021 performance period/2023 MIPS payment year even though we removed the category of health IT vendors for the Quality Payment Program beginning in the CY 2025 performance period/2027 MIPS payment year at § 414.1400(a)(1)(iii). These requirements being left in the regulation text caused confusion for some organizations interested in serving as third-party intermediaries because it was not clear that these additional requirements for health IT vendors were no longer in place. If an organization that was previously under the health IT vendor category as a third-party intermediary would like to continue serving as a

third-party intermediary for the Quality Payment Program, they must meet the requirements to become a qualified registry or QCDR. Therefore, to reduce confusion and further clarify our existing policies, in the CY 2027 PFS proposed rule (91 FR 44208), we proposed to add at § 414.1400(c)(2) that beginning with the CY 2025 performance period/CY 2027 MIPS payment year, health IT vendors cannot submit MIPS data unless they meet the requirements for a qualified registry or QCDR. We also proposed to modify § 414.1400(c)(1) to clarify that the additional requirements for health IT vendors only apply for the CY 2021 performance period/CY 2023 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year, when health IT vendors were still a separate type of third-party intermediaries.

We received a public comment on these proposals. The following is a summary of the comment we received and our response.

Comment: A commenter expressed concern with the removal of the health IT vendor category from third-party intermediaries as finalized in the CY 2024 PFS final rule and suggested that this removal led to increased costs associated with transferring data from an electronic health record (EHR) to a QCDR or qualified registry.

Response: As stated in the CY 2024 PFS final rule (88 FR 79391), we finalized our proposal to remove the health IT vendor category given we observed many EHRs can self-nominate to serve as registries or QCDRs under our existing requirements and many others can also facilitate direct reporting of MIPS data by clinicians and groups. Further, as noted in the 2024 PFS proposed rule (88 FR 52608), a lack of self-nomination process has made it difficult to fully understand the nature of the health IT vendors and therefore made it difficult to properly identify and develop corrective action plans for those with data issues. We acknowledge the commenter's concern that removal of the health IT vendor category may have resulted in increased costs associated with transferring data from an EHR to a QCDR or qualified registry in their particular situation. However, the removal of this category did not preclude EHR vendors from supporting MIPS data submission or from self-nominating to become a QCDR or qualified registry, provided they meet the current requirements. Instead, this change in policy acknowledged that without a process to identify health IT vendors, we did not have a process to review them, approve them, or develop corrective actions to ensure data accuracy.

Additionally, although we finalized removal of the health IT vendor category in the CY 2024 PFS final rule, the corresponding requirements remained in the regulation text, causing confusion for some organizations interested in serving as third-party intermediaries because it was not clear that these additional requirements for health IT vendors were no longer applicable.

After consideration of the public comment, we are finalizing our proposal to clarify at § 414.1400(c)(2) that beginning with the CY 2025 performance period/CY 2027 MIPS payment year, health IT vendors cannot submit MIPS data as a third-party intermediary unless they meet the requirements for a qualified registry or QCDR. We are also finalizing our proposal to modify § 414.1400(c)(1) to clarify that the additional requirements for health IT vendors only apply for the CY 2021 performance period/CY 2023 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year, when health IT vendors were still a separate type of third-party intermediary.

3. Conditions for Approval

a. Requirement To Provide Performance Feedback Reports at the Level of Data Submitted

In the CY 2017 Quality Payment Program final rule, we established requirements for performance feedback for QCDRs (81 FR 77367 through 77374) and qualified registries (81 FR 77383 through 77387) to provide timely feedback to clinicians, at least four times a year, on all MIPS performance categories that the QCDR or qualified registry would report. We also finalized that the feedback should be given to the individual MIPS eligible clinician or group (if participating as a group) at the individual participant level or group level, as applicable, for which the QCDR or qualified registry reports. In the CY 2020 PFS final rule, we codified the requirement for QCDRs (84 FR 63057 and 63058) and qualified registries (84 FR 63076 and 63077) to provide timely feedback at least four times per year along with a new requirement to provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure. In the CY 2022 PFS final rule (86 FR 65538 through 65550), we reorganized and consolidated the regulatory text governing third-party intermediaries for clarity and simplicity and specifically to consolidate regulations that applied identically to both QCDRs and qualified registries. In that reorganization, the previously established policy for QCDRs and qualified registries to provide feedback which had been established at § 414.1400(b)(1) and (c)(1) was consolidated and redesignated at § 414.1400(b)(3)(iii) without a change in requirements. In the initial codification of the requirements for performance feedback in the CY 2020 PFS final rule for QCDRs (84 FR 63057 and 63058) and qualified registries (84 FR 63076 and 63077), we did not codify but also did not propose to remove the requirements previously established in the CY 2017 Quality Payment Program final rule for QCDRs (81 FR 77367 through 77374) and qualified registries (81 FR 77383 through 77387) that the feedback should be given to the individual MIPS eligible clinician or group (if participating as a group) at the individual participant level or group level, as applicable, for which the QCDR or qualified registry reports. We also did not refer to this requirement in the CY 2022 PFS final rule reorganization and redesignation of the regulatory text.

We have identified situations in which QCDRs or qualified registries provide the required performance feedback reports, but the feedback may reflect the performance of the individual when the clinician is reporting within a group. Alternatively, the feedback report reflects the performance of a group, but it was the individual that is reporting. We believe that this undermines the improvement opportunity that is inherent in these feedback reports and the value of these QCDRs and qualified registries. For this reason, we proposed to add at § 414.1400(b)(3)(iii) that QCDRs and qualified registries must provide the performance feedback at the level at which the data was or will be submitted (for example, individual, group, virtual group, subgroup, APM entity) (91 FR 44208). This proposal would codify the requirements that were previously established but not codified in the CY 2017 Quality Payment Program final rule for QCDRs (81 FR 77367 through 77374) and qualified registries (81 FR 77383 through 77387) to provide feedback at the level at which data is submitted. We also proposed to remove the term ''clinicians and groups'' in both places in this portion of the regulation. We believe that this requirement aligns with the requirement originally established in the CY 2017 Quality Payment Program Rule (81 FR 77363) but reflects the increased types of reporting entities available to MIPS eligible clinicians to

include individuals, groups, virtual groups, subgroups, and APM entities.

We did not receive comments on our proposal to remove the term ''clinicians and groups'' from § 414.1400(b)(3)(iii). We received public comments on our proposal to require performance feedback at the level at which data was or will be submitted. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed our proposal to require performance feedback at the level at which data was or will be submitted, expressing a concern that decisions about the level of reporting are often not made until long after the relevant performance period has started.

Response: We recognize that the anticipated level of reporting may change during the performance period but would expect that the third—party intermediary provide feedback to the clinician or group at the level the clinician or group has indicated they intend to report at the time the feedback is provided. That is, we would expect that a third—party intermediary would provide feedback at the level the intermediary has on record for the clinician or group at the time feedback is issued. However, we believe that providing feedback at the applicable level of reporting is important to ensure the feedback is meaningful and useful to participants in understanding their performance. Accordingly, we believe this requirement balances the need to provide participants with relevant performance information while avoiding the unnecessary burden of requiring third-party intermediaries to provide feedback at every potential level of reporting.

Comment: A few commenters suggested that the requirement to provide feedback at the level of reporting would require third-party intermediaries to provide performance feedback to participants at all potential levels of reporting and expressed concern that this much data would be confusing for participants and/or would increase administrative burden in the MIPS program.

Response: We appreciate the commenters' concerns that requiring feedback at the level of reporting could be interpreted as requiring third-party intermediaries to provide performance feedback at all potential levels of reporting, which could result in confusing information for participants or unnecessary burden. We clarify that this requirement is not intended to require third-party intermediaries to provide feedback at every potential level of reporting. Rather, third-party intermediaries would be required to provide feedback that is specific to the level at which the participant will report data for the purposes of MIPS (for example, providing information on the performance of an individual pulmonologist on measures contained in the Pulmonology Care MVP). We believe that providing feedback at the applicable level of reporting will ensure participants receive meaningful information regarding their performance without requiring third-party intermediaries to provide information at reporting levels that are not applicable to the participant.

After consideration of public comments, we are finalizing, as proposed, our proposal to add at § 414.1400(b)(3)(iii) that QCDRs and qualified registries must provide the performance feedback at the level at which the data was or will be submitted (for example, individual, group, virtual group, subgroup, APM entity). We are also finalizing, as proposed, our proposal to remove the term ''clinicians and groups'' in both places in this portion of the regulation.

b. Data Validation Requirements

(1) Background

Section 414.1400(b)(3)(v) outlines the requirements for a third-party intermediary's annual data validation audit. As finalized in the CY 2024 PFS final rule (88 FR 79388), specified at § 414.1400(b)(3)(v)(E), the QCDR or qualified registry must conduct each data validation audit using a sampling methodology that meets the following requirements: (1) Uses a sample size of at least 3 percent of a combination of individual clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups and APM entities, and no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities; and (2) Uses a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

(2) Update Sampling Methodology for Data Validation Purposes

We noticed that recently certain third-party intermediaries are using less than the minimum sample size as required by § 414.1400(b)(3)(v)(E), which raises concern as to whether the data sample submitted is adequate. To ensure that our data remains true, accurate, and complete, we proposed the following updates (91 FR 44209):

- If the third-party intermediary submits MIPS data to CMS for fewer than 10 Quality Payment Program participants, the data validation audit sample must include all Quality Payment Program participants. We proposed to modify the existing requirements at § 414.1400(b)(2)(v)(E)(1) and (2) that govern a QCDR or qualified registry's data validation audit sampling methodology. Specifically, we proposed at § 414.1400(b)(2)(v)(E)(1) that if the third-party intermediary submits MIPS data to CMS for fewer than 10 Quality Payment Program participants, the data validation audit sample must include all Quality Payment Program participants. If the third-party intermediary submits data for 10 or more Quality Payment Program participants, it must use a sample size of at least 3 percent of a combination of the individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS. The sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups, or APM entities, and no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities.
- If there are fewer than 5 patient records from a Quality Payment Program participant, the patient record audit sample must include all patient records. We proposed at § 414.1400(b)(2)(v)(E)(2) that if there are fewer than 5 patient records, the patient record audit sample must include all patient records. If there are 5 or more patient records, the intermediary must use a sample that includes at least 25 percent of the patient records of the individual clinician, group, virtual group, subgroup, or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients. These updates would help third-party intermediaries submit data that is true, accurate, and complete while meeting their submission requirements for data validation purposes.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported both proposed updates to the data validation sampling strategy and suggested that high audit standards are an important element of high-quality data collection.

Response: We thank the commenters for their support.

Comment: A few commenters opposed the revised data validation sampling strategy and offered alternative suggestions in which third-party intermediaries would have more flexibility in demonstrating assurance of data accuracy which could be based on previous records of data compliance.

Response: We understand the interest in having greater flexibility in demonstrating assurance of data accuracy which could be based on previous records of data compliance. However, we believe it is important to avoid any ambiguity in our data validation standards and to maintain clearly established data validation requirements that apply consistently across all third-party intermediaries. We believe these requirements are necessary to provide assurance that the data third-party intermediaries submit are true, accurate, and complete and that third-party intermediaries continue to meet submission requirements for data validation purposes.

Comment: A commenter opposed the revised data validation sampling strategy as being unnecessarily complicated and duplicative of existing audits that CMS performs on MIPS eligible clinicians and suggested that these efforts undermine a statutory requirement to encourage the use of QCDRs to report quality measures.

Response: Audits that may be performed on MIPS eligible clinicians have a different intent from the data validation requirements for third-party intermediaries. Clearly established data validation requirements are necessary to ensure that the data submitted by third-party intermediaries are true, accurate, and complete and consistent with the information recorded by the clinician in their medical records. Establishing these standards for third-party intermediaries protects clinicians who are interested in using them to facilitate reporting MIPS. The need to establish clear data validation requirements does not undermine the statutory requirement to encourage the use of QCDRs to report quality measures because the statutory requirement does not suggest that data quality be ignored in encouraging their use. Rather, establishing clear data validation requirements provides appropriate assurance regarding the accuracy and completeness of data submitted across all of our third-party intermediaries.

We note that the preamble discussion in the CY 2027 PFS proposed rule for this issue included typographical errors that misplaced the specified proposed regulatory text change at § 414.1400(b)(2)(v)(E)(1)(2) (91 FR 44209). However, the proposed regulation text was correctly listed at 414.1400(b)(3)(v)(E)(1) and (2) in the regulation text section of the CY 2027 PFS proposed rule (91 FR 44284 and 44285). In addition, our rationale and discussion in the CY 2027 PFS proposed rule correctly reflect the substance of our policies. After consideration of public comments, we are finalizing as proposed, the following:

- Codifying § 414.1400(b)(3)(v)(E)(1) that if the intermediary submits MIPS data to CMS for fewer than 10 Quality Payment Program participants, the data validation audit sample must include all Quality Payment Program participants. If the intermediary submits data for 10 or more Quality Payment Program participants, it must use a sample size of at least 3 percent of a combination of the individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups, or APM entities, and no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities.
- Codifying at § 414.1400(b)(3)(v)(E)(2) that if there are fewer than 5 patient records the patient record audit sample must include all patient records. If there are 5 or more patient records, the intermediary must use a sample that includes at least 25 percent of the patient records of the individual clinician, group, virtual group, subgroup, or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

c. Require Submission of a Self-Nomination Plan for Third-Party Intermediaries That Do Not Submit Data for One Year

In the CY 2022 PFS final rule, we noted that we had identified several QCDRs and qualified registries that continued to self-nominate to become a third-party intermediary for MIPS but had not submitted data to CMS (86 FR 65545). We further noted as MIPS continues to mature, we wished to reduce the number of third-party intermediaries that self-nominate to become a CMS-approved third-party intermediary but do not actively participate in MIPS. Maintaining intermediaries who do not actively participate does not benefit MIPS, rather it creates interested parties' confusion by including these intermediaries in our qualified postings. We also noted that our goal was to decrease the operational burden on CMS and those third-party intermediaries that do not submit MIPS data to CMS (86 FR 65546).

Accordingly, we finalized requirements for approved QCDRs and qualified registries that have not submitted performance data to submit a participation plan as part of their self-nomination process. We finalized an incremental approach to addressing this issue. First, at § 414.1400(b)(3)(vii), we finalized a participation plan requirement, which requires a QCDR or qualified registry that was approved but did not submit data for any of the CY 2017 through 2020 performance periods/2019 through 2022 MIPS payment years to submit a participation plan in order to be approved for the CY 2023 performance period/2025 MIPS payment year (86 FR 65545 and 65546). Second, at § 414.1400(b)(3)(viii), we finalized that a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan in order for it to be approved for the CY 2024 performance period/2026 MIPS payment year or a future performance period/payment year (86 FR 65546).

While this policy has reduced the number of QCDRs and qualified registries that do not submit data, some QCDRs and qualified registries are still being listed on the qualified posting for as long as three years without submitting data. Maintaining these third-party intermediaries that do not actively participate does not benefit MIPS, rather it creates confusion for interested parties by including these third-party intermediaries in our qualified postings. We emphasize that our goal is to continue decreasing the operational burden on CMS and interested parties. CMS would decrease its operational burden by eliminating the need to screen these third-party intermediaries.

In an effort to avoid further confusion, reduce administrative burden for both CMS and interested parties, and ensure compliance, we proposed to reduce the timeframe available for a QCDR or qualified registry that was approved but did not submit any MIPS data to submit a participation plan. Currently, a QCDR

or qualified registry must submit a participation plan if they do not submit data for either of the 2 years preceding the applicable self-nomination period. We proposed to require a QCDR or qualified registry to submit a participation plan if they do not submit data for the year preceding the applicable self-nomination period. We proposed to redesignate and amend § 414.1400(b)(3)(viii) and add § 414.1400(b)(3)(viii)(A) and (B). Additionally, we also note that we encourage QCDRs and qualified registries to implement the participation plan at the beginning of the calendar year instead of waiting until the self-nomination period, which generally opens on July 1 and closes on September 1 of the year prior to the applicable MIPS performance period.

In summary, we specifically proposed to redesignate the existing text at § 414.1400(b)(3)(viii) to § 414.1400(b)(3)(vii)(B) and amend the text to reflect that this requirement applies from the CY 2024 performance period/2026 MIPS payment year through the CY 2026 performance period/2028 MIPS payment year (91 FR 44209). Additionally, we also proposed to add at § 414.1400(b)(3)(vii)(C) that beginning with the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for the year preceding the applicable self-nomination period must submit a participation plan for CMS' approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry. We also proposed to redesignate the existing text at § 414.1400(b)(3)(vii) to at § 414.1400(b)(3)(vii)(A) and add the heading participation plan for third-party intermediary not submitting data at § 414.1400(b)(3)(vii).

We received a public comment on these proposals. The following is a summary of the comment we received and our response.

Comment: A commenter opposed our proposed reduction in the timeframe available for a QCDR or qualified registry that was approved to submit data but did not do so. This commenter suggested that a one year gap in submitting is not evidence of a pattern of non-compliance and that requiring a participation plan after one year of not reporting would unduly increase administrative burden.

Response: We acknowledge that while submitting a participation plan may impose some additional burden on a third-party intermediary that has not submitted data for one year, this limited burden is appropriate to demonstrate the third-party intermediary's intent to actively participate in the program. Additionally, we note that the purpose of this requirement is not to establish a pattern of non-compliance. Rather we intend to reduce the number of third-party intermediaries that self-nominate to become a CMS-approved third-party intermediary but do not actively participate in MIPS. Maintaining these intermediaries does not benefit MIPS, rather it creates confusion. Therefore, finalizing this proposal will reduce potential confusion, support more efficiency across CMS, and help ensure that CMS-approved third-party intermediaries intend to actively participate in MIPS.

We note that the regulatory text section of the CY 2027 PFS Proposed Rule (91 FR 44284 and 44285) contained a typographical error such that the proposed regulatory text did not accurately reflect the placement of the regulatory text that was discussed in the preamble. This typographical error inadvertently placed the text identified within the preamble for § 414.1400(b)(3)(vii)(B) at § 414.1400(b)(3)(vii)(A) and the text identified within the preamble for § 414.1400(b)(3)(vii)(C) at § 414.1400(b)(3)(vii)(B). The proposed regulation text also inadvertently removed the existing text at § 414.1400(b)(3)(vii) that we proposed to redesignate to § 414.1400(b)(3)(vii)(A). However, the substance of our policies and placement of the regulation text were correctly described in the preamble. After consideration of public comments, we are finalizing our proposal as proposed, to redesignate the existing text at § 414.1400(b)(3)(viii) to § 414.1400(b)(3)(vii)(B) and amend the text to reflect that this requirement applies from the CY 2024 performance period/2026 MIPS payment year through the CY 2026 performance period/2028 MIPS payment year. Additionally, we are also finalizing our proposal to add at § 414.1400(b)(3)(vii)(C) that beginning with the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for the year preceding the applicable self-nomination period must submit a participation plan for CMS' approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry. Finally, we are also finalizing our proposal as proposed, to redesignate the existing text at § 414.1400(b)(3)(vii) to at § 414.1400(b)(3)(vii)(A) and add the heading participation plan for third-party intermediary not submitting data at § 414.1400(b)(3)(vii).

d. Update Qualified Posting

Every year, CMS publishes a qualified posting on the Quality Payment Program website (*https://qpp.cms.gov/*) containing a list of all CMS-approved third-party intermediaries that have self-nominated to submit data on behalf of MIPS eligible clinicians for the MIPS performance period. This list is updated to account for withdrawals, remedial action, or termination of third-party intermediaries. The qualified posting contains information about approved third-party intermediaries such as organization details, information about remedial action or termination, supported performance categories, specialty focus, a description of services they provide and associated costs, reporting options (MVP versus traditional MIPS) and participation options (individual clinician, group, subgroup, virtual group, APM entity) supported, and measures they are approved to support. MIPS eligible clinicians can refer to information in the qualified posting to identify and select a third-party intermediary.

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must sign a document that verifies their name, contact information, cost for MIPS eligible clinicians or groups to use the qualified registry, services provided, and the specialty-specific measure sets the qualified registry intends to report. As technology progressed, we no longer needed third-party intermediaries to sign a document and instead required an attestation. We became aware that this requirement was no longer consistent with our established policy in describing the manner in which the QCDR or qualified registry documents this information. To align with current processes, we finalized in the CY 2024 PFS final rule to add § 414.1400(b)(3)(xiv), which required that QCDRs and qualified registries attest that the information listed on the qualified posting is accurate (88 FR 79385). Additionally, we also finalized in the CY 2024 final rule, at § 414.1305, to define qualified posting as the document made available by CMS that lists QCDRs or qualified registries available for use by MIPS

eligible clinicians, groups, subgroups, virtual groups, and APM Entities (88 FR 79385). We noted that we had used the term qualified posting since the inception of the Quality Payment Program but had not previously defined the term.

We have recently been made aware that certain third-party intermediaries are making changes to the information they provided for their qualified posting after receiving CMS approval of the qualified posting. Examples of changes include updates to costs, services that are included in the initial cost, and other administrative changes. This creates an increased administrative burden for CMS, who must identify and rectify such changes, and it creates confusion amongst clinicians who contract with the third-party intermediary as to what they will pay for the cost of the third-party intermediary's services. Subsequently, we must make additional updates to the qualified posting, which increases the administrative burden on CMS. To reduce administrative burden for both clinicians and CMS, we proposed to update § 414.1400(b)(3)(xiv) by adding a requirement that changes to information (for example, cost, services included) on the qualified posting must be included and finalized during the qualified posting review period (91 FR 44210). We proposed specifying in regulatory text that third-party intermediaries will not be permitted to make changes after the qualified posting is publicly posted on the Quality Payment Program website (*https://qpp.cms.gov/*).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed general support for the goals associated with our proposal to not change information provided on the qualified posting following the qualified posting review period but suggested that in some cases external situations may alter what a third-party intermediary is able to provide and that it would be preferable to align that information with what is included on the qualified posting. Some of the commenters recommended a process for updating this information following the completion of the qualified posting review. A commenter requested that CMS remain flexible to accommodate the various differences in operating models across third-party intermediaries (for example., specialty society led QCDR vs. other QCDR entities).

Response: We understand that there may be circumstances outside of a third-party intermediary's control that may affect the services or capabilities the third-party intermediary can provide after the qualified posting review period has concluded. However, having a defined review period during which third-party intermediaries, including those that may have different operating models, can review and request changes to their information as necessary can ensure that qualified postings are finalized in a timely manner. It also allows us to provide consistent information to clinicians and groups needing information on third-party intermediaries. Establishing an additional process to make changes after the qualified posting review would require us to continually review and update information, thereby creating uncertainty for interested parties relying on the qualified postings to identify third-party intermediaries and the services they offer. Therefore, we do not see a need to establish an additional process for updating information following the conclusion of the qualified posting review period.

Comment: A commenter opposed our proposal stating their belief that it would increase administrative burden. The commenter suggested that this would require alignment of all business decisions by the third-party intermediary with the CMS qualified posting schedule and would discourage reporting through QCDRs.

Response: Establishing a defined period during which a third-party intermediary may review and request changes to their information is necessary to ensure the qualified postings are accurate and the information posted can be finalized in a timely manner. While we aim to reduce administrative burden as much as possible, clinicians are using these third-party intermediaries to participate in MIPS and therefore need to know which third-party intermediaries are qualified and what services they offer so the clinician or group can select a third-party intermediary that meets their needs. As such, there are some deadlines and other requirements that the business entity may need to accommodate to facilitate reporting for MIPS eligible clinicians.

The designated review period gives third-party intermediaries an appropriate opportunity to verify the accuracy of their information and identify any necessary changes before the qualified postings are finalized. Accordingly, this approach balances the need to provide third-party intermediaries with an opportunity to review their information with the need to maintain accurate, consistent, and timely information for clinicians and groups seeking to identify a third-party intermediary for their MIPS reporting. Establishing a defined qualified posting review period should not discourage the use of QCDRs but should instead provide greater certainty regarding the information available on qualified postings.

After consideration of public comments, we are finalizing our proposal as proposed, to update § 414.1400(b)(3)(xiv) by adding a requirement that changes to information (for example, cost, services included) on the qualified posting must be included and finalized during the qualified posting review period. We are also finalizing our proposal as proposed, to specify in regulatory text that third-party intermediaries will not be permitted to make changes after the qualified posting is publicly posted on the Quality Payment Program website (*https://qpp.cms.gov/*).

e. Update CMS Data Submission Requirements for Third-Party Intermediaries

In the CY 2017 Quality Payment Program final rule, we finalized at § 414.1400(b)(3)(x) and (b)(3)(x)(A) that a QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one outcome measure and if no outcome measure is available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure (81 FR 77368).

However, in CY 2027 PFS proposed rule, we proposed to remove the high-priority designation from MIPS quality measures beginning in the CY 2027 performance period/CY 2029 MIPS payment year (91 FR 44210). Additionally, we also proposed to remove the requirement to report an outcome measure and require reporting a MIPS core measure. Under the new proposal, MIPS eligible clinicians participating through traditional MIPS must submit data on at least six measures, including at least one MIPS core measure.

To align third-party intermediaries' requirements with the MIPS core measure set and high priority designation for MIPS quality measures proposals, we proposed to revise § 414.1400(b)(3)(x)(B) to state that beginning in the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry must be able to submit to CMS, data for at least six quality measures including at least one MIPS core measure (91 FR 44210). We also proposed to revise § 414.1400(b)(3)(x) and (b)(3)(x)(A) so that the requirement for a QCDR or

qualified registry to be able to submit an outcome measure and if the outcome measure is not available, then a high priority measure can be submitted, concludes with the CY 2026 performance period/CY 2028 MIPS payment year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed our proposed update to require qualified registries and QCDRs to report on at least one core measure. These commenters generally expressed concern that a QCDR or qualified registry could capture data on a more specialized set of clinicians than would be part of a broader MVP such as a clinician providing echocardiography as part of a cardiology group and that requiring support for at least one core measure would reduce the availability of QCDRs for specialized clinicians.

Response: Similar to our approach in establishing submission requirements for third-party intermediaries in the CY 2017 Quality Payment Program final rule, it is important to align requirements across third-party intermediaries where appropriate. The requirement to support at least one measure from the MIPS core measure set does not preclude a QCDR or qualified registry from continuing to support measures that are applicable to more specialized clinicians or clinical practice areas. Rather, this requirement establishes a minimum requirement for QCDRs and qualified registries while allowing them to continue to support the specialized measures and clinician populations they serve.

Comment: A commenter suggested that CMS publish the MIPS core measure list on a timeline that precedes the self-nomination period for the applicable performance year in order to ensure that the third-party intermediary can demonstrate the capability to submit at least one MIPS core measure during the self-nomination period.

Response: We note that the existing requirement is that a QCDR or qualified registry must be able to submit data to CMS for at least six quality measures, including at least one outcome measure or, if an outcome measure is not available, at least one other high-priority measure. Under the proposed policy, a QCDR or qualified registry would instead be required to be able to submit data to CMS for at least six quality measures, including at least one MIPS core measure. Consistent with the existing self-nomination process, QCDRs and qualified registries identify the measures they are capable of submitting based on the information available during the applicable self-nomination period. MIPS core measures will be cataloged and identified at the Quality Payment Program resource library (*https://qpp.cms.gov/resources/resource-library*). This same timeline would apply to the requirement to be able to submit at least one MIPS core measure. Identifying core measures for a particular MIPS performance period earlier than under the current timeline is not consistent with our overall review of the measure inventory on an annual basis which allows for updates to reflect changes in measure availability as close to the performance period as possible.

After consideration of public comments, we are finalizing our proposal as proposed, to revise § 414.1400(b)(3)(x)(B) to state that beginning in the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry must be able to submit to CMS, data for at least six quality measures including at least one MIPS core measure. We are also finalizing our proposal to revise § 414.1400(b)(3)(x) and (b)(3)(x)(A) so that the requirement for a QCDR or qualified registry to be able to submit an outcome measure and if the outcome measure is not available, then a high priority measure can be submitted, concludes with the CY 2026 performance period/CY 2028 MIPS payment year.

4. Remedial Action and Termination of Third-Party Intermediaries

a. Background

We refer readers to § 414.1400(e), the CY 2017 Quality Payment Program final rule (81 FR 77548) the CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), the CY 2021 PFS final rule (85 FR 84947), the CY 2022 PFS final rule (86 FR 65542 and 65550), and the CY 2023 PFS final rule (87 FR 70106 through 70108) for previously finalized policies for remedial action and termination of third-party intermediaries.

b. Termination of a Third-Party Intermediary That Does Not Submit Data for 1 Year

In the CY 2023 PFS final rule, we established that we will terminate QCDRs and qualified registries that are required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period and continue to not submit MIPS data to CMS for the applicable performance period (87 FR 70107 through 70108). Timely termination of third-party intermediaries that are not submitting data is important to minimize unnecessary operational and administrative tasks for both CMS and third-party intermediaries. Maintaining third-party intermediaries that do not actively participate does not provide a benefit to the MIPS program, rather it creates confusion for interested parties by including these third-party intermediaries in our qualified postings (86 FR 65545).

In the CY 2027 PFS proposed rule, we noted that the policy for termination of third-party intermediaries not submitting data would be impacted by the proposed requirement to submit a participation plan for third-party intermediaries that do not submit data for one year (91 FR 44211). This proposed policy means that we would terminate QCDRs and qualified registries that were required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for 1 year (rather than 2 years) preceding the applicable self-nomination period and continue to not submit MIPS data to CMS for the applicable performance period. However, because the data submission period lasts for one year following the performance period, there is a delay in CMS being made aware of whether a third-party intermediary submitted data for a given year. Therefore, currently, CMS does not have a mechanism to acquire the necessary knowledge to appropriately terminate a third-party intermediary until the year after the applicable performance period.

Currently, if a third-party intermediary does not submit data for the performance period for which they submitted a self-nomination participation plan, they will be terminated. However, CMS does not become aware of the third-party intermediary's failure to submit data for a given MIPS performance period until the year following the performance period. For example, under the current policy, if a third-party intermediary self-nominated for the 2024 performance period and was required to submit a self-nomination participation plan but does not submit data for the 2024 performance period, CMS would not know the third-party intermediary did not submit MIPS data for the 2024 performance period until the end of the submission period in March 2025. Therefore, the third-party intermediary can continue to participate for the 2025 MIPS performance period as if they

were already approved and posted as a 2025 CMS-approved third-party intermediary. To shorten the timeline of when CMS is aware that the third-party intermediary does not submit any data and when CMS appropriately terminates the third-party intermediary, we proposed to update our policy such that CMS would request documentation that the third-party intermediary has contracted with Quality Payment Program's participants who will submit MIPS data for the given MIPS performance period. CMS's query for documentation would occur before the end of the calendar year for the given MIPS performance period. If the appropriate documentation cannot be provided by the date specified by CMS, the third-party intermediary would be terminated. This proposal would provide the information needed to terminate a third-party intermediary during the applicable performance period year instead of waiting until the following year.

Specifically, we proposed adding a new requirement for third-party intermediaries to submit documentation about intent to submit MIPS data and to terminate a third-party intermediary if they do not submit the appropriate documentation by the date specified by CMS (91 FR 44211). We also proposed to add at § 414.1400(e)(5)(ii) that beginning with the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under § 414.1400(b)(3)(viii), but does not submit MIPS data for the applicable performance period for which they self-nominated under § 414.1400(b)(3)(viii), will be queried by CMS before the end of the calendar year of the given MIPS performance period for documentation that they have contracted with Quality Payment Program participants who will submit data for the given MIPS performance period. If the appropriate documentation cannot be provided, the third-party intermediary would be terminated. We also proposed redesignating the existing text at § 414.1400(e)(5) to § 414.1400(e)(5)(i). We also proposed to add the heading ''Termination for Third-party Intermediary not submitting data.'' at § 414.1400(e)(5).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed our proposal to update the requirements for submitting a participation plan after a year in which the QCDR or qualified registry did not submit data. The commenters supported the current policy requiring a submission plan after two years of failing to submit data but suggested that a single year in which the QCDR or qualified registry failed to submit data was not evidence of a pattern and that external circumstances may cause a QCDR or qualified registry to not report for a year. A commenter requested that if CMS were to finalize the policy, a process to demonstrate active engagement without submitting data should be developed.

Response: We clarify that the purpose of this requirement is not to establish a pattern of non-compliance and understand that external circumstances may cause a QCDR or qualified registry to not report for a year. However, maintaining these intermediaries who do not actively participate in MIPS does not provide a benefit to the program and may create confusion across interested parties when these vendors continue to appear on our qualified postings despite not submitting MIPS data. A submission plan is a way to demonstrate active engagement in lieu of submission of data. Therefore, finalizing this proposal will reduce potential confusion, support more efficiency across CMS, and help ensure that CMS-approved third-party intermediaries intend to actively participate in MIPS.

Comment: A commenter suggested that CMS clarify the documentation needed, the window within which the third-party intermediary must provide the documentation, and the criteria for approval in order to ensure that the third-party intermediary meets the submission requirements and avoids being terminated.

Response: We clarify that required documents to self-nominate have not changed outside of what is already posted. Intermediaries can refer to the ''2027–MIPS–QCDR-QualifiedRegistry-Self-Nomination-Fact-Sheet'' included in the ''2027 Self-Nomination Toolkit for QCDRs and Qualified Registries'' posted in the QPP Resource Library. This resource includes the requirement of participation of at least 25 participants, verification and maintenance of clinician information such as Business Associate Agreements and consents (intermediaries have contracted with QPP participants who will submit data) for the given MIPS performance period.

If the third-party intermediary does not intend to submit data to CMS on behalf of any of their clients, they should notify CMS at the end of the performance period (December 31st) that they will not be sending any data for that performance period. If the submitter could produce an acceptable reason for no data submission, CMS would consider that documentation, but the termination clause would be executed unless adequate reasoning was provided. With respect to the window, CMS would expect documentation to show why no data will be submitted for that performance period and why the third-party intermediary believes that they will have clinicians and/or groups submitting data to them for reporting for the next MIPS performance period. This documentation is due to CMS by December 31st of the performance period. Finally, we note that we will provide additional technical guidance, as appropriate, at a later date.

After consideration of public comments, we are finalizing our proposal as proposed, to add a new requirement for third-party intermediaries to submit documentation about submitting MIPS data and to terminate a third-party intermediary if they do not submit the appropriate documentation by the date specified by CMS. We are also finalizing at § 414.1400(e)(5)(ii) that beginning with the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under § 414.1400(b)(3)(viii), but does not submit MIPS data for the applicable performance period for which they self-nominated under § 414.1400(b)(3)(viii), will be queried by CMS before the end of the calendar year of the given MIPS performance period for documentation that they have contracted with Quality Payment Program participants who will submit data for the given MIPS performance period. If the appropriate documentation cannot be provided, the third-party intermediary would be terminated. Additionally, we are also finalizing our proposal as proposed, to redesignate the existing text at § 414.1400(e)(5) to § 414.1400(e)(5)(i). Finally, we are also finalizing as propose to add the heading ''Termination for Third-party Intermediary not submitting data.'' at § 414.1400(e)(5).

D. Calculating Final Score

1. Background

For a description of the statutory basis of and our previously finalized policies for calculating the final score for each MIPS eligible clinician, including performance category weights and reweighting the performance categories, we refer readers to § 414.1380(c) and the discussion in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, CY 2021, CY

2022, CY 2023, and 2025 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785 and 53895 through 53900, 83 FR 59868 through 59878, 84 FR 63020 through 63031, 85 FR 84908 through 84917, 86 FR 65509 through 65527, 87 FR 70093 through 70096, 89 FR 98455 through 98459 respectively).

In the CY 2027 PFS proposed rule, we proposed to change the data source that CMS uses to determine eligibility for reweighting under the MIPS automatic extreme and uncontrollable circumstances (EUC) policy beginning with the CY 2027 performance period/2029 MIPS payment year (91 FR 44212). We also proposed to change the deadline by which clinicians must request reweighting where data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third-party intermediary (91 FR 44213).

Section 1848(q)(5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to the performance standards for the applicable measures and activities for each performance category applicable to such clinician for a performance period and, using the methodology, provide for a final score (using a scoring scale of 0 to 100) for each MIPS eligible clinician for the performance period.

Additionally, section 1848(q)(5)(E) of the Act specifies how we must weigh the scores for each performance category in our calculation of the MIPS eligible clinician's final score. We have codified these weights at § 414.1380(c)(1). Meanwhile, section 1848(q)(5)(F) of the Act provides that, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of 0). We also have finalized at § 414.1380(c)(2) several policies addressing the basis for reweighting one or more performance categories, and how those weights will be redistributed to the remaining performance categories.

2. Alternative Data Sources To Determine Clinician Eligibility for the MIPS Automatic EUC

For the quality, cost, and improvement activities performance categories, under the current reweighting policies at § 414.1380(c)(2)(i)(A)(6) through (8), and for the Promoting Interoperability performance category, under the reweighting policies at § 414.1380(c)(2)(i)(C)(2) and (3), performance category weights may be redistributed to another performance category or categories in circumstances where MIPS eligible clinicians are subject to, or located in an area affected by, an EUC. This includes MIPS eligible clinicians with an approved application-based EUC reweighting request (83 FR 59871 through 59874 and 82 FR 53680 through 53687) or an automatic reweighting for a clinician identified as located in a CMS designated region affected by an EUC such as a Federal Emergency Management Agency (FEMA)-designated major disaster or a public health emergency (as determined by the Secretary of Health and Human Services) (82 FR 53895 through 53900). The MIPS automatic EUC policy for quality, cost, and improvement activities performance categories is described at § 414.1380(c)(2)(i)(A)(8) and the MIPS automatic EUC policy for the Promoting Interoperability performance category is described at § 414.1380(c)(2)(i)(C)(3). Additionally, we previously finalized at § 414.1380(c) that MIPS eligible clinicians scored on fewer than two performance category scores will receive a final score equal to the performance threshold, which will result in a neutral payment adjustment (81 FR 77326 through 77328 and 82 FR 53778 through 53779). We noted in the CY 2018 Quality Payment Program final rule that we anticipate the types of events that could trigger the MIPS automatic EUC policy would be events designated as a FEMA major disaster or a public health emergency declared by the Secretary, although we will review each situation on a case-by-case basis (82 FR 53897).

In the CY 2018 Quality Payment Program final rule, we specified that CMS will determine if an individual MIPS eligible clinician is located in an area affected by an EUC as identified by CMS based on the practice location address listed in the Provider Enrollment, Chain and Ownership System (PECOS) (82 FR 53898). Since adopting a policy to use PECOS data, recent clinician reweighting requests have increasingly identified clinicians who were incorrectly excluded from the MIPS automatic EUC policy because PECOS address data may be inaccurate or outdated in some cases. For example, individual MIPS eligible clinicians impacted by an EUC may not be identified by CMS in circumstances where a clinician has not updated their PECOS data or in circumstances where a clinician begins providing services in an additional geographic location or zip code. In order to ensure the accurate identification of impacted clinicians for subsequent performance periods, we proposed that beginning with the CY 2027 performance period/2029 MIPS payment year CMS will use the most current and reliable data available to determine if an individual MIPS eligible clinician is located in an area that has been identified as being affected by an EUC (91 FR 44212) that will trigger implementation of the MIPS automatic EUC policy. For example, we may use the zip codes on billed claims, that identify the location of service, to make this determination. This data source may be used in addition to or in lieu of the zip codes included in PECOS address data to achieve our goal of accurately identifying all impacted clinicians. This policy will ensure that all individual MIPS eligible clinicians affected by natural disasters and public health emergencies are accurately identified by CMS. We requested public comment on this proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to use the most current and reliable data available to determine if an individual MIPS eligible clinician is located in an area that has been identified as being affected by an EUC. Commenters noted that disasters may disrupt clinical operations, and that it is essential for CMS to finalize this proposal to identify all affected clinicians and limit clinicians' need to apply for reweighting while experiencing a hardship.

Response: We thank commenters for their support.

Comment: Several commenters recommended that when considering which data are most current and reliable, CMS use additional data sources to supplement PECOS data. Commenters noted that clinicians may practice in multiple locations and that using PECOS or claims data alone could exclude temporary service locations. A commenter also recommended that CMS check data sources regularly in order to comprehensively identify clinicians, and to confirm that the process is accurate.

Response: We agree that it is important to be as comprehensive as possible in identifying clinicians that are impacted by an EUC. We intend to use whatever data are most accurate to identify impacted clinicians and this may include, for example, both the zip codes on billed claims as well as PECOS address data to achieve the goal of

accurately identifying all impacted clinicians. Additionally, we intend to explore the feasibility of identifying and informing impacted clinicians more frequently. We will continue to assess the accuracy and reliability of these methods to ensure that all individual MIPS eligible clinicians affected by natural disasters and public health emergencies are accurately identified by CMS and to limit the need for clinicians to submit an EUC application.

After consideration of public comments, we are finalizing as proposed the policy that beginning with the CY 2027 performance period/2029 MIPS payment year we will use the most current and reliable data available to determine if an individual MIPS eligible clinician is located in an area that has been identified as being affected by an EUC.

3. Update to the Deadline for Clinicians To Inform CMS That Third-Party Intermediary Did Not Submit Data Due to Reasons Outside the MIPS Eligible Clinician's Control

We previously finalized at § 414.1380(c)(2)(i)(A)(10) and (c)(2)(i)(C)(12) that beginning with the CY 2024 performance period/2026 MIPS payment year, we may reweight one or more of the quality, improvement activities, and Promoting Interoperability performance categories where we determine, based on documentation submitted to us through a reweighting request on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of their data to a third-party intermediary, evidenced by a written agreement between the MIPS eligible clinician and the third-party intermediary, and the third-party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines (89 FR 62096). We previously finalized that this reweighting policy is available only for the quality, improvement activities, and Promoting Interoperability performance categories because a MIPS eligible clinician may delegate data submission to a third-party intermediary for these three performance categories, and not the cost performance category. MIPS eligible clinicians do not submit data separately for measures for the cost performance category; we score cost measures based solely on administrative claims data (89 FR 98455 through 98455).

As specified in the CY 2025 PFS final rule, we would only approve reweighting requests with evidence of a written agreement between the MIPS eligible clinician and a third-party intermediary. Such written agreement must provide that the MIPS eligible clinician delegated submission of their data to the third-party intermediary, and that the third-party intermediary agreed to submit data on their behalf in accordance with applicable deadlines, for the performance category or performance categories in question. We review requests and make determinations to reweight based on our assessment that data were not submitted due to reasons outside the control of the MIPS eligible clinician (89 FR 62096). Under this reweighting policy, the MIPS eligible clinician must submit reweighting requests beginning with the close of a relevant performance period's data submission period, only after it is confirmed that no data has been submitted in accordance with applicable deadlines. MIPS eligible clinicians were then required to submit reweighting requests on or before November 1st of the year preceding the associated MIPS payment year in order to allow time for CMS to re-calculate their final score and MIPS payment adjustment factor (89 FR 62096).

In the CY 2027 PFS proposed rule, we proposed to adjust the deadline by which clinicians would be able to submit reweighting requests for the quality, improvement activities, and Promoting Interoperability performance categories due to scenarios where a third-party intermediary did not submit data on their behalf in accordance with the applicable data submission deadlines (91 FR 44213). Specifically, we proposed that beginning with the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians would be able to submit reweighting requests on or before December 31st of the year preceding the relevant MIPS payment year (91 FR 44213). We are also codifying this updated deadline at § 414.1380(c)(2)(i)(A)(10) for the quality and improvement activities performance categories and at § 414.1380(c)(2)(i)(C)(12) for the Promoting Interoperability performance category. Under this reweighting policy, the MIPS eligible clinician may submit reweighting requests beginning with the close of a relevant performance period's data submission period, only after it is confirmed that no data has been submitted in accordance with applicable deadlines. MIPS eligible clinicians would then be able to submit reweighting requests before the beginning of the associated MIPS payment year.

The December 31st deadline for MIPS eligible clinicians to submit reweighting requests before the beginning of the associated MIPS payment year is aligned with the requirements finalized in the CY 2020 PFS final rule for clinicians to request reweighting in circumstances where data are inaccurate, unusable, or otherwise compromised. Under this policy, we apply reweighting only in cases when we learn of the compromised data before the beginning of the associated MIPS payment year (84 FR 63023 through 63026). We intend for this policy to offer increased flexibility to impacted clinicians and note that this timeline will encourage MIPS eligible clinicians and their third-party intermediaries to inform us of these concerns in a timely manner so we can update our data sets while minimizing the impacts to other interested parties who utilize MIPS data. The updated deadline will still allow CMS to re-calculate final scores and MIPS payment adjustments factor in a timely manner.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal that in scenarios where a third-party intermediary did not submit data on their behalf, clinicians would be able to submit reweighting requests on or before December 31st of the year preceding the relevant MIPS payment year. Commenters stated their support for policies that increase flexibility and ensure that clinicians are not penalized for events outside of their control. A few commenters also stated that aligning the deadline with the requirements for clinicians to request reweighting in circumstances where data are inaccurate, unusable, or otherwise compromised will reduce confusion.

Response: We thank the commenters for their support

Comment: A commenter recommended that CMS consider providing automatic reweighting in scenarios where a third-party intermediary did not submit data on behalf of a clinician, rather than requiring an application and documentation from impacted clinicians.

Response: We are extending the deadline for clinicians to submit reweighting requests in scenarios where a third-party intermediary did not submit data on their behalf in order to offer as much flexibility as possible and

to ensure that clinicians are not penalized for data submission issues that are outside of their control. Because CMS must be informed of any failure on the part of a third-party intermediary to submit data, it is not feasible to offer automatically applied reweighting when a third-party intermediary fails to submit data on behalf of a clinician. Additionally, before CMS can offer reweighting, CMS must consider the following in evaluating these requests: whether there is a written agreement between the MIPS eligible clinician and third-party intermediary; whether the MIPS eligible clinician knew or had reason to know of the issue with its third-party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third-party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines, which would also prohibit CMS from automatically applying reweighting.

Comment: A commenter recommended that CMS use a calendar year-end deadline for all reweighting and EUC hardship requests.

Response: We appreciate this recommendation and note that deadlines for reweighting requests are aligned to the extent possible. Under the automatically applied extreme and uncontrollable circumstances policy there is no deadline, as no application is required (83 FR 59875). Requests for reweighting must be submitted by December 31st of the performance period as specified in the CY 2018 QPP final rule for the Promoting Interoperability performance category both in the event of a significant hardship (82 FR 53683) and for the application based reweighting policy (82 FR 53781 through 53783). In scenarios where we are applying reweighting due to issues with data submission, we must set the application deadline later, during the data submission period, as clinicians would not be aware of issues during the performance period. Accordingly, the policy to update the application submission deadline to December 31st of the year preceding the payment year in scenarios where a third-party intermediary did not submit data on a clinician's behalf aligns with the policy specified in the CY 2020 PFS final rule for scenarios where data are inaccurate, unusable, or otherwise compromised. Specifically, in a scenario where data are inaccurate, unusable, or otherwise compromised CMS must learn the relevant information prior to the beginning of the associated MIPS payment year, which is December 31st of the year preceding the payment year (84 FR 63023 through 63026).

After consideration of public comments, we are finalizing as proposed the policy to require reweighting requests on or before December 31st of the year preceding the relevant MIPS payment year, and the proposal to codify this updated deadline at § 414.1380(c)(2)(i)(A)(10) for the quality and improvement activities performance categories and at § 414.1380(c)(2)(i)(C)(12) for the Promoting Interoperability performance category.

E. Public Reporting

1. Background

Public reporting of Merit-based Incentive Payment System (MIPS) eligible clinician performance information on the Compare Tool on medicare.gov (here after referred to as the ''Compare Tool'') is authorized under section 10331(a)(1) and (2) of the Affordable Care Act (ACA). Section 10331(a)(1) of the ACA established a physician compare website for the public reporting of clinician performance information.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) amended the Social Security Act by adding section 1848(q)(9), which requires the Secretary to continue to make publicly available, on the Compare Tool and in an easily understandable format, information regarding the performance of individual MIPS eligible clinicians and groups (81 FR 77391).

For previous discussions and established policies regarding public reporting on the Compare Tool, we refer readers to § 414.1395 as well as, the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), the CY 2020 PFS final rule (84 FR 63080 through 63083), the CY 2021 PFS final rule (85 FR 84947 through 84948), the CY 2022 PFS final rule (86 FR 65550 through 65554), the CY 2023 PFS final rule (87 FR 70109 through 70104), the CY 2024 PFS final rule (88 FR 79394 through 79401), and the CY 2026 PFS final rule (90 FR 49862). The Compare Tool is available at *https://www.medicare.gov/care-compare/* and in the Medicare Provider Data Catalog available at *https://data.cms.gov/provider-data/topics/doctors-clinicians*.

In this section of the final rule, we are finalizing removal of the requirement that prevents public reporting of any performance data reported through a MIPS Value Pathway (MVP) on new improvement activities and Promoting Interoperability measures on the Compare Tools for the first year the new measures and activities are included in such MVP. We also included a request for information (RFI) in the CY 2027 proposed rule to obtain feedback on potential improvements to the current star rating assignment methodology for quality measure scores reported under the administrative claims collection type.

2. Remove the Public Reporting Requirements for the MIPS Value Pathway (MVP) Requirement at § 414.1395(c)(2)

In the CY 2022 PFS final rule (86 FR 65550 through 65552), we finalized a policy under which we would not publicly report any MVP data, or MIPS performance data reported through an MVP, on a new improvement activity or new Promoting Interoperability measure, objective, or activity for the first year the new activity or measure is included in an MVP. For example, if a new improvement activity is finalized for inclusion in MIPS and an MVP for the CY 2027 performance period/CY 2029 MIPS payment year, under the current regulatory framework, we would not publicly report the first year of data for MIPS eligible clinicians who report the new improvement activity through the MVP. The intent of this requirement was to encourage participation in the new MVP reporting framework and to provide participants with additional time to transition to MVPs before their performance on new Promoting Interoperability measures or improvement activities were publicly reported. However, we have determined that this requirement has not served as an effective incentive for MVP participation because most improvement activities and Promoting Interoperability measures included in MVPs are not considered new as of 2026 and would be publicly reported, as they have been included in MIPS for over a year.

Consistent with section 1848(q)(9)(A)(i)(II) of the Act, we finalized in the CY 2017 Quality Payment Program final rule a decision to make all measures, objectives, or activities under the MIPS quality, cost, improvement activities, and PI performance categories available for public reporting on the Compare tools

(81 FR 77391 through 77396), using a phased approach for new performance information facilitated by section 1848(q)(9)(A) and (D). In the CY 2018 PFS final rule (82 FR 53825 through 53827), we further finalized that the first year of data for new improvement activities and Promoting Interoperability measures would be publicly reported for MIPS eligible clinicians on the Compare tools if all other public reporting criteria established under § 414.1395(b) are met. Since we established § 414.1395(c)(2), the annual consumer testing conducted consistent with the requirements of § 414.1395(b) demonstrates that patients and caregivers find the new improvement activities and Promoting Interoperability information understandable and useful for their decision-making. Therefore, this information should be publicly reported. The purpose of the Compare Tools is to provide patients with timely, clear, and credible information on provider performance that is available for public reporting.

Since the adoption of the requirement to not publicly report the first year of new improvement activity or Promoting Interoperability measure information for clinicians who report through an MVP, we have observed that the policy does not apply to a sufficient number of MIPS eligible clinicians to encourage meaningful participation in MVPs. For example, during 2025, only four individual clinician's performance information would not have been publicly reported for new improvement activities included in MVPs, and CMS did not include any new Promoting Interoperability measures in MVPs for 2025. This represented less than 1 percent of clinicians reporting the new improvement activities for that performance period. Similarly, we observed that this requirement applied to less than 1 percent of MIPS eligible clinicians reporting new improvement activities and Promoting Interoperability information overall since MVPs became available as a reporting framework beginning with the CY 2023 performance period. There has not been a sufficient number of new Promoting Interoperability measures or improvement activities included in MVPs, and there is not enough data to continue supporting this requirement.

In the CY 2027 proposed rule, we proposed to remove the requirement at § 414.1395(c)(2) that we would not publicly report any MVP data on new improvement activity or Promoting Interoperability measure, objective, or activity for the first year in which it is included in an MVP. Upon the removal of this requirement, we would revert to the original policy finalized in the CY 2018 PFS final rule (82 FR 53825 through 53827) and would include all eligible performance information for new improvement activities and new Promoting Interoperability measures in public reporting on the Compare Tools beginning with the first year in which the measures and activities are included in the program.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to remove the requirement that we will not publicly report any data on new improvement activities or Promoting Interoperability measures, objective, or activity during the first year in which it is included in an MVP. Several commenters agreed that this change will improve transparency in the quality of care. A commenter also noted that as MVP participation grows and stakeholders gain familiarity with the reporting framework, earlier public reporting is appropriate. Another commenter also discussed the low impact the first-year policy had on incentivizing MVP participation.

Response: We appreciate the commenters' support.

Comment: Some commenters supported the proposal but discussed the need for CMS to remain attentive to risks to data quality and compliance arising from accelerated public reporting timeframes. Commenters also recommended that CMS continue to provide clinicians with sufficient opportunity to review and correct reported information to ensure that publicly displayed results accurately reflect clinician performance.

Response: We appreciate the commenter's concern regarding data quality and compliance. We are required under sections 10331(a) and 10331(b) of the Affordable Care Act to include processes to ensure publicly reported data are valid, reliable, and accurate, and under section 1848(q)(9)(C) of the Act to provide clinicians with an opportunity to review information before it is publicly reported. Consistent with these requirements, we will continue to monitor data quality and maintain processes to assess, validate, and address potential data quality issues, and provide a 30-day preview period for clinicians and groups to review their performance information before it is public reported (80 FR 71120; 81 FR 77391; § 414.1395(d)).

Comment: Some commenters disagreed with the proposal. A few commenters stated that the first year allows clinicians needed time to adapt to new measures and activities before performance data are made public, and that removing the requirement may create unnecessary technical and workflow risks. A commenter also predicted that removing this requirement will increase hesitation for physicians to report MVPs.

Response: We appreciate the commenters' feedback regarding the time needed to adapt to new measures and activities, as well as potential workflow and technical challenges. These considerations can be addressed through clear guidance and education on any new improvement activity or Promoting Interoperability measure, objective, or activity. We have made this a priority since the beginning of MIPS and will continue to do so by providing a range of resources and support available through the Quality Payment Program website at *https://QPP.cms.gov*. We would also remind commenters of the nominal percentage of clinicians reporting new improvement activities and Promoting Interoperability measures overall since MVPs became available as a reporting option beginning with the CY 2023 performance period. Moreover, the limited reporting of new improvement activities and Promoting Interoperability measures suggests that the availability of such measures is not a significant driver of clinicians' decisions regarding MVP participation. Accordingly, we do not believe this policy is likely to materially influence clinicians' decisions to report MVPs.

Comment: Two commenters recommended expanding the current requirement so that CMS would not publicly report any data on new improvement activities or Promoting Interoperability measure during the first 2 years in which it is included in an MVP.

Response: Thank you for this recommendation. The primary concerns raised regarding the original proposal to remove the requirement to not publicly report MVP data on new improvement activities or Promoting Interoperability measures, objectives, or activities during its first year of availability to report focused on attributes of performance data from other performance categories, including measure attribution, calculation, risk adjustment methodologies, and benchmark development. Because individual MIPS eligible clinicians and groups simply attest to whether improvement activities and Promoting Interoperability measures were completed—and no calculation is involved at the measure or

activity level—we conclude that this does not provide a sufficient basis to postpone the public reporting of this information. Moreover, we believe that the recommendation to expand the initial public reporting grace period to 2 years would only further diminish transparency, particularly because this information continues to be meaningful to patients and supports their decision-making.

After consideration of the public comments, we are finalizing our proposal as proposed and removing the requirement at § 414.1395(c)(2) that we will not publicly report any MVP data on new improvement activities or Promoting Interoperability measures, objectives, or activities during the first year in which it is included in an MVP.

3. Request for Information: Star Rating Assignment Methodology for Administrative Claims Quality Measures

In the CY 2027 proposed rule, we issued an RFI to investigate potential improvements to the star rating methodology used to display administrative claims-based quality measure scores on clinician profile pages in the Medicare.gov Compare Tool. The option included in the RFI uses a standard deviation-based approach for the calculation of star rating cutoffs, reflecting the normally distributed nature of administrative claims-based measure scores. We requested feedback on whether this alternative method would be easily understood and more appropriate prior to public reporting of these scores. We appreciate the feedback we received in response to this comment solicitation and may consider this information for possible future rulemaking.

F. Advanced APMs

1. Overview

The Quality Payment Program provides incentives for eligible clinicians to engage in value-based, patient-centered care under Medicare Part B via MIPS and Advanced APMs. The structure of the Quality Payment Program enables us to advance accountability and encourage improvements in care. Our vision for increased clinician participation in Advanced APMs is aimed at integrating individuals' clinical needs across a spectrum of providers and settings to improve patient care and population health. In the CY 2026 PFS final rule (90 FR 50012), we finalized an update to our methodology to add an individual-level calculation to Qualifying APM Participant (QP) determinations, as set forth in § 414.1425(b)(3) and (c)(3), for all eligible clinicians participating in an Advanced APM, such that each eligible clinician would receive both APM Entity-level calculation and an individual-level calculation. Second, we finalized a policy at §§ 414.1435 and 414.1305 to perform QP determinations using both an E/M services approach and a Covered Professional Services approach.

2. QP Determination

a. General

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445), we finalized our policy for QP determinations at § 414.1425. We perform QP determinations for eligible clinicians three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a snapshot date that we use to determine the APM Entity group and to make QP determinations as described at § 414.1425.

In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77440) we established a process to calculate Partial QP status at § 414.1425(d). While to date our Partial QP policies have impacted only a small number of eligible clinicians, and thus we have not focused our discussion on this specific policy, we note that any changes to QP determinations at § 414.1425 also would likely require conforming changes to the policies for Partial QPs for consistency across the program.

b. Applying QP Determinations at the TIN/NPI Level

When we initially established our policy in the CY 2017 Quality Payment Program final rule to make most QP determinations at the APM Entity level, we also specified that we would apply QP status at the NPI level (81 FR 77440). In other words, for a given eligible clinician (NPI), were one of their TIN/NPI relationships to be determined a QP, that QP status has applied all of their TIN/NPI relationships, both for purposes of being excluded from MIPS as well as for the application of QP financial incentives. Given the complexity of the program, we believed it was the best approach at the time to create one QP status result for a clinician at all of their billing organizations. However, we did not intend for the policy to create conflicting incentives to participation in Advanced APMs. We realized that an NPI being a QP at all of their TINs also meant that they would receive the financial incentives of QP status, at the time the APM Incentive Payment, across all of those TINs, irrespective of whether those TINs were participating with Advanced APMs. However, we believed that the significance of that incentive would serve to increase clinician participation in Advanced APMs, and that the application of the QP thresholds would ensure that the clinician was appropriately incented to try to increase their individual Advanced APM participation. Further, we also had finalized at § 414.1450(c)(1) that we would pay the entire APM Incentive Payment amount to the TIN associated with the QP's participation in the Advanced APM Entity through which QP status had been attained (81 FR 77555), and we believed that by directing the lump sum entirely to the TIN participating with the Advanced APM Entity, we would reward the clinician without also rewarding non-participating TINs.

Upon gaining early experience implementing the APM Incentive Payments, we learned that for a variety of reasons (clinician movement, changes to a practice's TINs), we were not always able to send payment to the TIN associated with the APM Entity. We revised § 414.1450(c) in the CY 2021 PFS (88 FR 85035) to establish a hierarchy we would apply when determining where to send the APM Incentive Payments, which still prioritized TINs participating in Advanced APMs but allowed for payment to be sent to other, non-participating TINs if that was the only place we could find the clinician active at the time of payment. Still, we were satisfied that our prioritization of the lump-sum APM Incentive Payment to TINs that had Advanced APM participation remained a protection against providing non-participating TINs significant windfalls.

However, section 1848(d)(1)(A) of the Act establishes that, beginning with payment year 2026, QPs will receive a higher qualifying conversion factor update than non-QPs on their covered professional services claims. While the APM Incentive Payment has been extended multiple times as described in section III.G.6.d. of this final rule, the implementation of the QP conversion factor means that a QP financial incentive goes directly to TINs in the form of claims payment. Particularly as the QP conversion factor grows and constitutes a larger proportion of the QP incentive structure over time, we are

concerned that a significant proportion of incentives paid for QP status will be paid to TINs that are not part of an Advanced APM, creating a disincentive for these TINs to join an Advanced APM and meaningfully engage in risk-bearing value-based care.

As such, we proposed adding new provisions at § 414.1425(c)(8) and (d)(5) to apply QP status and Partial QP status, respectively, strictly to an eligible clinician as such term is defined at § 414.1305, specifically as a TIN/NPI combination, and that meets the definition at § 414.1305 of Qualifying APM participant (QP) or Partial QP, respectively, by participating in an Advanced APM during the QP performance period. Under the proposal, QP status and Partial QP status would therefore only apply to the clinician at the TIN that is participating with the APM Entity in the Advanced APM. Therefore, the financial incentives in the form of both the APM Incentive Payment and the QP conversion factor would apply to the NPI's claims only with those TINs, as would the ability of a Partial QP to opt into or out of MIPS.

For an eligible clinician who is participating in multiple APM Entities, the proposal's effects would be based on how the clinician becomes a QP or Partial QP. Section 414.1435(h)(2) specifies that CMS assigns to the eligible clinician the score that results in the greater QP status. In accordance with this provision, if an eligible clinician attains QP status at the individual level from participation in multiple APM Entities, under the proposal we would assign the QP status at each of the clinician's TINs participating across those APM Entities. However, if, the eligible clinician did not attain QP status at the individual level and did attain QP status as part of a specific APM Entity-level determination, we would assign QP status to the clinician at only the TIN(s) that are associated with the APM Entity or Entities that collectively attained QP status. If the eligible clinician did not attain any QP status through any determination but did attain Partial QP status, this same preference for the highest status would apply for Partial QP status. As we explained in the proposed rule, this proposed approach would maintain the longstanding policy within QPP to give the clinician the highest possible outcome available to them.

We proposed to no longer apply QP determinations to a clinician as a whole and we recognized the possibility of this being perceived as introducing complexity into an eligible clinician's QPP experience, for example because under the proposal some eligible clinicians would be a QP with one TIN and participating in MIPS with another. In these cases, the eligible clinician's QP status would apply at each of their TINs under the proposal. For the clinicians who are not already participating in an Advanced APM across all of their TIN reassignments, we explained that CMS believes that this policy would provide a meaningful incentive to increase their participation in an Advanced APM. Participation in Advanced APMs across Original Medicare continues to grow and we expect this policy to support our progress.

As we noted in the proposed rule, our proposal aligns with MIPS, which already operates on a TIN/NPI basis, meaning that QPP internal operations and communications would be the same for all clinicians. Under our current policy, we receive a significant number of inquiries from billing organizations where clinicians have been excluded from MIPS as a result of QP status with another billing organization where that organization is participating in an Advanced APM. In these cases, organizations have made a significant investment to report MIPS but do not receive a MIPS final score and MIPS payment adjustment for these clinicians. Our proposed policy would ensure that these billing organizations are in control of how MIPS eligibility criteria apply to clinicians that have been reassigned to their organizations.

In addition to programmatic alignment, we explained in the proposed rule that our operational experience tells us that, when a TIN has any clinicians who are subject to MIPS, it most often simply reports on all of its clinicians, as including everybody is easier than removing clinicians before reporting. As such, we believe that in the relatively few situations where the proposal would result in an eligible clinician with QP status at one TIN being subject to MIPS at one or more other TINs, the TINs where the clinician is subject to MIPS in many cases already report data for that clinician, meaning that neither the clinician nor their MIPS-participating TIN(s) would bear any new burden as a consequence of the proposed policy. Further, as it was established at the outset, operational experience indicates that MIPS eligible clinicians' experience has not been significantly impaired by the TIN/NPI operation of that portion of the program.

Finally, in the proposed rule we recognized that this proposal would decrease the dollar value of the financial incentives available for affected QPs. However, we believe that assigning QP status at the TIN/NPI level will serve to prevent an increasing windfall for TINs that do not participate in Advanced APMs, particularly given that the higher qualifying conversion factor update that is now part of the physician fee schedule. This update is baked into the amount Medicare pays on claims and therefore always is paid to the TIN through which the service was furnished without regard to whether that TIN is part of the Advanced APM that conferred QP status to the clinician. We believe that this proposal would prevent waste and potential for abuse, and that these matters outweigh concerns around complexity or reduced incentives. Notably, under current law the QP conversion factor will increase each year relative to the non-QP conversion factor. In addition, because payment of the claims is made directly to the TINs through which the services were billed means that CMS has no mechanism of directing these incentives to Advanced APM participating TINs in the way we have done with the APM Incentive Payment. As such, while relatively few QPs would be affected by this proposal, CMS anticipates the amount of the resulting windfall flowing directly to non-participating TINs under the current framework will increase over time, with little benefit to the clinician and no benefit to the practices that are doing the work of Advanced APM participation.

With respect to Partial QP status, the proposal would maintain programmatic alignment within QPP and would provide for the application of the ability to opt out of MIPS at the TIN/NPI level. While there are not financial incentives for these eligible clinicians in the same manner that there are for QPs, we believe that applying the opt-out flexibility at the TIN/NPI level similarly confers the burden reduction of Partial QP status. In our proposal we limited the application of Partial QP status to only to those TINs that are affiliated with the APM Entity participating in the Advanced APM. However, based on comments discussed in this section we are modifying our proposal and finalizing a policy that extends Partial QP status to all TIN/NPI combinations for a given NPI.

We proposed amending § 414.1425(c) to add new paragraph (8) to apply QP status strictly to the eligible clinician as such term is defined at § 414.1305, specifically as a TIN/NPI combination, and that meets the definition of Qualifying APM participant (QP) as defined at § 414.1305 by participating in an Advanced APM during the QP performance period. We also proposed amending § 414.1425(d) to add new paragraph (5) to establish the same

policy with respect to the application of Partial QP status.

We sought public comments on this proposal.

We received several public comments on these proposals. Comments were a mix of support and opposition. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed the proposal, citing administrative complexity for clinicians who bill under multiple TINs. Commentors noted that incentives for QPs are an important driver of Advanced APM participation, particularly for large organizations with multiple TINs. Commenters requested that we provide additional impact data.

Response: We appreciate the substantial interested parties' input on this proposal. We acknowledge commenter concerns regarding administrative burden for clinicians who bill under multiple TINs. In an effort to understand the potential for increased burden we have investigated how this policy would have impacted historical participation in QPP. We started by modeling participation data from 2025. We were particularly concerned about instances where TIN/NPIs would be required to report to MIPS. However, we found that there would be very few instances where a TIN/NPI no longer had QP status but was also MIPS eligible at an individual level. Out of all the TIN/NPIs participating in an Advanced APM in 2025 only 1.1 percent would fall into the category of having lost QP status, while also being MIPS eligible at the individual level. In other words, the overwhelming majority of TIN/NPIs in advanced APMs have seen no change in reporting requirements. In order to further investigate MIPS reporting feasibility for this subgroup we looked at their MIPS reporting data for the 2025 performance year. We found that more than half of the TIN/NPIs, represented in the aforementioned 1.1 percent, already had MIPS participation data at the APM entity, group, or individual level.

We have noted in the CY 2026 PFS final rule (90 FR 49994) that, projecting future participation in Advanced APMs and the impact is difficult. We also continue to believe that the benefit of TIN/NPI-level application of QP status furthers the goal of increasing participation in Advanced APMs. In an effort to be responsive to interested parties' concerns we are finalizing a modification to our proposed policy as discussed in the comment and response below. Our modification will ensure that NPIs who are otherwise meaningfully participating, in Advanced APMs, above the Partial QP thresholds, can be afforded the choice to opt in or out of MIPS participation.

As commentors noted we would expect our policy to have a greater impact on large integrated systems which are often comprised of more than one TIN. We believe our policy provides an incentive structure that favors the inclusion of more providers in Advanced APMs, including specialists. Where the previous policy may have further promoted the creation of multiple TINs and the exclusion of some providers within a large organization from Advanced APM participation our policy seeks to correct the incentive structure.

Comment: Several commenters noted potential issues for new TIN reassignment. Commentors noted that because there is a two-year delay between performance year and payment year our proposed policy may inhibit providers from joining new organizations or leaving their current organization.

Response: We acknowledge commentor concern around new and changing TIN assignment. With the gap in timing between the QP performance period and payment year where we expect new TIN/NPI combinations will be created both as a part of an Advanced APM and not participating in an Advanced APM. We share this concern and plan to further clarify the application of the qualifying APM conversion factor to new TIN/NPI combinations in these scenarios in future rulemaking.

Comment: Several commenters suggested that CMS' application of QP, and Partial QP status was inconsistent with the statutory provisions under section 1833(z) and 1848(q) of the Act.

Response: We thank commenters for their comments. However, our application of QP status at the TIN/NPI level is consistent with our previous application of ''qualifying APM participant'' as defined in section 1833(z)(2) of the Act. When we established our policy in the CY 2017 Quality Payment Program final rule to apply QP status at the NPI level (81 FR 77440) we also considered applying QP and Partial QP status at the TIN/NPI level. We elected not to do so, in large part, to promote administrative simplicity as we developed the infrastructure to operate the new program. Some commentors had suggested we should apply QP status at the TIN/NPI level, and while we disagreed at that time and noted that we believed the most logical reading of the statute was to apply QP status at the NPI level, we did not dismiss the alternative of the TIN/NPI approach as legally barred. We also note that applying QP and Partial QP status at the TIN/NPI level is consistent with the definition of ''Eligible professional'' at section 1848(k)(3)(B) of the Act. Furthermore, we established in the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77441) and have consistently made QP determinations at the APM entity group level as defined at § 414.1305, which we note is a group of ''eligible clinicians'' as defined at § 414.1305 specifically as identified as a unique TIN and NPI combination. In other words, QP determinations have consistently considered TIN/NPI as the basis for participation in an Advanced APM.

Comment: Several commenters supported the proposal as more accurately targeting incentives to TINs that assume Advanced APM risk. Commenters on this subject included practices that have been adversely impacted by some of their clinicians having QP and Partial QP status and therefore not receiving the positive MIPS payment adjustment. Commentors noted that active enrollments often exist for TINs where the clinician is no longer rendering a large volume of services and that in these cases the action of another organization impacts the payment they receive through their TIN. Commenters who raised this perspective have indicated the financial impact of not receiving the MIPS adjustments for member clinicians who attained QP status elsewhere.

Response: We appreciate the support for the proposed policy. Our aim is to balance program integrity and burden reduction. Applying QP status to the TINs participating in Advanced APMs ensures that organizations participating in these models are provided an earned incentive. We believe that this will result in a program where TINs are incentivized to participate in Advanced APMs. Furthermore, our policy aligns the application of QP and partial QP status at the TIN/NPI level with MIPS which for some TINs may reduce fragmentation within the program. In other words, when a group practice receives a MIPS payment adjustment based on their own performance and they are no longer impacted by the behavior of another group in QPP.

Comment: Several commenters requested that the policy be delayed, or that CMS adopt an alternative approach that preserves QP or partial QP status at the NPI level while limiting the financial incentive to participating TINs. These commenters note return on investment in Advanced APM

participation, as well as MIPS relief afforded by QP and partial QP status, as key considerations. Some commenters expressed that providing TIN/NPI-level QP information for education would allow for practices to track and plan.

Response: We appreciate commentor feedback. We recognize that commenters are in particular considering that the policy can lead to eligible clinicians being required to participate in MIPS with one or more TINs. However, we believe that delaying the implementation of the policy would extend the provision of the financial windfall described in this section without sufficient benefit to clinicians to be necessary. As proposed, the policy change is effective with the 2027 QP performance period, meaning that the first instance of MIPS reporting as a consequence of the policy would be in early 2028; further, while QPs are excluded from MIPS as clinicians, in significant numbers of cases, the QPs' other TINs (those that do not participate with Advanced APMs) already have MIPS reporting experience. We identified that when MIPS eligible TINs report for their practices, they commonly report for everyone, including clinicians who are QPs. As such, we do not believe that preparation for potential MIPS readiness warrants a delay. Further, we note that for TINs who are part of the APM Entities participating in Advanced APMs, the application of QP and Partial QP status at the TIN/NPI level would not increase burden or result in MIPS obligations. QP determinations always have involved the use of TIN/NPI-level data to form the numerator (APM Entity participation), so APM Entities and eligible clinicians who historically have attained QP status would not see that expectation change as a consequence of our proposed policy. Rather, the policy matches the resulting QP or partial QP status to the TIN/NPI combination(s) that were used in the determination itself. As such, TINs associated with participating APM Entities will not see changes in the QP or partial QP status results. The only thing that would change for these TINs is the amount of any APM Incentive Payment they might get in or after payment year 2029; we note that, under current law, there is no such incentive beyond payment year 2028.

The second suggestion made by these commenters was to continue applying QP and Partial QP status at the NPI level while limiting financial incentives to Advanced APM-participating TINs. This type of approach would stop the windfall we described in this section without leading to situations where MIPS participation is required for clinicians who have attained QP or Partial QP status. We recognize the appeal of such an approach, especially in cases where QP status or Partial QP status is earned at the individual level, signifying that the eligible clinician is individually and meaningfully participating in value-based care through one or more Advanced APM. As a result, we are modifying our proposed policy such that, in cases where QP or Partial QP status is attained at the individual level, the eligible clinician would be treated as a Partial QP across all of their TIN/NPI combinations. We believe that this modification preserves our goals with respect to program integrity and stopping wasteful spending without requiring eligible clinicians who are meeting or exceeding the Partial QP thresholds as individuals to also engage with MIPS. Notably, this approach also preserves the option for these clinicians to participate in MIPS, which we believe is important in light of supportive comments that we described earlier in this section.

Because Partial QP status means that reporting to MIPS is optional, this modification meets the preferences of both those commenters who are concerned about the burdens associated with MIPS reporting and those commenters who support the idea of having all of their clinicians participating in MIPS and receiving the attendant payment adjustments. Specifically, the modification would allow the TIN the choice of whether or not to participate in MIPS, allowing TINs to prioritize either MIPS adjustments or reduced burden, as they see fit.

We are finalizing the policy to amend § 414.1425(c) and (d) to add new subparagraphs that apply, respectively, QP status and Partial QP status at the TIN/NPI level, with a modification based on public comments that, for eligible clinicians whose QP or Partial QP status was determined at the individual level, we will apply Partial QP status to all TIN reassignments for the NPI as codified at § 414.1425(d), which will allow for the choice of whether or not to participate in MIPS for the applicable performance period.

3. APM Entity Terminations

a. Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77446 through 77447), we finalized for the timing of QP determinations that a QP Performance Period runs from January 1 through August 31 of the calendar year that is 2 years prior to the payment year. We finalized that during the QP Performance Period, we will make QP determinations at three separate snapshot dates (March 31, June 30, and August 31), each of which will be a final determination for the eligible clinicians who are determined to be QPs. The QP Performance Period and the three separate QP determinations apply similarly for both the group of eligible clinicians on a Participation List and the individual eligible clinicians on an Affiliated Practitioner List.

In the CY 2017 Quality Payment Program final rule, we finalized at § 414.1425(c)(5) and (d)(3) that an eligible clinician is not a QP or Partial QP for a year, respectively, if the APM Entity group voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period (81 FR 77446 through 77447). We also finalized at § 414.1425(c)(6) and (d)(4) that an eligible clinician is not a QP or Partial QP for a year if one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP or Partial QP payment amount threshold or QP or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities (81 FR 77446 through 77447).

b. APM Entity Terminations Before Financial Risk was Borne

In the CY 2020 PFS final rule (84 FR 63087 through 63089), we finalized revisions to § 414.1425(c)(5) to add § 414.1425(c)(5)(i) and (ii) to state, beginning with the 2020 QP Performance Period, that an eligible clinician is not a QP for a year if: (1) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; (2) or the APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs. We also finalized conforming revisions in § 414.1425(d)(3) with respect to Partial QP status. In addition, we finalized revisions to our regulation at § 414.1425(c)(6) and add § 414.1425(c)(6)(i) and (ii) to state, beginning with the 2020 QP Performance Period, that an eligible clinician is not a QP for a year if: (1) one or more of the APM Entities in which the eligible clinician participates

voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or (2) one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities. We also finalized conforming revisions in § 414.1425(d)(3) with respect to Partial QP status.

When we finalized the revisions in the CY 2020 PFS, due to a clerical error we inadvertently included language in the text of § 414.1425(c)(5)(ii) that we believe is unnecessary and has potential to cause confusion. Specifically, § 414.1425(c)(5)(ii) states that an eligible clinician is not an QP for a year when an APM Entity termination occurs ''at a date on which the APM Entity would not bear financial risk for that QP performance period under the terms of the Advanced APM*, even if such termination date occurs within such QP Performance Period*'' (emphasis added). The inclusion of the emphasized language was a clerical error. This language did not appear in the CY 2020 PFS proposed rule regulation text for § 414.1425(c)(5)(ii) (84 FR 40929) nor does it appear in the companion finalized regulation for Partial QP status at § 414.1425(d)(3)(ii). What's more, in the CY 2020 PFS final rule, we indicated that we were finalizing these policies ''without modification'' (84 FR 63089), but the addition of this clause would have constituted a modification that we would have discussed if intentionally made. Further, we believe the language is unnecessary because § 414.1425(c)(5)(i) already addresses terminations within the QP performance period. Therefore, we believe that the clause not only serves no meaningful purpose, but also that it could result in confusion because it could appear to be filling a regulatory gap that in fact does not exist. However, we do not believe any clarifying language is necessary. The principal reasons that cause us to change proposed regulatory text in final are to address public comments or fix an error or address an issue that we recognized only after the proposal was made. We had not received any comments that indicated any confusion regarding the applicable timeframe for the proposed version of § 414.1425(c)(5)(ii) (that again, did not include the relevant clause), and we had not independently identified any problems with the proposed text, so we did not have any reason to believe we needed to clarify the applicable timing. Furthermore, we have not experienced any problems in the implementation of the companion regulation with respect to Partial QP status, which also does not contain this additional clause.

Therefore, to align the QP regulation text at § 414.1425(c)(5)(ii) with the Partial QP regulation text at § 414.1425(d)(3)(ii), and to remove any potential for confusion with respect to the intended timeframe for APM Entity terminations before financial risk is borne in the Advanced APM, we proposed to amend the text of § 414.1425(c)(5)(ii) to remove '', even if such termination date occurs within such QP Performance Period.''

We sought but did not receive public comments on our provision to modify the text of § 414.1425(c)(5)(ii). Therefore, we are finalizing the text of § 414.1425(c)(5)(ii) to read ''The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that performance period under the terms of the Advanced APM.'' as proposed.

c. Clarification for APMs Without a Participation List

The definition of ''Participation List'' was first established in the CY 2017 QPP final rule, (81 FR 77008). In that rule, we codified the definition of ''Participation List'' at § 414.1305 as the mechanism by which CMS identifies the eligible clinicians associated with a given APM Entity for purposes of QP determinations and related QPP functions (81 FR 77246 through 77257). The definition has remained substantively unchanged since its initial adoption in the CY 2017 QPP final rule, though the regulatory provisions that rely upon it—including those governing QP determination methodology under § 414.1425, APM Entity group composition under § 414.1317, and APM Performance Pathway eligibility under § 414.1367—have been refined through subsequent annual rulemaking. The existing regulatory definition of ''Participation List'' does not expressly address the circumstance in which an APM does not require or generate a Participation List for its APM Entities. This gap has the potential to create interpretive ambiguity—particularly as CMS considers the design of future episode-based, mandatory, and other APMs under which Participation Lists may not be a structural feature of APM participation. To enhance regulatory clarity and ensure that the framework governing QP determinations and MIPS APM scoring can accommodate the full range of APM designs CMS may implement, we proposed a clarification to the definition of ''Participation List'' within § 414.1305 to ensure that in cases where a participation list is not operationally practicable, we would not include these APMs for MIPS scoring or QP determinations.

We sought but did not receive public comments on this provision. Therefore, we are finalizing our proposed clarification to the definition of ''Participant List'' within § 414.1305 as proposed.

4. APM Incentive Payment

a. Overview

Section 1833(z)(1) of the Act establishes an incentive payment for participation in eligible alternative payment models, which originally ran from payment years 2019–2024. As such, when we established the definition of ''APM Incentive Payment'' at § 414.1305 in the CY 2017 Quality Payment Program final rule (81 FR 77008) we included in the definition that the payment would be made from payment year 2019 through payment year 2024. We also established at § 414.1450(b)(1) that the amount of the APM Incentive Payment was ''equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year'' (81 FR 77554).

b. APM Incentive Payment Extension

The incentive payment originally was extended as part of the Consolidated Appropriations Act, 2023, which provided for a 3.5 percent payment in payment year 2025. In the CY 2023 PFS final rule (88 FR 79539), we finalized revisions to § 414.1450(a)(1)(i) to make reference payment years 2019 through 2025 and to § 414.1450(b)(1) to codify the legislative extension. The Consolidated Appropriations Act, 2024 provided an additional payment of 1.88 percent in payment year 2026, and in the CY 2024 PFS final rule (89 FR 98564) we again made conforming updates to § 414.1450(a)(1)(i) and (b)(1)

to incorporate that extension. As such, currently, in § 414.1450(a)(i) and (b)(1), the lump sum APM Incentive Payment is available for payment years 2019 through 2026, with the applicable percentage varying by year in accordance with the statute: 5 percent for payment years 2019 through 2024, 3.5 percent for payment year 2025, 1.88 percent for payment year 2026.

The Consolidated Appropriations Act, 2026, now has provided for a 3.1 percent APM Incentive Payment in payment year 2028. Accordingly, we proposed to codify this extension for 2028 into § 414.1450(a)(1)(i) and (b)(1). We also recognize that with several extensions of this payment now having occurred, and each extension having a new and unique applicable percentage, the current single-paragraph structure of the regulation at § 414.1450(b)(1) is beginning to get unwieldy and becoming harder to follow. Specifically, the relevant percentages and years have been listed within a single sentence at § 414.1450(b)(1) that describes the amount of the incentive payment. With each extension, this set of clauses has grown longer, creating greater distance between the concept of a percentage applying and the description of what the percentage in question applies to. Adding the most recent extension will make this sentence longer still.

Therefore, we proposed a technical restructuring of § 414.1450(b)(1), which would not change the policies of this paragraph but, we believe, simply make it easier to read in light of now having three years of extensions at different percentages. Under the proposal, we would pull out the references to percentages and years from the first sentence of (b)(1) into a new list of subparagraphs, mirroring the way that the QP and Partial QP thresholds are listed in § 414.1430. Specifically, we proposed to amend § 414.1450(b)(1) by: (1) remove all of the language in the first sentence that references percentages and payment years and begin the sentence ''The amount of the APM Incentive Payment is''; (2) insert after ''is'' the phrase ''the applicable percentage established for the payment year''; (3) add at the end of the subparagraph ''The applicable percentage is the following value for the indicated payment years:''; and (4) create new paragraphs (i) through (iv) to list the specific applicable percentages, including the extension for 2028. The proposed revised paragraph would read similar to the following:

The amount of the APM incentive payment is the applicable percentage established for the payment year of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment. The applicable percentage is the following value for the indicated payment years.

- 2019 through 2024: 5 percent.
- 2025: 3.5 percent.
- 2026: 1.88 percent.
- 2028: 3.1 percent.''

We believe that this proposed revised structure is cleaner than the current single paragraph with its increasingly long detailing of years and percentages, and therefore will provide an easier-to-follow explanation of the APM Incentive Payment amount. These proposed technical structural changes would not modify the substantive policies of this provision. The only substantive change we proposed is the codifying in new subparagraph § 414.1450(b)(1)(iv) of the 3.1 percent legislated for 2028.

We sought public comments on this proposal.

The following is a summary of the comments we received and our responses.

Comment: Commenters noted that these payments remain important to supporting physician participation in Advanced APMs and encouraging the transition toward value-based care. The commenters appreciated CMS's implementation of the congressional extension and urged CMS to continue supporting policies that provide stability and meaningful incentives for clinicians participating in Advanced APMs.

Response: We appreciate the commenter's support. After consideration of public comments, and for the reasons discussed in this section, we are finalizing as proposed our changes to § 414.1450 codifying in new paragraph § 414.1450(b)(1)(iv) of the 3.1 percent legislated for 2028.

c. APM Incentive Payment Definition

As described in the earlier, we established the definition of ''APM Incentive Payment'' at § 414.1305 in the CY 2017 Quality Payment Program final rule (81 FR 77008), we included language that specifically referenced payment years 2019 through 2024. However, when we revised § 414.1450 in the CY 2023 and CY 2024 PFS final rules to codify the legislative extensions of the APM Incentive Payment, we neglected to make conforming changes to the definition of ''APM Incentive Payment'' at § 414.1305 to reflect those subsequent legislative actions. As such, the current definition at § 414.1305 references only the original statutory payment years of 2019 through 2024, making it out-of-date. To address this, we proposed to update the definition to remove the references to specific years and instead refer to § 414.1450(b)(1). The revised definition would read: ''*APM Incentive Payment* means the lump sum incentive payment for a year as described in § 414.1450(b)(1) and that is paid for an eligible clinician who is a QP for the applicable year.'' This proposal would allow for the APM Incentive Payment definition to automatically be inclusive of any year that may be added through future legislation and codified at § 414.1450(b)(1) without the need for a conforming change to the definition at § 414.1305 itself.

We sought public comment on this proposal.

We did not receive public comments on this proposed revision to the definition of ''APM Incentive Payment'' within § 414.1305, and therefore, we are finalizing as proposed.

d. Summary

We proposed to codify the most recent legislative extension of the APM Incentive Payment by: (1) revising § 414.1450(a)(1)(i) to include the payment amounts for 2019 through 2028; and (2) revising § 414.1450(b)(1) to make structural changes that include the applicable percentages for 2019 through 2024, 2025, 2026, and 2028, respectively at § 414.1450(b)(1)(i) through (iv). We note that the only substantive change involved in these modifications would be the addition of the 2028 extension. The proposed structural changes would not affect the policies of this provision but simply improve the readability of this paragraph.

We also proposed to revise the definition of ''APM Incentive Payment'' at § 414.1305 to remove the current references to specific payment years and replace them with a reference to the years described in § 414.1450(b)(1).

We sought comment on our proposal to revise § 414.1450(a)(1)(i) and § 414.1450(b)(1) along with the definition of ''APM Incentive Payment'' at § 414.1305 but did not receive public comments on these provisions. Therefore, we are finalizing these revisions as proposed.

5. QP and Partial QP Thresholds

Section 1833(z)(2) of the Act specifies the thresholds for the level of participation in Advanced APMs

required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, has been applicable since payment year 2019 (performance period 2017). The All-Payer Combination Option, through which QP status is calculated using the Medicare Option in addition to an eligible clinician's participation in Other Payer Advanced APMs, has been applicable since payment year 2021 (performance period 2019). In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439), we finalized our policy for QP and Partial QP Thresholds for the Medicare Option as codified at § 414.1430(a) and for the All-Payer Combination Option at § 414.1430(b). Section 304(a)(2) of Division G, Title I, Subtitle C, of the Consolidated Appropriations Act (CAA), 2024 (Pub. L. 118–42, March 9, 2024), amended section 1833(z)(2) of the Act by extending a freeze for payment years 2025 and 2026 (performance periods 2023 and 2024) in the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status through the Medicare Option. Section 6204 of the CAA, 2026 (Pub. L. 119–75, February 3, 2026), applied these freezes to payment year 2028 (performance period 2026). Specifically, section 6204(a)(2) of the CAA, 2026 amended section 1833(z)(2) of the Act: (1) to freeze the QP payment amount threshold at 50 percent for payment year 2028 (performance period 2026); and (2) require that, for payment year 2026, the Secretary use the same percentage criteria for the QP patient count threshold that applied in payment year 2022. Further, section 6204(b) of the CAA, 2026, amended section 1848(q)(1)(C)(iii) of the Act to freeze in payment year 2028 the 40 percent Partial QP threshold and apply the 50 percent threshold for payment years 2027 and 2029 and thereafter. The law did not change the thresholds that apply.

To conform our regulation with the amendments made by the CAA, 2026, we sought comment on our proposed amendments to § 414.1430.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the temporary reduction in QP and Partial QP thresholds for performance year 2026 required by the Consolidated Appropriations Act, 2026, but expressed concern about the scheduled increase in future years and its effect on clinicians' ability to attain QP status.

Response: We appreciate commenters' support for the reduced QP and Partial QP thresholds applicable for performance year 2026. The QP and Partial QP payment-amount and patient-count thresholds, including the scheduled increases for future performance years, are established in statute under section 1833(z)(2) and section 1848(q)(1)(C)(iii) of the Act respectively. CMS does not have authority to permanently freeze these thresholds administratively; any such change requires congressional action. We will continue to provide timely, transparent guidance identifying the applicable thresholds for each performance year through the Quality Payment Program website, consistent with commenters' request.

After considering interested parties' comments we are finalizing as proposed amendments to § 414.1430 by revising paragraphs (a) and (b) to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count under the Medicare Option. Over the years, as legislative changes have been enacted, we have added new regulatory provisions. Additionally, we note that these thresholds increased for payment year 2027 (performance period 2025) before the CAA, 2026 restored them to lower levels for payment year 2028 (performance period 2026). To maintain relative structural simplicity in the regulation, we are finalizing condensed lists of applicable years and thresholds for both the Medicare Option and All-Payer Combination Option. The finalized structure would limit duplication in our description of the applicable thresholds.

We are finalizing the following revisions to § 414.1430(a) and (b) for the Medicare Option and All-Payer Combination Option QP and Partial QP thresholds as follows:

- Paragraph (a)(1)(vi) to state that for 2027 the amount is 75 percent, and a new paragraph (a)(1)(vii) to state that for 2028, the amount is 50 percent, and a new paragraph (a)(1)(viii) to state that for 2029 and later, the amount is 75 percent.
- Paragraph (a)(2)(vi) to state that for 2027 the amount is 50 percent, and a new paragraph (a)(2)(vi) to state that for 2028 the amount is 40 percent, and a new paragraph that for 2028 and later, the amount is 50 percent.
- Paragraph (a)(3)(vi) to state that for 2027 the amount is 50 percent, and a new paragraph (a)(3)(vii) to state that for 2028, the amount is 35 percent, and a new paragraph (a)(3)(viii) to state that for 2029 and later, the amount is 50 percent.
- Paragraph (a)(4)(vi) to state that for 2027 the amount is 35 percent, and a new paragraph (a)(4)(vii) to state that for 2028, the amount is 25 percent, and a new paragraph (a)(3)(viii) to state that for 2029 and later, the amount is 35 percent.
- Paragraph (b)(1)(i)(B) to state that for 2027 the amount is 75 percent, and a new paragraph (b)(1)(i)(C) to state that for 2028, the amount is 50 percent, and a new paragraph (b)(1)(i)(D) to state that for 2029 and later, the amount is 75 percent.
- Paragraph (b)(2)(i)(B) to state that for 2027 the amount is 75 percent and a new paragraph (b)(2)(i)(C) to state that for 2027, the amount is 50 percent, and a new paragraph (b)(2)(i)(D) to state that for 2028 and later, the amount is 75 percent.
- Paragraph (b)(3)(i)(B) to state that for 2027 the amount is 50 percent, and a new paragraph (b)(3)(i)(C) to state that for 2028, the amount is 35 percent, and a new paragraph (b)(3)(i)(D) to state that for 2029 and later, the amount is 50 percent.
- Paragraph (b)(4)(i)(B) to state that for 2027 the amount is 35 percent, and a new paragraph (b)(4)(i)(C) to state that for 2028, the amount is 25 percent, and a new paragraph (b)(4)(i)(D) to state that for 2029 and later, the amount is 35 percent.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. Collection of information is defined under 5 CFR 1320.3(c) of the PRAs implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Our July 16, 2026, proposed rule (CMS–1848–P, OMB 0938–1485)

solicited public comment on each of the aforementioned issues for the proposed provisions that contained confirmed or potential information collection requirements. As indicated below, comments were received for ICR #3 (Limiting Medicare Coverage of Certain Individuals) and ICR #5 (Medicare Prescription Drug Inflation Rebate). A summary of the comments and our responses follow under the applicable ICR section.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2025 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/tables.htm*). In this regard, Tables D–A1 and D–A2 present BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

We note that the BLS data does not include median hourly wage rates for multiple physician occupation types listed in Table D–A2; in these cases, the BLS identifies that the median wage rate is equal to or greater than $115.00/hr or $239,200 per year. BLS data for prior years, such as the May 2022 and May 2023 data, provide similar notes for median wage rates for occupations that are above the same threshold ($115.00/hr or $239,200 per year for the May 2022 BLS data (*https://www.bls.gov/oes/2022/may/oes_nat.htm*) and May 2023 BLS data (*https://www.bls.gov/oes/2023/may/oes_nat.htm*)). Therefore, for consistency with previous years for estimating physician wage rates, we have continued to use mean hourly wage rates across our wage estimates.

TABLE D-A1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES (EXCLUDING PHYSICIANS)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Billing and Posting Clerks	43-3020	24.55	24.55	49.10
Business Operations Specialists	13-1000	44.63	44.63	89.26
Computer System Analysts	15-1211	55.10	55.10	110.20
General and Operations Managers	11-1021	64.87	64.87	129.74
Licensed Practical and Licensed Vocational Nurses	29-2061	32.24	32.24	64.48
Medical and Health Services Managers	11-9110	67.77	67.77	135.54
Software Quality Assurance Analysts and Testers	15-1253	53.60	53.60	107.20
Training and Development Managers	11-3131	71.33	71.33	142.66

For our purposes, BLS' May 2025 National Occupational Employment and Wage Estimates does not provide an occupation that we could use for ''Physician'' wage data. To estimate a Physician's costs, we used an average conglomerate wage of $307.74/hr as demonstrated in Table D–A2.

TABLE D-A2: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES (PHYSICIANS)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Anesthesiologists	29-1211	173.35	173.35	346.70
Family Medicine Physicians	29-1215	122.99	122.99	245.98
General Internal Medicine Physicians	29-1216	128.46	128.46	256.92
Obstetricians and Gynecologists	29-1218	134.16	134.16	268.32
Orthopedic Surgeons, Except Pediatric	29-1242	179.60	179.60	359.20
Pediatric Surgeons	29-1243	241.37	241.37	482.74
Pediatricians, General	29-1221	101.98	101.98	203.96
Physicians, All Other	29-1229	125.98	125.98	251.96
Psychiatrists	29-1223	129.78	129.78	259.56
Surgeons	29-1240	175.17	175.17	350.34
Surgeons, All Other	29-1249	179.78	179.78	359.56
Total				3,385.24
Average Physician Wage (3,385.24/11)				307.74

Private Sector

To derive average costs, we used the most recently available data from the US Bureau of Labor Statistics (BLS), the May 2025 National Occupational Employment and Wage Statistics, for all salary estimates (*https://www.bls.gov/oes/tables.htm*). In this regard, Table D–A3 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE D-A3: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Billing and Posting Clerks	43-3021	24.55	24.55	49.10
Computer System Analysts	15-1211	55.10	55.10	110.20
General and Operations Managers	11-1021	64.87	64.87	129.74
Licensed Practical and Licensed Vocational Nurses	29-2061	32.24	32.24	64.48
Medical and Health Services Managers	11-9110	67.77	67.77	135.54
Physicians	29-1210	133.30	133.30	266.60
Software Quality Assurance Analysts and Testers	15-1253	53.60	53.60	107.20

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

Wages for Individuals

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $24.05/hr.

The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices [409] identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, we used a measurement of the usual weekly earnings of wage and salary workers of $1,159 [410] for 2024 and then divided by 40 hours to calculate an hourly pre-tax wage rate of $28.98/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent or $4.93/hr ($28.98/hr × 0.17), resulting in the post-tax hourly wage rate of $24.05/hr ($28.98/hr − $4.93/hr). Unlike our private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions (§ 414.504)

Section 1834A(h)(2) of the Act states that chapter 35 of title 44 United States Code (U.S.C.), which includes such provisions as the PRA, does not apply to information collected under section 1834A of the Act. Consequently, we are not setting out burden for the changes under § 414.504. Please refer to section VII.F.4. of this final rule for a discussion of the impacts associated with the changes to § 414.504 as described in section III.C. of this final rule.

2. ICRs Regarding Ambulatory Specialty Model

In this final rule, we are finalizing several provisions related to the Ambulatory Specialty Model (ASM), which is tested under the authority of section 1115A of the Act. As stated in the CY 2026 PFS final rule (90 FR 49973), under section 1115A(d)(3) of the Act, Chapter 35 of title 44 U.S.C., does not apply to the testing, evaluation, and expansion of models under section 1115A of the Act and, therefore, the information collection requirements associated with the ASM provisions described in this rule are not subject to the PRA.

3. ICRs Regarding Limiting Medicare Coverage of Certain Individuals

In accordance with section 1899C of the Act, this final rule updates the Medicare initial enrollment forms to expand the response options to include specific citizenship, nationality, and immigration status or category data elements to support Medicare Part A enrollment eligibility determinations. This is a small change that will not increase the burden that is currently approved by OMB under control numbers 0938–0251 (CMS 18–F–5), 0938–0245 (CMS 4040), 0938–1426 (CMS–10797) and 0938–0080 (CMS 43). The revised forms will be submitted to OMB for review and approval.

For the CMS–10797 form, the majority of respondents are expected to be U.S. citizens or nationals who will spend no more than one minute on the citizenship section, which is considered negligible. The currently approved burden for this collection reflects 34,612 respondents generating 34,612 total annual responses at 0.25 hours per response, for a total of 8,653 hours (34,612 responses × 0.25 hr/response) at a cost of $208,105 (8,653 hrs × $24.05/hr), or $6.01 per respondent ($208,105/34,612 respondents). We requested comment on our proposed burden assumptions for the CMS–10797.

Otherwise, the addition of the new SEP category to the CMS–10797 form creates additional burden for individuals who utilize the SEP to apply

[409] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//176806/VOT.pdf.*

[410] *https://fred.stlouisfed.org/series/LEU0252881500A.*

for enrollment in Medicare following a change in their citizenship, nationality, or immigration status or category. Individuals will need to provide information requested in the CMS–10797 to enroll or re-enroll in Medicare using the newly established SEP. We do not have historical data on which to base a precise estimate of SEP utilization, as this is a newly proposed enrollment pathway with no prior utilization experience. OACT estimates that approximately 32,000 individuals will lose Medicare coverage beginning in 2027. Therefore in the proposed rule, for purposes of this burden estimate, we assumed that approximately 10 percent of individuals projected to lose Medicare coverage, approximately 3,200 (32,000 × 0.10) individuals annually, may utilize the SEP to re-enroll in Medicare following a change in their citizenship, nationality, or immigration status or category. We estimated 3,200 total respondents annually at 0.25 hours per response, for an addition of 800 hours (3,200 responses × 0.25 hr/response) and $19,240 (800 hr × $24.05/hr), or $6.01 per respondent ($19,240/3,200 respondents), beginning in CY 2027. We assumed that the 0.25 hours per response applies to this SEP, as the burden associated with establishing or reestablishing immigration status or category and updating documentation, as necessary or applicable, is outside the Medicare enrollment process and, therefore, this burden estimate only accounted for time to enroll in Medicare.

The updated total burden for OMB control number 0938–1426, inclusive of both the currently approved burden and the additional SEP burden, was 37,812 respondents (34,612 + 3,200), 9,453 hours (8,653 hr + 800 hr), and $227,345 ($208,105 + $19,240).

The procedural steps that MA and Part D plans must take to receive and process disenrollment transactions are currently approved by OMB under control numbers 0938–0753 (CMS–R–267) and 0938–0964 (CMS–10141). We are not attributing any additional burden to this provision since the change is small relative to the number of disenrollment transactions processed by MA and Part D plans annually.

We sought public comments on all aspects of the proposed changes to entitlement and eligibility rules for Parts A and B, the underlying burden assumptions, and the changes to limit coverage under Medicare cost plans, MA plans, and Part D plans. We received the following comments on the underlying burden assumptions.

Comment: Some commenters noted that CMS's estimate of 32,000 individuals that will lose Medicare coverage in 2027 is lower than CBO's estimate of individuals potentially losing Medicare coverage. Commenters noted that if this estimate is incorrect, it may risk skewing the 2027 cost estimate related to the burden on individuals who need to complete the CMS–10797 form to enroll using the new SEP, as the burden estimate assumed approximately 10 percent of the 32,000 estimated to lose coverage would use the SEP to re-enroll in coverage after regaining status.

Response: We acknowledge the commenters' concerns. There is very little information available on the number of beneficiaries who will be affected by this provision of the law. CMS actuaries and CBO both prepare estimates to inform policymakers of the potential impact of enacted legislation and other regulatory policy proposals. Because of varied assumptions using this limited information, the estimates are likely to be different, and one may turn out to be more accurate than the other. However, based on the SSA's most recent estimate of approximately 300,000 preliminary notices that will be sent to individuals in November 2026 to request updated evidence of eligibility, we are revising our estimate of individuals using the newly established SEP to 10 percent of 300,000 or 30,000. Since the SEP is available to any individual who loses coverage or does not enroll due to the new eligibility requirements in section 1899C, we believe that a percentage of the individuals who receive the notices and will potentially lose coverage is a reasonable approximation of who will use the SEP to re-enroll.

Therefore, for purposes of the revised burden estimate for OMB control number 0938–1426, we assume that approximately 10 percent of individuals who receive the November preliminary notice, approximately 30,000 (300,000 × 0.10) individuals annually, may utilize the SEP to re-enroll in Medicare following a change in their citizenship, nationality, or immigration status or category. As noted in the proposed rule, there is no historical precedent on which to base the estimate and CMS will take into account actual utilization data in future years to estimate the burden of this new SEP. We estimate 30,000 total respondents annually at 0.25 hours per response, for an addition of 7,500 hours (30,000 responses × 0.25 hr/response) and $180,375 (7,500 hr × $24.05/hr), or $6.01 per respondent ($180,375/30,000 respondents), beginning in CY 2027. We assume that the 0.25 hours per response applies to this proposed SEP, as the burden associated with reestablishing immigration status and updating documentation is outside the Medicare enrollment process and therefore this burden estimate only accounts for time to enroll in Medicare.

The updated total burden for OMB control number 0938–1426, inclusive of both the currently approved burden and the additional SEP burden, is 64,612 respondents (34,612 + 30,000), 16,153 hours (8,653 hr + 7,500 hr), and $388,480 ($208,105 + $180,375).

4. ICRs Regarding Rebate Reduction Requests Under Sections 11101 and 11102 (§§ 427.402, 428.302, and 428.303)

This ICR collects information from manufacturers of Part B rebatable biosimilar biological products and generic Part D rebatable drugs and biosimilars that are requesting rebate reductions to inform CMS' determinations regarding such rebate reduction requests pursuant to the policies adopted in the CY 2025 PFS final rule (89 FR 97710). The information collection requirements for the Rebate Reduction Requests under sections 11101 and 11102 of the IRA ICR currently approved under OMB Control Number 0938–1474 are scheduled to expire on July 31, 2027. Upon publication of the CY 2027 PFS final rule, we will request renewal of this collection from OMB prior to its expiration. The renewal will continue the currently approved requirements with technical updates to the forms, such as the email address to submit rebate reduction requests and references to relevant sections of the CY 2025 PFS final rule. These technical updates do not materially affect burden from respondents or CMS. No policy changes related to this collection are proposed in this rule. Consequently, we are not setting out any proposed burden estimates under this section of this final rule.

5. ICRs Regarding Medicare Prescription Drug Inflation Rebate (§ 428.203(c))

The following changes will be submitted to OMB for approval under control number 0938–1485 (CMS–10930).

In section III.F.3.c.2.c. of this final rule, we are requiring all providers and suppliers that are covered entities as defined under § 10.3 (hereinafter collectively ''340B providers'' unless otherwise noted) to submit data elements from their Part D 340B claims to the 340B repository for all covered Part D drugs billed to Medicare Part D by such covered entity or its contractor(s) beginning in 2027 for Part

D claims with dates of service on or after January 1, 2027. To allow sufficient time for 340B providers to gather, validate, and submit the specified data to the 340B repository, we are requiring that 340B providers are expected to report data on a quarterly basis (though they may choose to submit more frequently) to the 340B repository within one calendar quarter following the close of the relevant calendar quarter. For example, for claims with dates of service between October 1, 2027 through December 31, 2027, 340B providers will submit the data elements from Part D 340B claims to the 340B repository no later than March 31, 2028. We are also finalizing a delayed deadline of September 30, 2027 for the first mandatory submission, which will cover claims data with dates of service during Q1 and Q2 2027.

340B providers will submit this data directly to CMS to be included in the 340B repository. We will rely upon the completeness and accuracy of the data submitted by 340B providers to the 340B repository, consistent with the 340B provider requirement to certify the accuracy of such submissions, to consider all data elements received by the 340B repository to be associated with Part D 340B claims. We are also requiring, as part of every submission to require 340B providers (or an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification) to certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, its submissions include all Part D 340B claims for the 340B provider at the time of submission for the relevant period. 340B providers or their authorized representative will be required to certify the completeness and accuracy of the data submitted and to certify that the submitter is authorized to submit on behalf of the 340B provider. We will match the stored data elements in the 340B repository to PDE transactions for each Part D rebatable drug dispensed during the applicable period and will evaluate 340B repository data for: (1) data integrity and (2) submission frequency and completeness across covered entity types and geographies.

The information collected by CMS from 340B providers will provide CMS with information to assess the usability of the data received and feasibility of CMS removing 340B units from the total number of units used to calculate the total rebate amount in the future based on the data submitted. This data and information are necessary to implement statutory requirements of the Medicare Part D Drug Inflation Rebate Program at section 1860D–14B(b)(1)(B) of the Act, which requires that beginning with plan year 2026, we shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Program. As stated earlier, we are requiring all 340B providers to submit data elements from their Part D 340B claims to the 340B repository for all covered Part D drugs billed to Medicare Part D beginning in 2027 for Part D claims with dates of service on or after January 1, 2027.

Based on internal CMS analyses of the unique 340B ID numbers in the OPAIS database that are active (that is, not terminated) with at least one contract pharmacy association listed, we estimate that approximately 14,000 340B providers would respond by submitting data 4 times per year (quarterly) to the 340B repository in the format and manner specified by CMS.

For a 340B provider or its third-party administrator (TPA), we estimate it would take 6 hours at $107.20/hr for a Software Quality Assurance Analyst and Tester sampling for each submission and 2 hours at $129.74/hr for a General and Operations Manager to review each submission. In addition to the recurring submissions, we estimate it would take a General and Operations Manager one hour at $129.74/hr to complete the one-time registration for the 340B repository.

In aggregate, we estimate an annual burden of 462,000 hours ([56,000 responses × 8 hr/response] + [14,000 340B providers × 1 hr/registration]) at a cost of $52,366,440 [(2 hr × $129.74/hr × 56,000 responses) + (6 hr × $107.20/hr × 56,000 responses) + (1 hr × $129.74/hr × 14,000 registrations)]) (see Table D–A4).

TABLE D-A4: SUMMARY OF TOTAL ANNUAL BURDEN FOR ALL 340B PROVIDERS OR TPAS TO COMPLETE 340B REPOSITORY DATA ELEMENTS FORM IN 2027

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 428.203(c) (Regarding the Medicare Prescription Drug Inflation Rebate Program under Sections 11101 and 11102 of the Inflation Reduction Act)	0938- 1485 (CMS-10930)	14,000 340B Providers or TPAs	70,000 (14,000 registrations/year + 56,000 responses/year	Varies	462,000	Varies	52,366,440

We received public comments on these estimates. The following is a summary of the comments we received and our responses.

Comment: A few commenters stated they would be able to submit the data requested for the 340B repository without undue burden. A few commenters who recognized our responsibility to remove 340B drug units from Part D inflation rebate calculations also expressed concerns about the burden of mandatory quarterly submissions to the 340B repository. Many commenters stated that the burden on covered entities to submit the proposed data was underestimated. Some commenters stated the burden estimate does not account for the burden associated with other 340B-related changes, including the requirement to add claim modifiers to 340B drugs reimbursed under the Outpatient Prospective Payment System and the 340B Rebate Pilot. A couple of

commenters stated the difficulty with implementing changes and processes to comply with mandatory submissions by January 1, 2027 because identifying and consolidating all Part D 340B claims across the various 340B TPAs and contract pharmacies with which they contract is challenging for smaller covered entities. One commenter stated that the burden to comply is much higher than CMS estimates because the scope of data collection is broader than necessary to achieve the agency's stated objectives.

Response: We thank the commenters for their feedback. We appreciate the commenters sharing their concerns regarding the burden of updating software, modifying workflows, and coordinating multiple sources of data to comply with the mandatory submissions to the 340B repository. We believe that the majority of concerns expressed are with regard to the initial setup for producing the requested data as opposed to burden associated with ongoing quarterly submissions. We expect that the initial submission will take longer due to 340B providers setting up processes to perform repeated submissions. However, subsequent submissions would require less time due to operational efficiency gained. For purposes of the burden estimate, the submission response times are averaged across the year such that the burden for initial setup for producing the required data is accounted for in the quarterly submission burden. CMS assumes 340B providers, or their TPAs, will have a dedicated Quality Assurance Analyst or team of analysts reviewing sample claim-level data elements, collecting and reporting the required data elements, and certifying that all data elements submitted are from verified 340B claims. CMS also assumes if a TPA submits claim-level data on behalf of a 340B provider, the 340B provider will not also submit this data. We estimate it would take a General and Operations Manager 1 hour to complete the one-time registration for the 340B repository, while we expect that each submission will take 6 hours for a Software Quality Assurance Analyst and Tester and 2 hours for a General and Operations Manager. CMS anticipates that TPAs would submit claims data to the 340B repository to support their covered entity clients, as is the practice in some State Medicaid 340B clearinghouses today.[411] As a result, CMS expects the number of parties submitting claims data may be less than what is previously outlined, which is representative of individual covered entities as potential respondents whereas TPAs may submit claims on behalf of multiple covered entities. We believe that these estimates are conservative because we have not taken into account the number of 340B providers that will use TPAs for submission of data and the fact that the TPAs may already have updated software, workflows in place, and coordination from multiple sources of data for similar requirements and submissions that can be leveraged to submit the required data to the 340B data repository on behalf of the 340B provider. We note that some 340B providers, or their TPAs, could have already registered and set up their system(s) for submission when the 340B data repository was a voluntary submission for covered entities.

The commenters' suggestion that the burden estimate does not account for the burden associated with other 340B-related changes, including the requirement to add claim modifiers to 340B drugs reimbursed under the Outpatient Prospective Payment System and the 340B Rebate Pilot, is out of scope for this final rule.

In response to the commenters that stated the difficulty with implementing changes and processes to comply with mandatory submissions by January 1, 2027, we clarify that the proposed deadline for submission of 340B claims from January 1 through March 31, 2027 was June 30, 2027, so covered entities would have needed to be able to send the required data by June 30, 2027 instead of by January 1, 2027. However, in response to commenters' feedback, we are extending the deadline for submitting 340B claims from January 1 through March 31, 2027 from June 30, 2027 to September 30, 2027. This 3-month change provides covered entities with an additional quarter in which to implement changes to comply with the mandatory submissions into the 340B repository.

In response to the commenter that stated the scope of data collection is broader than necessary to achieve the agency's stated objectives, we disagree that the scope of the data collection is too broad. The data collected is limited to the minimum necessary, which only includes Medicare Part D 340B claims. To be clear, 340B providers are not required to submit 340B claims data from other payers to include Medicaid and commercial or private insurance to the 340B repository. This scope aligns with the Medicare Part D Drug Inflation Rebate Program.

Comment: A couple of commenters recommended that CMS publish detailed file specifications and provide a test environment for covered entities prior to the first submission deadline to facilitate successful compliance with the mandatory data submissions into the 340B repository.

Response: We thank the commenters for their feedback. We note that detailed file specifications and other information about the 340B repository are located in the Medicare Part D Claims Data 340B Repository section of the Medicare Inflation Rebate Program website.[412] We also note that the 340B repository is publicly accessible as of October 1, 2026. Interested parties may access the repository and submit files to test their processes during the voluntary submission period prior to January 1, 2027.

6. ICRs Regarding the Medicare Shared Savings Program

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out Shared Savings Program burden estimates under this section of the rule. Please refer to the Regulatory Impact Analysis (section VI. of this final rule) for a discussion of the impacts associated with the proposed changes to the Shared Savings Program as described in section III.G. of this final rule.

7. ICRs Regarding the Quality Payment Program

a. Background

The following identifies finalized changes that will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

All changes to burden and information collections for Quality Payment Program ICRs due to changes associated with finalized policies will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). Non-rulemaking revisions, resulting from updated data and assumptions, will also be submitted to OMB. This section is intended to focus our PRA score on the impact of this rule's finalized policy changes.

We estimate that the finalized QPP policies will reduce annual information collection burden by 51,188 hours and $5,808,502 for the CY 2027 performance period/2029 MIPS payment year, primarily through removal of the Promoting Interoperability Security Risk Analysis measure and increased participation in MVPs following the

[411] See *https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20State%20Policy.doc.*

[412] *https://www.cms.gov/initiatives/medicare-prescription-drug-affordability/overview/medicare-inflation-rebate-program.*

addition of three new MVPs, with smaller reductions from removal of the ONC attestations, while required reporting of the two Promoting Interoperability electronic prior authorization measures will add 323 hours and $35,595 annually beginning with the CY 2028 performance period/2030 MIPS payment year.

However, independent of this final rule changes, we also intend to merge the information collection requests in the Virtual Groups PRA package (OMB control number 0938–1343, CMS–10652) into OMB control number 0938–1314 (CMS–10621) in order to consolidate QPP-related ICRs into a single collection of information request to avoid duplication. For more detailed information on our finalized policies, we refer readers to section IV. of this final rule.

We apply the updated BLS wage rate data identified in section V.A. of this final rule. We refer readers to section VII.F.10. of this final rule for the Regulatory Impact Analysis for discussion of impacts to final scores and payment adjustments.

(1) Framework for Understanding the Burden of MIPS Data Submission

Across organizations permitted or required to submit data on behalf of clinicians, there can be variation across the types of data provided, and whether a clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, a MIPS Alternative Payment Model (APM) participant, or an Advanced APM participant. MIPS eligible clinicians and other clinicians voluntarily submitting data to MIPS for the quality, Promoting Interoperability, and improvement activities performance categories may submit data as the following participation types: individual; group; virtual groups (available only for traditional MIPS); subgroups (available only for MIPS Value Pathways (MVPs); and APM Entities. Eligible clinicians who attain Partial Qualifying APM Participant (QP) status may be subject to data collection burden if they elect to participate in MIPS. MIPS eligible clinicians are not required to submit any data for the cost performance category, as CMS calculates performance on measures specified for this performance category based on claims-data. Virtual groups are subject to the same data submission requirements per performance category as groups, and therefore, we will refer only to groups for the remainder of this section, unless otherwise noted.

For the aforementioned participation types, we assessed the same burden per reporting option and assumed from our available data that all non-Medicare Shared Savings Program (Shared Savings Program) APM Entity submissions are assessed based on a single Taxpayer Identification Number (TIN). Per section 1899(e) of the Act, the PRA does not apply to the Shared Savings Program, thus we excluded submissions by Shared Savings Program APM Entities from our MIPS reporting estimates. The regulatory impact analysis in section VII.F.8. of this final rule discusses impacts to the Shared Savings Program from provisions associated with this final rule.

There are three MIPS reporting options: traditional MIPS, MVPs, and the APM Performance Pathway (APP). In section V.B.7.c.(1) of this final rule, we provide distinct estimates for the traditional MIPS and MVP reporting options for the quality performance category, focusing on changes to our currently approved burden estimates. As with the CY 2026 PFS final rule (90 FR 49942 through 49943), we have not separately estimated burden for traditional MIPS and MVPs for the Promoting Interoperability and improvement activity performance categories. Traditional MIPS and MVPs require reporting on all Promoting Interoperability performance category objectives and measures. Traditional MIPS reporting for the improvement activities performance category typically requires attestation to two improvement activities; however, clinicians, groups, and virtual groups with a special status designation are only required to attest to one improvement activity. All MVP participants are only required to attest to one improvement activity. For additional details on historic burden assumptions for the improvement activities performance category, we refer readers to the CY 2025 PFS final rule (89 FR 98492). In the related collection of information request (OMB control number 0938–1314, CMS–10621), we aggregate submissions across all reporting options. For additional burden historic frameworks, we refer readers to the CY 2024 PFS final rule (88 FR 79422 through 79424) and the CY 2025 PFS proposed rule (89 FR 62111 through 62114).

(2) Additional Data Considerations

The accuracy of our estimates of the total burden for data submission for MIPS performance categories may be impacted by several factors. First, we are unable to predict with certainty the number of participants who will obtain a QP status, thus exempt from MIPS reporting, for the CY 2027 performance period/2029 MIPS payment year and later years. Eligible clinicians who do not achieve QP status for a given performance period may be required to participate in MIPS. Second, it is difficult to predict whether Partial QPs, who can elect to report to MIPS, will choose to participate in the CY 2027 performance period/2029 MIPS payment year or later years. Therefore, the actual number of Partial QP participants and whether they elect to submit MIPS data may differ from our estimates. However, we believe our methodology for assessing burden, as described in the preceding Framework for Understanding the Burden of MIPS Data Submission section, is most appropriate given all the limitations. We refer readers to section VII.F.10.e.(2).(b). of this final rule for a discussion of the potential but unquantifiable burden implications on MIPS-related burden of the policy to modify the application of the QP and partial QP status, presented in section IV.F.2. of this final rule.

b. ICRs Regarding Third-Party Intermediaries (§ 414.1400)

We refer readers to § 414.1400(d) for our previously established requirements for CMS-approved third-party intermediaries that may submit data on behalf of MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities. The following sections detail in the finalized policy that impact existing ICRs relevant to Third-Party Intermediaries. Additionally, in section IV.C. of this final rule, we are finalizing our proposals to (1) add a requirement that CMS-approved third-party intermediaries may be terminated after failure to submit data for one year; and (2) add a new requirement for third-party intermediaries to submit documentation about intent to submit MIPS data and to terminate a third-party intermediary if they do not submit documentation by the date specified by CMS. We refer readers to section VII.F.10.e.(2).(c). of this final rule for additional discussion on the impact of these finalized policies for which burden is not quantifiable.

(1) Full and Simplified Self-Nomination for Qualified Clinical Data Registries (QCDRs) and Qualified Registries

As described in section IV.C. of this rule, we are finalizing our proposals to: (1) further clarify that additional requirements for health IT vendors do not apply beginning with the CY 2025 performance period/2027 MIPS payment year because health IT vendors are no longer allowed to submit MIPS data as third-party intermediaries starting in that year; (2) clarify the level at which performance feedback reports are provided; (3) update the existing

sampling methodologies for data auditing purposes; and (4) update the policy so that third-party intermediaries will not be permitted to make changes to the qualified posting after it is publicly posted on the Quality Payment Program resource library. We assume that there will be no impact on the time required to complete either the full or simplified self-nomination process due to these finalized policies. Additionally, related to our policy to implement core measures in traditional MIPS and MVPs in section IV.A.4.d.(1)(c) of this final rule, we are finalizing our proposal to revise the data submission requirement in which a QCDR or a qualified registry must be able to submit at least six qualified measures including at least one MIPS core measure, beginning with the CY 2027 performance period/2029 MIPS payment year. This policy does not alter the minimum number of measures a qualified registry or QCDR is required to support; therefore, we assume no impact to the overall time estimated for qualified registries or QCDRs to submit their information at the time of self-nomination. We are not revising our estimated responses and time per response for both the Full and Simplified Self-Nominations for Qualified Registries and QCDRs under OMB control number 0938–1314 (CMS–10621). We did not receive public comments on our burden estimates and assumptions for these provisions.

(2) Third-Party Intermediary Plan Audits

We are finalizing our proposed updates related to Third-Party Intermediary Plan Audits, which include targeted audit requirements, participation plan submissions, and corrective action and termination processes for third-party intermediaries.

(a) Participation Plans

In section IV.C.3.c. of this final rule, we are finalizing our proposal to update the conditions for approval related to participation plans such that third-party intermediaries that do not submit data for 1 year would be required to submit a participation plan during self-nomination. Currently, third-party intermediaries are required to submit a participation plan only after not submitting data for 2 consecutive years. We do not expect this policy to affect the number of participation plans submitted during the self-nomination process and therefore do not anticipate an impact on burden; therefore, we are not modifying our burden estimates under OMB control number 0938–1314 (CMS–10621). We did not receive public comments on our burden estimates and assumptions for this provision.

c. ICRs Regarding Quality Data Submission

(1) Changes to Quality Performance Category Submissions

In section IV.A.4.a. of this final rule, we are finalizing the addition of three new MVPs beginning with the CY 2027 performance period/2029 MIPS payment year. In section IV.A.3. of this final rule, we are finalizing with modification our proposal that MVPs and APP will be the only reporting option for MIPS beginning in the CY 2029 performance period/2031 MIPS payment year such that the proposal will take effect beginning with the CY 2031 performance period/2033 MIPS payment year. As the collection of information section of this rule provides estimates for the period in which the OMB control number 0938–1314 (CMS–10621) is approved, we will update our burden estimates for this provision in a future rule. Additionally, we are finalizing our proposal to include virtual groups in MVP reporting beginning in the CY 2029 performance period/2031 MIPS payment year.

Comment: A commenter recommended that we evaluate the significant financial, technical, and operational burdens that increased reliance on QCDRs and qualified registries for MVP reporting may place on medical practices and without adequate compensation to recover costs. The commenter asked for clarification on whether these costs are included in our burden estimates, including time to purchase, implement, integrate, maintain, monitor, and troubleshoot the technical requirements needed to produce an accurate report.

Response: We acknowledge the commenter's feedback and understand the concerns raised regarding the transition to MVP reporting. We generally estimate burden for information collection related to reporting, recordkeeping or third-party disclosure requirements; we do not include operational, technical, or financial costs in our burden estimates. We note that the majority of the clinicians may already participate in MIPS, and therefore, would have the technical infrastructure to support MVP reporting. Additionally, given the variation in group practice structures and in the MVPs selected, we are unable to reliably quantify the change in burden associated with transition to MVP reporting. As discussed in section IV.A.3. of this final rule, we are delaying the sunset of traditional MIPS by 2 years, with MVP reporting required for clinicians beginning in the CY 2031 performance period/2033 MIPS payment year. We will continue to consider these concerns, including the operational implications of fully implementing MVPs, in future rulemaking as we further develop and refine the MVP framework.

The following policies will not have an impact on burden as they do not affect the minimum reporting requirements for the respective quality performance category submission:

In section IV.A.4.a.(2). of this final rule, we are finalizing the proposal for MVP maintenance updates to our MVP inventory that are aligned with the MVP development criteria (85 FR 84849 through 84854), in section IV.A.4.d.(1).(c).(iii). of this final rule, we are finalizing our proposal for MIPS core measures in traditional MIPS and MVPs with an attestation process. In section IV.A.4.d(1).(e). of this final rule, we are also finalizing MIPS quality measure inventory updates. We did not receive public comments on our burden estimates and assumptions for these provisions.

In section IV.A.4.d.(1).(c).(iii). of this final rule, we are finalizing our proposal to establish a MIPS core measure attestation process whereby the clinician would be required to attest during the data submission period that there was not an available and applicable MIPS core measure for them to report. We are not adjusting our burden estimates due to this provision as we believe the currently approved burden for traditional MIPS and MVP quality measure submissions is sufficient to absorb the negligible effort of the attestation in lieu of reporting a quality measure. We did not receive public comments on our burden estimates and assumptions for this provision. In the following sections, we estimate the number of submissions for each collection type that require active reporting by individual clinicians, groups, subgroups (as applicable for MVP reporting), or non-Shared Savings Program APM Entities for the CY 2027 performance period/2029 MIPS payment year per the finalized policies previously discussed. Available collection types include B claims measures (small practices only), MIPS Clinical Quality Measures (CQM), QCDR measures, and electronic Clinical Quality Measures (eCQMs). We do not assess burden for the administrative claims-based quality measures, as CMS automatically calculates scores for individual clinicians, groups, subgroups (as applicable for MVP reporting), or non-Shared Savings Program APM

Entities that meet requirements to be scored. As there are no changes due to policy provisions related to the non-Shared Savings Program related APM Performance pathway, we assume no change to our currently approved burden estimates.

(a) CY 2027 Performance Period/2029 MIPS Payment Year

The following section details the burden estimate for the finalized proposal to add three new MVPs starting with the CY 2027 performance period/2029 MIPS payment year consistent with the finalized proposals outlined in section IV.A.4.a. of this rule.

(i) Updated Data Assumptions for Quality Submissions

For the traditional MIPS and MVP Quality Performance Category ICRs, our currently approved estimates used submission data from the CY 2023 performance period/2025 MIPS payment year and estimated that: (1) 14 percent of quality submissions will submit as an MVP based on the MVP inventory available in the CY 2026 performance period/2028 MIPS payment year; and (2) 20 subgroups (90 FR 49948 through 49949). At the time of this rulemaking, we have updated historic submission data for the CY 2024 performance period/2026 MIPS payment year, inclusive of individual, group, and non-Shared Savings Program APM Entities.

In Tables D–A5 and D–A6, we identify the updated response estimates by reporting option due to the availability of this updated data and add our estimate of 20 subgroup submissions currently approved under OMB control number 0938–1314 (CMS–10621). The response estimates for these ICRs apply our existing approach for estimating the impact of MVPs as a percentage of historic submissions, the currently approved estimate of 14 percent as established in the CY 2026 PFS Final Rule (90 FR 49949).

The impact on burden for each finalized proposal discussed in the following sections use these updated active response estimates when calculating change in total time and cost. The updated estimates will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

TABLE D-A5: RESPONDENT COUNTS FOR QUALITY PERFORMANCE CATEGORY AND MVP REGISTRATION ICRs

Reporting Option	Performance Category	Requirement	Currently Approved Responses*	Revised Responses **	Change Due to Updated Data
Traditional MIPS	Quality	Medicare Part B Claims Measure Collection Type Submission	8,350	7,307	(1,043)
Traditional MIPS	Quality	MIPS CQM and QCDR Measure Collection Type Submission	17,407	18,820	1,413
Traditional MIPS	Quality	eCQM Collection Type Submission	23,936	22,830	(1,106)
MVPs	N/A	MVP Registration	8,110	7,989	(121)
MVPs	Quality	Medicare Part B Claims Measure Collection Type Submission	1,359	1,189	(170)
MVPs	Quality	MIPS CQM and QCDR Measure Collection Type Submission	2,844	3,074	230
MVPs	Quality	eCQM Collection Type Submission	3,907	3,726	(181)

*Under OMB control number 0938-1314 (CMS-10621).

**Traditional MIPS updates calculated as updated submission data for CY 2024 performance period/2026 MIPS payment year submissions minus 14 percent (existing MVP submission rate). MVPs calculated as 14 percent of historic submissions plus estimated subgroup submissions (split evenly across the eCQM and MIPS CQM/QCDR measure collection types).

(ii) MVP Participation Estimate

We estimate the number of MVP submissions for the CY 2027 performance period/2029 MIPS payment year as a percent of the total traditional MIPS and MVP submissions from the CY 2024 performance period/2026 MIPS payment year (see Table D–A5). We assessed measure-level submission trends from the CY 2024 performance period/2026 MIPS payment year data for the new MVPs as finalized in section IV.A.4.a. of this final rule. The total average of quality measure submissions for the proposed new MVPs was equivalent to approximately 6 percent of the total quality performance category submissions in the CY 2024 performance period/2026 MIPS payment year. With the existing 14 percent estimate previously finalized in the CY 2026 PFS final rule (90 FR 32789) plus the incremental change of an additional 6 percent due to the proposed new MVPs, we estimate that 20 percent of quality performance category submissions may report via MVPs for the CY 2027 performance period/2029 MIPS payment year (row b). While this approach to estimate MVP submissions as a function of historic traditional MIPS and MVP submissions, and not just MVP submissions from a given year, is used to estimate future reporting behaviors with an expected increase in adoption due to the annual expansion of the MVP inventory, as summarized in section IV.A.4.a. of this final rule, there are limitations, such as lack of longitudinal data to appropriately assess behavior changes related to future adoptions or submissions in both new and existing MVPs. For example, the most recent submission data available is from the CY 2024 performance period/2026 MIPS payment year when the MVP inventory was composed of 16 MVPs, whereas for CY 2027 performance period/2029 MIPS payment year we are finalizing an MVP inventory of 30 MVPs. Consistent with the past approach, we project any increase to our expected MVP participation rate reduces the number of estimated submissions for each quality performance category collection type via traditional MIPS.

Table D–A6 of this final rule identifies our methods to estimate the number of individual clinicians, groups, and non-Shared Savings Program APM Entities that may submit data via each collection type in the CY 2027 performance period/2029 MIPS payment year, separating traditional MIPS and MVP estimates. We identify estimated submissions per collection type from CY 2024 performance period/2026 MIPS payment year data (row a). Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM/

QCDR, or eCQM collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table D–A6 are not mutually exclusive. We assume that each response or submission per collection type for traditional MIPS includes six quality measures, and that each response or submission per collection type for MVPs includes four quality measures.

TABLE D-A6: ESTIMATED NUMBER OF SUBMISSIONS FOR QUALITY PERFORMANCE CATEGORY BY COLLECTION TYPE

Burden and Submission Description	Medicare Part B Claims Measure	MIPS CQM/QCDR Measure	eCQM
Total 2027 Performance Period Quality Performance Category Submissions (Excludes QPs) (a)	8,496	21,894	26,556
2026 Performance Period Approved MVPs (14 percent) (b) = (a) × 0.14	1,189	3,065	3,718
2027 Performance Period Finalized MVPs (20 percent) (c) = (a) × 0.20	1,699	4,379	5,311
2027 Traditional MIPS Performance Period (Excludes QPs and Estimated MVP Submissions) (d) = (a) - (c)	6,797	17,515	21,245
Number of Submissions Moving to MVPs due to New MVPs (e) = (c) - (b)	510	1,313	1,593

* Estimates in the table are rounded to the nearest whole number, therefore the Number of Submissions Moving to MVPs due to New MVPs row may deviate from the provided formula due to rounding.

(iii) Traditional MIPS Quality Data Submission

The following estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians, groups, and non-Shared Savings Program APM Entities. For our most recent discussions of related burden, we refer readers to the CY 2024 PFS final rule (88 FR 70149 through 70151) and the CY 2025 PFS final rule (89 FR 98479 through 98483), and CY 2026 PFS final rule (90 FR 49946 through 49949). All estimates encompass time to review measure specifications unless otherwise noted.

(A) Medicare Part B Claims Measure Collection Type

The following estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians from a small practice with 15 or fewer clinicians. We acknowledge a range of times for computer system analysts to submit quality measure data (minimum, mean, and maximum burden estimates) for this collection type. We continue to apply the maximum burden in our total burden estimates.

For the CY 2027 performance period/2029 MIPS payment year, we estimate a decrease of 510 submissions due to the finalized addition of three new MVPs in this final rule. When considering a range of Computer System Analyst response times (from 1.15 to 8.2 hr/response) we estimate a maximum total decrease of 7,242 hours and $883,105 as demonstrated in Tables D–A7 through D–A9. We did not receive public comments on our burden estimates and assumptions.

TABLE D-A7: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR TRADITIONAL MIPS MEDICARE PART B CLAIMS MEASURE COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Range: Time/Cost	Time (hr) - Computer System Analyst	Time (hr) - Other Occupations	Total Time (hr)	Cost ($) - Computer System Analyst	Cost ($) - Other Occupations	Total Cost ($)
Minimum	(587)	(3,060)	(3,647)	(64,632)	(422,249)	(486,881)
Mean	(1,046)	(3,060)	(4,106)	(115,214)	(422,249)	(537,463)
Maximum	(4,182)	(3,060)	(7,242)	(460,856)	(422,249)	(883,105)

TABLE D-A8: ESTIMATED INFORMATION COLLECTION BURDEN RANGE FOR COMPUTER SYSTEM ANALYSTS IN TRADITIONAL MIPS MEDICARE PART B CLAIMS MEASURE COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Computer System Analyst	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Minimum	110.20	(510)	1.15	(587)	(64,632)
Mean	110.20	(510)	2.05	(1,046)	(115,214)
Maximum	110.20	(510)	8.2	(4,182)	(460,856)

TABLE D-A9: ESTIMATED INFORMATION COLLECTION BURDEN RANGE FOR OTHER OCCUPATIONS IN TRADITIONAL MIPS MEDICARE PART B CLAIMS MEASURE COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Other Occupations	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Billing Clerks	49.10	(510)	1	(510)	(25,041)
Licensed Practical Nurses (LPNs)	64.48	(510)	1	(510)	(32,885)
Medical and Health Service Managers	135.54	(510)	3	(1,530)	(207,376)
Physicians	307.74	(510)	1	(510)	(156,947)
Total	n/a	(510)	varies	(3,060)	(422,249)

(B) MIPS CQM and QCDR Measure Collection Types

For the CY 2027 performance period/2029 MIPS payment year, we estimate a decrease of 1,313 submissions due to the finalized addition of three new MVPs in this final rule. Multiplying the estimated change in submissions (1,313) by the time per submission by labor category, we estimate a decrease of 11,926 hours and $1,499,903 as demonstrated in Table D–A10. We did not receive public comments on our burden estimates and assumptions.

TABLE D-A10: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR TRADITIONAL MIPS CQM AND QCDR MEASURE COLLECTION TYPES FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Other Occupations	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	(1,313)	4.083	(5,361)	(590,782)
Billing Clerks	49.10	(1,313)	1	(1,313)	(64,468)
Licensed Practical Nurses (LPNs)	64.48	(1,313)	1	(1,313)	(84,662)
Medical and Health Service Managers	135.54	(1,313)	2	(2,626)	(355,928)
Physicians	307.74	(1,313)	1	(1,313)	(404,063)
Total	N/A	(1,313)	Varies	(11,926)	(1,499,903)

(C) MIPS eCQM Collection Type

For the CY 2027 performance period/2029 MIPS payment year, we estimate a decrease of 1,593 submissions due to the finalized addition of three new MVPs in this final rule. Multiplying the estimated change in submissions by the time per submission by labor category, we estimate a decrease of 12,744 hours and $1,629,639 as demonstrated in Table D–A11. We did not receive public comments on our burden estimates and assumptions.

TABLE D-A11: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR TRADITIONAL MIPS eCQM COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Other Occupations	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	(1,593)	3	(4,779)	(526,646)
Billing Clerks	49.10	(1,593)	1	(1,593)	(78,216)
Licensed Practical Nurses (LPNs)	64.48	(1,593)	1	(1,593)	(102,717)
Medical and Health Service Managers	135.54	(1,593)	2	(3,186)	(431,830)
Physicians	307.74	(1,593)	1	(1,593)	(490,230)
Total	N/A	(1,593)	Varies	(12,744)	(1,629,639)

(iv) MVP Registration: Individuals, Groups, Subgroups, and APM Entities

We estimate that the finalized addition of three new MVPs would result in an increase of 3,416 MVP registrations. Using the currently approved estimate of 0.25 hour per registration, we estimate an annual burden increase of 854 hours (+3,416 registrations × 0.25 hr/registration) at a cost of +$94,111 (+854 hr × $110.20/hr for a computer system analyst or equivalent). We did not receive public comments on our burden estimates and assumptions.

(v) MVP Quality Performance Category Submission

We estimate a change to the number of annual MVP quality performance category submissions per collection type from our currently approved burden estimates, beginning with the CY 2027 performance period/2029 MIPS payment year. These estimates include the figures detailed in section V.B.7.c.(1). of this final rule. These estimates aggregate individual clinician, group, subgroup, and non-Shared Savings Program APM Entity submissions. All estimates presume maximum submission time and encompass time to review measure specifications unless otherwise noted.

(A) Medicare Part B Claims Measure Collection Type

We estimate an increase of 510 submissions due to the finalized addition of three new MVPs. Multiplying the estimated change in submissions (+510) by the time per submission by labor category, we estimate a total increase of 4,816 hours at a cost of $587,143 as demonstrated in Table D–A12. We did not receive public comments on our burden estimates and assumptions.

TABLE D-A12: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR MVP MEDICARE PART B CLAIMS MEASURE COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	510	5.46	2,785	306,907
Medical and Health Service Managers	135.54	510	2	1,020	138,251
Licensed Practical Nurses (LPNs)	64.48	510	0.66	337	21,730
Billing Clerks	49.10	510	0.66	337	16,547
Physicians	307.74	510	0.66	337	103,708
Total	n/a	510	varies	4,816	587,143

(B) MIPS CQM and QCDR Measure Collection Type

We estimate an increase of 1,313 submissions due to the finalized addition of three new MVPs. Multiplying the estimated change in submissions (+1,313) by the time per submission by labor category, we estimate a total increase of 7,840 hours at a cost of $986,867 as demonstrated in Table D–A13. We did not receive public comments on our burden estimates and assumptions.

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TABLE D-A13: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR MVP CQM AND QCDR MEASURE COLLECTION TYPES FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	1,313	2.66	3,493	384,929
Medical and Health Service Managers	135.54	1,313	1.33	1,746	236,653
Licensed Practical Nurses (LPNs)	64.48	1,313	0.66	867	55,904
Billing Clerks	49.10	1,313	0.66	867	42,570
Physicians	307.74	1,313	0.66	867	266,811
Total	N/A	1,313	Varies	7,840	986,867

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(C) eCQM Collection Type

We estimate an increase of 1,593 submissions due to the finalized addition of three new MVPs. Multiplying the estimated change in submissions (+1,593) by the time per submission by labor category, we estimate a total increase of 8,442 hours at a cost of $1,079,350 as demonstrated in Table D–A14. We did not receive public comments on our burden estimates and assumptions.

TABLE D-A14: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR MVP eCQM COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	1,593	1.99	3,170	349,334
Medical and Health Service Managers	135.54	1,593	1.33	2,119	287,209
Licensed Practical Nurses (LPNs)	64.48	1,593	0.66	1,051	67,768
Billing Clerks	49.10	1,593	0.66	1,051	51,604
Physicians	307.74	1,593	0.66	1,051	323,435
Total	N/A	1,593	Varies	8,442	1,079,350

(vi) Summary of Quality Performance Category Estimated Information Collection Burden Change for CY 2027 Performance Period/2029 MIPS Payment Year

Across the quality performance category collection types for Traditional MIPS and MVPs, we estimate that the finalized policies will lead to a decrease in burden of 9,960 hours and a savings of $1,265,176 under OMB control number 0938–1314 (Table D–A15). We did not receive public comments on our burden estimates and assumptions.

TABLE D-A15: SUMMARY OF QUALITY PERFORMANCE CATEGORY ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Requirement	Change in Number of Respondents	Change in Time	Change in Cost ($)
Traditional MIPS Quality Submission	(3,416)	(31,912)	(4,012,647)
MVP Registration	3,416	854	94,111
MVP Quality Submission	3,416	21,098	2,653,360
Total	0*	(9,960)	(1,265,176)

* Respondents moving from Traditional MIPS to MVPs need to complete MVP registration plus MVP Quality Submission, therefore the net number of new respondents will be 0.

d. ICRs Regarding Reporting the MIPS Promoting Interoperability Performance Category

We refer readers to § 414.1375 for our previously established policies regarding reporting requirements for the MIPS Promoting Interoperability performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1325 for data submission requirements, and §§ 414.1380(b)(4) and 414.1365(d)(3)(iv) for MIPS Promoting Interoperability performance category scoring. For historic assumptions on reporting requirements for the MIPS Promoting Interoperability performance category, we refer readers to the CY 2024 PFS final rule (88 FR 79449 through 79451).

In the CY 2026 PFS final rule (90 FR 49952), the burden estimates represented an assumed number of 20,881 respondents, which is based on submission data from the CY 2023 performance period/2025 MIPS payment year. In the CY 2027 PFS proposed rule, we proposed to update the burden estimates to represent an assumed number of respondents to 19,325, which is based on submission data from the CY 2024 performance period/2026 MIPS payment year (91 FR 44234).

In the following paragraphs, we outline the finalized policy changes to the MIPS Promoting Interoperability performance category reporting requirements as discussed in section IV.A.4.d.(4) of this final rule. For the first three finalized, as proposed, policies (modifications to the definition of CEHRT, removal of the required ONC Direct Review attestation and optional ONC-Authorized Certified Bodies (ACB) Surveillance attestation, and modifications to the Electronic Prior Authorization measure), there are similar finalized, as proposed, policies for the Medicare Promoting Interoperability Program in the FY 2027 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment Systems (IPPS/LTCH PPS) final rule (91 FR 49573). The burden assumptions for the MIPS Promoting Interoperability performance category policies in this final rule are consistent with the burden assumptions for the Medicare Promoting Interoperability Program as described in the FY 2027 IPPS/LTCH PPS final rule (91 FR 50331 through 50332). For the fourth finalized, as proposed, policy (adoption of the new Electronic Prior Authorization for Prescription Drugs measure), there is a change in burden for the MIPS Promoting Interoperability performance category due to the addition of the new required measure. Lastly, for the finalized, as proposed, policy (removal of the Security Risk Analysis measure), there is a change in burden estimate for this performance category.

First, beginning with the CY 2027 performance period/2029 MIPS payment year, we are finalizing, as proposed, the proposal to modify the MIPS Promoting Interoperability performance category definition of Certified Electronic Health Record Technology (CEHRT) at 42 CFR 414.1305 as discussed in section IV.A.4.d.(4).(b). of this final rule, which aligns with proposals to remove certain certification criteria from the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program as detailed in Table C–G1 and as outlined in the Health Data, Technology, and Interoperability: ONC Deregulatory Actions to Unleash Prosperity (HTI–5) final rule (91 FR 67916). In the CY 2027 PFS proposed rule, we noted that the proposal to modify the definition of CEHRT would not impact reporting burden for the MIPS Promoting Interoperability performance category and as a result, we did not propose to modify the burden estimate pertaining to the proposed modifications to the definition of CEHRT (91 FR 44234). We proposed to maintain the burden estimates and assumptions for the proposed modifications to the definition CEHRT. We requested public comment on the proposal. We did not receive public comment on the proposal, and therefore, we are finalizing, as proposed, the proposal to maintain the burden estimates and assumptions for the proposed modifications to the definition CEHRT.

Second, beginning with the CY 2026 performance period/2028 MIPS payment year, we are finalizing, as proposed, the proposal to remove the required ONC Direct Review attestation and the optional ONC-Authorized Certified Bodies (ACB) Surveillance attestation from the MIPS Promoting Interoperability performance category to reduce administrative burden as discussed in section IV.A.4.d(4).(c). of this final rule. The CY 2024 submission data show that 79 percent of MIPS eligible clinicians elected to report the optional ONC–ACB Surveillance attestation. In the CY 2027 PFS proposed rule, we estimated that the removal of the required ONC Direct Review attestation would decrease burden by 1 minute (0.0167 hr) (91 FR 44234 through 44235). Also, in the CY 2027 PFS proposed rule, we estimate that removing the ONC Direct Review attestation would result in an annual decrease in total cost of $35,595 for all responses (-0.0167 hr per response × 19,325 responses)[413] × $110.20/hr for a computer systems analyst to submit MIPS Promoting Interoperability performance category data (91 FR 44235). Similarly, in the CY 2027 PFS proposed rule (91 FR 44235), we estimated that eligible clinicians who elected to submit the optional ONC–

[413] This figure is rounded to whole number.

ACB Surveillance attestation would experience a decrease in burden of 1 minute (0.0167 hr) which is consistent with the CY 2027 IPPS/LTCH PPS proposed rule (91 FR 19761). Also, in the CY 2027 PFS proposed rule, we estimated that removing this attestation will result in an annual decrease in total cost of $35,595 for all responses (-0.0167 hr per response × 19,325 responses) [414] × $110.20/hr for a computer systems analyst to submit MIPS Promoting Interoperability performance category data (91 FR 44235). We requested public comment on the proposals to reduce the burden estimate for the MIPS Promoting Interoperability performance category accounting for the removal of the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation. We did not receive public comment on the proposals, and therefore, we are finalizing, as proposed, the proposed burden estimates and assumptions for MIPS Promoting Interoperability performance category that account for the removal of the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation starting with the CY 2026 performance period/2028 MIPS payment year. Such burden estimate is consistent with the finalized, as proposed, burden estimates and assumptions in the CY 2027 IPPS/LTCH PPS final rule (91 FR 50332).

Third, we are finalizing, as proposed, the proposal to modify the Electronic Prior Authorization measure to an optional (bonus) measure for the CY 2027 performance period/2029 MIPS payment year as discussed in section IV.A.4.D.(4).(f). of this final rule, which will require the use of one or more specific FHIR-enabled health IT modules within CEHRT to complete at least one prior authorization request and determination for at least one medical item or service during the performance period. Also, we are finalizing, as proposed, the proposal to make the Electronic Prior Authorization measure required starting with the CY 2028 performance period/2030 MIPS payment year as discussed in section IV.A.4.d.(4).(f). of this final rule, which will require the use of all three specific FHIR-enabled health IT modules within CEHRT to complete at least one prior authorization request and determination for at least one medical item or service during the performance period.

The Electronic Prior Authorization measure was established in the CMS Interoperability and Prior Authorization final rule (89 FR 8758) and was referenced in the CY 2026 PFS final rule (90 FR 49952). Initially, the implementation of this measure as a requirement of the MIPS Promoting Interoperability performance category was specified starting with the CY 2027 performance period/2029 MIPS payment year. In the CY 2027 PFS proposed rule, we proposed updates to the burden estimates that account for the requirement to report such measure starting with CY 2028 performance period/2030 MIPS payment year. Under OMB control number 0938–1278 (CMS–10552), the currently approved burden estimate for this measure is 0.5 minutes (0.0083 hours) per eligible MIPS eligible clinician. In the CY 2027 PFS proposed rule, we noted that we are unable to estimate the number of MIPS eligible clinicians who may attest to the Electronic Prior Authorization measure as a bonus measure for the CY 2027 performance period/2029 MIPS payment year and did not propose to modify the burden estimates for CY 2027 performance period/2029 MIPS payment year. As discussed in the CY 2027 PFS proposed rule, the proposal to require the Electronic Prior Authorization measure starting with CY 2028 performance period/2030 MIPS payment year included an increase in burden estimate; we estimated that the requirement to attest ''Yes''/''No'' for the Electronic Prior Authorization measure would increase burden by 0.5 minutes (0.0083 hours) (91 FR 44235). Also, in the CY 2027 PFS proposed rule, we estimated that the proposal to modify the measure by making the measure required would result in an annual increase in total cost of $17,632 for all responses (+0.0083 hours per response × 19,325 responses) [415] × $110.20/hr for a computer systems analyst to submit Promoting Interoperability data (91 FR 44235). We requested public comment on the proposal to increase the burden estimates and assumptions that account for the required reporting of the Electronic Prior Authorization measure starting with the CY 2028 performance period/2030 MIPS payment year. We did not receive public comment on the proposal, and therefore, we are finalizing, as proposed, the proposed burden estimates and assumptions for Electronic Prior Authorization starting with the CY 2028 performance period/2030 MIPS payment year.

Fourth, we are finalizing, as proposed, the proposal to adopt a new measure, Electronic Prior Authorization for Prescription Drugs as discussed in section V.A.4.d.(4).(e). of this final rule, which will require the use of specific FHIR-enabled health IT modules within CEHRT to complete at least one prior authorization request and determination for prescription drugs and medications. The Electronic Prior Authorization for Prescription Drugs measure will be a required measure starting with the CY 2028 performance period/2030 MIPS payment year. In the CY 2027 PFS proposed rule, we noted that starting with the CY 2029 performance period/2031 MIPS payment year, we estimated that the requirement to attest ''Yes''/''No'' to this measure would increase burden by 0.5 minutes (0.0083 hours) (91 FR 44235). Also, in the CY 2027 PFS proposed rule, we estimated that the addition of the new measure would result in an annual increase in total cost of $17,632 for all responses (+0.0083 hr per response × 19,325 responses) [416] × $110.20/hr for a computer systems analyst to submit Promoting Interoperability data (91 FR 44235). We requested public comment on the proposal to increase the burden estimates and assumptions that account for the required reporting of the new Electronic Prior Authorization for Prescription Drugs measure starting with the CY 2028 performance period/2030 MIPS payment year. We did not receive public comment on the proposal, and therefore, we are finalizing, as proposed, the proposed burden estimates and assumptions for the new Electronic Prior Authorization for Prescription Drugs measure starting with the CY 2028 performance period/2030 MIPS payment year.

Lastly, starting with the CY 2027 performance period/2029 MIPS payment year, we are finalizing, as proposed, the proposal to remove the Security Risk Analysis measure from the MIPS Promoting Interoperability performance category to reduce burden as discussed in section IV.A.4.d.(4).(d). of this final rule. While the Security Risk Analysis measure has been required and included in the aggregate estimate for reporting burden for the MIPS Promoting Interoperability performance category (formerly the Advancing Care Information performance category and renamed in the CY 2019 PFS final rule (83 FR 59719)) since the inception of MIPS under the Quality Payment Program as described in the CY 2017 Quality Payment Program final rule (81 FR 77014), we do not have a historical burden estimate attributed separately for this specific measure.

With the 2015 Medicare EHR Incentive Program final rule serving as the basis for developing the requirements and structure for the

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[416] This figure is rounded to a whole number.

Advancing Care Information performance category under MIPS (81 FR 28215 through 28230), we reviewed how burden was historically estimated. We found that the 2015 Medicare EHR Incentive Program estimated burden by objective as follows: 10 minutes to attest to objectives with measures requiring a numerator and denominator to be generated, 1 minute to attest to objectives with measures with ''Yes''/''No'' attestations, and 6 hours to attest the Security Risk Analysis measure (80 FR 62918). The Security Risk Analysis measure requires providers to attest that they are protecting electronic health information which involves conducting or reviewing a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

In developing the MIPS Promoting Interoperability (formerly Advancing Care Information) performance category in the CY 2017 Quality Payment Program final rule, we streamlined the submission requirements that were outlined in the 2015 Medicare EHR Incentive Program final rule and removed two objectives and their associated measures, thereby reducing burden from nearly seven hours in the Medicare EHR Incentive Program final rule to three hours for the MIPS Advancing Care Information performance category (81 FR 77510). In the CY 2026 PFS final rule (90 FR 49952), the finalized burden estimate for the reporting requirements to submit MIPS Promoting Interoperability performance category data is 2.7 hours (162 minutes). As indicated in the CY 2027 PFS proposed rule, we applied the same burden assumptions used in the 2015 Medicare EHR Incentive Program final rule (apply 10 minutes of burden per objectives for measures requiring the generation of a numerator/denominator and 0.5 to 1 minute of time for measures requiring ''Yes''/''No'' attestations to the currently approved requirements for reporting MIPS Promoting Interoperability performance category data), which establishes a burden estimate of 36 minutes (91 FR 44235). As a result, we deduced that the remainder of time (126 minutes) can be attributed to the Security Risk Analysis measure (91 FR 44235). In the CY 2027 PFS proposed rule; we estimated that the removal of the Security Risk Analysis measure would decrease burden by 2.1 hours (126 minutes) (91 FR 44235). Also, in the CY 2027 PFS proposed rule, we estimated that the removal of the Security Risk Analysis measure would result in an annual decrease in total cost of $4,472,247 for all responses (-2.1 hr per response × 19,325 responses) [417] × $110.20/hr for a computer systems analyst to submit MIPS Promoting Interoperability performance category data beginning with the CY 2027 performance period/2029 MIPS payment year (91 FR 44235). We requested comment on the proposal that reduces the burden estimates and assumptions for the MIPS Promoting Interoperability performance category accounting for the removal of the Security Risk Analysis measure starting with the CY 2027 performance period/2029 MIPS payment year. We did not receive public comment on the proposal, and therefore, we are finalizing, as proposed, the burden estimates and assumptions for the MIPS Promoting Interoperability performance category accounting for the removal of the Security Risk Analysis measure starting with the CY 2027 performance period/2029 MIPS payment year.

Tables D–A16 and D–A17 detail the estimated change in burden for each finalized, as proposed, measure/attestation change by performance period (CY 2027 performance period/2029 MIPS payment year and the CY 2028 performance period/2030 MIPS payment year, respectively). Each table includes an adjusted total change in annual burden for submitting MIPS Promoting Interoperability performance category data.

TABLE D-A16: CHANGE IN ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Measure/Attestation	No. of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)*	Labor Cost ($/hr)	Total Cost ($)*
Removal of ONC Direct Review Attestation+	19,325	19,325	(0.0167)	(323)	110.20	(35,595)
Removal of ONC-ACB Surveillance Attestation+	19,325	19,325	(0.0167)	(323)	110.20	(35,595)
Removal of Security Risk Analysis Measure	19,325	19,325	(2.1000)	(40,583)	110.20	(4,472,247)
Total	19,325	19,325	(2.1334)	(41,228)	110.20	(4,543,326)

*Total Annual Time estimates in the table are rounded to the hour and Total Cost estimates are rounded to the dollar, therefore the Total row may deviate from the sum of all rows.

+The proposals to remove the ONC attestations begin with the CY 2026 performance period/2028 MIPS payment year and will be updated under OMB control number 0938-1314.

We are finalizing, as proposed, the proposals for establishing the burden estimate that reflect the removal of the required ONC Direct Review attestation and optional ONC–ACB Surveillance attestation starting with the CY 2027 performance period/2029 MIPS payment year, as identified in Table D–A16 of this final rule. Starting with the CY 2027 performance period/2029 MIPS payment year, we are adjusting the burden estimate by a total reduction of 2.1334 hours per response (0.0167 + 0.0167 + 2.1), resulting in an annual decrease in total hours of 41,228 (2.1334

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hr per response × 19,325 responses) [418] and total savings of $4,543,326 for all responses (-2.1334 hr per response × 19,325 responses) [419] × $110.20/hr for a computer systems analyst to submit MIPS Promoting Interoperability performance category data.

TABLE D-A17: CHANGE IN ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION FOR CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Measure/Attestation	No. of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)*	Labor Cost ($/hr)	Total Cost ($)*
Add Electronic Prior Authorization Measure	19,325	19,325	.0083	+161	110.20	+$17,742
Add Electronic Prior Auth for Prescription Drugs Measure	19,325	19,325	.0083	+161	110.20	+$17,742
Total	19,325	19,325	.0167	+323	110.20	+$35,595

*Total Annual Time estimates in the table are rounded to the hour and Total Cost estimates are rounded to the dollar, therefore the Total row may deviate from the sum of all rows.

We are finalizing, as proposed, the two proposals establishing the burden estimates that reflect the modifications to the Electronic Prior Authorization requiring the reporting of the measure starting with the CY 2028 performance period/2030 MIPS payment year and the addition/adoption of the new Electronic Prior Authorization for Prescription Drugs measure requiring the reporting of the measure starting with the CY 2028 performance period/2030 MIPS payment year, as identified in Table D–A17 of this final rule. Starting with the CY 2028 performance period/2030 MIPS payment year, we estimate a total increase in 0.0167 hours per response (0.00833 + 0.00833), resulting in an annual increase in total hours of 323 (0.0167 hr x 19,325 responses) [420] and a cost of $35,595 for all responses (+0.0167 hr per response x 19,325 responses) [421] x $110.20/hr for a computer systems analyst to submit MIPS Promoting Interoperability performance category data.

The finalized, as proposed, the proposals relevant to the submission of MIPS Promoting Interoperability performance category data requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

e. ICRs Regarding Reporting for the Improvement Activities Performance Category

We refer readers to §§ 414.1355 and 414.1365(c)(3) for our previously established policies regarding reporting for the improvement activities performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1360 for data submission requirements, and §§ 414.1380(b)(3) and 414.1365(d)(3)(iii) for improvement activities performance category scoring. For historic assumptions on reporting requirements for the improvement activities performance category, we refer readers to the CY 2024 PFS final rule (88 FR 79454 and 79455).

In section IV.A.4.d.(3) of this final rule, we are finalizing our proposed changes to the Improvement Activities Inventory for the CY 2027 performance period/2029 MIPS payment year and subsequent years. Consistent with our assumptions in the CY 2023 PFS final rule (87 FR 70211), the CY 2024 PFS final rule (88 FR 79519), the CY 2025 PFS final rule (89 FR 98492), the CY 2026 PFS final rule (90 FR 49953), we believe clinicians performing improvement activities will continue to perform the same activities because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified via rulemaking (82 FR 54175). We did not receive public comments on our burden estimates and assumptions for these provisions. We refer readers to section VII.F.10.e.(2).(a). of this final rule for additional discussion.

Independent of these policies, we are updating the number of submissions due to the availability of updated submission data from the CY 2024 performance period/2026 MIPS payment year. While not scored in this rule, the non-policy changes will be submitted to OMB under control number 0938–1314 (CMS–10621).

f. ICRs Regarding the Cost Performance Category

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by Compact Disc or hardcopy. The policy to update the Operational List of care episode and patient condition groups and codes beginning with the CY 2027 performance period/2029 MIPS payment year, detailed in section IV.A.4.d.(2) of this final rule, will not result in the need to add, revise, or delete any claims data fields. Consequently, we are not making adjustments under the aforementioned OMB control number.

g. ICRs Regarding Voluntary Participants Election to Opt Out of Performance Data Display on Compare Tools

As described in section IV.E.2. of this final rule, we are finalizing our proposal to amend § 414.1395(c)(2) to remove the 1—year delay for publicly reporting new improvement activities and Promoting Interoperability measures, objectives, or activities included in a Merit—based Incentive Payment System Value Pathway (MVP), provided the data meet the public reporting standards at § 414.1395(b).

We are not updating our burden estimates under OMB control number 0938–1314 (CMS–10621) as this provision affects the timing of public

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reporting for measures and activities included in MVPs but does not modify the existing process by which voluntary participants may elect to opt—out of having their performance data publicly displayed on Care Compare tools, as established under § 414.1395. We did not receive public comments on our burden estimates and assumptions for this provision.

h. ICRs Regarding the Virtual Group Election

As described in section IV.A.3.d. of this final rule, we are finalizing, as proposed, the proposal to include Virtual Groups in MVP reporting starting with the CY 2029 performance period/2031 MIPS payment year. In the CY 2027 PFS proposed rule, we noted that we are not updating the burden estimates under OMB control number 0938–1314 (CMS–10621) as the operational details of the implementation of Virtual Group reporting in MVPs have not yet been developed. Thus, in this final rule, we note that we will seek OMB approval for changes in burden once the details pertaining to the implementation of Virtual Group reporting in MVPs are sufficiently developed.

C. Summary of Annual Burden Estimates

Tables D–A18 through D–A20 set out the burden for this rulemaking's finalized policies that are subject to the PRA. It does not score burden adjustments that are strictly based on updated data and are unrelated to any of this rule's finalized policies. Table D–A21 sets out the burden for this rulemaking's finalized provisions that are subject to the PRA. It does not score burden adjustments that are strictly based on updated data and are unrelated to any of the provisions.

TABLE D-A18: ANNUAL REQUIREMENTS AND BURDEN ESTIMATES (CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR)

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802 and 414.804	0938-1921 (CMS-10110)						
§§ 414.802 and 414.804	0938-1921 (CMS-10110)						
§§ 414.1325, 414.1335, 414.1365, and 414.1375 Quality Payment Program (CY 2027 performance period/2029 MIPS payment year)	0938-1314 (CMS-10621)	3,416	3,416	Varies	(51,188)	Varies	(5,808,502)
TOTAL	n/a						

TABLE D-A19: ANNUAL REQUIREMENTS AND BURDEN ESTIMATES (CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR)

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.1325, 414.1335, 414.1365, and 414.1375 Quality Payment Program (CY 2028 performance period/2030 MIPS payment year)	0938-1314 (CMS-10621)	19,325	19,325	.0167	323	Varies	35,595
TOTAL	n/a						

TABLE D-A21: ANNUAL REQUIREMENTS AND BURDEN ESTIMATES

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Limiting Medicare Coverage of Certain Individuals	0938-1426 (CMS 10797)	300,000	30,000	0.25	7,500	$24.05	180,375
§§ 427.402(c)(4) and (5), 428.302(c)(4) and (5), and 428.303(c)(4) and (5) (Regarding Rebate Reduction Requests Submitted Under Sections 11101 and 11102 of the Inflation Reduction Act)	0938-1474 (CMS-10858)	20	20	31	620	Varies	76,801.60
Regarding the Medicare Prescription Drug Inflation Rebate Program under Sections 11101 and 11102 of the Inflation Reduction Act	0938-1485 (CMS-10930)	14,000 340B Providers or TPAs	70,000 [(14,000 x 4 submissions per year) + 14,000 registrations]	Varies	462,000	Varies	52,366,440

VII. Regulatory Impact Analysis

A. Statement of Need

In this final rule, we are finalizing payment and policy changes under the Medicare PFS. Our final policies in this rulemaking specifically address: changes to the PFS and other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; modifications to the Medicare Shared Savings Program (Shared Savings Program); updates to the Quality Payment Program (MIPS and Advanced APMs); changes to payment policies for drugs and biological products paid under Medicare Part B; changes to the Clinical Laboratory Fee Schedule requirements; other changes to Medicare Part B payment policies for Rural Health Clinics and Federally Qualified Health Centers; and changes to the regulations associated with the Ambulance Fee Schedule. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Clinical Laboratory Fee Schedule (CLFS)—Revisions Consistent With Recent Statutory Changes

In section III.C. of this final rule, we are finalizing the conforming regulations text changes for CLFS data reporting requirements due to the enactment of section 6226 of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75, February 3, 2026). Specifically, section 6226 of the CAA, 2026 revised the next required data reporting period for CDLTs that are not ADLTs to be May 1, 2026 through July 31, 2026, and specified that the applicable data collection period is January 1, 2025 through June 30, 2025. Additionally, section 6226 of the CAA, 2026 amended section 1834A(b)(3) of the Act to specify that the applicable percent was 0 percent for all of CY 2026, meaning that the payment amount determined for a CDLT for CY 2026 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2025, and to extend the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2029. Therefore, the applicable percent of up to 15 percent will apply for CYs 2027 through 2029.

Discretionary Provisions

a. Medicare Shared Savings Program

In section III.G. of this final rule, we finalized modifications to the Shared Savings Program regulations that would accelerate accountable care service delivery, further CMS's goal of aligning spending and value in Original Medicare, and support achieving other related strategic objectives. The finalized changes to the Shared Savings Program include the following.

We are finalizing our proposed changes to Shared Savings Program policies for determining beneficiary assignment, applicable for the performance year starting on January 1, 2028, and subsequent performance years, to exclude from assignment calculations allowed charges for primary care services billed through a non-ACO TIN by an ACO professional used in assignment and modify assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status. We also are finalizing our proposed changes to revise the definition of primary care services for the performance year starting on January 1, 2027, and subsequent performance years, to align with payment policy proposals and include, among other services for purposes of beneficiary assignment, services for Screening, Brief Intervention, and Referral to Treatment, Vaccine Adverse Effects Management, and Advance Care Planning.

We are finalizing our proposals to revise the quality performance standard and other quality reporting requirements, by extending the availability of the MIPS CQMs collection type and the MIPS CQM reporting incentive for Shared Savings Program ACOs, extending the scoring of Shared Savings Program ACOs reporting Medicare CQMs using flat benchmarks,

revising the Shared Savings Program quality reporting requirements, establishing the Medicare eCQMs collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set, revising the definition of a beneficiary eligible for Medicare CQMs, revising the Shared Savings Program scoring policy for excluded APP Plus measures and APP Plus measures that lack a benchmark, and updating the APP Plus quality measure set. We are also finalizing our proposals to simplify the Shared Savings Program CEHRT use requirements by sunsetting existing Shared Savings Program CEHRT use and public reporting requirements, providing new options for ACOs to meet the Shared Savings Program CEHRT use requirement, and requiring that they publicly report their selected option.

We are finalizing our proposed changes to the Shared Savings Program's benchmarking and financial methodology to strengthen financial incentives for ACOs to participate in the program while mitigating selection issues and benchmark rebasing concerns. We are finalizing the following changes that would be applicable to agreement periods beginning on January 1, 2027, and in subsequent years: increasing the sharing rate under Level E of the BASIC track, reducing the maximum weight on the regional adjustment for lower-spending ACOs under the ENHANCED track, modifying the prior savings adjustment to increase the scaling factor, risk adjusting the 5 percent cap on upward adjustments to the historical benchmark, and incentivizing new participation through a growth adjustment to the historical benchmark. We also are finalizing our proposed reforms to the ACPT component of the three-way blended benchmark update factor to improve accuracy and strengthen Shared Savings Program financial incentives.

To expand the tools available to ACOs to support beneficiary engagement, we are finalizing our proposal to allow eligible Shared Savings Program ACOs that have submitted a Part B cost sharing support application and for which CMS has approved their application to reduce or eliminate Part B cost sharing for eligible beneficiaries. We also are finalizing the proposal to discontinue availability of the option for prepaid shared savings.

We are finalizing our proposal to modify the methodology for determining quarterly advance investment payment amounts (for eligible ACOs), by removing use of the area deprivation index and adding instead a rural criterion within an approach where we would use a flat per-beneficiary payment amount. We also are finalizing our proposed revisions to the definitions of experienced and inexperienced with performance-based risk Medicare ACO initiatives used in determining an ACO's eligibility for certain participation options. Finally, we are finalizing our proposal to modify Shared Savings Program beneficiary notification requirements, by revising distribution timing of standardized written notices and removing the requirement to provide a beneficiary follow-up notice.

b. Drugs and Biological Products Paid Under Medicare Part B

In section III.A.1. of this final rule, as part of our continued implementation of section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (IIJA), which amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter, refundable drug), we discuss one application received for increased applicable percentage.

c. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this final rule, we are finalizing changes to the payment of Diabetes Self-Management and Training (DSMT) and Medical Nutrition Therapy (MNT) services in RHCs. We are finalizing the policy to recognize DSMT and MNT services as qualified visits that are covered and paid as stand-alone billable visits under the RHC benefit. We are also finalizing revisions to § 405.2463(a) and (b)(2) to reflect that DSMT and MNT services will be stand-alone billable visits in RHCs.

In section III.B.3 of this final rule, we are finalizing conforming regulatory text changes at §§ 405.2463(b)(3) and 405.2469(d) since section 6209(d) of the CAA, 2026 extended the abeyance of the RHC and FQHC mental health in-person requirements through December 31, 2027. This provision requires that the in-person visit requirements not apply to any services furnished through to December 31, 2027. We are also finalizing technical changes to §§ 405.2464(g) and 405.2469(d).

In section III.B.4 of this final rule, we discuss the final CY 2027 FQHC PPS market basket update. Section 1834(o)(2)(B)(ii) requires the FQHC PPS base rate be updated annually by the percentage increase in a market basket of FQHC goods and services as issued through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1842(i)(3) of the Act) for the year involved. For CY 2027, we are finalizing to use an estimate of the 2022-based FQHC market basket to update payments to FQHCs based on the best available data. Consistent with CMS practice, we used the update based on the most recent historical data available at the time of publication of the final rule.

d. Ambulatory Specialty Model (ASM)

In section III.D. of this final rule, we discuss final policies related to the Ambulatory Specialty Model (ASM), a mandatory alternative payment model that will be tested by the Innovation Center under the authority at section 1115A of the Act. Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and CHIP beneficiaries.

Health care is becoming more fragmented as Medicare beneficiaries are increasingly seeing a greater number of specialists on a more regular basis. We believe there are opportunities to improve coordination between specialists and primary care providers and increase beneficiary engagement in care decisions, particularly with respect to preventing the onset and progression of chronic disease. ASM will evaluate select specialists that furnish a requisite volume of services related to heart failure or low back pain as measured by historic episode-based cost measure (EBCM) episode volume and test whether rewarding them based on measures of quality, cost, care coordination, and Promoting Interoperability results in enhanced quality of care and reduced costs through more effective upstream chronic condition management for ASM's targeted chronic conditions. We expect that a more targeted approach where specialists are evaluated: (1) on a set of relevant performance measures they are required to report; and (2) among specialists furnishing similar sets of services for similar chronic conditions, will produce final scores and subsequent payment adjustments that are more reflective of clinician performance. A more targeted approach to measurement will also offer more insight into how clinical decisions and processes, such as care coordination, affect patient outcomes. We believe this insight is necessary to support and encourage accountable care, increasing

beneficiary access to coordinated specialty care.

We believe that ASM's meaningful comparisons of performance to similar specialists furnishing a substantial volume of services related to ASM's targeted chronic conditions when matched with a payment methodology that creates impactful Medicare Part B payment adjustments will encourage quality improvements in specialty care and meaningful engagement with primary care providers to both prevent and manage the onset of chronic conditions, all while achieving net savings to Medicare.

We finalized ASM through notice and comment rulemaking in CY 2026 PFS final rule (90 FR 49562 through 49720). The final policies within this final rule address policy gaps and make technical or conforming updates to ensure ASM has sound and well-developed technical, administrative, and operational policies.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866, Regulatory Planning and Review, Executive Order 13563, ''Improving Regulation and Regulatory Review;'' Executive Order 14192, ''Unleashing Prosperity Through Deregulation;'' the Regulatory Flexibility Act (RFA) (Pub. L. 96—354); section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); and Executive Order 13132, ''Federalism'', and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits.

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under section 3(f)(1) of Executive Order 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1)). Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners, and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *https://www.sba.gov/document/support-table-size-standards* (refer to the 620000 series).) Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other suppliers, and providers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, Medicare payment is made under the PFS for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this rulemaking will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately $193 million. This rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this rulemaking does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which, together with the information provided in the rest of this rule, meets all assessment requirements. The analysis explains the rationale for and purposes of this rule; details the costs and benefits of this rulemaking; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this rule, we discussed various changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services and to implement provisions of the statute. We provide information for each policy change in the relevant sections of this final rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this rule. The relevant sections of this rulemaking describe significant alternatives we considered, if applicable.

C. Executive Order 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' This final rule is exempt from otherwise-applicable requirements under E.O. 14192, per footnote 1 of OMB's Accounting Methods.[422]

D. Effects of the Changes in Relative Value Units (RVUs)

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the

[422] *https://www.reginfo.gov/public/pdf/eo14192/Accounting_Methods_under_EO_14192.pdf.*

year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compare payment rates for CY 2026 with payment rates for CY 2027 using CY 2025 Medicare utilization. The payment impacts described in this rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical diagnostic laboratory tests that are paid under the Clinical Laboratory Fee Schedule (CLFS).

As required by section 1848(d)(1)(A) of the Act, beginning in CY 2026, there are two separate conversion factors (CFs): one for items and services furnished by a qualifying APM participant as defined in section 1833(z)(2) of the Act (referred to as the qualifying APM conversion factor) and another for other items and services (referred to as the nonqualifying APM conversion factor), equal to the respective conversion factor for the previous year multiplied by the update established under section 1848(d)(20) of the Act for such respective conversion factor for such year. As specified by section 1848(d)(20) of the Act, the update to the qualifying APM conversion factor for CY 2027 is 0.75 percent while the update to the nonqualifying APM conversion factor for CY 2027 is 0.25 percent.

To calculate the estimated CY 2027 PFS conversion factors, we took the CY 2026 conversion factors without the payment increase of 2.50 percent provided by statute that applied to services furnished from January 1, 2026 through December 31, 2026 and multiplied them by the budget neutrality adjustment required as described in the preceding paragraphs, then multiplied by the qualifying APM and nonqualifying APM updates specified by section 1848(d)(20) of the Act. We estimate the CY 2027 PFS qualifying APM CF to be 32.9548 which reflects a -0.12 percent budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.75 percent update adjustment factor specified under section 1848(d)(20) of the Act. We estimate the CY 2027 PFS nonqualifying APM CF to be 32.6286 which reflects a -0.12 percent budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.25 percent update adjustment factor specified under section 1848(d)(20) of the Act. We estimate the CY 2027 anesthesia qualifying APM CF to be 20.3068 and the CY 2027 anesthesia nonqualifying APM CF to be 20.1056, reflecting the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE D-B1: CALCULATION OF THE CY 2027 PFS QUALIFYING APM CONVERSION FACTOR

CY 2026 Conversion Factor		33.5675
Conversion Factor without One Year 2.50% Increase		32.7488
CY 2027 Qualifying APM Update Factor	0.75 percent (1.0075)	
CY 2027 RVU Budget Neutrality Adjustment	-0.12 percent (0.9988)	
CY 2027 Conversion Factor		**32.9548**

TABLE D-B2: CALCULATION OF THE CY 2027 PFS NON-QUALIFYING APM CONVERSION FACTOR

CY 2026 Conversion Factor		33.4009
Conversion Factor without One Year 2.50% Increase		32.5863
CY 2027 Non-Qualifying APM Update Factor	0.25 percent (1.0025)	
CY 2027 RVU Budget Neutrality Adjustment	-0.12 percent (0.9988)	
CY 2027 Conversion Factor		**32.6286**

TABLE D-B3: CALCULATION OF THE CY 2027 ANESTHESIA QUALIFYING APM CONVERSION FACTOR

CY 2026 National Average Anesthesia Conversion Factor		20.5998
Conversion Factor without One Year 2.50% Increase		20.0974
CY 2027 Qualifying APM Update Factor	0.75 percent (1.0075)	
CY 2027 RVU Budget Neutrality Adjustment	-0.12 percent (0.9988)	
CY 2027 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.41 percent (1.0041)	
CY 2027 Conversion Factor		**20.3068**

TABLE D-B4: CALCULATION OF THE CY 2027 ANESTHESIA NON-QUALIFYING APM CONVERSION FACTOR

CY 2026 National Average Anesthesia Conversion Factor		20.4976
Conversion Factor without One Year 2.50% Increase		19.9976
CY 2027 Non-Qualifying APM Update Factor	0.25 percent (1.0025)	
CY 2027 RVU Budget Neutrality Adjustment	-0.12 percent (0.9988)	
CY 2027 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.41 percent (1.0041)	
CY 2027 Conversion Factor		**20.1056**

In the interest of greater accessibility, we are posting the CY 2027 PFS Estimated Impact on Total Allowed Charges by Specialty table as a public use file as opposed to a table within the preamble text. We believe that posting this table as a separate file will make it easier for interested parties to access the data within the table as well as making the data more readable outside of a text-based format. This public use file shows the impact on PFS payment for physicians' services based on the policies included in this rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in the CY 2027 PFS Estimated Impact on Total Allowed Charges by Specialty public use file. This file is available on the CMS website under ''Downloads'' for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-noticesl*.

In recent years, we have received requests from interested parties to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented us with high-level information suggesting that Medicare payment policies are directly responsible for consolidating privately owned physician practices and freestanding supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in healthcare delivery, especially concerning independent versus facility-based practices. We published an RFI in the CY 2023 PFS proposed rule to gather feedback on this issue and refer readers to the discussion in the CY 2023 PFS final rule (87 FR 69429 through 69438). As part of our holistic review of how best to update our data and offer interested parties' additional information that addresses some of the concerns raised, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under ''downloads'' for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

2. CY 2027 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty-level impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The proposals to update code valuation and improve the accuracy of the practice expense methodology are estimated to have a significant positive impact on clinical psychologists and clinical social workers, with smaller increases to physical and occupational therapists, interventional radiology, and vascular surgery. To a lesser degree, projected increases for some specialties would result from the proposed changes to HCPCS code G2211 and the fourth and final year of the behavioral health work update. Increases would also result from proposed increases in valuation for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, and increased payments resulting from supply and equipment pricing updates. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the Clinical Lab Fee Schedule.

Specialties that we estimate would see a significant decrease include dermatology, otolaryngology, orthopedic surgery, and hand surgery, and to a smaller extent, ophthalmology, podiatry, audiologists, neurosurgery, portable x-ray suppliers, and plastic surgeons. These changes can largely be attributed to the proposed changes to modifier -25 and the proposal to remove the Indirect Practice Cost Index (IPCI) from the calculation of the PE RVUs, although the effects on PE are mitigated by the proposed PE stabilization adjustment. The estimated impacts also reflect decreased payments due to continued implementation of previously finalized code-level reductions that are being phased in over several years.

The proposal to reduce payment when a separately identifiable office/outpatient E/M visit is furnished by the same physician (or a physician in the same group practice) on the same day as a 0-, 10-, or 90-day global procedure and identified on the claim with modifier -25 is projected to have the largest negative impact on otolaryngology, dermatology, and podiatry, and to a smaller extent, hand surgery, physicians assistant, and colon and rectal surgery. These specialties frequently report E/M services with modifier -25 in conjunction with a 0-, 10-, or 90-day global procedure. Most other specialties are projected to receive a small increase due to the redistribution of those RVUs. Our utilization estimates for this proposal are reflected in the file titled ''CY 2026 PFS Proposed Rule 2025 Utilization Data Crosswalked to 2027'' available under ''downloads'' for the CY 2027 PFS final rule on the CMS website at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.*

We received many comments about the impact of this proposal. Most of the discussion of these impacts can be found in section II.D. of this final rule. We are finalizing to reduce payment to all but the highest paid service by 20 percent when a separately identifiable office/outpatient E/M visit is furnished by the same physician (or a physician of the same specialty in the same group practice) on the same day as a 0-day global procedure and identified on the claim with modifier -25. This policy is estimated to still have the largest

impacts on dermatology, otolaryngology, and podiatry, but the percentage of the impacts have been reduced with the decrease in payment reduction from 50 percent to 20 percent in response to commenters. We estimate that the impacts to specialties will be reduced by around 1 percent by limiting this policy to only 0-day global services, rather than 0-, 10-, and 90-day global services as proposed.

We are finalizing the proposal to replace HCPCS code G2211 with a modifier (MOD1) that is set to 16 percent of the total RVUs for the E/M service on the claim. This policy is expected to have minimal impact given that the volume previously reported using HCPCS code G2211 would now be reported with the modifier, and that was accounted for using the weighted average of the percent increase for utilization of HCPCS code G2211 and adjusted for budget neutrality. The proposal to pay for services furnished in an ACO using a modifier (MOD2) that pays 32 percent of the total RVUs for the E/M service on the claim is expected to increase payment for practitioners that furnish a higher percentage of their services in ACOs. We note that MOD1 and MOD2 were placeholder codes. We are finalizing that MOD1 is now modifier B1, and MOD2 is now modifier B2. Our utilization estimates for MOD1 and MOD2 are reflected in the file titled ''CY 2026 PFS Proposed Rule 2025 Utilization Data Crosswalked to 2027'' available under ''Downloads'' for the CY 2027 PFS proposed rule on the CMS website at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table, including comments received in response to the valuations. We remind interested parties that although the estimated impacts are displayed at the specialty level, typically, the changes are driven by the valuation of a relatively small number of new and potentially misvalued codes. The percentage changes in the specialty impact table are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty and compared to the same summed total from the previous calendar year. Therefore, they are averages and may not necessarily represent what is happening to the particular services furnished by a single practitioner within any given specialty.

As previously discussed, we have reviewed our suite of PUFs and have worked on new ways to offer interested parties' additional information that addresses concerns about the lack of granularity in our impact tables. To illustrate how impacts can vary within specialties, we created a PUF that models the expected percentage change in total RVUs per practitioner. We also note the code level RVU changes are available in the Addendum B PUF available on the CMS website under ''downloads'' for the CY 2027 PFS final rule at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.*

The specialty impacts reflect changes within the pool of total RVUs. The specialty impacts table, therefore, includes any changes in spending that result from proposed policies that are subject to the statutory budget neutrality requirement at section 1848(c)(2)(B)(ii)(II) of the Act but does not include any changes in spending which result from proposed policies that are not subject to the statutory budget neutrality adjustment, and therefore, have a neutral impact across all specialties. The 0.75 percent and 0.25 percent updates to the CY 2027 and nonqualifying APM conversion factors, respectively, are statutory changes that take place outside of BN, and therefore, are not captured in the specialty impacts.

b. Impact

Column G of specialty level impacts displays the estimated CY 2025 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high-volume procedures is available under ''downloads'' on the CY 2027 PFS final rule website at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.* We selected these procedures for the sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and non-facility rates are shown. For an explanation of facility and non-facility PE, we refer readers to Addendum A on the CMS website at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices.*

E. Effects of the Changes Related to Telehealth Services

We are finalizing as proposed to add several codes to the Medicare Telehealth We are finalizing as proposed to revise the code descriptors for CPT codes G0508 and G0509 to align with the permanent removal of telehealth frequency limitations. We are finalizing as proposed to allow teaching physicians to bill for services involving residents when either the teaching physician or resident is in the same physical location as the beneficiary. These services, in addition to other Medicare Telehealth Services, are expected to substitute for in-person visits and as such would not increase overall utilization of these services.

Section 6209(a) and (b) of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75, February 3, 2026) extends the flexibilities for Medicare telehealth services to remove the geographic restrictions, expand the list of acceptable originating sites, and expand the array of practitioners eligible to furnish telehealth services from January 30, 2026 to the extended date of December 31, 2027. Section 6209(d) of the CAA, 2026 delays the in-person visit requirements for mental health services furnished through telehealth from January 30, 2026 to the extended date of January 1, 2028. Section 6209(e) of the CAA, 2026 extends the flexibilities to allow audio-only Medicare telehealth services from January 30, 2026 to the extended date of January 1, 2028. Additionally, section 6209(g) of the CAA, 2026, requires CMS to establish modifiers for telehealth services in certain instances, effective January 1, 2027. We anticipate that our provisions will result in continued utilization of services that can be furnished as Medicare telehealth services during CY 2027 at levels comparable to observed utilization of these services during CY 2026.

F. Other Provisions of the Final Rule

1. Impacts Related to Technical Corrections of Comprehensive Outpatient Rehabilitation Facility (CORF) Services Regulations

As discussed in section II.F. of this final rule, we proposed to amend the regulatory text at §§ 410.105 and 414.1105 for accuracy that we overlooked during CY 2008 PFS rulemaking when we amended § 410.100. As such, there are no impacts for the policies in section II.F. of this final rule.

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is either as noted in section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological or as

noted in section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In the CY 2023, 2024, and 2025 PFS final rules, we finalized several policies to implement the provision. In September of 2026, CMS sent discarded drug refund reports for CY 2024 ''updated refund quarters'' and CY 2025 ''new refund quarters,'' as defined at § 414.902. The total refunds owed for these quarters amount to more than $224 million, reflecting a 29.5 percent increase from the prior year, and are required by law to be deposited into the Supplementary Medical Insurance Trust Fund. In section III.A.1 of this final rule, we discuss one application (CMS 10835, OMB 0938–1435) for increased applicable percentage which will have no impact on Medicare spending.

3. Impacts Related to Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2.c. of this final rule, to improve access to preventive services in RHCs, we are finalizing changes to the payment of DSMT and MNT services in RHCs. We are finalizing the policy to recognize DSMT and MNT services as qualified visits that are covered and paid as stand-alone billable visits under the RHC benefit. A national claims-based analyses of evaluation and management billing patterns indicated that a nominal volume of DSMT and MNT services were bundled within payments to RHCs during 2025.

Since DSMT and MNT services are generally underutilized by the Medicare population, we believe that increase to Medicare Part B expenditures due to the final policy will be negligible. As discussed in section III.B.2.c of this final rule, an analysis of Medicare claims data from 2024 indicates that utilization of DSMT and MNT in RHC settings is substantially lower than in comparable care settings. In CY 2024, DSMT services were furnished to approximately 125 RHC beneficiaries, representing 0.005 percent of the total RHC beneficiary population of approximately 2.3 million. MNT services were furnished to approximately 439 RHC beneficiaries, representing 0.019 percent of the total RHC beneficiary population. On a claims basis, DSMT accounted for 0.002 percent and MNT for 0.007 percent of total RHC claims in CY 2024. By comparison, FQHCs showed DSMT utilization rates approximately 22 times higher and MNT utilization rates approximately 28 times higher than RHCs on a per-beneficiary basis. On a claim basis, FQHC utilization of DSMT and MNT exceeded RHC utilization by approximately 31 times and 32 times, respectively. Rural physician offices, which share the geographic and demographic characteristics of RHC patient populations, showed that overall, DSMT and MNT utilization rates were approximately 17 times and 7 times higher than RHCs, respectively, on a per-beneficiary basis. The analysis further demonstrated that within the PFS setting where DSMT and MNT are most readily identifiable in claims data, these services represent a very small share of total Medicare spending—less than 0.01 percent and 0.02 percent of total PFS line payments, respectively, in CY 2024. We believe that while our final policy supports an increase in the furnishing DSMT and MNT at RHCs, we do not expect a significant increase for CY 2027 since RHCs would need to determine potential changes to their care delivery and staffing which may impact timing for uptake.

4. Impacts Related to the Clinical Laboratory Fee Schedule (CLFS): CAA, 2026

In section III.C. of this final rule, we outline statutory amendments to section 1834A of the Act that revise the data reporting period, data collection period, and requirements for the phase-in of payment reductions under the CLFS. In accordance with section 6226 of the CAA, 2026, we are finalizing certain conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we are finalizing revisions at § 414.502 that update the definitions of both the ''data collection period'' and ''data reporting period,'' specifying that the data collection period is the 6-month period from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period, and that the data reporting period for CDLTs that are not ADLTs is the 3-month period, May 1 through July 31, and for ADLTs is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period. We are also finalizing revisions at § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning May 1, 2026. In addition, we are finalizing conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 6226 of the CAA, 2026. Specifically, we are finalizing revisions at § 414.507(d) to indicate that for CY 2026, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2025, and for CYs 2027 through 2029, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates for the CLFS payment rates, have changed since the initial data collection period (January 1, 2016 through June 30, 2016) and data reporting period (January 1, 2017, through March 31, 2017). In addition, as outlined in section III.C. of this final rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the CAA, 2026 amendments to the data reporting period will implement the use of updated private payor rate data to set revised CLFS payment rates for CDLTs that are not ADLTs.

Due to unforeseen changes in private payor rates due to shifts in market-based pricing for laboratory tests and the unpredictable nature of test volumes and their impact on calculating updated CLFS payment rates based on the weighted median of private payor rates, for purposes of this final rule, we are unable to estimate a budgetary impact. CMS published preliminary weighted median private payor rates for CY 2027 on September 21, 2026, based on applicable information reported during the 2026 data reporting period. CMS anticipates finalizing the CY 2027 payment rates for clinical diagnostic laboratory tests under the CLFS in November 2026. Final CY 2027 payment rates remain subject to public comment and the statutory limit on annual payment reductions. Consequently, we anticipate providing impact information related to updated CLFS rates, including the impact of the CAA, 2026 provisions, subsequent to the issuance of this final rule.

We are also finalizing a correction to § 414.523(a)(1) to restore regulatory language concerning the statutory $2.00 increase in the specimen collection fee for qualifying collections in a skilled nursing facility or by a laboratory on behalf of a home health agency. Because CMS already applies this increase in its payment policy and claims processing, we do not expect the correction to

change payments or impose additional costs.

5. Impacts Related to the Ambulatory Specialty Model (ASM)

In section III.D. of this final rule, we discuss the Ambulatory Specialty Model (ASM) tested by the CMS Center for Medicare and Medicaid Innovation (hereinafter ''Innovation Center'') under the authority of section 1115A of the Act. Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. ASM will test whether adjusting payment for eligible specialists who furnish services related to ASM's targeted chronic conditions (that is, heart failure and low back pain) based on performance across targeted measures of quality, cost, care coordination, and meaningful use of certified electronic health record (EHR) technology (CEHRT) results in enhanced quality of care and reduced costs through more effective upstream chronic condition management. By testing ASM, we aim to reduce avoidable hospitalizations and unnecessary procedures, improve patient experience and outcomes, and lower Original Medicare expenditures by incentivizing preventive care, more effective management of chronic conditions, and enhanced coordination and collaboration among specialists and primary care providers. We finalized ASM's provisions in the CY 2026 PFS final rule (90 FR 49562 through 49720), including the framework for identifying ASM participants, performance evaluation, scoring, and payment adjustments.

Based on feedback we received from interested parties after the publication of the CY 2026 PFS final rule and our own internal review, we proposed and are finalizing several technical refinements and adjustments to ASM, including but not limited to revising select definitions, revising and adding ASM participant exceptions from specific ASM requirements, adjusting data submission requirements, incorporating a rural scoring adjustment to final scores, adjusting provisions related to collaborative care arrangements under ASM, and making minor adjustments to specific ASM performance category policies in this final rule. We believe our final policies will improve the clarity, practicality, and alignment of ASM implementation. Further, our final policies do not modify the fundamental framework of ASM for identifying ASM participants over the course of the ASM test period, overall performance evaluation, scoring, or payment adjustments and continue to support CMS priorities related to reducing low—value care, promoting preventive care, enhancing management of chronic conditions, and improving coordination and collaboration among specialists and primary care providers.

Accordingly, we believe our finalized policies in this final rule would not increase federal costs or alter the estimated Medicare program savings described in the CY 2026 PFS final rule (90 FR 49969 through 49975). In the CY 2026 PFS final rule, we estimated an impact of $177 million in net savings to the Medicare program due to ASM from January 1, 2029 through December 31, 2033 (90 FR 49972). This estimate reflects relevant finalized provisions including the ASM test period, geographic scope, participant eligibility, ASM risk levels, the amount of ASM incentive pools distributed to ASM participants in the form of payment adjustments, and the estimated amount of Medicare Part B covered professional service payments subject to ASM payment adjustments. We refer readers to the ASM section of the regulatory impact analysis of CY 2026 PFS final rule for additional information on our methodology and sensitivity analysis (90 FR 49969 through 90 FR 49975). Because we did not propose changes to key assumptions used to previously calculate the Medicare program savings estimate, we do not expect the final policies in this final rule to materially affect the Medicare program savings estimates in the CY 2026 PFS final rule. For example, we do not anticipate that the provisions related to ASM participant exceptions from specific ASM requirements would substantially affect the number of ASM participants meeting ASM requirements over the ASM test period because we believe any exceptions would be balanced by other participation provisions that allow for clinicians who newly meet the ASM participant eligibility criteria to be added as ASM participants over the course of the ASM test period. Therefore, ASM's previously estimated financial impact to the Medicare program remains unchanged from the CY 2026 PFS final rule.

6. Impacts Related to the Limiting Medicare Coverage of Certain Individuals

Section 71201 of the Working Families Tax Cut (WFTC) legislation, which added section 1899C to the Social Security Act (the Act), restricts Medicare eligibility to individuals who meet one of the following criteria: (1) U.S. citizens or nationals; (2) lawful permanent residents; (3) Cuban and Haitian entrants; or (4) individuals who lawfully reside in the United States in accordance with a Compact of Free Association. Individuals who do not meet these criteria and who were enrolled in Medicare on or before July 4, 2025, will have their coverage terminated effective February 1, 2027, which is the date that is 18 months after enactment of the WFTC legislation (July 4, 2025). As established in section 1899C(a) of the Act, individuals enrolled after July 4, 2025, who do not meet the eligibility requirements, are subject to denial or termination under the framework established at proposed §§ 406.14, 406.28 and 407.27.

Based on estimates from OACT, approximately 32,000 individuals are projected to lose Medicare coverage beginning in 2027, representing approximately 0.05 percent of the total Medicare-aged enrollment. OACT's estimate was derived from a 2025 Pew Research study on race and ethnicity in the United States and by using a Congressional report authored by the Department of Homeland Security (DHS). Recently, the SSA has estimated that approximately 300,000 notices will be sent out in November 2026 to individuals who may lose coverage. These individuals will get the opportunity to provide the necessary documentation to continue eligibility so the actual number who lose coverage remains unknown. Because of this, and significant time constraints, OACT is not revising their estimate.

In addition, citing research on lower health care utilization by immigrants, OACT assumes that affected individuals have average Medicare spending equal to approximately two-thirds of the average Medicare beneficiary, reflecting the generally healthier and younger age profile of this population, as well as lower utilization due to increased barriers in accessing health care including language barriers, limited familiarity with the U.S. health system, and concerns related to immigration status that may discourage enrollment and utilization even among those who are eligible. The population captured in this estimate is certain immigrants with temporary protections who no longer meet the revised eligibility requirements of section 1899C(a) of the Act.

TABLE D-B5: ESTIMATED IMPACT ON MEDICARE SPENDING – LIMITING MEDICARE COVERAGE OF CERTAIN INDIVIDUALS ($ MILLIONS)

Year	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2027-2036 Total
FY Cash	-$220	-$390	-$420	-$450	-$490	-$520	-$560	-$600	-$640	-$680	-$4,970

Source: Office of the Actuary (OACT), May 1, 2026. Negative values indicate reductions in Medicare program outlays.

The financial impact of this provision is classified as a transfer—specifically, a reduction in Medicare program outlays that would otherwise have been paid to plans and providers on behalf of affected individuals. Based on OACT's estimates, the 10-year reduction in Medicare spending attributable to this provision is approximately $4.97 billion, ranging from approximately $220 million in 2027 to approximately $680 million in 2036 (see Table D–B5).

Disenrollments from Medicare Advantage, Part D, and Medicare cost plans resulting from loss of entitlement to Part A and/or enrollment in Part B (as applicable) will be processed automatically by CMS when SSA provides updated eligibility and entitlement records. Plans do not process these disenrollments and are not required to provide additional notification, as SSA provides a loss of entitlement notice directly to affected individuals. All information impacts related to the procedural steps plans must take to receive and process enrollment and disenrollment transactions have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) and 0938–0964 (CMS–10141). The burden associated with the revision of Medicare initial enrollment forms to support eligibility determinations under this provision is described in the Collection of Information Requirements section of this rule.

Dahl and Forbes (2023) estimate that 46 percent of individuals are willing to pay $638 per person, in 2011 dollars—or approximately $873 when updated for inflation—to avoid switching medical providers (specifically, primary-care physicians).[423] For purposes of this regulatory impact analysis, it is assumed that $873 is a reasonable estimate of an average that includes the 46-percent of WTP amounts above it and the 54-percent below. Multiplying this $873 annual amount by 32,000 disenrollments yields a cost estimate of $28 million. This quantitative estimate is characterized by various forms of uncertainty, including:

- *Tendency toward underestimation.* Switching insurance plans, or newly lacking insurance coverage altogether, involves a more sweeping set of changes than just reestablishing a new primary-care physician, so WTP to avoid the latter probably understates WTP to avoid the former.
- *Tendency toward overestimation.* The relatively low level of churn associated with employer-sponsored insurance (ESI) may offer a greater opportunity to establish doctor-patient relationships than what is available to individuals affected by this provision (due to many of them having non-permanent immigration status), so extrapolating an ESI-derived estimate may overstate the WTP for continuity that would be relevant for this regulatory impact analysis.

We received multiple comments on the regulatory impact analysis of the provisions related to limiting Medicare coverage of certain individuals. The following is a summary of the comments we received and our response.

Comment: Several commenters noted that CMS's estimates of individuals that will lose Medicare coverage due to the implementation 1899C was lower than the Congressional Budget Office's (CBO) estimate that 100,000 people will lose coverage. Commenters shared concerns that CMS may be underestimating the number of impacted individuals and that accurate projections are necessary for legislators, policy makers, and external stakeholders to assess policy impacts and make future budget decisions. CMS should consider other reliable data sources, including CBO, for more accurate projections.

Response: We acknowledge the commenters' concerns. There is very little information available on the number of beneficiaries who will be affected by this provision of the law. CMS actuaries and CBO both prepare estimates in order to inform policymakers of the potential impact of enacted legislation and other regulatory policy proposals. Because of varied assumptions using this limited information, the estimates are likely to be different, and one may turn out to be more accurate than the other. However, the implementation of this provision is independent of the estimate and is not the only data used to estimate the operational needs to implement the new provision. CMS is working closely with SSA to monitor the number of potentially impacted individuals and resources needs and will continue to do so throughout the implementation of 1899C.

7. Impacts Related to the Medicare Prescription Drug Inflation Rebate Program

In section III.F. of this final rule, as part of our continued implementation of the Inflation Reduction Act of 2022 (IRA), which established the Medicare Prescription Drug Inflation Rebate Program under sections 11101 and 11102 of the Act, we finalized several modifications. For the Medicare Part B Drug Inflation Rebate Program, this rulemaking modifies the excluded product category for Part B rebatable drugs so that the exclusion applies only to certain skin substitute products and clarifies what Consumer Price Index for all Urban Consumers (CPI–U) data CMS will use in the event CPI–U data are unavailable. Additionally, we are clarifying the definition of ''first marketed date'' as used in the context of the Part B Drug Inflation Rebate Program. For the Medicare Part D Drug Inflation Rebate Program, this rulemaking clarifies what CPI–U data CMS will use in the event CPI–U data are unavailable, modifies the methodology finalized in the CY 2026 PFS final rule to account for 340B-eligible units for AIDS Drug Assistance Programs (ADAPs), and requires all providers and suppliers that are covered entities as defined under § 10.3 (hereinafter collectively ''340B providers'' unless otherwise noted) to submit data elements from their Part D 340B claims to the 340B repository beginning in 2027. As described in III.F.3.c.2.c. of this final rule, we are finalizing a delayed deadline for the first mandatory reporting deadline by 1 quarter. That is, 340B providers would not need to submit claims with dates of service between January 1, 2027 and March 31, 2027 to the 340B repository until September 30, 2027, though they

[423] Dahl, G.B. & Forbes, S.J. (2023). Doctor switching costs. *Journal of Public Economics, 221,* 104858, *https://doi.org/10.1016/j.jpubeco.2023.104858.*

may choose to submit earlier. The first mandatory submission will cover two calendar quarters of data (the first and second quarters of 2027) and will be due September 30, 2027.

We do not expect the finalized policies regarding the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program to have a material impact on the calculation of total rebates in aggregate, as these proposals are refinements to regulatory requirements that improve program efficiency and do not otherwise change the current scope of rebatable drugs.

In section III.F.3.c.2.c. of this final rule, we are finalizing a requirement that all 340B providers submit data elements from their Part D 340B claims for all covered Part D drugs billed to Medicare Part D by such covered entity or its contractor(s) beginning with claims with a date of service on or after January 1, 2027. 340B providers will be required to follow the processes and requirements that CMS established for voluntary reporting starting in 2026 and the associated information collection currently approved under OMB control number 0938–1485. CMS will require that each 340B provider report data on a quarterly basis (though they may choose to submit more frequently) within one calendar quarter following the close of the relevant calendar quarter, with the exception of the first quarter, as described above. CMS will consider all data elements received by the 340B repository to be associated with Part D 340B claims; therefore, the 340B repository will rely on the accuracy and completeness of the submitted, certified data to the 340B repository to verify the 340B status of a claim, and CMS will analyze these data to determine if they could be used reliably in the future to remove 340B units from Part D inflation rebate calculations in accordance with section 1860D–14B(b)(1)(B) of the Act. Under this process, CMS will require, as part of every submission, 340B providers (or an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification) to certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, its submissions include all Part D 340B claims for the 340B provider at the time of submission for the relevant period. 340B providers, or their authorized representative, will be required to certify the completeness and accuracy of the data submitted and to certify that the submitter is authorized to submit on behalf of the 340B provider.

In section III.F.3.c.1. of this final rule, we finalized a modification to the Prescriber-Pharmacy Methodology whereby all claims for Part D drugs dispensed to beneficiaries identified as having ADAP supplemental coverage will be treated as 340B-eligible and excluded from Part D inflation rebate calculations, with safeguards to prevent double-counting of units already identified under the existing methodology. This modification addresses a limitation to the Prescriber-Pharmacy Methodology that may under-identify 340B units for drug claims associated with ADAPs that use pharmacies not registered in the OPAIS database as contract pharmacies. This change may result in overestimation of 340B-eligible units associated with ADAPs, although it is expected to have minimal or no impact on the percentage of Part D units identified as 340B eligible for most drug classes with the exception of antiretroviral medications used in the treatment of HIV. The change will be effective for Rebate Reports issued for applicable periods beginning October 1, 2025 and subsequent applicable periods.

In sections III.F.2.c. and III.F.3.b. of this final rule, we amended §§ 427.302, 428.20, and 428.202 to address gaps in monthly CPI–U data by establishing a methodology that uses the first available CPI–U data following any unavailable month. CMS calculates the inflation-adjusted payment amount for Part B rebatable drugs using benchmark and rebate period CPI–U data, with the benchmark period CPI–U determined based on a drug's FDA approval and first marketed date, and the rebate period CPI–U set as the greater of the benchmark CPI–U or the CPI–U from two calendar quarters prior to the applicable quarter. CMS calculates inflation-adjusted payment amount for Part D rebatable drugs using benchmark period and applicable period CPI–U data, with the benchmark period CPI–U determined based on a drug's FDA approval and first marketed date, and the applicable period CPI–U set as the CPI–U for the first month of the applicable period. However, it was necessary to account for situations in which a monthly CPI–U figure is unavailable. Alternative approaches, including the Department of the Treasury's inflation contingency index, a CMS-calculated inflation factor, or using the prior month's data, were considered but not proposed as either less consistent with statutory requirements or administratively impracticable.

We do not anticipate our inflation rebate policies will result in an incrementally significant financial impact on the Medicare program relative to a baseline that reflects the status quo in the absence of any modifications to inflation rebate regulations at parts 427 and 428 as these finalized policies are refinements to regulatory requirements.

We solicited comments on the regulatory impact analysis for these proposals.

We did not receive public comments on the regulatory impact analysis for the Medicare Prescription Drug Inflation Rebate Program, and therefore, we are finalizing as proposed.

8. Impacts Related to the Medicare Shared Savings Program

a. General Impacts

As of January 1, 2026, the Shared Savings Program has 511 ACOs with over 700,000 healthcare providers and organizations providing care to over 12.6 million assigned beneficiaries.[424] The policies in this final rule are designed, in part, to strengthen financial incentives for ACOs to participate in the Shared Savings Program while mitigating selection issues and benchmark rebasing concerns, expand the population of Original Medicare beneficiaries for which ACOs are held accountable for quality and cost of care while minimizing gaming, advance ACOs' use of digital quality measures, reduce participant burden, and increase beneficiary engagement.

As we described in the CY 2026 PFS final rule (90 FR 32814), the ACOs in the program in PY 2023 combined to cover $128 billion in benchmark target spending. Actual ACO spending totaled approximately $123 billion, which is approximately $5.2 billion below the PY 2023 combined benchmark. After accounting for $3.1 billion in net shared savings to ACOs, the remaining difference of $2.1 billion would represent federal savings from the program if benchmarks proved to be a perfect counterfactual in aggregate. The Regulatory Impact Analysis in the December 2018 final rule (see 83 FR 68044 through 68050) provided evidence that the benchmarks for PY 2016 combined to represent a lower spending target than the theoretical counterfactual for estimating what spending would have been in the total FFS Medicare Program had ACOs not

[424] See CMS, ''Shared Savings Program Fast Facts—As of January 1, 2026'', available at *https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf*.

been present that year. Evidence included all of the following:

- Lower combined market level spending trends observed for cohorts of Hospital Referral Regions (HRRs) with significant ACO formation relative to other HRRs without material ACO activity.
- Spillover effects on spending outside of ACO benchmarks, including non-assigned beneficiaries served by ACO providers and suppliers.
- Program design elements that restrained benchmark levels, including rebasing with agreement periods of only 3 years, feedback of communal ACO effects on national trends used to update benchmarks, and restrictions on risk adjustment.

The Regulatory Impact Analysis in the December 2018 final rule (83 FR 68048) estimated that ACOs may have been responsible for half of the 1.2 percent difference in spending trend observed between national average and the subset of HRRs with minimal ACO activity through 2016. This scaled impact represented about four times the gross savings measured relative to benchmarks, or about 0.5 percent net savings across the entire FFS program after accounting for shared savings payments despite benchmarks only officially showing roughly equivalent overall reductions in spending relative to benchmark compared to total outlays from shared savings payments. Since 2016, changes to the Shared Savings Program have potentially moved the benchmarks closer to what the spending would have been in the absence of the program.

In the CY 2026 PFS final rule (90 FR 49975 through 49976), we explained that updating the earlier study to compare more recent trends for markets with varying levels of ACO activity requires updates to the initial study approach, as ACOs have become active in an increasing majority of markets across the nation. There no longer exists a sufficient number of HRRs with nominal ACO penetration in 2023 to construct a de facto counterfactual similar to the study in the December 2018 final rule. An alternate method, however, continued to show spending trends inversely correlated with ACO penetration over time. Roughly 5 percent of beneficiaries live in HRRs with ACO penetration consistently below the national average by 10 percentage points or more over the 2013 to 2023 time series (''Lagging''), while about 9 percent of beneficiaries live in HRRs with ACO penetration 10 percentage points or more above the national average over the same period (''Leading''). Relative to the 2011 base year immediately preceding the Shared Savings Program's introduction, growth in average unadjusted per capita spending in 2023 for Lagging and Leading markets was 4.3 percent higher and 3.9 percent lower than the national average. The divergence in spending growth was even wider after HCC risk adjustment: 5.3 percent higher for Lagging markets and 4.6 percent lower for Leading markets.

These market trends potentially overstate the impact that ACOs may have had on program spending in 2023. The portion of the difference in spending growth driven by risk adjustment may reflect efforts by ACOs to increase coding intensity. Leading markets may exhibit higher participation rates in CMMI models. ACO participation may naturally flock to markets with lower trend for exogenous reasons. Still, conservatively assuming only 35 percent of the unadjusted trend gap is causally related to Shared Savings Program ACOs would roughly validate the $5.2 billion gross savings indicated by comparing aggregate program benchmarks to actual ACO spending in 2023, and the roughly $2 billion in net savings to FFS Medicare. A more optimistic estimate, assuming Shared Savings Program ACOs were responsible for 50 percent of the risk-adjusted spending growth difference (mirroring assumptions used in the December 2018 final rule), would imply net savings roughly 3 times greater, or roughly $6 billion net savings for FFS Medicare.

In the CY 2026 PFS final rule (90 FR 49976), we explained that a study of benchmark performance for cohorts of ACOs that participated in both PY 2022 and PY 2023 revealed that the BASIC track is the primary driver of net savings (as measured by program benchmark target spending less actual spending and shared savings payments). An updated analysis, summarized in Table D–B6, finds that ACOs remaining in the BASIC track continued to demonstrate roughly 50 percent higher net savings in PY 2024 (2.3 percent of benchmark) than ACOs that remained in the ENHANCED track over the same 3 year period (1.5 percent of benchmark), where ''net savings'' is calculated as the difference in combined cohort spending from combined cohort benchmark spending net of combined cohort shared savings outlays, expressed as percentage of combined cohort benchmark (column D in Table D–B6). Meanwhile, ACOs moving into the ENHANCED track from the BASIC track show a marked decline in net savings. Thirty-eight ACOs moved from the BASIC track in PY 2022 (with net savings of 2.5 percent) to the ENHANCED track by PY 2024 with net savings dropping to 1.7 percent of benchmark. Mean net savings declined for the 38 ACOs that moved to the ENHANCED track despite gross savings growing after rebasing into ENHANCED (1.8 percentage point increase from 2022 to 2024 shown in column B) by a greater margin than average gross savings growth for the 210 ACOs that remained in BASIC over the same period (1.0 percentage point increase from 2022 to 2024) and despite both cohorts showing roughly identical average unadjusted per capita spending growth from 2022 to 2024 (not shown in Table D–B6).

TABLE D-B6: WEIGHTED AVERAGE FINANCIAL PERFORMANCE BY ACO COHORT DEFINED BY PATH OF PARTICIPATION OVER PY 2022 TO PY 2024 ($ BILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

Participation Pathway From PY22 to PY24	ACO Count	Benchmark ($B) [A]	Gross Savings % of Benchmark [B]			Shared Savings % of Benchmark [C]			Net Difference % of Benchmark [D]		
			2022	2023	2024	2022	2023	2024	2022	2023	2024
BASIC All 3 Years	210	51	-3.1	-3.4	-4.1	1.3	1.4	1.8	-1.8	-2.0	-2.3
BASIC->ENHANCED	38	14	-4.5	-5.8	-6.3	2.0	3.5	4.6	-2.5	-2.4	-1.7
ENHANCED All 3 Years	123	50	-4.8	-5.1	-5.8	3.5	3.8	4.3	-1.2	-1.4	-1.5

Notes: "Participation Pathway" are the following groups of ACOs, identified by the track/level of their participation in PY 2022, PY 2023 and PY 2024: "BASIC All 3 Years" are ACOs that remained in the BASIC track (Level A, B, C, D, or E) for PY 2022, PY 2023 and PY 2024; "BASIC->ENHANCED" are ACOs that participated in BASIC in PY 2022 and either (a) remained in BASIC in PY 2023 before then advancing to the ENHANCED track in PY 2024, or (b) advanced to the ENHANCED track in PY 2023 and remained in the ENHANCED track in PY 2024; and "ENHANCED ALL 3 Years" are ACOs that remained in the ENHANCED track for PY 2022, PY 2023 and PY 2024.
"Benchmark" [A] is the total PY 2024 benchmark spending for each cohort, in billions of dollars.
"Gross Savings % of Benchmark" [B] is the percentage that a cohort's combined spending deviated from their combined benchmark spending (a negative percentage implies savings).
"Shared Savings % of Benchmark" [C] is the cohort's combined shared savings (and losses) paid to (from) ACOs expressed as a percentage of benchmark.
"Net Difference % of Benchmark" [D] is the sum of "Gross Savings % of Benchmark" [B] and "Shared Savings % of Benchmark" [C] and represents the portion of gross savings (as measured by program benchmarks) retained by the Trust Funds.

Favorable regional adjustments have helped certain ACOs maximize earnings in the ENHANCED track without taking on a high degree of real risk.[425] Only about 2 percent of ENHANCED track ACOs owed losses in PY 2024 while 90 percent earned shared savings. The ENHANCED track has grown from including only 14 percent of ACOs in 2020 to 58 percent in 2026. Without the benefit of demonstrating lower actual spending growth (as found absent for ACOs migrating from BASIC to ENHANCED from 2022 to 2024 relative to those remaining in BASIC—as noted previously in this section), the existing ENHANCED track continues to appear to be overly generous relative to the incentives that are more efficiently provided to ACOs participating in the BASIC track.

The first impact estimate in this section assesses the coordinated set of provisions to rebalance the incentives between the BASIC track and ENHANCED track. These provisions include reducing the maximum weight used in calculating the positive regional adjustment for lower-spending ACOs under the ENHANCED track from 50 percent to 35 percent, increasing the prior savings adjustment's scaling factor from 50 percent to 75 percent, and increasing the shared savings rate for BASIC track Level E from 50 percent to 60 percent. A stochastic modeling approach consistent with the regulatory impact analysis from previous rules was employed to simulate the impact this set of provisions would have on existing ACOs and potential new ACOs over the 10-year scoring period. The changes will reduce the propensity for ACOs to be able to passively earn shared savings at the highest sharing rate by solely relying on baseline efficiency through the regional adjustment to the benchmark and instead will place a stronger incentive on generating new efficiency over the agreement period. New efficiency will also be incentivized by the increase in the prior savings adjustment's scaling factor. That change, combined with the higher sharing rate in BASIC track Level E, will likely attract a greater number of new ACOs serving populations that often have high spending at baseline relative to the regional average. The increase to the prior savings adjustment scaling factor would strengthen the degree that such higher spending ACOs would continue to share in savings originally made in their first agreement period despite then facing rebasing into a subsequent agreement period—a dynamic further enhanced by the policy to risk adjust the cap on benchmark adjustments (currently defined as 5 percent of unadjusted national average assignable per capita spending). These policies are together estimated to better allocate shared savings payments to ACOs, creating new gains in efficiency as opposed to ACOs merely maintaining their historical baseline efficiency, and resulting in $4.59 billion lower spending over 10 years, ranging from $6.42 billion lower spending to $2.88 billion lower spending at the 10th and 90th percentiles, respectively. The annual and 10-year total projections for the changes to Shared Savings Program participation options are detailed in Table D–B7.

[425] Additional analysis for the role that benchmark adjustments have in generating increased payments to ACOs, including ENHANCED ACOs in particular, is included in comment response in Section III.G.5.c.(2).(b).

TABLE D-B7: PROJECTED IMPACT OF FINANCIAL METHODOLOGY PROVISIONS TO REDUCE THE REGIONAL ADJUSTMENT WEIGHTING FOR ENHANCED TRACK ACOS, INCREASE SHARING RATE FOR BASIC TRACK LEVEL E, AND INCREASE THE PRIOR SAVINGS ADJUSTMENT PERCENTAGE ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	−580	−650	−720	−850	−980	−100	−140	−170	−190	−210	**−4,590**
Estimate Range:											
Low Estimate (10th Percentile)	−730	−810	−930	−1,150	−1,310	−300	−380	−420	−480	−510	**−6,420**
High Estimate (90th Percentile)	−450	−480	−510	−560	−680	100	70	70	70	100	**−2,880**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The second area of material impact on program spending is for the creation of a growth adjustment to incentivize new participation among providers and suppliers that have not been part of a Medicare ACO within the past 5 years. As described in sections III.G.5.a and III.G.5.f of this final rule, participation in the Shared Savings Program has grown substantially since the program began in 2012, from approximately 3 million beneficiaries assigned in its first year to more than 12 million assigned beneficiaries as of January 2026. This growth has occurred alongside strong program performance; we have observed that when participation in the program increases, we see increases in both quality improvements for beneficiaries and increased savings to the Trust Funds. The Shared Savings Program has had eight consecutive years of generating savings for Medicare relative to benchmarks, with over $12 billion in total savings,[426] with an upward trend in savings year over year. (As noted previously in this discussion, these savings measured by benchmarks are reasonably substantiated by lower observed per capita spending trend in markets with early ACO adoption versus higher average per capita spending trend in markets with lagging ACO adoption.) Additionally, we have observed that ACOs in the Shared Savings Program have demonstrated improved quality over time and higher quality relative to other physician groups, suggesting that the Shared Savings Program is achieving savings while improving quality of care.

This historical experience supports our expectation that expanding participation would extend the program's quality benefits to additional beneficiaries and create further opportunities for Medicare savings. The growth adjustment is part of a complementary package of modifications to the benchmark methodology intended to realign financial incentives and grow participation, thus expanding the reach of quality improvements demonstrated in the Shared Savings Program and encourage further savings.

The growth adjustment would be applied on top of the highest of the existing benchmark adjustments, including regional adjustment, prior savings adjustment, or population adjustment (if eligible), and would not exceed a risk adjusted 5 percent cap for consistency with the finalized approach to capping other upward adjustments to the historical benchmark. The policy is estimated to have the greatest impact on new ACOs that would have the greatest potential to bring in beneficiaries who have not been previously assigned to ACOs. The growth adjustment is projected to increase ACO shared savings payments by $5.3 billion over 10 years, but most of that cost would be offset by new savings on reduced benefit spending from bringing additional populations into care management under Shared Savings Program ACOs. As a result, the estimated net cost to the program is estimated to be considerably less than the increase in net sharing to ACOs. This policy is estimated to result in a net increase in spending by $1.67 billion over 10 years, with the annual increase declining in later years as savings from increased participation grow while the effect of the growth adjustment on benchmarks eventually moderates. We have observed that beneficiaries receive higher quality of care (as evidenced by ACOs' quality performance) when assigned to ACOs in the Shared Savings Program, and increasing participation in the Shared Savings Program through the growth adjustment has the potential to broaden higher quality of care to additional Medicare FFS beneficiaries. The range of uncertainty spans costs of $1.13 billion to $2.28 billion at the 10th and 90th percentiles, respectively. The annual and 10-year total projections for these provisions are detailed in Table D–B8.

[426] Additional information on past years Shared Savings Program Performance Year Finance and Quality Results is available at: *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results.*

TABLE D-B8: PROJECTED IMPACT FOR GROWTH ADJUSTMENT INCENTIVE TO ENCOURAGE NEW PARTICIPATION ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	290	270	310	320	330	20	10	30	50	40	**1,670**
Estimate Range:											
Low Estimate (10th Percentile)	240	210	250	300	300	-60	-120	-100	-80	-70	**1,130**
High Estimate (90th Percentile)	330	270	380	370	420	140	120	120	150	160	**2,280**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The third portion of our impact estimate is for the changes to beneficiary assignment, including removing from assignment calculations allowed charges for primary care services billed through a non-ACO TIN by an ACO professional used in assignment, and modifying regulatory criteria that exclude from eligibility for assignment Medicare FFS beneficiaries with any months of Part A only or Part B only enrollment, or Medicare or group health plan enrollment (including MA) during the assignment window. These changes would marginally increase the number of beneficiaries assigned to a given ACO. More importantly, they would improve the ability for the program to hold ACOs accountable for more of the patients actually served by ACO clinicians, including those with accentuated need for care management. The first policy would reduce the ability for an ACO, through billings for primary care services by ACO professionals used in assignment, to ''lemon drop''—a potential form of gaming where patients with high needs are purposefully billed services through a TIN external to the ACO to engineer their assignment away from the ACO. The second policy helps reduce a notable blind spot in the current assignment methodology. As enrollment in Medicare Advantage (MA) has grown over recent years, so has the number of beneficiaries switching back to OM from MA—a population that the revised assignment criteria would more nimbly pick up for inclusion in ACO assignment. This provision would also improve the symmetry in assignment for ACOs relative to the national and regional assignable populations because the Shared Savings Program does not currently employ the same exclusions based on Medicare enrollment status for identifying the assigned and assignable populations. Together these provisions are estimated to reduce program spending by $2.3 billion over 10 years, ranging from $2.97 billion to $1.69 billion savings at the 10th and 90th percentiles, respectively. Savings from these changes could effectively be materially higher if gaming of assignment were to otherwise significantly grow in popularity at baseline.

TABLE D-B9: PROJECTED IMPACT FOR CHANGES TO ASSIGNMENT METHODOLOGY ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	−380	−280	−220	−200	−200	−300	−230	−190	−160	−140	**−2,300**
Estimate Range:											
Low Estimate (10th Percentile)	−410	−330	−300	−300	−320	−410	−350	−320	−310	−290	**−2,970**
High Estimate (90th Percentile)	−350	−230	−140	−100	−80	−210	−120	−80	−10	−20	**−1,690**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The last provision estimated to have a material impact on spending is the change to the methodology for the ACPT. The current policy includes a discretionary option for CMS to reduce the weight on the ACPT's contribution to the three-way blended update to ACO benchmarks if unforeseen circumstances arise. The finalized changes would create uniform annual one-year growth projections common to ACOs in overlapping agreement periods—eliminating reliance on multi-year projections that the ACPT currently employs—and a policy that, for agreement periods beginning on or after January 1, 2027, would limit the effect of under-projection or over-projection as compared to actual retrospective national expenditure trend such that an effective ACPT trend (cumulatively from BY3 to a given performance year) is no more than one percentage point below (or no more than 1.5 percentage points above) national growth. The asymmetry of these guardrails preserves a limited degree of margin related to the ideal scenario where ACOs as a group cause national trend to slow relative to projected trend over the course of a given agreement period, but more importantly has several notable advantages relative to the current methodology with potential down-weighting. It protects the validity of benchmark updates by limiting how far

the projected trend used in the ACPT portion of the three-way blended update factor would be allowed to deviate from observed national trend, and does so under an objective formula that eliminates the subjectivity of the current down-weighting policy that could otherwise potentially be invoked to a greater degree in years where down-weighting would favor ACOs as opposed to public pressure to maintain the one-third weighting in years where over-projection could favor ACOs. The policy would also improve on the current down-weighting policy because it would preserve the role of national trend in the overall update, which can help preserve the incentive for neighboring ACOs to collectively lower spending in their overlapping service area (an outcome that down-weighting would penalize by increasing the effective weighting on regional trends in calculating benchmark updates). Despite estimating higher spending in 2027 and 2028 related partly to our separate finalized policy to only apply the lower 1.0 percentage point threshold for ACOs in existing agreement periods, the total impact over ten years is estimated to be a savings of $350 million, ranging from a $1.11 billion savings to a $340 million cost at the 10th and 90th percentiles, respectively. The estimates are shown in Table D–B10:

TABLE D-B10: PROJECTED IMPACT FOR CHANGES TO ACPT AND ASSOCIATED GUARDRAILS ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	130	70	−10	−50	−70	−80	−90	−90	−80	−70	**−350**
Estimate Range:											
Low Estimate (10th Percentile)	−60	−40	−90	−140	−200	−250	−290	−300	−200	−190	**−1,110**
High Estimate (90th Percentile)	350	200	80	10	20	30	30	40	20	30	**340**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The remaining changes to the Shared Savings Program regulations, as described in section VI.A.2.a. of this final rule, are not estimated to have an impact on program spending at the aggregate level.

The policies detailed previously in this section are expected to increase assignment to ACOs in the program by 0.5 to 1.0 million beneficiaries on average per year. The combined impacts from all Shared Savings Program provisions on federal spending are shown in Table D–B11. Because estimates are rounded to the nearest $10 million, and because the percentiles are independently sorted for each year and for the 10-year totals, the annual estimates may not sum to exactly match the total 10-year estimates. Together these policies are estimated to reduce program spending by $5.5 billion over 10 years, ranging from $8.9 billion to $2.3 billion savings at the 10th and 90th percentiles, respectively.

TABLE D-B11: PROJECTED IMPACT OF MEDICARE SHARED SAVINGS PROGRAM PROVISIONS (INDIVIDUALLY SHOWN IN TABLES D-B8 THROUGH D-B11) ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	−580	−640	−690	−830	−960	−410	−400	−360	−330	−340	**−5,550**
Estimate Range:											
Low Estimate (10th Percentile)	−970	−1,010	−1,090	−1,280	−1,510	−920	−980	−970	−890	−910	**−8,870**
High Estimate (90th Percentile)	−180	−300	−300	−400	−420	40	80	130	160	190	**−2,310**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The policies are expected to both decrease and increase net shared savings payments across the overall distribution of ACOs. The mean projection is an overall increase in such payments by $1.05 billion over 10 years, ranging from a $2.6 billion decrease to a $4.63 billion increase at the 10th and 90th percentiles, respectively. The increase in shared savings payments to ACOs is driven by the growth adjustment policy, and without this policy the majority of savings to Medicare would be achieved through reductions in shared savings payments. Annual and total projections for the impact on shared savings net of shared losses are shown in Table D–B12.

TABLE D-B12: PROJECTED IMPACT OF MEDICARE SHARED SAVINGS PROGRAM PROVISIONS ON SHARED SAVINGS PAYMENTS TO ACOS ($ MILLIONS; POSITIVE VALUES REPRESENT INCREASED NET PAYMENTS TO ACOS)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	−220	−230	−200	−260	−300	270	350	450	560	640	**1,050**
Estimate Range:											
Low Estimate (10th Percentile)	−620	−560	−580	−700	−900	−220	−210	−150	10	50	**−2,600**
High Estimate (90th Percentile)	210	130	200	180	230	720	850	990	1,060	1,180	**4,630**

b. Compliance With Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and the new policies described in this rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following finalized policies require the use of our authority under section 1899(i) of the Act: modifications to the ACPT component of the three-way blended benchmark update factor (described in section III.G.5.g. of this final rule); discontinuing availability of the option for prepaid shared savings (described in section III.G.6.b. of this final rule); and changes to the calculation methodology for quarterly advance investment payments (described in section III.G.7. of this final rule). When considered together, these changes to the Shared Savings Program are expected to improve the quality and efficiency of items and services furnished under the Medicare program by improving the accuracy of the benchmark update factor and strengthening financial incentives under the Shared Savings Program, decreasing administrative burden and conserving resources by discontinuing the availability of the prepaid shared savings option given low uptake and anticipated limited participation, and simplifying the calculation of quarterly amounts of advance investment payment (for eligible ACOs) while encouraging ACO formation in rural areas. These changes are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies we have adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

In the CY 2023 PFS final rule (87 FR 70195 and 70196), we estimated that the projected impact of the payment methodology that incorporates all policies finalized by that final rule would result in $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excluded the policies that we have enacted relying on the authority of section 1899(i)(3) of the Act. The marginal impact of the changes in the CY 2024 PFS final rule (88 FR 79496) were estimated to lower net spending by $330 million over the subsequent 10-year period (2024 through 2033) for all new policies combined. The marginal impact of the changes in the CY 2025 PFS final rule (89 FR 98527) were estimated to lower net spending by an additional $200 million in total through 2034. The marginal impact of the changes in the CY 2026 PFS final rule (90 FR 49978) were estimated to be a $20 million reduction in net spending through 2035. The marginal impact of the changes in this final rule is estimated to be $5.5 billion reduction in net spending through 2036. The incremental changes have been estimated to improve program financial savings since the CY 2023 PFS final rule, and hence the cumulative impact of all policies (including those in this rule) is estimated to result in more than the previously-estimated $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excludes the policies we have enacted relying on section 1899(i)(3) of the Act as authority. Therefore, we estimate that program expenditures associated with the implementation of the provisions in this final rule, in combination with other policies associated with the statutory payment model and current policies we have adopted under the authority of section 1899(i)(3) of the Act, are expected to improve the quality and efficiency of items and services furnished under the Medicare program and would not be expected to increase program expenditures relative to those of the statutory payment model.

We will continue to reexamine this projection in the future to ensure that an alternative payment model does not result in additional program expenditures and so continues to satisfy the requirement under section 1899(i)(3)(B) of the Act. Additional Shared Savings Program data accumulating after the end of the PHE for COVID–19, along with emerging information on the characteristics of, and performance trends for, new entrants in the Shared Savings Program for agreement periods beginning on January 1, 2024, January 1, 2025, and January 1, 2026, are anticipated to gradually improve our ability to reevaluate program impacts in a comprehensive fashion. If we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we will undertake notice and comment rulemaking to adjust the payment model to ensure continued compliance with the statutory requirements.

9. Impacts Related to the Ambulance Fee Schedule

As outlined in section III.H.2. of this final rule, section 6203 of the Consolidated Appropriations Act, 2026 amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons sets forth in those sections through December 31, 2027. The ambulance extender provisions are enacted through legislation that is self-implementing. We are finalizing our proposals to revise dates at § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self—implementing statutory requirements.

A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there are no policy proposals associated with these legislative provisions. We have estimated the cost of these provisions to be $260 million over the 10-year period and the Congressional Budget Office (CBO)'s estimated cost of these provisions was $52 million in FY 2026, $111 million in FY 2027, and $34 million in FY 2028 with minimal costs for the remaining years of this 10- year period, resulting in a net effect of $197 million from FY 2026 to FY 2035 (*https://www.cbo.gov/system/files/2026-01/hr7148-CAA-2026.pdf,* page 4).

As discussed in section III.H.4., of this final rule, we are finalizing our proposal to make use of the revised OMB delineations as set forth in the July 21, 2023 OMB Bulletin No. 23–01 and the most recent modifications of the RUCA codes for purposes of payment under the AFS. By adopting OMB's revised delineations and the updated RUCA codes, ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be Micropolitan or otherwise outside of MSAs based on OMB's revised delineations or in a rural census tract of an MSA based on the updated RUCA codes (but are currently within urban areas) may experience increases in payment for such transports because they may become eligible for the rural adjustment factors discussed previously, while those ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be urban based on OMB's revised delineations and the updated RUCA codes (but are currently in Micropolitan Areas or otherwise outside of MSAs, or in a rural census tract of an MSA) may experience decreases in payment for such transports because they would no longer be eligible for the rural adjustment factors discussed previously.

The use of the revised OMB delineations and the updated RUCA codes would mean the recognition of new urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2010 and 2020. As discussed previously in this section, we are finalizing our proposal to use the updated 2020 RUCA codes to identify rural census tracts within MSAs, such that the census tracts falling at or above RUCA level 4.0 would continue to be designated as rural areas.

Based on our analysis, the geographic designations for approximately 95.87 percent of ZIP codes would be unchanged by using OMB's revised delineations and the updated RUCA codes. There are more ZIP codes that would change from urban to rural (1,172, or 2.73 percent) than rural to urban (602, or 1.40 percent). In general, it is expected that ambulance providers and suppliers in 1,172 ZIP codes within 47 States and Puerto Rico may experience payment increases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from urban to rural. The State of Maryland would have the highest percentage oft ZIP codes changing from urban to rural with a total of 49, or 7.78 percent. Ambulance providers and suppliers in 602 ZIP codes within 43 States may experience payment decreases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from rural to urban. The State of South Carolina would have the highest percentage of ZIP codes changing from rural to urban (20, or 3.68 percent). Adoption of the revised OMB delineations and the updated RUCA codes would have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the revised OMB delineations and the updated RUCA codes. We estimate that the adoption of the revised OMB delineations and the updated RUCA codes will have a minimal fiscal impact on the Medicare program.

We did not receive any public comments on the impact section for the Ambulance Fee Schedule. As stated previously, we are finalizing our proposals to revise dates at § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self—implementing statutory requirements. We are also finalizing our proposal to make use of the revised OMB delineations as set forth in the July 21, 2023 OMB Bulletin (No. 23–01 and the most recent modifications of the RUCA codes to recognize levels of rurality in census tracts falling at or above RUCA code level 4.0 as rural areas for purposes of payment under the AFS.

10. Impacts Related to the Quality Payment Program

In this section of the final rule, we estimate the impacts of the Quality Payment Program policies. We estimate participation, final scores, and payment adjustments for eligible clinicians participating through MIPS, the Advanced APMs, and MVPs. For Advanced APMs, we estimate the impacts on the number of Qualified Participants (QPs) that are associated with our policies.

a. Overall Impact Modeling Approach and Data Assessment

(1) MIPS Impact Modeling Approach

For this final rule, we used a similar modeling approach as the CY 2026 PFS final rule (90 FR 49266 through 50481). We created two MIPS impact models: a baseline and a policies model. Our baseline model includes previously finalized policies that are still in effect for the CY 2027 performance period/ 2029 MIPS payment year and in the absence of any of the new policies in this rule. Examples of previously finalized policies included in the baseline model are revised administrative claims quality measure benchmarking methodology, modifications to the Total Per Capita Cost measure, and removal of the topped-out measure scoring cap and application of the defined topped out measure benchmarks to 19 quality measures identified for CY 2026 performance period/2028 MIPS payment year. Please refer to CY2026 PFS final rule for a comprehensive, detailed discussion of finalized policies (90 FR 49266).

The policies model builds on the baseline model and incorporates the new MIPS policies we proposed for the CY 2027 performance period/2029 MIPS payment year included in this final rule. By comparing the baseline model to the policies model, we are able to estimate the impact of the policies in this final rule.

Our modeling approach utilizes the same scoring engine that is used to determine MIPS payment adjustments. This approach enables our model to align as much as possible with actual MIPS scoring

(2) Data Used to Estimate Future MIPS Performance

In the CY 2026 PFS proposed and final rules, we used data from performance year 2023 to construct baseline and policies model simulations. For this proposed and final rule, we used data from performance year 2024. This is the most recent available data and reflects our most up-to-date information on program participation, final scores, and payment adjustments.

b. APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

Beginning with QP Performance Period 2017 (payment year 2019), through the Medicare Option, eligible clinicians who are determined to have

a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs are QPs for the applicable QP performance period and the corresponding payment year. In payment years 2019 through 2024, these QPs received a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for covered professional services furnished during the base year (the calendar year immediately preceding the payment year). In payment year 2025, eligible clinicians who attained QP status for QP Performance Period 2023 will receive a lump-sum APM Incentive Payment equal to 3.5 percent of their estimated aggregate paid amounts for covered professional services furnished during CY 2024. In payment year 2026, eligible clinicians who attained QP status in QP Performance Period 2024 will receive a lump-sum APM Incentive Payment equal to 1.88 percent of their estimated aggregate paid amounts for covered professional services furnished during CY 2025. In payment year 2028, eligible clinicians who attained QP status in QP Performance Period 2026 will receive a lump-sum APM Incentive Payment equal to 3.1 percent of their estimated aggregate paid amounts for covered professional services furnished during CY 2027.

Beginning with QP Performance Period 2019 (payment year 2021), in addition to the Medicare Option, the All-Payer Combination Option also affords eligible clinicians an opportunity at QP status. The All-Payer Combination Option allows eligible clinicians to become QPs by assessing a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a given QP Performance Period are not subject to MIPS reporting requirements and payment adjustments for the contemporaneous MIPS performance period/payment year. Eligible clinicians who do not become QPs but meet a lower threshold requirement to become Partial QPs for the year may elect to (or not to) report to MIPS. If they elect to report, they are subject to MIPS scoring and payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status and is not excluded from MIPS on another basis, the eligible clinician will be subject to the MIPS reporting requirements and will receive the corresponding MIPS payment adjustment.

Separately from the APM Incentive Payment, beginning in payment year 2026, there are two separate PFS CFs—one for QPs for the year (the qualifying APM CF), and the other for all non-QP eligible clinicians and other suppliers paid under the PFS (the nonqualifying APM CF). The update to the qualifying APM CF for a year is 0.75 percent, whereas the update to the non-qualifying APM CF for a year is 0.25 percent. Such updates produce approximately a 0.5 percent difference in the two conversion factors each year.

The thresholds to achieve QP status in the 2027 QP Performance Period (2029 payment year) are set to 75 percent for the payment amount, and 50 percent for the patient count. Overall, we estimated that for the 2026 QP Performance Period, between 517,800 and 530,900 eligible clinicians will become QPs, and therefore will be excluded from MIPS reporting requirements and payment adjustments.

In the CY2026 PFS final rule, we finalized our proposal to use two new definitions, ''Covered professional service attribution-eligible beneficiary'' and ''E/M attribution-eligible beneficiary'' such that we conduct two determination calculations, one that includes any beneficiary who has received a covered professional service furnished by the eligible clinician (NPI) for whom we are making the QP determination and one that continues to use Evaluation and Management services furnished by the eligible clinician (NPI) for whom we are making the QP determination. We also finalized our proposal to add a QP determination at the individual level for all Advanced APM participants, beginning with the 2026 QP Performance Period.

We project the number of eligible clinicians who will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2027 QP Performance Period. The following APMs are expected to be Advanced APMs for the 2027 QP Performance Period:

- Enhancing Oncology Model (EOM);
- Kidney Care Choices Model (Comprehensive Kidney Care Contracting Options, Professional Option and Global Option);
- Long Term Enhanced ACO Design (LEAD) Model;
- Medicare Shared Savings Program (Level E of the BASIC Track and the ENHANCED Track);
- States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model; and
- Transforming Episode Accountability Model (TEAM).

We used the Participation Lists and Affiliated Practitioner Lists, as applicable (see § 414.1425(a) for information on the APM Participant Lists used for QP determinations) for the 2024 QP performance period third snapshot QP determination date to estimate the number of QPs for the 2027 QP Performance Period. For models starting in the 2027 QP Performance Period we estimated performance based on projected participation. We examined the extent to which Advanced APM participants will meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries were attribution eligible thresholds.

c. Estimated Number of MIPS Eligible Clinicians in the CY 2027 Performance Period/2029 MIPS Payment Year

(1) Initial Population of Clinicians Included in the RIA Baseline and Policies Models

For this final rule, we applied the same assumptions as in the CY 2026 PFS final rule (90 FR 49980) to estimate our initial population of clinicians using 2024 performance data. Specifically, we used the CY 2024 final reconciled eligibility determination file, same as the 2023 file described in the CY 2026 PFS final rule (90 FR 49980). This file reconciles eligibility from two determination periods and aligns with the CY 2024 performance period submissions data on which we based this model. Our analysis included 1,984,786 clinicians with PFS claims in this initial population. This initial population of clinicians was used to determine eligibility using the methodology described in the following sections.

(2) Estimated Number of MIPS Eligible Clinicians After Applying Eligibility Assumptions

(a) Methods and Assumptions Used To Estimate Eligibility

After identifying the clinician population with PFS claims, we applied the same eligibility assumptions and determination process described in the CY 2026 PFS final rule (90 FR 49980). We did not propose any modifications to MIPS eligibility requirements and the same eligibility assumptions apply to both the baseline and policies model.

For our impact analysis, we established the ''required eligibility''

category, which means the clinician exceeds the low-volume threshold in all three criteria (§§ 414.1305 and 414.1310 (b)(1)(iii)) and is subject to a MIPS payment adjustment. We based this estimate on the CY 2024 performance period data described in this section of the final rule, which includes the three low-volume criteria.

Our next two eligibility assumptions concern clinicians participating in MIPS through groups. They may voluntarily participate in MIPS but are not required to participate. First, our group eligibility, includes clinicians with a group submission, and their group exceeds all three low-volume threshold criteria. Second, we apply our opt-in eligibility assumptions. Individuals or groups who exceed the low-volume threshold in at least one criterion, but not all three, may elect to opt in. Based on the number of individuals who opted in to MIPS in performance year 2024, our model estimates that these clinicians will continue to opt in to MIPS in CY2027 performance period/ 2029 MIPS payment year.

Additionally, we estimate the number of ''Potentially MIPS Eligible'' clinicians. These clinicians are not included in our total number of MIPS eligible clinicians. These clinicians are potentially eligible because they are either opt-in eligible but did not opt-in or group eligible but did not report.

Finally, we estimate the number of clinicians who are neither MIPS eligible nor potentially MIPS eligible. They include clinicians who are below all three low-volume threshold criteria (both as an individual and as a group), QPs, and clinicians excluded from MIPS for other reasons, such as those with a non-MIPS-eligible clinician type or newly enrolled in Medicare

After applying these assumptions to our initial population, we estimate that there will be 586,925 MIPS eligible clinicians with ~$51.70 billion in allowed charges in the CY2027 performance period/2029 MIPS payment year.

(b) MIPS Eligibility Estimates

In our policies model, we estimate to have 586,925 MIPS eligible clinicians Table D–B13 summarizes our eligibility estimates for the policies model after applying our assumptions outlined in this section of the final rule.

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TABLE D-B13: ESTIMATION OF MIPS ELIGIBILITY STATUS FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR USING THE CY 2027 PFS FINAL RULE ASSUMPTIONS

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians	Number of Clinicians	PFS allowed charges ($ in mil)[1]
MIPS Eligible Clinicians			
MIPS eligible (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Reported to MIPS	94,895	$28,668
	Did not Report to MIPS	36,898	$11,100
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	451,654	$11,710[2]
Subgroup Eligible	MVP Subgroup reporting	286	$14
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS)	Opted-in To MIPS	3,192	$204
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**586,925**	**$51,695**
Potentially MIPS Eligible Clinicians			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Opt-in Eligible; Do not opt-in	176,361	$5,594
	Group Eligible; Did not Report	497,433	$11,590
Total Number of Clinicians Potentially MIPS Eligible		673,794	$17,184
Not MIPS Eligible Clinicians			
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	130,199	$807
Excluded for other reasons (Non-eligible clinician type, newly enrolled)	Not applicable	91,962	$635
Qualified Participant (QP)	Not applicable	501,906	$23,259
Total Number of Clinicians Not MIPS Eligible		724,067	**$24,701**
Total Number of Clinicians Not MIPS Eligible or Potentially MIPS Eligible But Did Not Opt-in/Report		1,397,861	**$41,885**
Total Number of Clinicians (MIPS, Potentially, and Not MIPS Eligible)		**1,984,786**	**$93,580**

[1]Allowed charges estimated in 2024 dollars and projected to 2029 dollars (payment year. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

[2]Most clinicians are represented by Group submissions yet are below LVT and have low allowed charges.

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d. Modeling Approach and Methods for MIPS Value Pathways (MVPs) and Traditional MIPS

(1) Summary of Approach

In this final rule, we present several proposals that impact the measures and activities, the performance category scores, final scores, and MIPS payment adjustments for MIPS eligible clinicians. In section IV.A. of this final rule, we outline these changes in more detail and describe our methodology to estimate MIPS payment adjustments for the CY 2027 performance period/2029 MIPS payment year. We then present the impact of the policies in the CY 2027 performance period/2029 MIPS payment year by comparing select metrics to the baseline model. By comparing model outputs between the baseline model and the policies model, we are able to observe the impact of the

policies for the CY 2027 performance period/2029 MIPS payment year. MIPS eligible clinicians' final scores are calculated based on the clinicians' performance on measures and activities specified under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS eligible clinicians can participate in the four MIPS performance categories as an individual, group, virtual group, APM Entity, and via traditional MIPS, the APM Performance Pathway (APP), or MVP reporting options. MIPS APM participants who are ACOs participating in the shared saving program are required to report through the APP/APP Plus measure set. The APP or APP Plus reporting option only scored on three performance categories: quality, improvement activities, and Promoting Interoperability. Our simulation applies the finalized and baseline policies to the existing scoring engine.

(2) Methodology To Assess Impact for MIPS Value Pathways

At § 414.1365(b), we require MVP Participants (which can be a group, individual, subgroup, or APM entity) to register to report a particular MVP prior to submitting. We assessed whether to use 2024 MVP registration data to estimate MVP participation and policy impact but elected not to simulate the impact for MVP because we do not have sufficient MVP scoring data for modeling and simulation. Thus, modeling based on limited data is less reliable for impact assessment. As more MVP scoring data becomes available in the future, we will reassess our methodology for estimating MVP participation, final scores, and payment adjustments.

(3) Methodology To Assess Impact for Traditional MIPS

To estimate the impact of the policies on MIPS eligible clinicians, we use the data from performance year 2024, including data submitted for the quality, cost, improvement activities, and Promoting Interoperability performance categories and claims data for the cost performance category.

We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, administrative claims data for certain quality measures, and other data sets. For the CY 2027 performance period/2029 MIPS payment year, we calculate hypothetical final scores for the baseline and policies models for each MIPS eligible clinician by applying appropriate measure level, performance category, and final scoring policies.

(a) Methodology To Estimate the Quality Performance Category Score

We used the CY 2026 PFS final rules as the starting point of our baseline model (90 FR 49982). This includes our policies regarding the new benchmark for Administrative Claims measures and scoring topped out measures impacted by limited measure choice. Please refer to the CY 2026 PFS final rule for a comprehensive, detailed discussion of finalized policies (90 FR 49266).

Our policies model incorporates the following policies from this final rule:

- In section IV.B.1.b.(3) of this final rule, to facilitate fairer scoring, we proposed to remove the scoring cap and change the benchmarking approach for additional topped out measures applicable to clinicians facing both limited measure choice and limited scoring opportunities as well as MIPS Core Measures. We do not simulate the addition or removal of quality measures outlined in section IV.A.4.d.(1) of this final rule because current data from the CY 2024 performance period do not include new measures, and we cannot estimate the impact of removing measures since we are not able to predict clinician response in measure selections.

In section IV.B.1.b.(1) of this final rule, we proposed to remove the requirement to submit one outcome or high priority measures and instead require the submission of a MIPS Core Measure. We proposed that small practices with no more than 15 clinicians would be exempt from the MIPS Core Measure requirement. CMS internal analysis found 57 percent of the MVP submissions in performance year 2024 did not contain any of the MIPS Core measures. Modeling quality performance category score with insufficient historical submission data will introduce uncertainty and complexity to the modeling simulation. Working under this limitation, we believe the previous outcome/high-priority reporting requirement and scoring rules reflected in the performance year 2024 data can serve as a proxy for core measure reporting in the models. As a result, we do not simulate the MIPS Core Measure reporting policy. We did, however, model the impact of the core measure exemption for small practices.

(b) Methodology To Estimate the Cost Performance Category Score

We estimate the cost performance category score using the same methodology as described in the CY 2026 PFS final rule (90 FR 49982) for the baseline and the policies models.

We do not model the impact of the Acute Kidney Injury requiring New Inpatient Dialysis (AKI) measure because it was suppressed for the CY 2024 performance period/2026 MIPS payment year. Therefore, there was no performance data available in 2024 to model the impact of the Acute Kidney Injury requiring New Inpatient Dialysis (AKI) measure

(c) Methodology To Estimate the Promoting Interoperability Performance Category Score

We estimate the Promoting Interoperability performance category score using the same methodology as described in the CY 2026 PFS final rule (90 FR 49982) for the baseline model and the policies models.

For the policies model, we simulate the following changes:

In section IV.A.4.d.(4) of this final rule, we proposed the removal of three attestations in the Promoting Interoperability performance category: ONC Direct Review, ONC–ACB Surveillance, and Security Risk Analysis.

(d) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline model, we use the same method to estimate the improvement activities performance category score as described in the CY 2026 PFS final rule (90 FR 49983), including alignment with the clarification provided regarding IA automatic weighting for APM participants (89 FR 79366).

In section IV.A.4.d.(3) of this final rule, we proposed updates to the Improvement Activities inventory, such as removing activities. There is no historical data reflecting IA inventory updates, such as activity removal, for us to estimate potential impact. Our RIA models cannot predict how clinicians will alter their behavior once activities are removed.

(e) Methodology To Estimate the Complex Patient Bonus Points

This final rule does not include policies to modify the complex patient bonus. Therefore, for the baseline and policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996).

(f) Methodology To Estimate the Final Score

We did not propose any changes to how we calculate the MIPS final score. Our baseline and policies models assign

a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For both models, after adding any applicable complex patient bonus, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

For the purposes of this model, if a MIPS eligible clinician was approved for reweighting of one or more performance categories in the baseline model according to the data from the CY 2024 performance period/2026 MIPS payment year, we continue to apply that reweighting in our policies model by assigning them a neutral score equal to the performance threshold if all categories were reweighted or assigning the applicable weights to the categories which were reweighted. Although it is unlikely (but possible) that the exact same clinicians will apply for and receive reweighting in both the CY 2024 performance period/2026 MIPS payment year (which our data is based on) and the CY 2027 performance period/2029 MIPS payment year (which we are simulating), we believe that this assumption appropriately reflects future clinician behavior for two reasons. First, while the exact same MIPS eligible clinicians may not receive reweighting in two different years, we believe that this assumption allows us to quantify the impact of the reweighting on a population level. In other words, even if the same clinicians do not apply for and receive reweighting in these two different years, the absolute number of reweighting and the characteristics of practices that receive reweighting are likely to remain similar. Secondly, if we were not to assign reweighting to those MIPS eligible clinicians, many of them would receive a very low final score because they did not submit data for one or more performance categories during the year in which they received reweighting. We do not believe that it is a realistic assumption that, in the absence of reweighting, those clinicians will continue not to submit data. For these reasons, we assume that clinicians who received reweighting in the CY 2024 performance period/2026 MIPS payment year are also approved for reweighting in the CY 2027 performance period/2029 MIPS payment year. These clinicians are assigned a score of the performance threshold (75) in our model because this corresponds with a neutral (0 percent) payment adjustment.

(g) Methodology To Estimate the MIPS Payment Adjustment

For the baseline and policies models, we applied the hierarchy as finalized in the CY 2024 PFS final rule (86 FR 65536 through 65537) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We then calculate the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, and minimum and maximum adjustment percentages.

For the baseline model, we apply the performance threshold of 75 points finalized in the CY 2026 PFS final rule. In this final rule, we do not make any changes to the performance threshold. Therefore, for both the baseline and policies models, we use a performance threshold of 75 to calculate the exchange function for MIPS payment adjustments. We note that the results of this exchange are not identical between the baseline and policies models. This is because the scaling factor used to determine positive adjustments is dependent on the total dollar amount of negative payment adjustments, and those adjustments differ as final scores are not identical between both models.

For both the baseline and policies models, we use these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Methodology To Assess Impact for APM Performance Pathways

Shared Savings Program Accountable Care Organizations, participating in MIPS through a MIPS APM are scored on performance in the quality, Promoting Interoperability, and Improvement Activities performance categories. We included the following previously finalized policies for SSP ACOs participating in a MIPS APM into the CY 2027 baseline model:

- In 2024, the CMS Web Interface continued to be a collection type available to Shared Savings Program Accountable Care Organizations (SSP ACOs) reporting under the Advanced Payment Pathway. Because our model simulation relies on data from performance year 2024, including CMS Web Interface submissions, we are unable to predict which collection type SSP ACOs will adopt in lieu of the web interface for CY 2027 performance period/2029 MIPS payment year, given that the Web Interface collection type was no longer available after the CY 2025 performance period/2027 MIPS payment year.

We do incorporate the following policies into the policies model:

- In section IV.B.1.c.(1) of this final rule, we proposed to score all Medicare CQMs using flat benchmarks retroactively beginning in CY 2026.

(5) Simulation Results and Projected Impact to MIPS Eligible Clinicians

Based on the methodology described in section VII.F.11.d(3) of this final rule, we create a baseline and policies simulation. Using this simulation, we estimate the impact of the policies of this final rule.

(a) Impact on Clinician Eligibility

In section VII.F.11.(c) of this final rule, we noted that we do not modify clinician eligibility and therefore there is no difference in the total number of MIPS eligible clinicians between our models.

(b) Impact on Clinician's Final Scores for Traditional MIPS

Table D–B14 shows the median final score by practice size and the percentage of MIPS eligible clinicians of each practice size with a positive, neutral, or negative adjustment.

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TABLE D-B14: CY 2027 FINAL SCORE ESTIMATES BY PRACTICE SIZE

Practice Size[1]	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate[2]	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
(1) Solo	15,427	75.00	34.98	26.27	38.75
(a) Reporting	7,326	89.61	73.66	9.00	17.35
(b) Non-Reporting[3]	8,101	24.7	0.00	41.90	58.10
(2) Small (2 to 15)	60,634	87.98	67.60	14.84	17.36
(a) Reporting	47,596	91.35	86.37	4.02	9.62
(b) Non-Reporting[4]	13,040	75	0.04	54.33	45.64
(3) Medium (16 to 99)	115,077	88.63	89.91	7.17	11.92
(4) Large (100+)	395,787	89.20	94.19	1.67	4.14
Overall	586,925	88.83	87.30	4.76	7.94
Policies					
(1) Solo	15,427	75.00	34.77	26.28	38.95
(a) Reporting	7,325	90.23	73.23	9.00	17.77
(b) Non-Reporting	8,101	24.70	0.00	41.90	58.10
(2) Small (2 to 15)	60,634	88.61	67.65	14.83	17.52
(a) Reporting	47,596	91.84	86.17	4.01	9.82
(b) Non-Reporting	13,040	75	0.04	54.33	45.64
(3) Medium (16 to 99)	115,077	89.14	81.08	7.14	11.78
(4) Large (100+)	395,787	89.48	94.80	1.63	3.57
Overall	586,925	89.21	87.73	4.72	7.55

[1]Practice size refers to the number of NPIs in a TIN

[2]The median final score includes clinicians who receive reweighting for all MIPS performance categories our policies at § 414.1380(c)(2). These clinicians who have all performance categories reweighted are assigned a score of 75 (neutral payment adjustment) in our model.

[3]52.51% of the solo practitioners did not report by not submitting any data

[4]21.51% of the small practice providers did not report by not submitting any data

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MIPS performance and financial distribution remain stable with marginal improvements in the overall median final scores and slightly higher overall percentage of clinicians receiving a positive payment adjustment. The overall median final score is 88.83 in the baseline model and 89.21 in the policies model, a slight increase for all practice sizes. About 87.3 percent of eligible clinicians receive a positive payment adjustment in the baseline model and 87.73 percent in the policies model Overall, the percentage of eligible clinicians with negative payment adjustment will drop slightly, from 7.94 percent baseline to 7.55 percent policies.

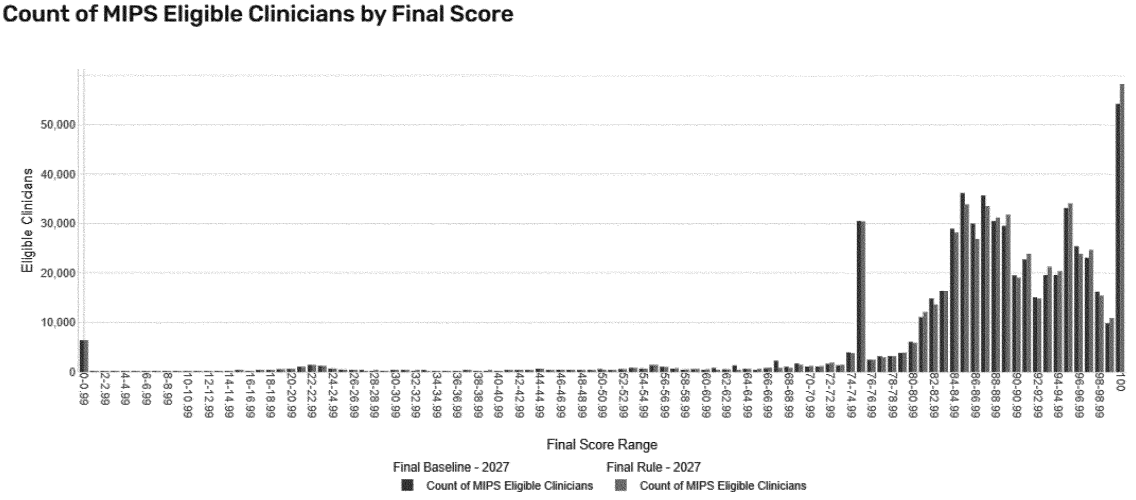
Table D–B15 shows the median quality category score for MIPS eligible clinicians who are scored on the quality performance category for the baseline and policies models. Overall, the median quality performance category score showed a marginal increase from 83.16 to 83.72. Solo practitioners, who actively report, experience the most noticeable increase (+2.25) in median quality performance category score compared to those of other practice sizes.

TABLE D-B15: CY 2027 QUALITY SCORE ESTIMATES BY PRACTICE SIZE

Practice Size	MIPS Eligible Clinicians Receiving Quality Score	Total Number of MIPS Eligible Clinicians	Percent of MIPS Eligible Clinicians Receiving Quality Score	Median Quality Score Estimate
Baseline				
Solo (1)	11,289	15,427	73.18	52.61
(a) Reporting	6,602	7,326	90.12	85.95
(b) Non-reporting	4,687	8,101	57.86	0
Small (2-15)	49,995	60,634	82.45	86.31
(a) Reporting	44,043	47,594	92.54	89.15
(b) Non-reporting	5,952	13,038	45.65	0
Medium (16-99)	97,892	115,077	85.07	81.89
Large (100+)	377,846	395,787	95.47	83.29
Overall	**537,022**	**586,925**	**91.50**	**83.16**
Policies				
Solo (1)	11,288	15,427	73.17	51.91
(a) Reporting	6,601	7,325	90.12	88.2
(b) Non-reporting	4,687	8,102	57.85	0
Small (2-15)	49,999	60,634	82.46	87.93
(a) Reporting	44,047	47,596	92.54	90.63
(b) Non-reporting	5,952	13,038	45.65	0
Medium (16-99)	97,926	115,077	85.10	83.13
Large (100+)	378,001	395,787	95.51	83.72
Overall	**537,214**	**586,925**	**91.53**	**83.72**

Figure D–B1 shows the distribution of final scores for all MIPS eligible clinicians. Note that there is a noticeable size of MIPS eligible clinicians with a final score of 75. MIPS eligible clinicians whom we approved for reweighting all MIPS performance categories in accordance with our reweighting policies at § 414.1380(c)(2) are assigned a final score of exactly the performance threshold (75). Overall, the distribution is left skewed, indicating that many more clinicians would receive final scores on the higher side.

FIGURE D-B1: Count of MIPS Eligible Clinicians by Final Score



(i) Impact to Small and Solo Practices

Across both the baseline and policies models, approximately 15,427 MIPS-eligible clinicians are solo practitioners, accounting for 2.63 percent of all MIPS-eligible clinicians.

The median final score for solo practitioners who actively report data is 89.61 in the baseline model and 90.23

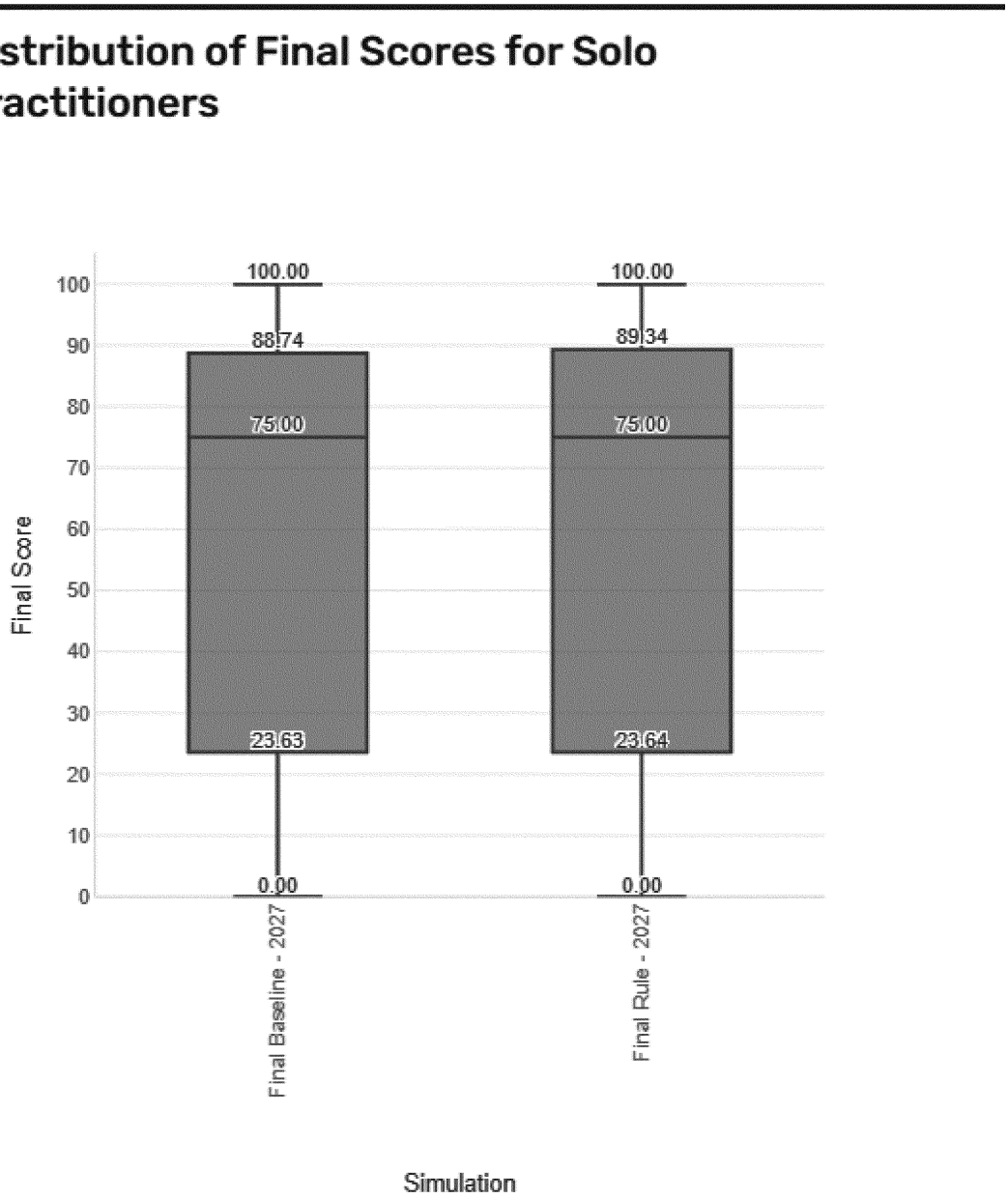
in the policies model. However, the median final scores for solo practitioners who do not report data are substantially lower: 24.7 in both baseline and policies models. The portion of all solo practitioners receiving a positive adjustment is starkly different between reporting and non-reporting solo practitioners. About 73.66 percent (baseline) and 73.23 percent (policies) reporting solo practitioners will receive a positive payment adjustment; whereas 0 percent (both baseline and policies) non-reporting solo practitioners will receive a positive payment adjustment.

Many solo practitioners do not actively submit data to MIPS despite being MIPS eligible clinicians. Based on the 2024 performance data, we estimate that about 52.51 percent of solo practitioners receiving a MIPS payment adjustment do not submit any data to MIPS.

Table D–B16 shows that, even among reporting solo practitioners, the percentage receiving a positive payment adjustment is lower than that of clinicians from small, medium, or large practices. Similarly, even for reporting solo practitioners, a higher proportion of them face negative payment adjustments compared to those in small, medium, and large practices Figure D–B2 shows the distribution of final scores for solo practitioners. Both baseline and policies box plots show identical final score distributions, and both baseline and policies models show a large distance between the lower and upper quartiles. Figure D–B3 shows the final score distribution for all MIPS eligible clinicians between the baseline and the policies models. These box plots also show identical final score distributions; however, the distance between lower and upper quartiles is substantially narrower for all MIPS eligible clinicians than it is for solo practitioners.

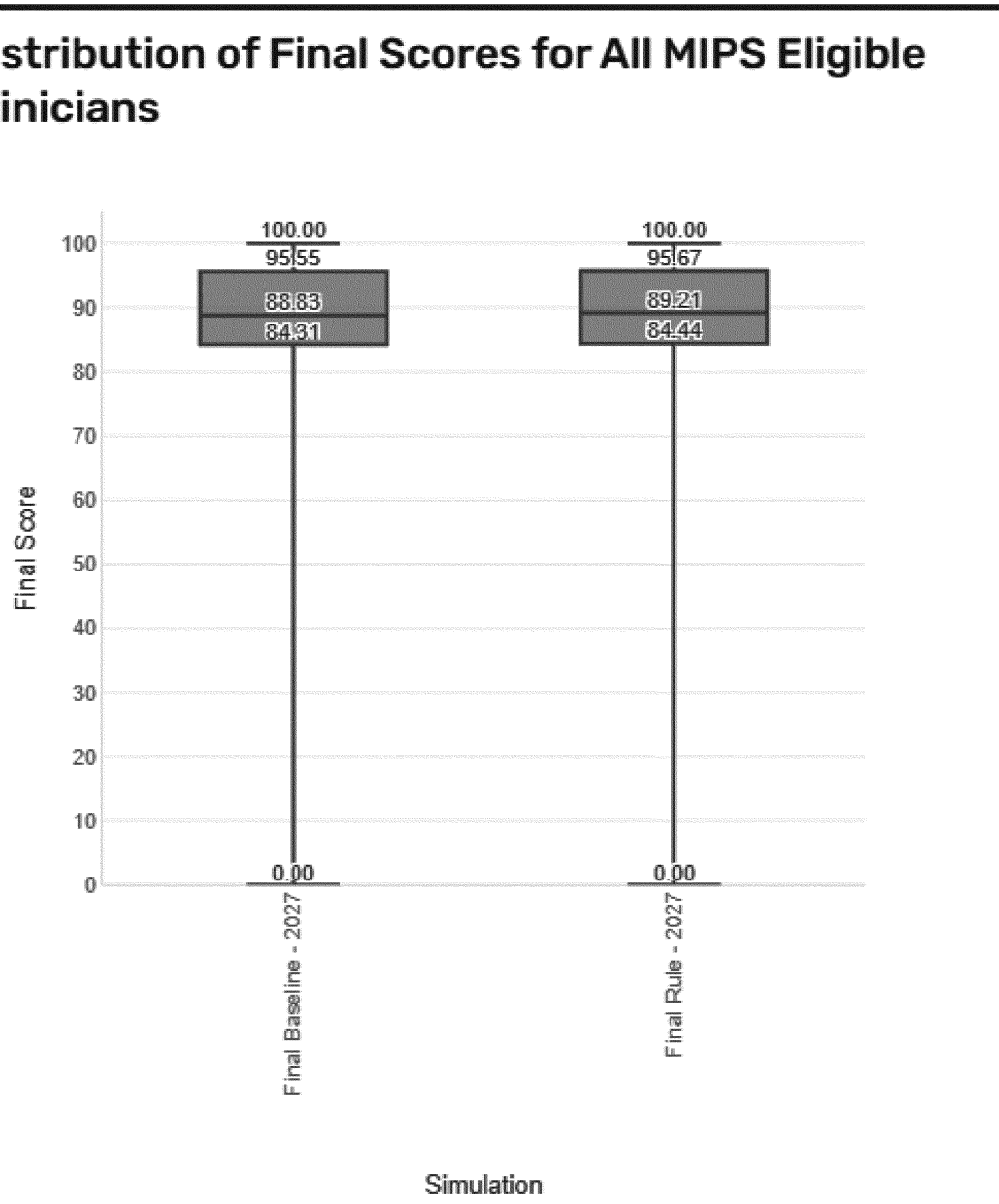
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FIGURE D-B2: Distribution of Final Scores for Solo Practitioners



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FIGURE D-B3: Distribution of Final Scores for All MIPS Eligible Clinicians



Small practices, defined at § 414.1305 as groups with 2 to 15 clinicians, have a median final score of 87.98 in the baseline and 88.61 in the policies model. However, as shown in Table D–B14, the median final score for the reporting small practice providers is 91.35 (baseline) and 91.84 (policies), substantially higher than the median final score of 75—in both baseline and policies models—for the non-reporting small practice providers. They are also higher than the median final scores for all MIPS eligible clinicians who submit data, which are 89.85 in the policies model and 89.66 in the baseline model. This indicates that small practice providers who submit MIPS data can perform better than it is for the medium-sized and large practice providers. Table D–B16 shows the percentage of clinicians, by practice size, either do or do not submit data to MIPS and their corresponding median final scores. Note that, in the policies model, the median final scores for small, medium, and large practice clinicians who do not submit data are 75. This indicates that many small, medium or large practice clinicians who do not submit data to MIPS have been approved for reweighting of all of their MIPS performance categories under our policies at § 414.1380(c)(2). In contrast, the median final scores for solo clinicians, who do not submit data are 24.70. This indicates that many of them are either not being eligible for or not applying for our reweighting policies for extreme uncontrollable circumstances or hardships. Over 90 percent of the medium-sized and large practice clinicians submit data to MIPS. It is possible that the remaining 10 percent or less MIPS eligible clinicians who do

not submit data to MIPS are primarily those who have received reweighting under our policies at § 414.1380(c)(2).

TABLE D-B16: PERCENTAGE OF MIPS ELIGIBLE CLINICIANS WHO SUBMIT DATA AND MEDIAN FINAL SCORE

	Percent of MIPS Eligible Clinicians who Submit Data (by practice size)	Median Final Score of MIPS Eligible Clinicians who Submit Data	Median Final Score of MIPS Eligible Clinicians who Do not submit data.
Baseline			
(1) Solo	47.49	89.61	24.70
(2) Small (2 to15)	78.49	91.35	75.00
(3) Medium (16 to 99)	90.67	89.74	75.00
(4) Large (100+)	97.67	89.37	75.00
Overall	**93.00**	**89.66**	**75.00**
Policies			
(1) Solo	47.48	90.23	24.70
(2) Small (2 to 15)	78.50	91.84	75.00
(3) Medium (16 to 99)	90.71	90.26	75.00
(4) Large (100+)	97.71	89.66	75.00
Overall	**93.03**	**89.85**	**75.00**

(ii) Impact to Rural Providers

In our data we assign rural practitioners a special status. Impact assessment of this group of clinicians indicates that their overall final scores are slightly lower than the overall MIPS eligible clinicians. Table D–B17 shows the median final score and the percentage of eligible clinicians with a positive, neutral, or negative adjustment by practice size for rural practitioners.

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TABLE D-B17: CY 2027 FINAL SCORE ESTIMATES BY PRACTICE SIZE FOR RURAL PRACTITIONERS ONLY

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
Solo (1)	1,941	75.00	39.41	16.80	43.79
(a) Reporting	1,038	88.34	73.70	5.68	20.62
(b) Non-reporting[1]	903	22.74	0.00	29.57	70.43
Small (2-15)	8,652	88.58	72.03	9.50	18.47
(a) Reporting	7,218	90.92	86.34	2.47	11.19
(b) Non-reporting[2]	1,434	26.77	0.00	44.91	55.09
Medium (16-99)	20,529	89.21	84.70	4.25	11.04
Large (100+)	35,683	87.23	96.07	1.48	2.45
Overall	**66,805**	**87.37**	**87.82**	**3.82**	**8.37**
Policies					
Solo (1)	1,941	75.00	39.26	16.80	43.95
(a) Reporting	1,038	88.9	73.41	5.68	20.91
(b) Non-reporting[1]	903	22.74	0.00	29.57	70.43
Small (2-15)	8,652	89.08	72.11	9.50	18.39
(a) Reporting	7,218	91.33	86.44	2.47	11.10
(b) Non-reporting[2]	1,434	26.77	0.00	44.91	55.09
Medium (16-99)	20,524	89.8	84.63	4.23	11.14
Large (100+)	35,684	87.22	96.09	1.42	2.49
Overall	**66,801**	**87.46**	**87.81**	**3.77**	**8.41**

[1]46.52% of the rural, solo practitioners did not report by not submitting any data[2]14.22% of the rural, small practice providers did not report by not submitting any data.

The overall median final score for rural practitioners is 87.37 in the baseline model and 87.46 in the policies model. This is slightly lower than the median final score for all MIPS eligible clinicians, which is 88.83 in the baseline model and 89.21 in the policies model. According to the results from the policies model, rural clinicians in large practices have a slightly lower median final score (87.22) than it is for reporting, rural, solo practitioners (88.9), reporting, rural, small practice providers (91.33), and rural medium-size practice providers (89.80).

(iii) Impact to Safety Net Providers

(A) Updated Definition of Safety Net Providers

In the CY 2022 PFS final rule (87 FR 70094), we finalized our complex patient bonus methodology. This bonus is composed of two distinct calculations which are added together: Medical Complexity and Social Risk. Medical Complexity is determined based on a MIPS eligible clinicians Hierarchical Conditions Categories risk score and social risk is determined based on the proportion of a MIPS eligible clinicians Medicare patient population who are dually eligible for both Medicare and Medicaid.

In the 2024 PFS final rule (88 FR 79513), we compared the performance of clinicians who received the complex patient bonus with our overall population. As we further developed our model, we decided to adopt a more precise definition of safety net providers. We believe that by narrowing our definition of safety net providers to clinicians fall in the top 20 percentile for their percentage of patients who are dually eligible for Medicare and Medicaid, we can identify providers who care for a large proportion of socially vulnerable individuals.

Table D–B18 shows the median final score estimates for safety net providers under this definition. In the policies model, safety net providers have a higher median final score (93.22) than the overall MIPS eligible clinicians (89.21). Safety net solo practitioners who actively report data have a substantially higher median final score (93.84 in the policies model) than that from the non-reporting, safety net, solo practitioners (29.41 in the policies model). Almost 57 percent of safety net solo practitioners and over 30 percent of safety net small practice providers did not report by not submitting any MIPS data, compared to ~53 percent and ~22 percent of the overall solo practitioners and small practice providers, respectively.

TABLE D-B18: CY 2027 FINAL SCORE ESTIMATES BY PRACTICE SIZE FOR SAFETY NET PRACTITIONERS ONLY

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
(1) Solo	4,396	75.00	32.21	30.94	36.85
(a) Reporting	1,918	93.35	73.83	10.74	15.43
(b) Non-Reporting[1]	2,478	29.41	0.00	46.57	53.43
(2) Small (2 to 15)	11,557	85.70	58.48	18.36	23.16
(a) Reporting	8,060	94.35	83.80	5.19	11.02
(b) Non-Reporting[2]	3,497	59.21	0.11	48.73	51.16
(3) Medium (16 to 99)	27,009	91.38	78.14	7.99	13.87
(4) Large (100+)	75,673	93.42	93.90	1.20	4.90
Overall	**118,635**	**92.54**	**84.58**	**5.52**	**9.90**
Policies					
(1) Solo	4,396	75.00	32.19	30.94	36.87
(a) Reporting	1,918	93.84	73.77	10.74	15.48
(b) Non-Reporting	2,478	29.41	0.00	46.57	53.43
(2) Small (2 to 15)	11,557	85.75	58.72	18.35	22.93
(a) Reporting	8,060	95.44	84.14	5.17	10.68
(b) Non-Reporting	3,497	59.22	0.11	48.73	51.16
(3) Medium (16 to 99)	27,004	92.59	78.87	7.95	13.18
(4) Large (100+)	75,677	93.93	96.74	1.09	2.18
Overall	**118,634**	**93.22**	**86.57**	**5.44**	**7.99**

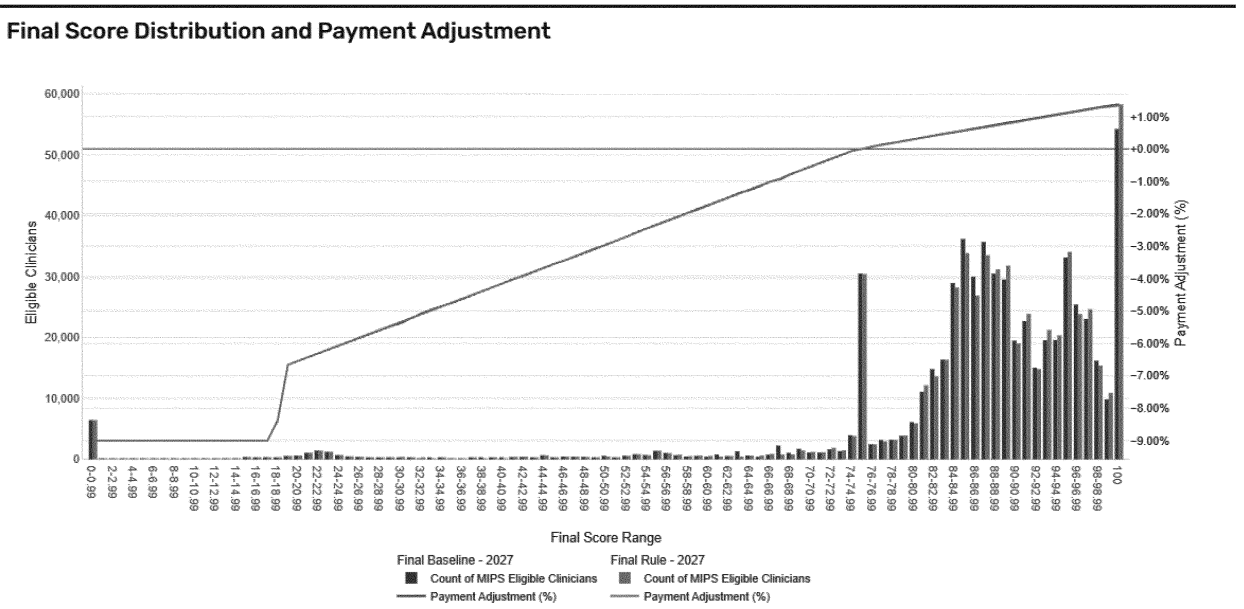
[1]56.37% of the safety-net, solo practitioners did not report by not submitting any data
[2]30.26% of the safety-net, small practice providers did not report by not submitting any data

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(c) Impact to MIPS Eligible Clinicians' Payment Adjustments

We did not propose to increase the performance threshold in this final rule. Table D–B20 shows that the payment adjustments are very similar between the baseline and policies model. This is because our policies can maintain program stability. The maximum positive payment adjustment is 1.37 percent in the baseline model and 1.34 percent in the policies model. The baseline model estimates redistributing $332 million, and the policies model estimates redistributing $330 million. This slight decrease is due to slightly higher proportions of clinicians receiving positive payment adjustments in the policies model (87.73 percent) than it is in the baseline model (87.30 percent). As the proportion of MIPS eligible clinicians receiving a positive payment adjustment increases slightly, the portion of clinicians receiving a negative payment adjustment also slightly decreases accordingly (7.55 percent in the policies model vs. 7.94 percent in the baseline model). As the proportion of MIPS eligible clinicians receiving negative payment adjustments decreases slightly, the budget neutral funds available for redistribution also decrease somewhat.

FIGURE D-B5: Final Score Distribution and Payment Adjustment



We also report on the median positive and negative payment adjustments by practice size in Table D–B19.

TABLE D-B19: CY 2027 MEDIAN POSITIVE AND NEGATIVE PAYMENT ADJUSTMENT ESTIMATES BY PRACTICE SIZE

Practice Size	Median Positive Payment Adjustment[1]	Median Negative Payment Adjustment
Baseline		
Solo (1)	+1.01	-6.43
(a) Engaged	+1.01	-2.67
(b) Non-Reporting	N/A[2]	-9.00
Small (2-15)	+0.96	-6.08
(a) Reporting	+0.96	-1.50
(b) Non-Reporting	+0.08	-6.74
Medium (16-99)	+0.87	-1.92
Large (100+)	+0.81	-1.35
Overall	+0.83	-2.46
Policies		
Solo (1)	+1.03	-6.42
(a) Engaged	+1.03	-2.53
(b) Non-Reporting	N/A	-9.00
Small (2-15)	+0.97	-6.06
(a) Reporting	+0.97	-1.47
(b) Non-Reporting	+0.08	-6.74
Medium (16-99)	+0.88	-1.92
Large (100+)	+0.80	-2.08
Overall	+0.83	-2.62

[1]Final score above the performance threshold. The median negative adjustment is defined as the medium payment adjustment among clinicians with a final score below the performance threshold. Neither median includes clinicians with a final score equal to the performance threshold.

[2]There are no solo practitioners who did not report data and received a Positive payment adjustment. The maximum they could receive is from the Quality Admins Claims, and even if they received excellent scores, it would still be less than the performance threshold.

The overall median negative payment adjustment in the policies model is slightly lower than it is in the baseline model. That is because the policies model has a higher mean final score than the baseline model (89.21 policies vs. 88.83 baseline).

e. Additional Impacts From Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting payment adjustments, we are finalizing several policies that will impact burden. In section V.B.7. of this final rule, we estimate the burden impacts of finalized policy provisions.

(2) Additional Impacts to Clinicians

We provide additional burden discussions for policy provisions that we are unable to quantify.

(a) Modifications to the MIPS Improvement Activities Inventory

As discussed in section IV.A.4.d.(3) of this final rule, we are finalizing our proposed updates to the MIPS Improvement Activities Inventory beginning with the CY 2027 performance period/2029 MIPS payment year. We do not expect these changes to affect our burden estimates for the number of estimated respondents or response time, as most of the improvement activities in the MIPS Improvement Activities Inventory remain unchanged for the CY 2027 performance period/2029 MIPS payment year. We refer readers to section IV.A.4.d.(3) of this final rule for details on the changes to the MIPS Improvement Activities Inventory.

(b) Qualifying Alternative Payment Model (APM) Participant (QP) Determinations

In section IV.F.2. of this final rule, we are finalizing with modification, our proposal to apply QP and partial QP status at the TIN/NPI level. We note that year-over-year participation changes have historically had outsized impacts on our projections. For example, ACOs frequently add or remove participants as part of their operations. These changes in participation make it difficult to project how these proposals will impact clinicians who are determined to be QPs, Partial QPs, or previously reported MIPS (at the individual, group, subgroup, or APM Entity level), if at all. Accordingly, we have not adjusted our estimates related to performance category submissions due to these proposals. For details on these policies, see section IV.F.2. of this final rule.

(c) Third-Party Intermediaries

In section IV.C. of this final rule, we are finalizing our proposal to (1) add a requirement that CMS-approved third-party intermediaries may be terminated after failure to submit data for 1 year; and (2) clarify that if a third-party intermediary does not submit data for 1 year, they would be required to provide documentation and would be terminated if documentation cannot be provided and/or the documentation shows that they would not be submitting data for the given MIPS performance period. Due to the technical nature of these changes, there is no data available to quantify the burden for third-party intermediaries during the CY 2027 performance period/2029 MIPS payment year. We refer readers to section IV.C. of this final rule for additional information on the policy provisions related to third-party intermediaries.

G. Alternatives Considered Related to the Ambulatory Specialty Model

In section III.D. of this final rule, we discuss the mandatory ASM. We will test whether ASM leads to improved chronic condition management, higher quality care, and reduced costs by incentivizing ASM participants with the opportunity for positive payment adjustments to Medicare Part B covered professional services payments based on their performance on data reported on quality, cost, improvement activities, and CEHRT interoperability.

Throughout this final rule, we identified our proposed policies and alternatives that we considered and provided information as to the effects of these alternatives and summaries of public comments received on the proposed policies. This final rule provides descriptions of the requirements that we will mandate and presents rationales for our decisions and, where relevant, alternatives that we considered. For example, we considered whether we should waive the requirement for ASM participants in rural areas to attest to complete IA–2: Establishing Communication and Collaboration Expectations with Primary Care using Collaborative Care Arrangements (CCAs) instead of providing the proposed rural scoring adjustment to an ASM participant's final score. Although ASM participants in rural areas may face challenges forming partnerships with primary care providers due to limited primary care availability, we believe that a rural scoring adjustment more broadly accounts for challenges that could affect ASM participant performance across the four ASM performance categories compared to only waiving IA–2.

We solicited comments on our proposals and on the alternatives, which are addressed in this final rule.

H. Impact on Beneficiaries

As noted previously, we estimate that a combination of the finalized proposals for the Shared Savings Program, including introducing a growth adjustment, the increase to the sharing rate in BASIC track Level E, and the increase in the scaling factor for the prior savings adjustment, are expected to increase the number of ACOs in the program and correspondingly the size of the population of beneficiaries assigned to ACOs by up to one million beneficiaries per year, with roughly two-thirds of such increase attributable to the proposed growth adjustment. This growth in participation is likely to feature beneficiaries who might particularly benefit from care management because the growth adjustment is designed to attract new providers without experience in the program who are serving beneficiaries new to value-based care. Additionally, the increase to the scaling factor for the prior savings adjustment, together with risk-adjusting the 5 percent cap on benchmark adjustments, could moderate the rebasing ratcheting effect and thereby improve the business case for ACOs serving high needs populations to invest additional resources in care management.

In the CY 2027 PFS proposed rule (91 FR 44274), we noted that in PY 2024, ACOs performed better on certain patient-experience and performance measures than physician groups participating in MIPS (90 FR 50003 and 50004) and referred readers to our discussion in the CY 2026 PFS final rule for additional details on ACOs' measure performance (90 FR 50002). Since the publication of the CY 2027 PFS proposed rule, preliminary PY 2025 data on ACOs' measure performance and measure performance relative to physician groups participating in MIPS has become available.

ACOs have been found to perform better on certain patient experience and performance measures than physician groups participating in MIPS (as shown in Table D–B20). In PY 2025, ACOs scored better than comparable MIPS groups[427] on the three eCQMs in the APP Plus quality measure set that are available in traditional MIPS and the

[427] Quality Payment Program measurement data are for MIPS groups that have 16 or more clinicians. The mean number of beneficiaries for MIPS groups with 16 or more clinicians is 11,012.

difference was statistically significant for Quality ID: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan ($p < .05$) and Quality ID: 236 Controlling High Blood Pressure ($p < .05$). ACOs also performed better than comparable MIPS groups on one of the three MIPS CQMs in the APP Plus quality measure set that are available in traditional MIPS and the difference was statistically significant for Quality ID: 236 Controlling High Blood Pressure ($p < .05$). Additionally, ACOs performed better than comparable MIPS groups on six of the ten patient experience summary survey measures that contribute to Quality ID: 321 Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS, and for one of these summary survey measures the difference was statistically significant: CAHPS–1 Getting Timely Care, Appointments and Information ($p <.05$).

We note there are key differences between the Shared Savings Program and MIPS that limit our analysis of ACOs' performance on the eCQMs/MIPS CQMs and the CAHPS for MIPS Summary Survey Measures compared to MIPS groups. Specifically, Shared Savings Program ACOs are required to report the eCQMs/MIPS CQMs included in the APP Plus quality measure set; whereas MIPS groups can choose which eCQMs and MIPS CQMs they report on and tend to choose those they will perform well on. Shared Savings Program ACOs are required to administer the CAHPS for MIPS Survey, while it is optional for MIPS groups. A large number of MIPS groups do not administer the CAHPS for MIPS Survey as they are less likely to meet the minimum sample size required to administer the survey, coupled with the tendency of MIPS groups to choose measures they will perform well on.

BILLING CODE 4169–69–P

TABLE D-B20: PY 2025 QUALITY MEASURES THAT SHARED SAVINGS PROGRAM ACOs PERFORMED BETTER ON THAN COMPARABLE MIPS GROUPS

Quality #	Measure Title	Difference in Mean ACO and MIPS Group Performance Rates for PY 2025 (%)[1]
	eCQMs	
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-3.5[2]
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	4.39[3]
236	Controlling High Blood Pressure	3.48[3]
	MIPS CQMs	
236	Controlling High Blood Pressure	3.99[3]
321	**CAHPS for MIPS**	0.15
CAHPS-1	Getting Timely Care, Appointments, and Information	2.15[3]
CAHPS-3	Health Promoting and Education	0.09
CAHPS-6	Shared Decision Makin	0.23
CAHPS-7	Health Status and Functional Status	0.06
CAHPS-8	Care Coordination	0.24
CAHPS-11	Stewardship of Patient Resources	0.69

[1] The numbers in this column represent the mean ACO performance rate minus the mean MIPS group performance rate for each measure.
[2] This is an inverse measure, and a lower number indicates better quality performance.
[3] Indicates statistically significant differences between ACOs and comparable MIPS groups ($p < 0.05$).

BILLING CODE 4169–69–C

TABLE D-B21: eCQMS, MEDICARE CQMs, AND CAHPS SUMMARY SURVEY MEASURES WITH IMPROVEMENT AMONG SHARED SAVINGS PROGRAM ACOS BETWEEN PY 2024 AND PY 2025

Quality #	Measure Title	Difference in Mean ACO Performance Rates between PY 2024 and PY 2025 (%)[1]
	eCQMs	
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-3.73[2,3]
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	1.5
236	Controlling High Blood Pressure	2.65[3]
	MEDICARE CQMs	
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-3.07[2]
236	Controlling High Blood Pressure	6.73[3]
321	**CAHPS for MIPS**	0.22
CAHPS-1	Getting Timely Care, Appointments, and Information	0.52[3]
CAHPS-2	How Well Providers Communicate	0.28[3]
CAHPS-3	Patient's Rating of Provider	0.25[3]
CAHPS-4	Access to Specialists	0.59[3]
CAHPS-5	Health Promotion and Education	1.49[3]
CAHPS-6	Shared Decision Making	1.09[3]
CAHPS-7	Health Status and Functional Status	0.24[3]
CAHPS-8	Care Coordination	0.57[3]
CAHPS-9	Courteous and Helpful Office Staff	0.18[3]

[1] The numbers in this column represent the mean ACO performance rate in PY 2025 minus the mean ACO performance rate in PY 2024 for each measure.

[2] This is an inverse measure, and a lower number indicates better quality performance.

[3] Indicates statistically significant differences between ACOs' mean performance rates between PY 2024 and PY 2025 ($p < 0.05$).

On average, ACOs have improved their performance on a variety of quality measures from PY 2024 to PY 2025. In PY 2025, ACOs improved their performance on three of the eCQMs in the APP Plus quality measure set and the difference in their performance was statistically significant for two of these eCQMs, Quality ID: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (≤9%) ($p < .05$)) and Quality ID: 236 Controlling High Blood Pressure ($p < .05$). ACOs also improved their performance on two of the Medicare CQMs in the APP Plus quality measure set in PY 2025 and the difference in their performance was statistically significant for one of these Medicare CQMs, Quality ID: 236 Controlling High Blood Pressure ($p < .05$). ACOs improved their performance on nine of the ten patient experience summary survey measures that contribute to Quality ID: 321 CAHPS for MIPS, and for all nine the difference in their performance was statistically significant ($p < .05$). We note that a comparison of ACOs' average performance on Quality ID: 112 Breast Cancer Screening between PY 2024 and PY 2025 is not available since PY 2025 was the first year this measure was available in the APP Plus quality measure set that Shared Savings Program ACOs are required to report.

Based on ACOs' quality performance results historically (as shown in Tables D–B20 and D–B21), we anticipate that the policies in this final rule will enable ACOs to continue to improve the quality of care for the beneficiaries they serve. Increased participation in the Shared Savings Program would extend ACO care coordination to additional beneficiaries which can help improve the quality of care they receive.

1. Quality Payment Program

There are several changes in this final rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we believe the policies in this final rule will improve the quality and value of care provided to Medicare beneficiaries.

Several of the new quality measures include patient-reported outcome-based measures, which could be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and could also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which will not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

2. Ambulatory Specialty Model

We believe that the refinements to ASM's provisions finalized in this final rule will not change the potential effects of ASM on beneficiaries. We continue to believe that ASM will have no impact on cost to beneficiaries because ASM payment adjustments will not affect Medicare beneficiary coinsurance amounts. The coinsurance will be calculated based on the Medicare allowed amounts before any ASM payment adjustment multipliers are applied to Medicare Part B payments for covered professional services.

I. Estimating Regulatory Familiarization Costs

Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is

possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers choose not to comment on the proposed rule. We welcomed any public comments on the approach in estimating the number of entities that would review the proposed rule. We did not receive any public comments specific to our solicitation.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rulemaking is $119.10, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately [8 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $952.80 ($119.10 x 8). Therefore, we estimated that the total cost of reviewing this regulation is $410,475,77 ($952.80 x 43,081 reviewers on this year's proposed rule).

J. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*), in Tables D–B20 and D–B21 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2026 to CY 2027 based on the FY 2027 President's Budget baseline.

TABLE D-B20: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

CATEGORY	TRANSFERS
CY 2027 Annualized Monetized Transfers	Estimated decrease in expenditures of $2.1 billion for PFS CF update.
Bearers of Transfer Gain	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE D-B21: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

CATEGORY	TRANSFER
CY 2027 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.4 billion
Bearers of Transfer Gain	Beneficiaries to Federal Government.

TABLE D-B22: ACCOUNTING STATEMENT FOR PROVISIONS FOR MEDICARE SHARED SAVINGS PROGRAM (CYS 2027 to 2036) ($ MILLIONS)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
BENEFITS				
Annualized monetized: Discount rate: 3%	-$565 million	-$1,058 million	-$115 million	Tables D-B7 through D-B10; summarized in total in Table D-B11
Annualized monetized: Discount rate: 7%	-$579 million	-$1,063 million	$134 million	Tables D-B8 through D-B10; summarized in total in Table D-B11

Notes: Negative values reflect a reduction in Federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects would be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

K. Conclusion

The analysis in the previous sections, together with the remainder of this final rule, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this rule, provides an RIA. In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

VIII. Waiver of Delay in Effective Date

The Congressional Review Act (CRA) (Pub. L. 104–121, Title II) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3) and 808(2).

We believe that further notice and public procedure are unnecessary, and that it would be impracticable and contrary to the public interest to delay the effective date of the PFS final rule for the following reasons.

If the effective date of this final rule is delayed by 60 days, the finalized policies addressed in the rule (including changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies; new policies for the

Medicare Prescription Drug Inflation Rebate Program; provisions limiting Medicare coverage of certain individuals; updates to the Ambulatory Specialty Model; updates to drugs and biological products paid under Part B; the Medicare Shared Savings Program requirements; updates to the Quality Payment Program; updates to policies for Rural Health Clinics and Federally Qualified Health Centers; updates to the Ambulance Fee Schedule regulations; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2026 provisions; updates to Clinical Laboratory Fee Schedule regulations; and updates to the Medicare Promoting Interoperability Program), will not be effective as of the beginning of the payment year, and CMS will be compelled to continue to use obsolete reimbursement rates which will disadvantage health care providers and suppliers.

In accordance with section 1848(b)(1) of the Act, the PFS is a calendar year payment system. We typically issue the PFS final rule by November 1 of each year to comply with the statutory requirement under section 1848(b)(1) of the Act to establish the fee schedules annually and to ensure 60-days' notice so that the payment policies for the system are effective on January 1, the first day of the calendar year to which the policies are intended to apply. The policies described previously are intended to align with the PFS payment system.

In this final rule, we review and revise values for specific services and adopt or revise other policies that relate to the PFS for CY 2027 or future years. Section 1848(b)(1) of the Act requires that no less often than annually, the Secretary shall establish fee schedules that establish payment amounts for all physicians' services furnished in all fee schedule areas. Section 1848(c)(2)(B)(ii)(II) of the Act also requires that adjustments to relative values under the PFS be made in a budget neutral manner. We find that, in order to comply with the statutory requirements to annually review and update this payment system, to preserve budget neutrality as required by statute, and to promote an orderly transition to a new payment year, it is in the public interest to ensure that the rule is effective no later than 1 full year after the effective date of the previous year's update (that is, January 1 of each year). Moreover, it is in the public interest to waive the 60-day delay of the effective date, so that providers, and suppliers are adequately reimbursed starting at the beginning of the calendar year, so that an adjusted conversion factor applies to services furnished on or after January 1, 2027, and so that budget neutrality can be maintained. Therefore, we find good cause to waive the 60-day delay in the effective date for this final rule.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on XXXX XX, 2026.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 406

Health facilities, Diseases, and Medicare.

42 CFR Part 407

Medicare.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 427

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 428

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 400—INTRODUCTION; DEFINITIONS

■ 1. The authority for part 400 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 44 U.S.C. Chapter 35.

■ 2. Section 400.200 is amended by adding a definition for ''Eligible noncitizen'' in alphabetical order to read as follows:

§ 400.200 General definitions.

* * * * *

Eligible noncitizen means an individual who, effective July 4, 2025, is an—

(1) Alien lawfully admitted for permanent residence under the Immigration and Nationality Act;

(2) Alien who has been granted the status of Cuban and Haitian entrant, as defined in section 501(e) of the Refugee Education Assistance Act of 1980; or

(3) Individual who lawfully resides in the United States in accordance with a Compact of Free Association referred to in 8 U.S.C. 1612(b)(2)(G).

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 3. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 4. Section 405.2463 is amended by—
■ a. Adding paragraph (a)(1)(iii);
■ b. In paragraph (b)(2) introductory text, removing the phrase ''a FQHC patient'' and adding in its place the phrase ''an FQHC patient or a RHC patient''; and
■ c. In paragraph (b)(3), removing the phrase ''Not before October 1, 2025'' and adding in its place the phrase ''Not before January 1, 2028'';

The addition reads as follows:

§ 405.2463 What constitutes a visit.

(a) * * *
(1) * * *
(iii) Furnished under the direct supervision of the RHC practitioner, a face-to-face encounter between a patient and either of the following:
(A) A qualified provider of medical nutrition therapy services as defined in part 410, subpart G, of this chapter.
(B) A qualified provider of outpatient diabetes self-management training services as defined in part 410, subpart H, of this chapter.
* * * * *

§ 405.2464 [Amended]

■ 5. Section 405.2464 is amended by—
■ a. In paragraph (b)(1), removing the phrase ''paragraphs (d) and (e) of this section'' and adding in its place the phrase ''paragraphs (c) through (h) of this section'';
■ b. In paragraph (b)(2)(i), removing the reference ''§ 405.2462(c)(1)'' and adding in its place the reference ''§ 405.2462(e)(1)'';
■ c. In paragraph (b)(2)(ii), removing the reference ''§ 405.2462(c)(2)'' and adding in its place the reference ''§ 405.2462(e)(2)''; and
■ d. In paragraph (g), removing the term ''an encounter'' wherever it appears and adding in its place the term ''services''.

■ 6. Section 405.2469 is amended by revising paragraph (d) to read as follows:

§ 405.2469 FQHC supplemental payments.

* * * * *

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter, or an encounter furnished using interactive, real-time, audio and video telecommunications technology, or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology, for the purposes of diagnosis, evaluation, or treatment of a mental health disorder, occurs between a Medicare Advantage enrollee and a practitioner as set forth in § 405.2463. A mental health encounter furnished using interactive, real-time, audio and video telecommunications technology, or audio-only interactions, is not payable unless the FQHC is in compliance with the in-person requirements set forth in § 405.2463(b)(3).

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

■ 7. The authority for part 406 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395i–2, 1395i–2a, 1395p, 1395q, and 1395hh.

■ 8. Section 406.5 is amended by revising paragraph (a) to read as follows:

§ 406.5 Basis of eligibility and entitlement.

(a) *Hospital insurance without premiums.* Hospital insurance is available to most individuals without payment of a premium if they meet the following conditions:
(1) The individual—
(i) Is age 65 or over;
(ii) Has received social security or railroad retirement disability benefits for 25 months; or
(iii) Has end-stage renal disease. Subpart B of this part explains the requirements such individuals must meet to obtain hospital insurance without premiums.
(2) Effective July 4, 2025, the individual is a citizen or national of the United States or an eligible noncitizen as defined in 42 CFR 400.200.
* * * * *

■ 9. Section 406.6 is amended by revising paragraph (b) and adding paragraph (f) to read as follows:

§ 406.6 Application or enrollment for hospital insurance.

* * * * *

(b) *Individuals who need not file an application for hospital insurance.* An individual who meets the requirements of § 406.5(a)(2), and any of the following conditions need not file an application for hospital insurance:
* * * * *

(f) *Special rules for eligible noncitizens.* Individuals who only meet the requirements of § 406.5(a)(1), but do not also meet the requirements of § 406.5(a)(2), may subsequently meet both § 406.5(a)(1) and (2) due to a change in U.S. citizenship, U.S. nationality, or immigration status or category. For these individuals, the following requirements apply:
(1) An individual who meets the conditions of paragraph (b) of this section must contact SSA to initiate entitlement to hospital insurance. Entitlement may be retroactive for up to 6 months, but not earlier than the first month in which the individual met all of the requirements of § 406.5(a).
(i) If acceptable evidence establishes the month in which the individual first satisfied § 406.5(a)(2), SSA will use that month, subject to the applicable retroactivity limits noted in paragraph (f)(1) of this section.
(ii) If the earliest month of eligibility cannot be established based on acceptable documentary evidence, entitlement will begin on the first day of the month in which SSA verifies that the individual satisfies § 406.5(a)(2), based on applicable data made available by the Department of Homeland Security.
(2) An individual who meets the conditions of paragraph (c) of this section must contact SSA to file an application for hospital insurance. Entitlement may be retroactive for up to 6 months, but not earlier than the first month in which the individual met all of the requirements of § 406.5(a).
(i) If acceptable evidence establishes the month in which the individual first satisfied § 406.5(a)(2), SSA will use that month, subject to the applicable retroactivity limits noted in paragraph (f)(2) of this section.
(ii) If the earliest month of eligibility cannot be established based on acceptable documentary evidence, entitlement will begin on the first day of the month in which SSA verifies that the individual satisfies § 406.5(a)(2), based on applicable data made available by the Department of Homeland Security.

■ 10. Section 406.10 is amended by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

§ 406.10 Individual age 65 or over who is entitled to social security or railroad retirement benefits, or who is eligible for social security benefits.

(a) *Requirements.* An individual is entitled to hospital insurance benefits under section 226 of the Act under the following conditions:
(1) The individual has attained age 65 and is—
(i) Entitled to monthly social security benefits under section 202 of the Act;
(ii) A qualified railroad retirement beneficiary who has been certified as

such to the Social Security Administration by the Railroad Retirement Board in accordance with section 7(d) of the Railroad Retirement Act of 1974; or

(iii) Effective January 1, 1981, eligible for monthly social security benefits under section 202 of the Act and has filed an application for hospital insurance.

(2) Effective July 4, 2025, the individual is a citizen or national of the United States or an eligible noncitizen as defined in 42 CFR 400.200.

(b) * * *

(3) Entitlement continues until the date entitlement is terminated in accordance with § 406.14(b) or (c).

■ 11. Section 406.11 is amended by revising paragraph (b)(2) to read as follows:

§ 406.11 Individual age 65 or over who is not eligible as a social security or railroad retirement benefits beneficiary, or on the basis of government employment.

* * * * *

(b) * * *

(2) *Residence and citizenship.* He or she is a resident of the United States and is

(i) A citizen or national of the United States;

(ii) An alien lawfully admitted for permanent residence under the Immigration and Nationality Act who has continuously resided in the United States for 5 years immediately preceding the first month in which he or she meets all other requirements for entitlement to hospital insurance;

(iii) An alien who has been granted the status of Cuban and Haitian entrant, as defined in section 501(e) of the Refugee Education Assistance Act of 1980; or

(iv) An individual who lawfully resides in the United States in accordance with a Compact of Free Association (COFA), as referred to in 8 U.S.C. 1612(b)(2)(G).

* * * * *

■ 12. Section 406.12 is amended by revising paragraph (a) and adding paragraph (d)(2)(v) to read as follows:

§ 406.12 Individual under age 65 who is entitled to social security or railroad retirement disability benefits.

(a) *Basic requirements.* An individual under age 65 is entitled to hospital insurance benefits under the following conditions:

(1) If, for 25 months, the individual has been—

(i) Entitled or deemed entitled to social security disability benefits as an insured individual, child, widow, or widower who is ''under a disability''; or

(ii) A disabled qualified beneficiary certified under section 7(d) of the Railroad Retirement Act.

(2) Effective July 4, 2025, the individual is a citizen or national of the United States or an eligible noncitizen as defined in 42 CFR 400.200.

* * * * *

(d) * * *

(2) * * *

(v) The date entitlement is terminated in accordance with § 406.14(b) or (c).

* * * * *

■ 13. Section 406.13 is amended by revising paragraphs (c) and (f) to read as follows:

§ 406.13 Individual who has end-stage renal disease.

* * * * *

(c) *Requirements.* An individual who has been medically determined to have ESRD is entitled to hospital insurance benefits under the following conditions:

(1) He or she is—

(i) Fully or currently insured under the social security program (title II of the Act) or would be fully or currently insured if his or her employment (after 1936) as defined under the Railroad Retirement Act were considered ''employment'' under the Act;

(ii) Entitled to monthly social security or railroad retirement benefits; or

(iii) The spouse or dependent child of a person who meets the requirements of paragraph (c)(1)(i) or (c)(1)(ii) of this section.

(2) He or she has filed an application for Medicare Part A.

(3) He or she has satisfied the waiting period explained in paragraph (e) of this section.

(4) Effective July 4, 2025, the individual is a citizen or national of the United States or an eligible noncitizen, as defined in 42 CFR 400.200.

* * * * *

(f) *End of entitlement.* Entitlement ends under any of the following conditions:

(1) With the end of the 12th month after the month in which a regular course of dialysis ends.

(2) With the end of the 36th month after the month in which the individual received a kidney transplant. Beginning January 1, 2023, an individual who is no longer entitled to Part A benefits due to this paragraph may be eligible to enroll in Part B solely for purposes of coverage of immunosuppressive drugs as described in § 407.55 of this subchapter.

(3) With the date entitlement is terminated in accordance with § 406.14(b) or (c).

* * * * *

■ 14. Section 406.14 is added to read as follows:

§ 406.14 End of entitlement due to change in U.S. citizenship, U.S. nationality, or immigration status or category.

(a) *Basis.* Individuals whose U.S. citizenship, U.S. nationality, or immigration status or category changes such that they no longer meet the requirements of § 406.5(a)(2) of this part will lose entitlement to hospital insurance benefits without premiums.

(b) For individuals who were entitled to, or enrolled for, hospital insurance benefits without premiums as of July 4, 2025, the SSA must, not later than 1 year after July 4, 2025, complete a review of individuals for purposes of identifying individuals not described by § 406.5(a)(2). SSA must notify each individual identified under such review that if SSA determines that an individual does not meet the requirements of § 406.5(a)(2), the individual's entitlement to, or enrollment for, hospital insurance benefits will be terminated in accordance with paragraph (d) of this section.

(c) Entitlement will end as provided under paragraph (d) of this section for individuals who were entitled to, or enrolled for, hospital insurance benefits without premiums who were not identified and notified by the SSA per § 406.14(b) and were subsequently determined by the SSA as not meeting the requirements of § 406.5(a)(2).

(d) *Termination notice.* The SSA will send notice to individuals if they no longer satisfy the requirements of § 406.5(a)(2). The notice contains the following information:

(1) Specifies the individual's appeal rights in accordance with 20 CFR part 404, subpart J.

(2) States the effective date of the hospital insurance benefits entitlement termination action, which will be the end of the month following the month in which the termination notice is dated.

(3) States that the individual should contact the SSA if their citizenship, nationality, or immigration status or category changes such that they may be entitled to, or enrolled for, hospital insurance benefits under this part.

(e) *Resumption of benefits.* An individual whose hospital insurance benefits were terminated under paragraph (d) of this section may request resumption of benefits if the individual's U.S. citizenship, U.S. nationality, or immigration status or category changes such that the individual meets the requirements of § 406.5(a)(2) of this part. To request resumption of entitlement, the individual must contact SSA and provide information sufficient to

establish that the requirements of § 406.5(a)(2) are met.

■ 15. Section 406.20 is amended by revising paragraph (b)(2) and adding paragraph (c)(5) to read as follows:

§ 406.20 Basic requirements.

* * * * *

(b) * * *

(2) Is a resident of the United States and, effective July 4, 2025, is—

(i) A citizen or national of the United States;

(ii) An alien lawfully admitted for permanent residence under the Immigration and Nationality Act who has continuously resided in the United States for 5 years immediately preceding the first month in which they meet all other requirements for entitlement to hospital insurance;

(iii) An alien who has been granted the status of Cuban and Haitian entrant, as defined in section 501(e) of the Refugee Education Assistance Act of 1980; or

(iv) An individual who lawfully resides in the United States in accordance with a Compact of Free Association referred to in 8 U.S.C. 1612(b)(2)(G).

* * * * *

(c) * * *

(5) Meets the eligibility requirements in paragraph (b)(2) of this section.

■ 16. Section 406.27 is amended by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) to read as follows:

§ 406.27 Special enrollment periods for exceptional conditions.

* * * * *

(f) *Special enrollment period for verification of eligible noncitizen/citizenship status.* An SEP exists for individuals who have not been entitled to, or enrolled for, Medicare due to failure to meet the requirements of § 406.20(b)(2), but subsequently meet the requirements or whose Medicare entitlement or enrollment was terminated due to loss of U.S. citizenship, U.S. nationality, or eligible noncitizen status, who subsequently meet the citizenship, nationality, or immigration status or category requirements specified in § 406.20(b)(2).

(1) *SEP parameters.* (i) An individual is eligible for this SEP if the individual otherwise met the eligibility requirements for Medicare, except for § 406.20(b)(2), and the individual subsequently meets the applicable Medicare eligibility requirements, including § 406.20(b)(2).

(ii) An individual is eligible for this SEP if the individual's prior Medicare entitlement or enrollment was terminated because the individual did not meet the requirements of § 406.20(b)(2) and the individual subsequently meets the applicable Medicare eligibility requirements, including § 406.20(b)(2).

(iii) An individual does not need to miss an enrollment period to be eligible for this SEP.

(2) *SEP duration.* The SEP begins on the first day of the month in which the individual contacts the SSA and provides information sufficient to establish that the requirements of § 406.20(b)(2) are met and ends on the last day of the 12th month after the month in which the SEP began.

(3) *Entitlement.* (i) *General rule.* Entitlement begins the first day of the month following the month of enrollment.

(ii) *Special rule.* An individual who enrolls during the SEP in accordance with subparagraph (1) has the option of requesting entitlement for a coverage effective date that is the later of the first day of the sixth month before the month of enrollment or the first day of the month in which the individual first met all of the eligibility requirements, provided the coverage effective date does not precede the month in which the individual met the eligibility requirements and the individual pays the monthly premiums for the period of coverage (as required under § 406.32(f) of this subchapter).

* * * * *

■ 17. Section 406.28 is amended by adding new paragraph (g) to read as follows:

§ 406.28 End of entitlement due to change in citizenship, nationality, or immigration status or category.

* * * * *

(g) *Loss of eligibility due to lack of U.S. citizenship, U.S. nationality, or eligible noncitizen status.* Individuals whose U.S. citizenship, U.S. nationality, or immigration status or category changes such that they no longer meet the requirements of § 406.20(b) of this part will lose entitlement to premium hospital insurance benefits.

(1) For individuals who were entitled to, or enrolled for, premium hospital insurance benefits as of July 4, 2025, the SSA must, not later than 1 year after July 4, 2025, complete a review of individuals for purposes of identifying individuals not described by § 406.20(b)(2). SSA must notify each individual identified under such review that if SSA determines that an individual does not meet the requirements of § 406.20(b)(2), the individual's entitlement to, or enrollment for, premium hospital insurance benefits will be terminated in accordance with paragraph (g)(3) of this section.

(2) Entitlement will end as provided under paragraph (g)(3) of this section for individuals who were entitled to, or enrolled for, premium hospital insurance benefits who were not identified and notified by the SSA per § 406.28(g)(1) and were subsequently determined by the SSA as not meeting the requirements of § 406.20(b)(2).

(3) *Termination notice.* The SSA will send notice to individuals if they no longer satisfy the requirements of § 406.20(b)(2). The notice contains the following information:

(i) Specifies the individual's appeal rights in accordance with 20 CFR part 404, subpart J.

(ii) States the effective date of the hospital insurance benefits entitlement termination action, which will be the end of the month following the month in which the termination notice is dated.

(iii) States that the individual should contact the SSA if their eligibility status changes such that they may be entitled to, or enrolled for, hospital insurance benefits under this part.

■ 18. Section 406.50 is amended by revising the section heading and paragraph (a) to read as follows:

§ 406.50 Nonpayment of benefits on behalf of eligible noncitizens.

(a) Hospital insurance benefit payments may not be made for services furnished to any eligible noncitizen, as defined in 42 CFR 400.200, for any month in which his or her monthly social security benefits are suspended (or would be suspended if he or she were entitled to those benefits) because the eligible noncitizen remains outside the United States for more than 6 months.

(b) Benefits will be payable beginning with services furnished in the first full calendar month the eligible noncitizen is back in the United States.

* * * * *

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

■ 19. The authority for part 407 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395p, 1395q, and 1395hh.

■ 20. Section 407.10 is amended by revising paragraph (a) to read as follows:

§ 407.10 Eligibility to enroll.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, an

individual is eligible to enroll for SMI if he or she—

(1) Is entitled to hospital insurance under any of the rules set forth in §§ 406.10 through 406.15 of this chapter; or

(2) Meets the following requirements:

(i) Has attained age 65. (An individual is considered to have attained age 65 on the day before the 65th anniversary of his or her birth.)

(ii) Is a resident of the United States and, effective July 4, 2025, is—

(A) A citizen or national of the United States;

(B) An alien lawfully admitted for permanent residence under the Immigration and Nationality Act, who has resided continuously in the United States during the 5 years preceding the month in which he or she applies for enrollment;

(C) An alien who has been granted the status of Cuban and Haitian entrant, as defined in section 501(e) of the Refugee Education Assistance Act of 1980; or

(D) An individual who lawfully resides in the United States in accordance with a Compact of Free Association as referred to in 8 U.S.C. 1612(b)(2)(G).

* * * * *

■ 21. Section 407.23 is amended by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) to read as follows:

§ 407.23 Special enrollment periods for exceptional conditions.

* * * * *

(f) *Special enrollment period for verification of eligible noncitizen/citizenship status.* An SEP exists for individuals who have not been entitled to, or enrolled for, Medicare due to failure to meet the requirements of § 407.10(a)(2), but subsequently meet the requirements or whose Medicare entitlement or enrollment was terminated due to loss of U.S. citizenship, loss of U.S. nationality, or eligible noncitizen status, who subsequently meet the citizenship, nationality, or immigration status or category requirements specified in § 407.10(a)(2).

(1) *SEP parameters.* (i) An individual is eligible for this SEP if the individual otherwise met the eligibility requirements for Medicare, except for § 407.10(a)(2), and the individual subsequently meets the applicable Medicare eligibility requirements, including § 407.10(a)(2).

(ii) An individual is eligible for this SEP if the individual's prior Medicare entitlement or enrollment was terminated because the individual did not meet the requirements of § 407.10(a)(2) and the individual subsequently meets the applicable Medicare eligibility requirements, including § 407.10(a)(2).

(iii) An individual does not need to miss an enrollment period to be eligible for this SEP.

(2) *SEP duration.* The SEP begins on the first day of the month in which the individual contacts the SSA and provides information sufficient to establish that the requirements of § 407.10(a)(2) are met and ends on the last day of the 12th month after the month in which the SEP began.

(3) *Entitlement.* (i) *General rule.* Entitlement begins the first day of the month following the month of enrollment.

(ii) *Special rule.* An individual who enrolls during the SEP in accordance with subparagraph (1) has the option of requesting entitlement for a coverage effective date that is the later of the first day of the sixth month before the month of enrollment or the first day of the month in which the individual first met all of the eligibility requirements, provided the coverage effective date does not precede the month in which the individual met the eligibility requirements and the individual pays the monthly premiums for the period of coverage (as required under § 408.4 of this subchapter).

* * * * *

■ 22. Section 407.27 is amended by adding paragraph (e) to read as follows:

§ 407.27 Termination of entitlement: Individual enrollment.

* * * * *

(e) *Loss of eligibility due to lack of U.S. citizenship, U.S. nationality, or eligible noncitizen status.* Individuals whose U.S. citizenship, U.S. nationality, or immigration status or category changes such that they do not meet the requirements of § 407.10(a)(2)(ii) of this part will lose entitlement to SMI.

(1) For individuals who were entitled to, or enrolled for, SMI as of July 4, 2025, the SSA must, not later than 1 year after July 4, 2025, complete a review of individuals for purposes of identifying individuals not described by § 407.10(a)(2). SSA must notify each individual identified under such review that if SSA determines that an individual does not meet the requirements of § 407.10(a)(2), the individual's entitlement to, or enrollment for, SMI will be terminated in accordance with paragraph (e)(3) of this section.

(2) Entitlement will end as provided under paragraph (e)(3) of this section for individuals who were entitled to, or enrolled for, SMI who were not identified and notified by the SSA per § 407.27(e)(1) and were subsequently determined by the SSA as not meeting the requirements of § 407.10(a)(2)(ii).

(3) *Termination notice.* The SSA will send notice to individuals if they no longer satisfy the requirements of § 407.10(a)(2). The notice contains the following information:

(i) Specifies the individual's appeal rights in accordance with 20 CFR part 404, subpart J.

(ii) States the effective date of the SMI entitlement termination action, which will be the end of the month following the month in which the termination notice is dated.

(iii) States that the individual should contact the SSA if their citizenship, nationality, or immigration status or category changes such that they may be entitled to, or enrolled for, SMI under this part.

■ 23. Section 407.55 is amended by revising paragraph (a) to read as follows:

§ 407.55 Eligibility to enroll.

(a) Basic rules.

(1) Except as specified in paragraph (b) of this section, an individual is eligible to enroll, be deemed enrolled, or reenroll in the Part B–ID benefit if their Part A entitlement ends as described in § 406.13(f)(2) of this subchapter.

(2) Effective July 4, 2025, the individual must meet the eligibility criteria set forth in § 407.10(a)(2)(ii).

* * * * *

■ 24. Section 407.62 is amended by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) to read as follows:

§ 407.62 Termination of coverage.

* * * * *

(f) Enrollment in the Part B–ID benefit ends the date entitlement is terminated in accordance with § 407.27(e) due to the individual's failure to meet the citizenship, nationality, or eligible noncitizen requirements described in § 407.10(a)(2).

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 25. The authority for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 25A. Section 410.26 is amended by revising paragraphs (a) and (b) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

* * * * *

(b) * * *

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner).

(i) Designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner).

(ii) Behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or other practitioner).

(iii) Health coaching services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or other practitioner).

(iv) The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly.

(v) Only the supervising physician (or other practitioner) may bill Medicare for incident to services.

* * * * *

■ 26. Section 410.78 is amended by—

■ a. Revising paragraph (a)(3);

■ b. Adding paragraphs (b)(2)(xiii), (b)(3)(xiv)(D), (b)(3)(xv), and (b)(6); and

■ c. Revising paragraph (f);

The revisions and additions read as follows:

§ 410.78 Telehealth services.

(a) * * *

(3) *Interactive telecommunications system* means, except as otherwise provided in this paragraph (a)(3), multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

(i) An interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a patient in their home on or before December 31, 2027.

(ii)(A) For telehealth services furnished after December 31, 2027 date, interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a patient in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined in this paragraph (a)(3), but the patient is not capable of, or does not consent to, the use of video technology.

(B) The following modifiers must be appended to a claim for telehealth services furnished using two-way, real-time audio-only communication technology to verify that the conditions set forth in paragraph (a)(3)(ii)(A) of this section have been met:

* * * * *

(b) * * *

(2) * * *

(xiii) Occupational therapists, physical therapists, speech-language pathologists, or audiologists, through December 31, 2027.

* * * * *

(3) * * *

(xiv) * * *

(D) Consistent with section 6209(d) of the CAA, 2026, in-person visit requirements for the purposes of diagnosis, evaluation, or treatment of a mental health disorder do not apply through December 31, 2027.

* * * * *

(6) Consistent with section 6209(a) of the CAA, 2026, the geographic requirements specified in paragraph (b)(4) of this section do not apply through December 31, 2027.

* * * * *

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph (f), changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. CMS maintains the list of services that are Medicare telehealth services under this section, including the current HCPCS codes that describe the services on the CMS website.

§ 410.105 [Amended]

■ 27. Section 410.105 is amended in paragraph (b)(3)(ii) by removing the reference ''§ 410.100(m)'' and adding in its place the reference ''§ 410.100(1)''.

■ 28. Section 410.175 is amended by revising paragraphs (a) and (b) to read as follows:

§ 410.175 Alien absent from the United States.

(a) Medicare does not pay Part B benefits for services furnished to an eligible noncitizen, as defined in 42 CFR 400.200, if those services are furnished in any month for which the individual is not paid monthly social security cash benefits (or would not be paid if he or she were entitled to those benefits) because he or she has been outside the United States continuously for 6 full calendar months.

(b) Payment of benefits resumes with services furnished during the first full calendar month the eligible noncitizen, as defined in 42 CFR 400.200, is back in the United States.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 29. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 30. Section 414.502 is amended by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period.

Data reporting period for CDLTs that are not ADLTs is the 3-month period, May 1 through July 31, and for ADLTs is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period.

* * * * *

§ 414.504 [Amended]

■ 31. Section 414.504 is amended in paragraph (a)(1) by removing the date ''January 1, 2026'' and adding in its place the date ''May 1, 2026''.

■ 32. Section 414.507 is amended by—

■ a. Revising paragraph (d) introductory text and paragraph (d)(9); and

■ b. Adding paragraph (d)(12).

The revisions and addition read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2029, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(9) 2026—0.0 percent of the payment rate established in 2025.

* * * * *

(12) 2029—15 percent of the payment rate established in 2028.

* * * * *

■ 33. Section 414.523 is amended by revising paragraph (a)(1)(v) to read as follows:

§ 414.523 Payment for laboratory specimen collection fee and travel allowance.

(a) * * *

(1) * * *

(v) For a specimen collected from a Medicare beneficiary in a skilled nursing facility or on behalf of a home health agency, the specimen collection fee otherwise payable under paragraph (a)(1) of this section is increased by $2.00.

■ 34. Section 414.610 is amended by—

■ a. Revising paragraph (c)(1)(ii) introductory text; and

■ b. In paragraph (c)(5)(ii) removing the date ''September 30, 2025'' and adding in its place the date ''December 31, 2027''.

The revision reads as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through December 31, 2027, ambulance services originating in either of the following:

* * * * *

■ 35. Section 414.1105 is amended by revising paragraph (c) introductory text to read as follows:

§ 414.1105 Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) services.

* * * * *

(c) *Payment for supplies and durable medical equipment, prosthetic and orthotic devices.* Supplies and durable medical equipment that are CORF services under § 410.100(k), prosthetic device services that are CORF services under § 410.100(f), and orthotic devices that are CORF services under § 410.100(g) are paid the lesser of 80 percent of the following:

* * * * *

■ 36. Section 414.1305 is amended by revising the definitions of ''APM Incentive Payment'', ''Certified Electronic Health Record Technology (CEHRT)'' paragraph (2), ''Collection type'', ''MVP participant'' and ''Participant List'' to read as follows:

§ 414.1305 Definitions.

* * * * *

APM Incentive Payment means the lump sum incentive payment for a year as described in § 414.1450(b)(1) and that is paid for an eligible clinician who is a QP for the applicable year.

* * * * *

Certified Electronic Health Record Technology (CEHRT) * * *

(2) * * *

(i) For CY 2019 through CY 2026, at 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) * * *

(A) For CY 2019 through CY 2026, the applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3), and for CY 2019 through CY 2026, optionally (c)(4), and can be electronically accepted by CMS.

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs); and Medicare Electronic Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs).

* * * * *

MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2026 performance period/2028 MIPS payment year and future years, MVP participant means an individual MIPS eligible clinician, single-specialty group, multispecialty group that meets the requirements of a small practice, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. Beginning in the CY 2029 performance period/2031 MIPS payment year, MVP participant means an individual MIPS eligible clinician, single specialty group, multispecialty group that meets the requirements of a small practice, virtual group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

* * * * *

Participation List means the list of participants in an APM Entity that is compiled from a CMS-maintained list where practicable.

* * * * *

■ 37. Section 414.1330 is amended by revising paragraph (c)(2)(iv) to read as follows.

§ 414.1330 Quality performance category.

(c) * * *

(2) * * *

(iv) Whether the quality measure is designated as high priority or not, through the CY 2026 performance period/2028 MIPS payment year.

* * * * *

■ 38. Section 414.1335 is amended by—

■ a. Revising paragraphs (a)(1)(i) introductory text, (a)(1)(ii), and (a)(4)(i);

■ b. Adding paragraph (a)(1)(iii);

■ c. Revising paragraph (a)(4)(i); and

■ d. Adding paragraph (a)(5).

The revisions and additions read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) * * *

(1) * * *

(i) For the CY 2017 through 2026 performance periods/2019 through 2028 MIPS payment years, except as provided in paragraph (a)(1)(ii) of this section, submits data on at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, reports one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician, group, virtual group, or APM Entity, reports on each measure that is applicable. Beginning in the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians, except as provided in paragraphs (a)(1)(ii) and (a)(1)(iii) of this section, submits data on at least six measures, including at least one MIPS core measure. If there is not an available and applicable MIPS core measure, a MIPS eligible clinician must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure. If fewer than six measures apply then the MIPS eligible clinician, group, virtual

group, or APM Entity must report on each measure that is applicable.

* * * * *

(ii) For the CY 2017 through 2026 performance periods/2019 through 2028 MIPS payment years, a MIPS eligible clinician, group, virtual group, and APM Entity that report on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, group, virtual group, or APM Entity, report on each measure that is applicable. Beginning in the CY 2027 performance period/2029 MIPS payment year, except as provided in paragraph (a)(1)(iii) of this section, a MIPS eligible clinician that reports on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one MIPS core measure. If there is not an available and applicable MIPS core measure, a MIPS eligible clinician must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure within that set. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, report on each measure that is applicable.

* * * * *

(iii) *Small practices.* Beginning with the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians in small practices are not required to submit at least one MIPS core measure or attest to not having an applicable and available MIPS core measure. MIPS eligible clinicians in small practices must submit data on at least six measures, if applicable.

* * * * *

(4) *For Medicare CQMs.* (i) A MIPS eligible clinician, group, and APM Entity reportingquality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set or APP Plus measure set (as applicable) and administering the CAHPS for MIPS Survey as required under the APP.

(ii) [Reserved]

(5) *For Medicare eCQMs.* (i) A MIPS eligible clinician, group, and APM Entity reporting on the Medicare eCQMs (reporting quality data on beneficiaries eligible for Medicare eCQMs as defined at § 425.20) within the APP Plus measure set and administering the CAHPS for MIPS Survey as required under the APP.

(ii) [Reserved]

* * * * *

■ 39. Section 414.1340 is amended by—
■ a. Revising paragraphs (d) and (e); and
■ b. Adding paragraph (f).

The revisions and additions read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

* * * * *

(d) APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations meeting reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on the following:

(1) At least 75 percent of the applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria for MIPS payment year 2026 and future MIPS payment years.

(e) APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations meeting reporting requirements under the APP, submitting quality measure data on Medicare eCQMs must submit data on the following:

(1) At least 75 percent of the applicable beneficiaries eligible for the Medicare eCQM, as defined at § 425.20, who meet the measure's denominator criteria for MIPS payment years 2029 and future MIPS payment years.

(2) [Reserved]

(f) If quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5).

■ 40. Section 414.1365 is amended by—
■ a. Adding paragraph (a)(2); and
■ b. Revising paragraphs (c)(1) introductory text and (c)(1)(ii).

The revisions and additions read as follows:

§ 414.1365 MIPS Value Pathways.

(a) * * *

(2) Beginning in the CY 2031 performance period/2033 MIPS payment year, except for MIPS eligible clinicians reporting through the APM Performance Pathway in accordance with § 414.1367, all MIPS eligible clinicians must report through an MVP.

* * * * *

(c) * * *

(1) *Quality.* Through the CY 2026 performance period/2028 MIPS payment year, except as provided in paragraph (c)(1)(i) of this section, an MVP participant must select and report, if applicable, four quality measures, including one outcome measure (or, if an outcome measure is not available, one high priority measure), included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section. Beginning in the CY 2027 performance period/2029 MIPS payment year, except as provided in paragraphs (c)(1)(i) and (c)(1)(ii) of this section, an MVP participant must select and report, if applicable, four quality measures, including one MIPS core measure available in the MVP, excluding the population health measure required under paragraph § 414.1365(c)(4)(ii). If there is not an available and applicable MIPS core measure, an MVP participant must attest to not having an available and applicable MIPS core measure and submit a separate MIPS quality measure within the MVP.

* * * * *

(ii) *Small practices.* Beginning with the CY 2027 performance period/2029 MIPS payment year, an MVP participant that meets the requirements of a small practice is not required to submit at least one MIPS core measure or attest to not having an available and applicable MIPS core measure. Except as provided in paragraph (c)(1)(i) of this section, an MVP participant that meets the requirements of a small practice must select and report, if applicable, at least four quality measures included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section.

* * * * *

■ 41. Section 414.1375 is amended is amended by revising paragraphs (b)(2)(ii)(A) and (b)(3)(i) introductory text to read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(A) Through the 2028 MIPS payment year, report that the MIPS eligible clinician completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs;

* * * * *

(3) * * *

(i) *Supporting providers with the performance of CEHRT (SPPC).*

From the 2019 MIPS payment year through the 2027 MIPS payment year, to engage in activities related to supporting providers with the performance of CEHRT, the MIPS eligible clinician—

* * * * *

■ 42. Section 414.1380 is amended by—
■ a. Revising paragraphs (b)(1)(ii)(E) and (b)(1)(ii)(F);
■ b. Adding paragraphs (b)(1)(ii)(G) and (H), and (b)(1)(iv)(D);
■ c. Revising paragraphs (b)(3)(i) and (b)(4)(ii)(C)(*3*);
■ d. Adding paragraph (b)(4)(ii)(C)(*4*); and
■ e. Revising paragraphs (c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(E) For the CY 2025 and 2026 performance periods/2027 and 2028 MIPS payment years, CMS will publish a list of topped out measures determined to be impacted by limited measure choice in the **Federal Register** on a yearly basis. Beginning with the CY 2027 performance period/2029 MIPS payment year, CMS will publish a list of topped out measures determined to be impacted by limited measure choice on the QPP website. Measures included on the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

(F) *Medicare CQMs collection type benchmarks.*

(*1*) Beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQMs collection type use flat benchmarks for their first two performance periods in MIPS.

(*2*) Beginning with the CY 2026 performance period/2028 MIPS payment year, measures of the Medicare CQMs collection type use flat benchmarks.

(G) *Medicare eCQMs collection type benchmarks.*

(*1*) Beginning with the CY 2027 performance period/2029 MIPS payment year, measures of the Medicare eCQMs collection type use flat benchmarks.

(*2*) [Reserved]

(H) Beginning in the CY 2027 performance period/2029 MIPS payment year, MIPS core measures, which are required under § 414.1335(a)(1)(i) and (ii), for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years, are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

* * * * *

(iv) * * *

(D) Beginning with the CY 2027 performance period/2029 MIPS payment year, MIPS core measures, which are required under § 414.1335(a)(1)(i) and (ii), are not subject to the 7 measure achievement point cap specified in paragraph (b)(1)(iv)(B) of this section.

* * * * *

(3) * * *

(i) For MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent.

* * * * *

(4) * * *

(i) * * *

(C) * * *

(ii) * * *

(C) * * *

(3) Beginning with the CY 2026 performance period/2028 MIPS payment year, the total number of bonus points available to be earned when reporting one optional measure, more than one optional measure, or all optional measures under the Public Health and Clinical Data Exchange objective is a total of 5 bonus points.

(4) For the CY 2027 performance period/2029 MIPS payment year, the total number of bonus points available to be earned when reporting the Electronic Prior Authorization optional measure is a total of 10 bonus points.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(10) Beginning with the 2026 MIPS payment year, for the quality and improvement activities performance categories, CMS determines based on documentation provided to the agency that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third-party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third-party intermediary, and the third-party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. To determine whether to apply reweighting to the affected performance category(ies), CMS will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third-party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third-party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines.

(i) For the 2026 MIPS payment year, requests must be submitted by November 1st of the year preceding the relevant MIPS payment year.

(ii) Beginning with the 2027 MIPS payment year, requests must be submitted by December 31st of the year preceding the relevant MIPS payment year.

* * * * *

(C) * * *

(12) Beginning with the 2026 MIPS payment year, CMS determines based on documentation provided to the agency that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third-party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third-party intermediary, and the third-party intermediary did not submit the data for the performance category on behalf of the MIPS eligible clinician in accordance with applicable deadlines. To determine whether to apply reweighting to the Promoting Interoperability performance category, CMS will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third-party intermediary's submission of the clinician's data for the performance category; whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third-party intermediary caused no data to be submitted for the performance category in accordance with applicable deadlines.

(i) For the 2026 MIPS payment year, requests must be submitted by

November 1st of the year preceding the relevant MIPS payment year.

(ii) Beginning with the 2027 MIPS payment year, requests must be submitted by December 31st of the year preceding the relevant MIPS payment year.

* * * * *

§ 414.1395 [Amended]

■ 43. Section 414.1395 is amended by removing paragraph (c)(2) and redesignating paragraph (c)(1) as paragraph (c).

■ 44. Section 414.1400 is amended by—

■ a. Revising paragraphs (b)(3)(iii), (b)(3)(v)(E)(*1*),

■ b. Redesignating paragraph (b)(3)(vi) and (viii) as (b)(3)(vii)(A) and (B), respectively;

■ c. Adding paragraph (b)(3)(vii)(C);

■ d. Reserving paragraphs (b)(3)(vi) and (viii);

■ e. Revising paragraphs (b)(3)(x), (b)(3)(xiv), and (c)(1) introductory text;

■ b. Adding paragraphs (c)(2); and

■ c. Revising paragraph (e)(5);

The revisions and additions read as follows:

§ 414.1400 Third-party intermediaries.

* * * * *

(b) * * *

(3) * * *

(iii) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must provide performance feedback at least 4 times a year and provide specific feedback on how they compare to other clinicians who have submitted data on a given measure within the QCDR or qualified registry. Feedback must be provided at the level at which data is submitted. Exceptions to this requirement may occur if the QCDR or qualified registry submits notification to CMS within the performance period promptly within the month of realization of the impending deficiency and provides sufficient rationale as to why they do not believe they would be able to meet this requirement (for example, if the QCDR does not receive the data from their clinician until the end of the performance period).

* * * * *

(v) * * *

(E) * * *

(*1*) If the intermediary submits MIPS data to CMS for fewer than 10 Quality Payment Program participants, the data validation audit sample must include all Quality Payment Program participants. If the intermediary submits data for 10 or more Quality Payment Program participants, it must use a sample size of at least 3 percent of a combination of the individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups or APM entities, and no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities.

(*2*) If there are fewer than 5 patient records, the patient record audit sample must include all patient records. If there are 5 or more patient records, the intermediary must use a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

* * * * *

(vi) [Reserved].

(vii) Participation plan for third-party intermediary not submitting data.

(A) For the CY 2023 performance period/2025 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for any of the 2019 through 2023 MIPS payment years must submit a participation plan for CMS' approval. The participation plan must include the QCDR and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(B) For the CY 2024 performance period/2026 MIPS payment year through CY 2026 performance period/2028 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(C) Beginning with the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for the year preceding the applicable self-nomination period must submit a participation plan for CMS' approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(viii) [Reserved].

* * * * *

(x) For the CY 2017 performance period/2019 MIPS payment year through CY 2026 performance period/CY 2028 MIPS payment year, a QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one outcome measure.

(A) For the CY 2017 performance period/2019 MIPS payment year through CY 2026 performance period/CY 2028 MIPS payment year, if no outcome measure is available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure.

(B) Beginning with CY 2027 performance period/2029 MIPS payment year, a QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one MIPS core measure.

* * * * *

(xiv) A QCDR or a qualified registry must attest that the information listed on the qualified posting is accurate. Changes to information (for example, cost, services included) on the qualified posting must be included and finalized during the qualified posting review period. Third-party intermediaries will not be permitted to make changes after the qualified posting is publicly posted on the Quality Payment Program website.

* * * * *

(c) * * *

(1) For the CY 2021 performance period/2023 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year, health IT vendors must be able to submit data for the MIPS performance categories as follows:

* * * * *

(2) Beginning with the CY 2025 performance period/2027 MIPS payment year, health IT vendors cannot submit MIPS data.

* * * * *

(5) *Termination for third-party intermediary not submitting data.*

(i) Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under paragraph (b)(3)(viii) of this section, but does not submit MIPS data for the applicable performance period for which they self-

nominated under paragraph (b)(3)(viii) of this section, will be terminated.

(ii) Beginning with the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under paragraph (b)(3)(viii) of this section, but does not submit MIPS data for the applicable performance period for which they self-nominated under paragraph (b)(3)(viii) of this section, will be queried by CMS before the end of the calendar year for the given MIPS performance period requesting documentation that they have contracted with Quality Payment Program participants who will submit data for the given MIPS performance period. If appropriate documentation cannot be provided or the third-party intermediary will not be submitting MIPS data or both for the given MIPS performance period, the third-party intermediary will be terminated.

■ 45. Section § 414.1425 is amended by—

■ a. Revising paragraph (c)(5); and

■ b. Adding paragraphs (c)(8) and (d)(5).

The revision and additions read as follows:

§ 414.1425 Qualifying APM participant determination: In general.

* * * * *

(c) * * *

(5) * * *

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that QP performance period under the terms of the Advanced APM, even if such termination date occurs within such QP Performance Period.

* * * * *

(8) Beginning in the 2027 QP Performance Period, application of QP determination is limited strictly to eligible clinicians as defined at § 414.1305 and that meet the definition of Qualifying APM participant (QP) as defined at § 414.1305 by participating in an Advanced APM during the QP performance period. Partial QP status is also applied to all eligible clinicians receiving QP status for an individual QP determination as codified at § 414.1425(d).

* * * * *

(d) * * *

(5) Beginning in the 2027 QP Performance Period, application of Partial QP determination as part of an APM entity group as defined at § 414.1305 is limited strictly to eligible clinicians as defined at § 414.1305 that meet the definition of Partial Qualifying APM Participant (Partial QP) as defined at § 414.1305 by participating in an Advanced APM during the QP performance period. Partial QP status is also applied to all eligible clinicians receiving partial QP status for an individual determination as codified at § 414.1425(d)

* * * * *

■ 46. Section § 414.1430 is amended by revising paragraphs (a), (b)(1)(i), (2)(i), (3)(i), and (4)(i) to read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *

(1) *QP payment amount threshold.* The QP payment amount thresholds are the following values for the indicated payment years: (i) 2019 and 2020: 25 percent.

(ii) 2021 through 2026: 50 percent.

(iii) 2027: 75 percent.

(iv) 2028: 50 percent.

(v) 2029 and thereafter: 75 percent.

(2) *Partial QP payment amount threshold.* The Partial QP payment amount thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 20 percent.

(ii) 2021 through 2026: 40 percent.

(iii) 2027: 50 percent.

(iv) 2028: 40 percent.

(v) 2029 and thereafter: 50 percent.

(3) *QP patient count threshold.* The QP patient count thresholds are the following values for the indicated payment years: (i) 2019 and 2020: 20 percent.

(ii) 2021 through 2026: 35 percent.

(iii) 2027: 50 percent.

(iv) 2028: 35 percent.

(v) 2029 and thereafter: 50 percent.

(4) *Partial QP patient count threshold.* The Partial QP patient count thresholds are the following values for the indicated payment years: (i) 2019 and 2020: 10 percent.

(ii) 2021 through 2026: 25 percent.

(iii) 2027: 35 percent.

(iv) 2028: 25 percent.

(v) 2029 and thereafter: 35 percent.

(b) * * *

(1) * * *

(i) * * *

(A) 2021 through 2026: 50 percent

(B) 2027: 75 percent.

(C) 2028: 50 percent.

(D) 2029 and thereafter: 75 percent.

(2) * * *

(i) * * *

(A) 2021 through 2026: 40 percent

(B) 2027: 50 percent.

(C) 2028: 40 percent.

(D) 2029 and thereafter: 75 percent.

* * * * *

(3) * * *

(i) * * *

(A) 2021 through 2026: 35 percent.

(B) 2027: 50 percent.

(C) 2028: 35 percent.

(D) 2029 and thereafter: 50 percent.

* * * * *

(4) * * *

(i) * * *

(A) 2021 through 2026: 25 percent

(B) 2027: 35 percent.

(C) 2028: 25 percent.

(D) 2029 and thereafter: 35 percent.

* * * * *

■ 47. Section § 414.1450 is amended by revising paragraphs (a)(1)(i) and (b)(1) to read as follows:

§ 414.1450 APM Incentive Payment.

(a) * * *

(1) * * *

(i) For payment years in which an APM incentive payment is authorized under section 1833(z)(1)(A) of the Act, CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section for the applicable payment year and in the manner described in paragraphs (d) and (e) of this section.

(b) * * *

(1) The amount of the APM incentive payment is the applicable percentage established for the payment year of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment. The applicable percentage is the following value for the indicated payment years:

(i) 2019 through 2024: 5 percent.

(ii) 2025: 3.5 percent.

(iii) 2026: 1.88 percent.

(iv) 2028: 3.1 percent.

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 48. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 49. Section 415.172 is amended by revising paragraphs (a) introductory text and (b)(2) to read as follows:

(a) *General rule.* If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for

which payment is sought. This includes Medicare telehealth services, provided through audio/video real-time communications technology, when either the teaching physician or resident is in the same physical location as the beneficiary or in instances when the service is a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations.

* * * * *

(b) * * *

(2) For all teaching settings, except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document whether the teaching physician was physically present or present through audio/video real-time communications technology at the time the service (including a Medicare telehealth service) is furnished. The medical records must contain a notation describing the specific portion(s) of the service for which the teaching physician was present through audio/video real-time communications technology. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

■ 50. Section 415.174 is amended by revising paragraph (a) introductory text to read as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

(a) In the case of certain evaluation and management codes (as specified by CMS in program instructions), MACs may make physician fee schedule payment for a service furnished by a resident without the presence of a teaching physician. For the exception to apply, all of the following conditions must be met:

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 51. The authority for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

■ 52. Section 417.2 is amended by revising paragraph (b) to read as follows:

§ 417.2 Basis and scope.

* * * * *

(b) Subparts G through R of this part set forth the rules for Medicare contracts with, and payment to, HMOs and competitive medical plans (CMPs) under sections 1876 and 1899C of the Act and 8 U.S.C. 1611.

* * * * *

■ 53. Section 417.422 is amended by revising paragraph (h) to read as follows:

§ 417.422 Eligibility to enroll in an HMO or CMP.

* * * * *

(h) Effective July 4, 2025, is a United States citizen or national, or an eligible noncitizen as defined in 42 CFR 400.200.

■ 54. Section 417.460 is amended by revising paragraphs (b)(2)(iv) and (j) to read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *

(b) * * *

(2) * * *

(iv) No longer meets the requirements of § 417.422(h); or

* * * * *

(j) *Enrollee is not a United States citizen or national, or an eligible noncitizen.* Disenrollment is effective the first day of the month following the month in which the HMO or CMP receives a notice from CMS that the individual is ineligible in accordance with § 417.422(h).

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 55. The authority for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 56. Section 422.1 is amended by adding paragraph (a)(1)(xii) and removing and reserving paragraph (a)(2) to read as follows:

§ 422.1 Basis and scope.

(a) * * *

(1) * * *

(xii) 1899C—Limiting Medicare coverage of certain individuals.

(2) [Reserved]

* * * * *

■ 57. Section 422.50 is amended by revising paragraph (a)(7) to read as follows:

§ 422.50 Eligibility to elect an MA plan.

* * * * *

(a) * * *

(7) Effective July 4, 2025, is a United States citizen or national, or an eligible noncitizen as defined in 42 CFR 400.200.

* * * * *

■ 58. Section 422.62 is amended by revising paragraph (b)(16) to read as follows:

§ 422.62 Election of coverage under an MA plan.

* * * * *

(b) * * *

(16) Verification of eligible noncitizen/citizenship status.

(i) The SEP begins when the individual provides SSA with sufficient information to demonstrate that the requirements of § 406.20(b)(2) and § 407.10(a)(2)(ii) have been met and receives notice of their entitlement to Medicare Part A and enrollment in Medicare Part B. The SEP continues for 2 additional calendar months after the month the notice is received.

* * * * *

■ 59. Section 422.74 is amended by revising paragraphs (b)(2)(v) and (d)(9) to read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(b) * * *

(2) * * *

(v) The individual no longer meets the requirements of § 422.50(a)(7).

* * * * *

(d) * * *

(9) *Enrollee loses U.S. citizenship, U.S. nationality, or eligible noncitizen status.* Disenrollment is effective the first day of the month following the month in which the MA organization receives a notice from CMS that the individual is ineligible in accordance with § 422.50(a)(7) of this chapter.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 60. The authority for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 61. Section 423.1 is amended by adding a section in numerical order in paragraph (a)(1) and removing and reserving paragraph (a)(3) to read as follows:

§ 423.1 Basis and scope.

(a) * * *

(1) * * *

1899C. Limiting Medicare coverage of certain individuals.

* * * * *

(3) [Reserved]

* * * * *

■ 62. Section 423.30 is amended by revising paragraph (a)(1)(iii) to read as follows:

§ 423.30 Eligibility and enrollment.

(a) * * *

(1) * * *

(iii) Effective July 4, 2025, is a United States citizen or national, or an eligible noncitizen as defined in 42 CFR 400.200.

* * * * *

■ 63. Section 423.38 is amended by revising paragraphs (c)(21)(i) and (ii) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(21) * * *

(i) Verification of eligible noncitizen/citizenship status.

(ii) The SEP begins when the individual provides SSA with sufficient information to demonstrate that the requirements of § 406.20(b)(2) or § 407.10(a)(2)(ii) have been met and receives notice of their entitlement to, or enrollment for, either Medicare Part A or Part B. The SEP continues for 2 additional calendar months after the month the notice of the Part A entitlement or Part B enrollment is received, whichever is earlier.

* * * * *

■ 64. Section 423.44 is amended by revising paragraphs (b)(2)(vi) and (d)(8) to read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(b) * * *

(2) * * *

(vi) The individual no longer meets the requirements of § 423.30(a)(1)(iii).

* * * * *

(d) * * *

(8) *Individual loses U.S. citizenship, U.S. nationality, or eligible noncitizen status.* Disenrollment is effective the first day of the month following the month in which the PDP sponsor receives a notice from CMS that the individual is ineligible in accordance with § 423.30(a)(1)(iii) of this chapter.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 65. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 66. Section 424.516 is amended by adding paragraph (f)(4) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(f) * * *

(4) A provider or supplier that is a covered entity as defined at 42 CFR 10.3 is required to—

(i) Submit to CMS the documentation set forth at § 428.203(c)(1) and (2) relating to covered Part D drugs written or ordered by such provider or supplier.

(ii) Comply with the submission requirements set forth at § 428.203(c)(3) through (5).

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 67. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 68. Section 425.20 is amended by—

■ a. Revising and republishing the definition of ''Beneficiary eligible for Medicare CQMs'';

■ b. Adding the definition of ''Beneficiary eligible for Medicare eCQMs'' in alphabetical order;

■ c. Revising paragraph (2) in the definition of ''Experienced with performance-based risk Medicare ACO initiatives'';

■ d. Revising paragraph (2) in the definition of ''Inexperienced with performance-based risk Medicare ACO initiatives''; and

■ e. Adding the definition of ''Rural county status'' in alphabetical order.

The revisions, republication, and additions read as follows:

§ 425.20 Definitions.

* * * * *

Beneficiary eligible for Medicare CQMs means a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who meets the following requirements (as applicable):

(1) For performance years 2024 through 2026, the beneficiary is either of the following:

(i) A Medicare fee-for-service beneficiary (as defined at § 425.20) who—

(A) Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

(B)(*1*) For performance year 2024, had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

(*2*) For performance years 2025 and 2026, had at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

(ii) A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

(2) For performance years 2027 and subsequent performance years, a beneficiary that is assigned to the ACO under subpart E of this part.

Beneficiary eligible for Medicare eCQMs means a beneficiary identified for purposes of reporting Medicare eCQMs for ACOs participating in the Medicare Shared Savings Program (Medicare eCQMs), who is a beneficiary that is assigned to the ACO under subpart E of this part.

* * * * *

Experienced with performance-based risk Medicare ACO initiatives * * *

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years, unless the ACO participant TIN did not have a written agreement to participate in the performance-based risk Medicare ACO initiative.

* * * * *

Inexperienced with performance-based risk Medicare ACO initiatives * * *

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years. An ACO participant is considered to

have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years, unless the ACO participant TIN did not have a written agreement to participate in the performance-based risk Medicare ACO initiative.

* * * * *

Rural county status means a county that has a status of Micropolitan (population of 10,000 to 50,000 individuals) or Noncore (population less than 10,000 individuals) per the Federal Office of Rural Health Policy (FORHP) county designation using the most recently available version of the United States Census Bureau Delineation File.

* * * * *

■ 69. Section 425.304 is amended by—

■ a. In paragraph (a)(2), removing the phrase ''paragraph (b) or (c) of this section'' and adding in its place the phrase ''paragraph (b), (c), or (e) of this section''; and

■ b. Adding paragraph (e).

The addition reads as follows:

§ 425.304 Beneficiary incentives.

* * * * *

(e) *Part B Cost Sharing Support*—(1) *General.* ACOs, subject to certain conditions and safeguards, may enter into Part B cost sharing support arrangements with ACO participants, pursuant to which the ACO participants reduce or eliminate cost sharing for those categories of eligible Part B items and services and eligible beneficiaries identified by the ACO. This cost sharing support could include both or either of Medicare FFS deductible and coinsurance amounts.

(2) *Application of the CMS-sponsored model safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§ 1001.952(ii)(1) and (2) of this title) is available to protect remuneration exchanged under Part B cost sharing support arrangements between ACOs and ACO participants, and patient incentives in the form of Part B cost sharing support furnished to eligible beneficiaries under the Shared Savings Program that meet all of the requirements of this section and the anti-kickback statute safe harbor requirements set forth at § 1001.952(ii) of this title.

(3) *Application procedures*—(i) *General.* An ACO must submit a Part B cost sharing support implementation plan in the form and manner and by a deadline specified by CMS. The implementation plan must include the following:

(A) The categories of eligible beneficiaries for which the ACO plans to make Part B cost sharing support available.

(B) The categories of eligible Part B items and services for which the ACO plans to make Part B cost sharing support available.

(C) A description of how the ACO's planned Part B cost sharing support strategy meets at least one of the clinical goals in paragraph (e)(4)(iii) of this section.

(D) The procedures that the ACO will implement to ensure that ACO participants that have entered into a Part B cost sharing support arrangement with the ACO have access to the most current list of beneficiaries eligible to receive Part B cost sharing support.

(E) A requirement for the ACO to submit to CMS a complete and accurate list of ACO participants that have entered into a Part B cost sharing support arrangement with the ACO according to paragraph (e)(5)(i) of this section.

(F) An attestation that, in any marketing or communications regarding the availability of Part B cost-sharing support, the ACO and its ACO participants will not represent such support as a substitute for supplemental insurance coverage or encourage beneficiaries to reduce or terminate such coverage.

(G) Such other information as may be specified by CMS.

(ii) *CMS review.* CMS evaluates an ACO's implementation plan and approves or denies the application. An ACO may only offer Part B cost sharing support to beneficiaries if CMS approves its application. CMS may reject the ACO's application on the basis of one or more of the following:

(A) The ACO's and the ACO participant's history of noncompliance in the Shared Savings Program.

(B) The ACO's history of noncompliance in CMMI ACO models.

(C) Whether the implementation plan complies with the requirements of § 425.304.

(D) Such other factors as CMS deems reasonable to protect the integrity of the Shared Savings Program, including concerns that the use of Part B cost sharing support may contribute to fraud, waste or abuse.

(iii) *Changes to the implementation plan.* If an ACO wants to make a change to its implementation plan, the ACO must submit a description of the change to CMS in a form and manner and by a deadline or deadlines specified by CMS. CMS evaluates the proposed change and either approves or rejects it.

(4) *Part B cost sharing support requirements*—(i) *Beneficiary eligibility.* Beneficiaries are eligible to receive Part B cost sharing support if they meet the following criteria:

(A) The beneficiary is assigned to the applying ACO (as described at § 425.400(a)(1)(i)) if the ACO has selected prospective assignment or the beneficiary is an assignable beneficiary (as defined at § 425.20), if the applying ACO has selected preliminary prospective assignment with retrospective reconciliation.

(B) The beneficiary does not have secondary insurance that covers the associated Part B cost sharing obligation.

(C) The beneficiary's overall health is expected to be improved or maintained by receiving the associated Part B item or service.

(ii) *Eligible Part B items and services.* ACOs may reduce or eliminate beneficiary cost sharing for all Medicare FFS Part B items and services except durable medical equipment, prosthetics, orthotics, supplies, and prescription drugs.

(iii) *Clinical goals.* Cost sharing support must advance one or more of the following clinical goals:

(A) Adherence to a treatment regime.

(B) Adherence to a drug regime.

(C) Adherence to a follow-up care plan.

(D) Management of a chronic disease or condition.

(5) *Part B cost sharing support arrangements*—(i) *ACO participant agreements.* The ACO must have a written agreement with each ACO participant that has agreed to reduce or eliminate Part B cost sharing for eligible ACO beneficiaries under a Part B cost sharing support arrangement with the ACO. The terms of the Part B cost sharing support agreement must include all of the following:

(A) The categories of eligible beneficiaries and eligible Part B items and services for which the ACO participant may reduce or eliminate Part B cost sharing.

(B) A requirement that the ACO participant reduce or eliminate cost sharing in accordance with the ACO's approved implementation plan.

(C) The amount and frequency with which the ACO will reimburse the ACO participant for the cost sharing amounts not collected.

(D) A requirement for ACO participants to maintain copies of records that identify each beneficiary who received a reduction or elimination

of Part B cost sharing, the type and date of item or service for which cost sharing support was provided, and the dollar amount of the cost sharing support.

(E) The ability for the ACO or ACO participant to terminate the Part B cost sharing support agreement if the ACO or ACO participant fails to comply with the requirements of this section.

(F) A requirement that the ACO or ACO participants will not market to beneficiaries the availability of the Part B cost sharing support as a substitute for their supplemental insurance coverage.

(ii) *Other rules governing participation.* (A) An ACO participant must not be required by an ACO to participate in a Part B cost sharing support arrangement.

(B) An ACO may participate in Part B cost sharing support in accordance with an approved implementation plan even if not all of its ACO participants agree to participate.

(iii) *Source of funding.* The ACO must finance all payments made to ACO participants in accordance with the Part B cost sharing support agreement from its own funds.

(6) *Record retention.* (i) The ACO must maintain copies of the written Part B cost sharing support agreement with ACO participants, as well as the following records:

(A) Records that identify each beneficiary who received a reduction or elimination of Part B cost sharing.

(B) Records that document the type and date of the Part B item or service for which Part B cost sharing was reduced or eliminated.

(C) Records that document the dollar amount of Part B cost sharing that was reduced or eliminated.

(D) Records that document the ACO participant that furnished the item or service for which Part B cost sharing was reduced or eliminated.

(ii) The ACO must provide the records specified in paragraph (e)(6)(i) of this section to CMS upon request.

(7) *Addressing compliance problems.* At any time, CMS may suspend or prohibit the ACO or any ACO participant from participating in a Part B cost sharing support arrangement if CMS determines that the ACO or its ACO participants have failed to comply with any of the requirements of this part. This suspension or prohibition will be effective, in CMS' discretion, regardless of whether the ACO has corrected or otherwise resolved the noncompliance.

■ 70. Section 425.308 is amended by—

■ a. In paragraph (b)(9) introductory text, removing the phrase ''For performance year 2025 and subsequent performance years,'' and adding in its place the phrase ''For performance years 2025 and 2026,''; and

■ b. Adding paragraph (b)(11).

The addition reads as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(11) For performance year 2027 and subsequent performance years, the CEHRT use activity selected by the ACO for the purpose of meeting the ACO CEHRT use requirement at § 425.507(c).

* * * * *

■ 71. Section 425.312 is amended by—

■ a. Revising the last sentence in paragraph (a)(2)(iii);

■ b. Adding a new sentence at the end of paragraph (a)(2)(iv); and

■ c. Removing paragraph (a)(2)(v).

The revision and addition read as follows:

§ 425.312 Beneficiary notifications.

(a) * * *

(2) * * *

(iii) * * * The standardized written notice must be furnished to all of these beneficiaries by May 30, unless CMS specifies a later date during the performance year.

(iv) * * * The standardized written notice must be furnished to all of these beneficiaries by May 30, unless CMS specifies a later date during the performance year.

* * * * *

■ 72. Section 425.400 is amended by revising paragraph (c)(1)(x) introductory text and adding paragraph (c)(1)(xi) to read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(x) For the performance year starting on January 1, 2026, as follows:

* * * * *

(xi) For the performance year starting on January 1, 2027, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 97550, 97551, and 97552 (codes for caregiver training services).

(*4*) 98016 (code for virtual check-in).

(*5*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*6*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a skilled nursing facility (SNF)).

(*7*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*8*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(xi)).

(*10*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*11*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*12*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*13*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*14*) 99439 (code for non-complex chronic care management).

(*15*) 99452 (code for interprofessional consultation service).

(*16*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*17*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*18*) 99495 and 99496 (codes for transitional care management services).

(*19*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0019 and G0022 (codes for community health integration services).

(*2*) G0023 and G0024 (codes for principal illness navigation services).

(*3*) G0101 (code for cervical or vaginal cancer screening).

(*4*) G0136 (code for physical activity and nutritional assessment services).

(*5*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*6*) G0402 (code for the Welcome to Medicare visit).

(*7*) G0438 and G0439 (codes for the annual wellness visits).

(*8*) G0442 (code for alcohol misuse screening service).

(*9*) G0443 (code for alcohol misuse counseling service).

(*10*) G0444 (code for annual depression screening service).

(*11*) G0463 (code for services furnished in electing teaching amendment (ETA) hospitals).

(*12*) G0506 (code for chronic care management).

(*13*) G0537 and G0538 (codes for cardiovascular risk assessment and risk management services).

(*14*) G0539 and G0540 (codes for individual behavior management/modification caregiver training services).

(*15*) G0541, G0542, and G0543 (codes for direct care caregiver training services).

(*16*) G0544 (code for post-discharge telephonic follow-up contacts intervention).

(*17*) G0556, G0557, and G0558 (codes for advanced primary care management services).

(*18*) G0560 (code for safety planning interventions).

(*19*) G0568 and G0569 (codes for behavioral health integration add-on when furnished with advanced primary care management services).

(*20*) G0570 (code for psychiatric collaborative care model add-on when furnished with advanced primary care management services).

(*21*) G0572 and G0573 (codes for advance care planning).

(*22*) G0576 (code for assessment and treatment of vaccine adverse effects).

(*23*) G2010 (code for the remote evaluation of patient video/images).

(*24*) G2011, G0396, G0397 (codes for screening, brief intervention, and referral to treatment).

(*25)* G2012 and G2252 (codes for virtual check-in).

(*26*) G2058 (code for non-complex chronic care management).

(*27*) G2064 and G2065 (codes for principal care management services).

(*28*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*29*) G2211 (code for visit complexity inherent to evaluation and management services add-on).

(*30*) G2214 (code for psychiatric collaborative care model).

(*31*) G3002 and G3003 (codes for chronic pain management).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(xi)(A) of this section or a HCPCS code specified in paragraph (c)(1)(xi)(B) of this section, when the assignment window or expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

* * * * *

■ 73. Section 425.401 is revised and republished to read as follows:

§ 425.401 Criteria for a beneficiary to be assigned to an ACO.

(a) *Assignment eligibility criteria.* A beneficiary may be assigned to an ACO under the assignment methodology in §§ 425.402 and 425.404, for a performance or benchmark year, if the beneficiary meets all of the following criteria during the assignment window:

(1) For performance years starting prior to January 1, 2028 (as applicable):

(i)(A) Has at least 1 month of Part A and Part B enrollment; and

(B) Does not have any months of Part A only or Part B only enrollment.

(ii) Does not have any months of Medicare group (private) health plan enrollment.

(iii) Is not assigned to any other Medicare shared savings initiative.

(iv) Lives in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

(2) For the performance year starting on January 1, 2028, and subsequent performance years:

(i) Has at least 1 month of Part A and Part B enrollment and does not have Medicare group (private) health plan enrollment during that same month during the assignment window.

(ii) Is not assigned to any other Medicare shared savings initiative.

(iii) Lives in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

(b) *Prospective assignment exclusion criteria.* A beneficiary is excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each performance year consistent with § 425.400(a)(3)(ii), or at the end of CY 2019 as specified in § 425.609(b)(1)(ii) and (c)(1)(ii) if the beneficiary meets any of the following criteria during the performance or benchmark year:

(1) For performance years starting prior to January 1, 2028 (as applicable):

(i)(A) Does not have at least 1 month of Part A and Part B enrollment; and

(B) Has any months of Part A only or Part B only enrollment.

(ii) Has any months of Medicare group (private) health plan enrollment.

(iii) Did not live in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residency at the end of the year.

(2) For the performance year starting on January 1, 2028, and subsequent performance years:

(i) Does not have at least 1 month of Part A and Part B enrollment without Medicare group (private) health plan enrollment during that same month during the assignment window.

(ii) Did not live in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residency at the end of the year.

■ 74. Section 425.402 is amended by revising and republishing paragraphs (b)(3), (b)(4) and (b)(5)(iv) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(b) * * *

(3)(i) Under the first step, a beneficiary identified in paragraph (b)(1) of this section is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are—

(A) ACO professionals in any other ACO; or

(B) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(ii) For performance year 2028 and subsequent performance years, if an ACO professional for which CMS identifies a primary care service under paragraph (b)(2) of this section also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then CMS excludes from consideration in assignment under paragraph (b)(3)(i) of this section the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable assignment window.

(4)(i) The second step considers the remainder of the beneficiaries identified in paragraph (b)(1) of this section who have not had a primary care service rendered by any primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist, either inside

the ACO or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by physicians who are ACO professionals with specialty designations as specified in paragraph (c) of this section are greater than the allowed charges for primary care services furnished by physicians with specialty designations as specified in paragraph (c) of this section—

(A) Who are ACO professionals in any other ACO; or

(B) Who are unaffiliated with an ACO and are identified by a Medicare-enrolled billing TIN.

(ii) For performance year 2028 and subsequent performance years, if an ACO professional for which CMS identifies a primary care service under paragraph (b)(2) of this section also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then CMS excludes from consideration in assignment under paragraph (b)(4)(i) of this section the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable assignment window.

(5) * * *

(iv)(A) A beneficiary identified in paragraph (b)(5)(ii) of this section is assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, physicians with specialty designations included in paragraph (c) of this section, or non-physician ACO professionals during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations as specified in paragraph (c) of this section, nurse practitioners, physician assistants, and clinical nurse specialists who are—

(*1*) ACO professionals in any other ACO; or

(*2*) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(B) For performance year 2028 and subsequent performance years, if an ACO professional for which CMS identifies a primary care service under paragraph (b)(5)(iii) of this section also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then CMS excludes from consideration in assignment under paragraph (b)(5)(iv)(A) of this section the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable expanded window for assignment.

* * * * *

■ 75. Section 425.507 is amended by—

■ a. In paragraph (a) introductory text, removing the phrase ''For performance years beginning on or after January 1, 2025,'' and adding in its place the phrase ''For performance years 2025 and 2026,'';

■ b. In paragraph (b) introductory text, by adding the words ''For performance years 2025 and 2026,'' to the beginning of the first sentence; and

■ c. Adding paragraph (c).

The addition reads as follows:

§ 425.507 Incorporating Promoting Interoperability requirements related to the Quality Payment Program for performance years beginning on or after January 1, 2025.

* * * * *

(c) For performance years beginning on or after January 1, 2027, an ACO must demonstrate the use of CEHRT (as defined in paragraph (3) of the CEHRT definition at § 414.1305 of this chapter) in one of the following manners:

(1) The ACO uses CEHRT (as defined in paragraph (3) of the CEHRT definition at § 414.1305 of this chapter) that also supports the calculation and reporting of clinical quality measures by being certified to the ONC health IT certification criteria at 45 CFR 170.315(c)(2) and (c)(3), to completely report at least one of the measures in the APP Plus quality measure set using the eCQMs or Medicare eCQMs collection types and meets the data completeness requirement at § 414.1340 of this chapter for the applicable performance year.

(2) The ACO completely reports at least one measure in the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this chapter for the applicable performance year using EHR technology that meets paragraph (3) of the CEHRT definition at § 414.1305 of this chapter and attests that it used data collected from an HL7® Fast Healthcare Interoperable Resources (FHIR®)-based API to support quality measurement using a Health IT Module (as defined in 45 CFR 170.102) that has been certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access.

(3) The ACO attests to at least one of the Shared Savings Program CEHRT use metrics from the list of metrics established for the applicable performance year.

■ 76. Section 425.508 is amended by adding paragraphs (c)(1) through (4) to read as follows:

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

* * * * *

(c) * * *

(1) For performance years beginning on or after January 1, 2026. ACOs may exclude one or more TINs of ACO participants from an ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure as required in this paragraph (c). Applicable exclusions may include:

(i) Unforeseen circumstance(s) that are outside of the control of the ACO, such as the unexpected closure of a group or individual's practice that bills under the ACO participant TIN.

(ii) An ACO participant TIN has a CEHRT that is intended for specialty use and does not support the measure(s) included in the APP Plus quality measure set.

(iii) Other circumstances as determined by CMS.

(2) ACOs may not exclude an ACO participant TIN from the ACO's quality data submission for each measure based on the following:

(i) The demographics of the beneficiaries who had an encounter during the performance year with an ACO participant TIN.

(ii) The health status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN.

(iii) The estimated impact of the ACO participant TIN on the ACO's quality performance.

(3) The ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the ACO under subpart E of this part prior to the application of the measure specifications.

(4) CMS retains the right to audit and validate eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data reported by an ACO and may request documentation from the ACO related to the exclusion of ACO participant TINs under paragraph (c)(1) of this section. Failure to report quality measure data accurately, completely, and timely may result in compliance actions as described in §§ 425.216 and 425.218.

* * * * *

■ 77. Section 425.512 is amended by—

■ a. In paragraph (a)(2)(iv), removing the phrase ''eCQMs/Medicare CQMs'' and adding in its place the phrase ''eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs'';

■ b. In paragraph (a)(5)(i)(B) introductory text, removing the phrase ''For performance years 2025 and 2026,'' and adding in its place the phrase ''For performance year 2025 and subsequent performance years,'';
■ c. Removing paragraph (a)(5)(i)(C);
■ d. In paragraph (a)(5)(iii)(C), removing the phrase ''eCQMs/Medicare CQMs'' and adding in its place the phrase ''eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs'';
■ e. In paragraph (a)(7)(ii), removing the phrase ''For performance year 2025 and subsequent performance years,'' and adding in its place the phrase ''For performance years 2025 and 2026''; and
■ f. Adding paragraph (a)(7)(iii).

The addition reads as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(*7*) * * *

(iii) For performance year 2027 and subsequent performance years, if an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1) of this subchapter, for the relevant performance year, and the ACO meets the following—

(A) The ACO's MIPS Quality performance category score is calculated on less than five measures; and

(B) Any unscored measure(s) must meet all of the following:

(*1*) The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.

(*2*) The ACO's total measure achievement points used to calculate the ACO's MIPS Quality performance category score are not reduced under § 414.1380(b)(1)(iii) of this subchapter.

* * * * *

§ 425.600 [Amended]

■ 78. Section 425.600 is amended by—

in paragraph (f)(4)(ii) by removing the references ''§§ 425.601(f), and 425.656(e)'' and adding in their place the references ''§ 425.601(f), and § 425.656(e) and (f)''.

■ 79. Section 425.605 is amended by—
■ a. Revising paragraph (d)(1)(v)(A)(*3*)(*ii*), the first sentence of paragraph (d)(1)(v)(A)(*4*) introductory text, and paragraph (d)(1)(v)(A)(*4*)(*ii*);
■ b. Adding paragraph (d)(1)(v)(A)(*5*);
■ c. In paragraph (h)(2), removing the references ''paragraph (d)(1)(i)(A)(*4*), (d)(1)(ii)(A)(*4*), (d)(1)(iii)(A)(*4*), (d)(1)(iv)(A)(*4*), or (d)(1)(v)(A)(*4*) of this section'' and adding in their place the references ''paragraph (d)(1)(i)(A)(*4*), (d)(1)(ii)(A)(*4*), (d)(1)(iii)(A)(*4*), (d)(1)(iv)(A)(*4*), (d)(1)(v)(A)(*4*) or (d)(1)(v)(A)(*5*) of this section'';
■ d. In paragraph (i)(2)(i) introductory text, removing the phrase ''paragraph (i)(2)(ii) of this section'' and adding in its place the phrase ''paragraph (i)(2)(ii) or (i)(2)(iii) of this section, as applicable''; and
■ e. Adding new paragraph (i)(2)(iii).

The revisions and additions read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

* * * * *

(d) * * *

(1) * * *

(v) * * *

(A) * * *

(*3*) * * *

(*ii*) 50 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For ACOs in agreement periods beginning on July 1, 2019, through January 1, 2026, for performance years beginning on or after January 1, 2024.*

* * *

(*ii*) 50 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(*5*) *For ACOs in agreement periods beginning on or after January 1, 2027, for performance years beginning on or after January 1, 2027.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 60 percent for an ACO that that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 60 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

* * * * *

(i) * * *

(2) * * *

(iii) For agreement periods beginning on or after January 1, 2024, and before January 1, 2027, for performance year 2025 and subsequent performance years of the ACO's agreement period. CMS calculates the benchmark-based loss recoupment limit as follows:

(A) Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year prior to the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

(B) Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year after the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

(C) Calculates the product of the percentage specified in paragraph (d)(1)(iii)(D)(*2*), (d)(1)(iv)(D)(*2*), and (d)(1)(v)(D)(*2*) of this section, as applicable, and the lesser of the ACO's total benchmark expenditures calculated according to paragraphs (i)(2)(iii)(A) and (i)(2)(iii)(B) of this section.

■ 80. Section 425.610 is amended by—
■ a. In paragraph (l)(2) introductory text, removing the phrase ''paragraph (l)(3) of this section'' and adding in its place the phrase ''paragraph (l)(3) or (l)(4) of this section, as applicable''; and
■ b. Adding paragraph (l)(4).

The addition reads as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

* * * * *

(l) * * *

(4) For agreement periods beginning on or after January 1, 2024, and before January 1, 2027, for performance year 2025 and subsequent performance years of the ACO's agreement period. The amount of shared losses for which an eligible ACO is liable may not exceed 15 percent of the lesser of the following:

(i) Total benchmark expenditures calculated as the product of an ACO's per capita updated benchmark expenditures for the performance year prior to the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

(ii) Total benchmark expenditures calculated as the product of an ACO's per capita updated benchmark expenditures for the performance year

after the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

§ 425.612 [Amended]

■ 81. Section 425.612 is amended in paragraph (a)(1)(iv)(A)(*2*) by removing the references ''§ 425.401(a)(1) and (2)'' and adding in its place the references ''§ 425.401(a)(1)(i) and (ii) and (a)(2)(i) (as applicable)''.

■ 82. Section 425.630 is amended by—

■ a. In paragraph (e)(1), removing the phrase ''social determinants of health'' and adding in its place the phrase ''upstream drivers of health'';

■ b. Revising paragraph (f)(2)(ii) introductory text to add a new first sentence; and

■ c. Revising and republishing paragraphs (f)(2)(iii) and (f)(2)(iv).

The revisions and republications read as follows:

§ 425.630 Option to receive advance investment payments.

* * * * *

(f) * * *

(2) * * *

(ii) For performance years 2023 through 2027.

* * * * *

(iii) Determines a beneficiary's payment amount.

(A) For performance years 2023 through 2027. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS determines the payment amount that corresponds to the beneficiary's risk factors-based score determined in paragraph (f)(2)(ii) of this section. The beneficiary payment amount is as follows:

TABLE 1 TO PARAGRAPH (f)(2)(iii)(A)

Risk factors-based score	1–24	25–34	35–44	45–54	55–64	65–74	75–84	85–100
Payment amount	$0	$20	$24	$28	$32	$36	$40	$45

(B) For performance year 2028 and subsequent performance years. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS determines the quarterly payment amount, as follows:

(*1*) An ACO will receive a quarterly payment of $45 for each beneficiary that meets any of the following criteria:

(*i*) Is enrolled in the LIS.

(*ii*) Is dually eligible for Medicare and Medicaid.

(*iii*) Is residing in a county with rural county status (as defined at § 425.20). CMS determines the county of residence for the beneficiary based on the beneficiary's mailing address.

(*2*) An ACO will receive a quarterly payment of $25 for each beneficiary that does not meet any of the criteria listed in paragraph (f)(2)(iii)(B)(*1*) of this section.

(iv) Calculates the ACO's quarterly payment amount.

(A) For performance years 2023 through 2027. The ACO's quarterly payment amount is the sum of the beneficiary payment amounts corresponding to each assigned beneficiary's risk factors-based score, specified in paragraph (f)(2)(iii)(A) of this section, capped at 10,000 beneficiaries. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, CMS will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores determined according to paragraph (f)(2)(ii) of this section.

(B) For performance year 2028 and subsequent performance years. The ACO's quarterly payment amount is the sum of the beneficiary payment amounts corresponding to the quarterly payments specified in paragraph (f)(2)(iii)(B) of this section. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, CMS will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest quarterly payment amount determined according to paragraph (f)(2)(iii)(B) of this section.

* * * * *

■ 83. Section 425.640 is amended by—

■ a. In paragraph (b)(1)(i), removing the phrase ''January 1, 2026, or in subsequent years'' and adding in its place the phrase ''January 1, 2026 or January 1, 2027'';

■ b. In paragraph (c)(1), removing the phrase ''January 1, 2026, or in subsequent years'' and adding in its place the phrase ''January 1, 2026 or January 1, 2027''; and

■ c. Revising paragraphs (f)(1)(i) and (ii).

The revisions read as follows:

§ 425.640 Option to receive prepaid shared savings.

* * * * *

(f) * * *

(1) * * *

(i) An eligible ACO entering an agreement period beginning on January 1, 2026 or January 1, 2027 will receive quarterly prepaid shared savings payments through December 31, 2027, unless the payment is withheld or terminated under paragraph (h) of this section.

(ii) An eligible ACO participating in an agreement period beginning on January 1, 2025, will receive quarterly prepaid shared savings payments starting with the performance year beginning on January 1, 2026 through December 31, 2027, unless the payment is withheld or terminated under paragraph (h) of this section. The ACO will not receive additional or catch-up payments for performance year 2025.

* * * * *

§ 425.650 [Amended]

■ 84. Section 425.650 is amended in paragraph (a) by removing the references ''§§ 425.652 through 425.662'' and adding in their place the references ''§§ 425.652 through 425.664''.

■ 85. Section 425.652 is amended by adding paragraph (a)(8)(iii) to read as follows:

§ 425.652 Establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(a) * * *

(8) * * *

(iii) For agreement periods beginning on January 1, 2027, and in subsequent years, in addition to any adjustment applied to the historical benchmark in accordance with paragraph (a)(8)(ii) of this section (either a regional adjustment, prior savings adjustment, or population adjustment, as applicable), the ACO will receive a growth adjustment (as calculated under § 425.664), if eligible. The sum of the adjustment amount (if any) applied in paragraph (a)(8)(ii) of this section and the growth adjustment (determined according to § 425.664(i)(1)) may not exceed an amount equal to the cap specified in § 425.664(i)(2).

* * * * *

■ 86. Section 425.656 is amended by—

■ a. Revising paragraph (a);

■ b. In paragraph (c)(2), removing the phrase ''paragraph (e) of this section'' and adding in its place the phrase

''paragraphs (e) or (f) of this section (as applicable)'';

■ c. Revising and republishing paragraph (c)(3);

■ d. Revising paragraph (e) introductory text;

■ e. Redesignating paragraph (f) as paragraph (g);

■ f. Adding new paragraph (f); and

■ g. In newly redesignated paragraph (g) introductory text, removing the phrase ''paragraphs (b) through (e) of this section'' and adding in its place the phrase ''paragraphs (b) through (f) of this section''.

The revisions, republications, and addition read as follows:

§ 425.656 Calculating the regional adjustment to the historical benchmark.

(a) *General.* This section describes the methodology for calculating the regional adjustment to the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. This section applies to regional adjustment calculations for agreement periods beginning on January 1, 2024, and in subsequent years, except as specified otherwise.

* * * * *

(c) * * *

(3)(i) For agreement periods beginning on or after January 1, 2024 and before January 1, 2027. Caps the per capita dollar amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under paragraph (c)(2) of this section at a dollar amount equal to a percentage of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary. The cap is applied as follows:

(A) For positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(B) For negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 1.5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(ii) For agreement periods beginning on January 1, 2027, and in subsequent years. Caps the per capita dollar amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under paragraph (c)(2) of this section at a dollar amount, as follows:

(A) For positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at a dollar amount calculated as follows:

(*1*) Calculate the product of the following:

(*i*) The amount of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

(*ii*) The ACO's weighted average CMS–HCC risk score for the enrollment type for BY3.

(*2*) Calculate 5 percent of the enrollment type-specific product determined in paragraph (c)(3)(ii)(A)(*1*) of this section.

(B) For negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at a dollar amount equal to negative 1.5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

* * * * *

(e) *Phase-in of weights used in the regional adjustment calculation for agreement periods beginning on or after January 1, 2024 and before January 1, 2027.*

* * * * *

(f) *Phase-in weights used in the regional adjustment calculation for agreement periods beginning on January 1, 2027, and in subsequent years.* (1) The first time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(2) The second time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) For an ACO participating under the BASIC track—

(A) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

(B) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(ii) For an ACO participating under the ENHANCED track—

(A) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

(B) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(3) The third time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) For an ACO participating under the BASIC track—

(A) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

(B) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to

have higher spending than the ACO's regional service area.

(ii) For an ACO participating under the ENHANCED track—

(A) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

(B) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(4) The fourth or subsequent time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) For an ACO participating under the BASIC track, using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark.

(ii) For an ACO participating under the ENHANCED track—

(A) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

(B) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(5) To determine if an ACO has lower or higher spending compared to the ACO's regional service area, CMS does the following:

(i) Multiplies the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark for each population of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) as calculated under paragraph (c)(1) of this section by the applicable proportion of the ACO's assigned beneficiary population (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) for BY3 of the historical benchmark.

(ii) Sums the amounts determined in paragraph (f)(5)(i) of this section across the populations of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries).

(iii) If the resulting sum is a net positive value, the ACO is considered to have lower spending compared to the ACO's regional service area. If the resulting sum is a net negative value, the ACO is considered to have higher spending compared to the ACO's regional service area.

(iv) If during the term of the agreement period CMS adjusts the ACO's benchmark, as specified in § 425.652(a)(9), CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (f)(1) through (4) of this section used in calculating the regional adjustment.

* * * * *

■ 87. Section 425.658 is amended by—

■ a. Revising paragraph (c)(1) introductory text and paragraph (c)(2); and

■ b. In paragraph (d), removing the phrase ''paragraph (c)(1) of this section'' and adding in its place the phrase ''paragraph (c) of this section''.

The revisions read as follows:

§ 425.658 Calculating the prior savings adjustment to the historical benchmark.

* * * * *

(c) * * *

(1) For agreement periods beginning on or after January 1, 2024 and before January 1, 2027. If an ACO is eligible for the prior savings adjustment as determined in paragraph (b)(3) of this section, the prior savings adjustment will equal the lesser of the following:

* * * * *

(2) For agreement periods beginning on January 1, 2027, and in subsequent years. If an ACO is eligible for the prior savings adjustment as determined in paragraph (b)(3) of this section, the prior savings adjustment will equal the lesser of the following:

(i) 75 percent of the pro-rated average per capita amount computed in paragraph (b)(3)(ii) of this section.

(ii) A single per capita value that is calculated as follows:

(A) Calculate the product of the following for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries)—

(*1*) The national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary; and

(*2*) The ACO's weighted average CMS–HCC risk score for that enrollment type for BY3.

(B) Calculate 5 percent of each enrollment type-specific product determined in paragraph (c)(2)(ii)(A) of this section.

(C) Calculate the single per capita value as a person-year weighted average by multiplying each of the enrollment type-specific values determined in accordance with paragraph (c)(2)(ii)(B) of this section by the proportion of the ACO's assigned beneficiaries within that particular enrollment type, and then summing the results.

* * * * *

■ 88. Section 425.660 is revised to read as follows:

§ 425.660 Accountable Care Prospective Trend (ACPT).

(a) *General.* The methodology by which CMS calculates and adjusts a projected growth rate called the Accountable Care Prospective Trend (ACPT) is described in this section. CMS incorporates the ACPT into the blended update factor described in § 425.652(b) when updating an ACO's benchmark for each performance year of the agreement period, for agreement periods beginning on January 1, 2024, and in subsequent years.

(b) *Determination of ACPT.* An ACPT is a flat dollar amount calculated using one or more annualized growth rates based on national fee-for-service Medicare expenditures projected by the CMS Office of the Actuary. In determining the ACPT for a Medicare enrollment type for each performance year, CMS does all of the following:

(1) *Calculate annualized projected growth rates.* The annualized projected growth rates are calculated as an annual rate of growth in projected expenditures relative to the prior year. CMS projects annualized per capita growth in Parts A and B fee-for-service expenditures for each performance year of the ACO's agreement period. In calculating the annualized projected growth rates, CMS does all of the following:

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Aged/Disabled.

(iii) Calculates one or more annualized projected growth rates for the ESRD population of beneficiaries described in paragraph (b)(1)(ii)(A) of this section, and one or more annualized growth rates for the Aged/Disabled population of beneficiaries described in paragraph (b)(1)(ii)(B) of this section, as follows:

(A) Using a uniform annualized projected rate of growth over each of the 5 performance years of the 5-year agreement period (for agreement periods beginning on or after January 1, 2024, and before January 1, 2027), or for each performance year (for agreement periods beginning on January 1, 2027, and in subsequent years), as applicable; or

(B) If annualization as specified in paragraph (b)(1)(iii)(A) of this section is determined not to reasonably fit the anticipated growth curve, CMS applies an alternative annualization technique using two or more annualized growth rates reflecting the projected rates of growth during the 5 performance years comprising the 5-year agreement period (for agreement periods beginning on or after January 1, 2024, and before January 1, 2027), or for each performance year (for agreement periods beginning on January 1, 2027, and in subsequent years), as applicable.

(2) *Calculate cumulative projected growth rate.* For each performance year, CMS calculates cumulative projected growth rates relative to the ACO's benchmark year (BY) 3, using the annualized projected growth rates, determined in accordance with paragraph (b)(1) of this section, for each population of beneficiaries: the ESRD population and the Aged/Disabled population.

(3) *Express cumulative projected growth rate as a flat dollar amount.* For each performance year, CMS multiplies the applicable cumulative projected growth rate described in paragraph (b)(2) of this section by BY3 truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) identified for the 12-month calendar year corresponding to BY3 to express the cumulative projected growth rate as a flat dollar amount as follows:

(i) The ESRD cumulative projected growth rate calculated in accordance with paragraph (b)(2) of this section is used for the ESRD population.

(ii) The Aged/Disabled cumulative projected growth rate calculated in accordance with paragraph (b)(2) of this section is used for the following populations: disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4) *Risk adjust the flat dollar amount.* CMS adjusts the flat dollar amounts described in paragraph (b)(3) of this section for each performance year for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population for each Medicare enrollment type identified for the 12-month calendar year corresponding to BY3.

(5) *Calculate ACO-specific ACPT growth rates.* CMS divides the risk adjusted flat dollar amounts described in paragraph (b)(4) of this section by the ACO's historical benchmark expenditures described in § 425.652(a) for each Medicare enrollment type to calculate the percentage increase to be included in the blended update factor described in § 425.652(b)(4).

(6) *Timing of calculations.* (i) For agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

(A) At the beginning of the ACO's agreement period, CMS calculates the annualized projected growth rates for all performance years of the ACO's agreement period in accordance with paragraph (b)(1) of this section. These annualized projected growth rates will remain fixed over the ACO's agreement period.

(B) For a given performance year, CMS calculates an ACO-specific ACPT value, in accordance with paragraphs (b)(2) through (b)(5) of this section, using the annualized projected growth rates calculated at the beginning of the ACO's agreement period, as described in paragraph (b)(6)(i)(A) of this section.

(ii) For agreement periods beginning on January 1, 2027, and in subsequent years.

(A) In the calendar year preceding a given performance year, CMS calculates the annualized projected growth rates in accordance with paragraph (b)(1) of this section for that performance year.

(B) For a given performance year, CMS calculates an ACO-specific ACPT value, in accordance with paragraphs (b)(2) through (b)(5) of this section, using the annualized projected growth rates calculated in the preceding calendar year, as described in paragraph (b)(6)(ii)(A) of this section.

(c) *Recomputation of ACPT.* At financial reconciliation for a given performance year, CMS may recompute the ACO-specific ACPT value for a Medicare enrollment type initially determined at paragraph (b)(5) of this section for that performance year, to address under-projection or over-projection of the ACPT (as applicable), as follows:

(1) For agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

(i) For performance year 2025 and subsequent performance years of the ACO's agreement period, CMS separately calculates for the ESRD and Aged/Disabled populations the difference between the cumulative projected growth rates calculated in paragraph (b)(2) of this section and the cumulative observed growth in per capita expenditures for the national assignable FFS population.

(ii) For the ESRD and Aged/Disabled populations separately, if the difference calculated in paragraph (c)(1)(i) of this section is less (more negative) than −1.0 percentage point, CMS will recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at paragraph (b)(5) of this section. CMS will calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with paragraphs (b)(3) through (b)(5) of this section, using the cumulative observed growth in expenditures for the national assignable FFS population minus 1.0 percentage point.

(iii) For the ESRD and Aged/Disabled populations separately, if the difference calculated in paragraph (c)(1)(i) of this section is greater than (less negative) or equal to −1.0 percentage point, CMS will not recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at paragraph (b)(5) of this section.

(2) For agreement periods beginning on January 1, 2027, and in subsequent years.

(i) CMS separately calculates for the ESRD and Aged/Disabled populations the difference between the cumulative projected growth rates calculated in paragraph (b)(2) of this section and the cumulative observed growth in per capita expenditures for the national assignable FFS population.

(ii) For the ESRD and Aged/Disabled populations separately, if the difference calculated in paragraph (c)(2)(i) of this section is less (more negative) than −1.0 percentage point, CMS will recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at paragraph

(b)(5) of this section. CMS will calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with paragraphs (b)(3) through (b)(5) of this section, using the cumulative observed growth in expenditures for the national assignable FFS population minus 1.0 percentage point.

(iii) For the ESRD and Aged/Disabled populations separately, if the difference calculated in paragraph (c)(2)(i) of this section is greater than +1.5 percentage points, CMS will recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at paragraph (b)(5) of this section. CMS will calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with paragraphs (b)(3) through (b)(5) of this section, using the cumulative observed growth in expenditures for the national assignable FFS population plus 1.5 percentage point.

(iv) For the ESRD and Aged/Disabled populations separately, if the difference calculated in paragraph (c)(2)(i) of this section is between −1.0 and +1.5 percentage points, inclusive, CMS will not recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at paragraph (b)(5) of this section.

■ 89. Section 425.662 is amended by revising and republishing paragraph (b)(2) to read as follows:

§ 425.662 Calculating the population adjustment to the historical benchmark.

* * * * *

(b) * * *

(2)(i) For agreement periods beginning on January 1, 2025, or January 1, 2026. Calculates a scaler as the difference between 5 percent of the national per capita expenditure amount, expressed as single value as calculated in paragraph (b)(1) of this section, and the higher of: the regional adjustment, expressed as a single value as described in § 425.656(d); the per capita prior savings adjustment determined in § 425.658(c); or no adjustment, in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment under § 425.658(b)(3)(i).

(ii) For agreement periods beginning on January 1, 2027, and in subsequent years. Calculates a scaler as the difference between the following:

(A) A single per capita value that is calculated as follows:

(*1*) Calculate the product of the following for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries):

(*i*) The national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

(*ii*) The ACO's weighted average CMS–HCC risk score for that enrollment type for BY3.

(*2*) Calculate 5 percent of each enrollment type-specific product determined in paragraph (b)(2)(ii)(A)(*1*) of this section.

(*3*) Calculate a single per capita value as a person-year weighted average by multiplying each of the enrollment type-specific values determined in accordance with paragraph (b)(2)(ii)(A)(*2*) of this section by the proportion of the ACO's assigned beneficiaries within that particular enrollment type, then summing the results.

(B) The highest among—

(*1*) The regional adjustment, expressed as a single value as described in § 425.656(d);

(*2*) The per capita prior savings adjustment determined in § 425.658(c); or

(*3*) No adjustment, in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment under § 425.658(b)(3)(i).

* * * * *

■ 90. Section 425.664 is added to read as follows:

§ 425.664 Calculating the growth adjustment to the historical benchmark.

(a) *General.* This section describes the methodology for calculating the growth adjustment to the historical benchmark for agreement periods beginning on January 1, 2027, and in subsequent years.

(b) *Determine an ACO's new growth share of assigned beneficiary person years*—(1) *Identify shared savings initiatives for the growth adjustment.* CMS means, for purposes of this part, an initiative implemented by CMS, including the following options and initiatives—

(i) The Shared Savings Program;

(ii) The Innovation Center ACO models; or

(iii) Other initiatives that may be specified by CMS.

(2) *Identify ACO professionals who are inexperienced in shared savings initiatives.* CMS determines that an ACO professional is inexperienced in a shared savings initiative if the ACO professional has not billed primary care services through a participant in the Shared Savings Program, or participated in an Innovation Center ACO model, or other initiative specified by CMS in financial reconciliation for one or more performance years under such initiative during any of the 5 performance years directly preceding the start of the current agreement period.

(3) *Identify beneficiaries who are inexperienced with shared savings initiatives assigned to the ACO.* CMS determines that a beneficiary assigned to an ACO is inexperienced with shared savings initiatives if the beneficiary was not included in assignment in financial reconciliation to an ACO in the Shared Savings Program, Innovation Center ACO model, or other initiative specified by CMS in the performance year that corresponds to the ACO's BY3.

(4) *Calculate an ACO's new growth for the applicable performance year.* CMS calculates an ACO's new growth as follows:

(i) CMS determines the number of beneficiary person years for beneficiaries who are inexperienced with shared savings initiatives (as determined under paragraph (b)(3) of this section) with an ACO professional who is inexperienced with shared savings initiatives (as determined under paragraph (b)(2) of this section) as the ACO professional who provided the highest number of primary care services at the ACO within the assignment window, or to whom the beneficiary was voluntarily aligned, in the performance year as follows:

(A) Count the primary care services (as defined at § 425.20) each assigned beneficiary who is inexperienced with shared savings initiatives (as determined under paragraph (b)(3) of this section) has with each ACO professional participating in the ACO within the assignment window, or to whom the beneficiary was voluntarily aligned for the applicable performance year.

(B) For the purposes of this calculation, attribute the assigned beneficiary who is inexperienced with shared savings initiatives (as determined under paragraph (b)(3) of this section) to the ACO professional with whom the beneficiary had the highest number of primary care services (as defined at § 425.20) for the applicable performance year.

(C) CMS counts, as new growth for the performance year, the number of beneficiary person years for beneficiaries who are inexperienced with shared savings initiatives (as determined under paragraph (b)(3) of this section) and who received the

highest number of primary care services (as defined at § 425.20) for the applicable performance year from an ACO professional who is inexperienced with shared savings initiatives (as determined under paragraph (b)(2) of this section).

(ii) [Reserved]

(c) *Determine an ACO's overall growth assigned beneficiary person years.* CMS calculates an ACO's overall growth as the number of assigned beneficiary person years in the performance year minus the number of assigned beneficiary person years in the performance year that corresponds to the ACO's BY3. If the ACO is a new entrant or re-entering ACO, the overall growth is equal to the number of assigned beneficiary person years in the performance year.

(d) *Determine an ACO's capped new growth for the performance year.* An ACO's new growth is the lesser of an ACO's new growth (as determined in paragraph (b) of this section) and an ACO's overall growth (as determined in paragraph (c) of this section).

(e) *Apply the minimum new growth thresholds for the performance year.* CMS applies the minimum new growth threshold for each performance year, expressed in absolute terms and relative terms. CMS determines the minimum new growth threshold that applies as the lesser of the relative minimum new growth threshold multiplied by the number of total assigned beneficiary person years and the absolute minimum new growth threshold. The absolute minimum new growth threshold and the relative minimum new growth threshold are as follows:

TABLE 1 TO PARAGRAPH (e)

	PY 1	PY 2	PY 3	PY 4	PY 5
Absolute Minimum New Growth Threshold	100	300	600	900	1,200
Relative Minimum New Growth Threshold	0.5%	1.5%	3.5%	5.5%	7.5%

(f) *Calculate the new growth above the minimum and below the cap for the performance year.* CMS calculates the new growth above the minimum and below the cap for each performance year as the difference between an ACO's capped new growth for the applicable performance year (as determined under paragraph (d) of this section) and the minimum new growth threshold applied for the performance year (as determined under paragraph (e) of this section), or zero, if negative. The ACO is eligible for a growth adjustment for the applicable performance year if the new growth above the minimum and below the cap is greater than zero.

(g) *Calculate the new growth share for the performance year.* CMS calculates the new growth share for the performance year as the new growth above the minimum and below the cap in the performance year (as determined under paragraph (f) of this section) divided by the total assigned beneficiary person years in the performance year.

(h) *Determine ACO's incentive factor.* The ACO's incentive factor is an ACO-specific per capita dollar amount calculated as 5 percent of the per capita historical benchmark expressed as a single value before the application of the adjustments to the historical benchmark specified at § 425.652(a)(8)(ii) (as applicable).

(i) *Determine the ACO's growth adjustment to the historical benchmark.* (1) CMS calculates the growth adjustment to the historical benchmark as the product of the ACO's new growth share (as determined under paragraph (g) of this section) and the ACO's incentive factor (as determined under paragraph (h) of this section).

(2) The per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the product of the following—

(i) The national per capita expenditure amount for the enrollment type for BY3; and

(ii) The ACO's weighted average CMS–HCC risk score for the enrollment type for BY3.

§ 425.672 [Amended]

■ 91. Section 425.672 is amended in paragraph (c)(2)(iv) by removing the reference ''§ 425.658(c)(1)(ii)'' and adding in its place the references ''§ 425.658(c)(1)(ii) and (c)(2)(ii)''.

§ 425.702 [Amended]

■ 92. Section 425.702 is amended in paragraph (c)(1)(iii) introductory text by removing the phrase ''For performance year 2024 and subsequent performance years,'' and adding in its place the phrase ''For performance years 2024 through 2026,''.

PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

■ 93. The authority citation for part 427 continues to read as follows:

Authority: 42 U.S.C. 1395w–3a(i), 1302, and 1395hh.

■ 94. Section 427.20 is amended by revising the definition of ''First marketed date'' to read as follows:

§ 427.20 Definitions.

* * * * *

First marketed date means the earliest date of first sale of any NDC–11 within a billing and payment code among all products and package sizes under the same FDA application. The first marketed date will be identified using ASP data reported by NDC–11 to CMS by a manufacturer as required under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2) of the Act, if available. If an ASP first marketed date is not available, the first marketed date will be identified using an alternative public source, such as the NDC Directory.

■ 95. Section 427.101 is amended by revising paragraph (b)(5) to read as follows.

§ 427.101 Identification of the Part B rebatable drugs.

(b) * * *

(5) *Skin substitutes.* A product included within the suite of cellular- and tissue-based products that aid wound healing, other than skin substitute products that are licensed as a drug or biological product under section 351 of the Public Health Service Act.

■ 96. Section 427.302 is amended by adding paragraph (e)(6) and revising paragraph (f) to read as follows.

§ 427.302 Calculation of the per unit Part B rebate.

* * * * *

(e) * * *

(6) For paragraphs (e)(2) through (e)(5) of this section, in the event CPI–U data are unavailable for the month described in such paragraph, CMS will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.

(f) *Identification of the rebate period CPI–U.* For each Part B rebatable drug by billing and payment code, CMS will identify and use the greater of the benchmark period CPI–U index level or the CPI–U index level for the first month of the calendar quarter that is 2 calendar quarters before the applicable

calendar quarter in which the Part B rebatable drug is furnished.

(1) In the event CPI–U data are unavailable for the month described in such paragraph, CMS will use the first month for which CPI—U data are available following the month for which CPI–U data are unavailable.

(2) [Reserved]

PART 428—MEDICARE PART D DRUG INFLATION REBATE PROGRAM

■ 97. The authority citation for part 428 continues to read as follows:

Authority: 42 U.S.C. 1395w–114b, 1302, and 1395hh.

■ 98. Section 428.20 is amended by revising the definition of ''Applicable period Consumer Price Index for All Urban Consumers (CPI–U)'' to read as follows.

§ 428.20 Definitions.

* * * * *

Applicable period Consumer Price Index for All Urban Consumers (CPI–U) means, with respect to an applicable period, the CPI–U for the first month of such applicable period (that is, October). In the case where the first month's CPI–U data are unavailable, CMS will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.

■ 99. Section 428.202(e) is amended by adding paragraph (e)(6) to read as follows.

§ 428.202 Calculation of the per unit Part D rebate amount.

* * * * *

(e) * * *

(6) For paragraphs (e)(2) through (e)(5) of this section, in the event CPI–U data are unavailable for the month described in such paragraph, CMS will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.

■ 100. Section 428.203 is amended by adding paragraph (c) to read as follows:

§ 428.203 Determination of the total number of units dispensed under Part D.

* * * * *

(c) *Data reporting requirement.* (1) Beginning with claims with a date of service on or after January 1, 2027, a provider or supplier that is a covered entity as defined at § 10.3 must submit the data elements associated with each claim for a covered Part D drug billed to Medicare Part D for which such covered entity or its contractor(s) (such as contract pharmacies) dispensed units of a drug for which a manufacturer provides a discount under the 340B Program to such covered entity:

(i) Date of service.

(ii) Prescription or service reference number.

(iii) Fill number.

(iv) Dispensing pharmacy NPI.

(v) NDC–11.

(2) In addition to submitting the data elements set forth in paragraph (c)(1) of this section, such provider or supplier must submit its 340B ID and name as designated in the 340B Office of Pharmacy Affairs Information System (OPAIS) database.

(3) The data elements and information set forth in paragraphs (c)(1) and (2) of this section must be submitted on a quarterly basis and in a form and manner specified by CMS in accordance with the following timelines:

(i)(A) Except as specified in paragraph (c)(3)(i)(B) of this section, data elements and information associated with claims with dates of service during the first quarter of a calendar year must be submitted by the close of the second quarter of that calendar year.

(B) Claims with dates of service during the first quarter of CY 2027, must be submitted by the close of the third quarter of CY 2027.

(ii) Data elements and information associated with claims with dates of service during the second quarter of a calendar year must be submitted by the close of the third quarter of that calendar year.

(iii) Data elements and information associated with claims with dates of service during the third quarter of a calendar year must be submitted by the close of the fourth calendar quarter of that calendar year.

(iv) Data elements and information associated with claims with dates of service during the fourth quarter of that calendar year must be submitted by the close of the first calendar quarter of the immediately following calendar year.

(4) Data elements and information submitted in accordance with paragraph (c)(3) of this section that is either incomplete or contains invalid data must be resubmitted at a later time in a form and manner specified by CMS.

(5) Data elements and information submitted in accordance with paragraph (c)(3) of this section must be certified by one of the following:

(i) The chief executive officer (CEO) of the provider or supplier that is a covered entity;

(ii) The chief financial officer (CFO) of the provider or supplier that is a covered entity;

(iii) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO.

(iv) An individual or contractor with the delegated authority as an authorized representative of the provider or supplier that is a covered entity to perform the certification on behalf of one of the individuals specified in paragraphs (c)(5)(i) through (c)(5)(iii) of this section and is authorized to submit the data elements in this submission on behalf of such provider or supplier.

PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR CERTAIN MODELS

■ 101. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 102. Section 512.705 is amended by—

■ a. Revising the definition for ''ASM beneficiary'', ''Dual eligible proportion'', and ''Small practice''; and

■ b. Adding definitions for ''PECOS'' and ''Rural area'' in alphabetical order.

The revisions and additions read as follows:

§ 512.705 Definitions.

* * * * *

ASM beneficiary means a Medicare FFS beneficiary who is being treated by an ASM participant for an ASM targeted chronic condition.

* * * * *

Dual eligible proportion means the share of an ASM participant's beneficiaries who are dually eligible Medicare beneficiaries.

* * * * *

PECOS stands for the Provider Enrollment, Chain, and Ownership System.

* * * * *

Rural area has the same meaning as the term is defined at 42 CFR 414.1305 under MIPS.

* * * * *

Small practice means a TIN consisting of 15 or fewer clinicians at the time CMS selects ASM participants for an ASM performance year as described at *§ 512.710(g).*

* * * * *

■ 103. Section 512.710 is amended by—

■ a. Revising paragraph (a)(1) introductory text;

■ b. Revising paragraphs (a)(2) and (c);

■ c. Revising the introductory text of paragraphs (d)(1) and (d)(2); and

■ d. Adding paragraph (h).

The revisions and additions read as follows:

§ 512.710 Participant eligibility and selection.

(a) * * *

(1) A clinician selected by CMS as an ASM participant for any ASM

performance year and who furnishes covered services during any applicable ASM performance year remains an ASM participant for the duration of the ASM test period unless CMS either terminates ASM in accordance with § 512.165 or the ASM participant receives notice of termination as described in paragraph (h) of this section.

* * * * *

(2) *Effect of not meeting ASM participant eligibility criteria for an ASM performance year.* For any ASM performance year within the ASM test period that an ASM participant does not meet the eligibility criteria for mandatory participation set forth in this section, the ASM participant is—

(i) Not subject to §§ 512.715, 512.720, and 512.745 for the applicable ASM performance year;

(ii) Not subject to § 512.750 for the corresponding ASM payment year;

(iii) Not eligible for the waivers described in § 512.775 for the applicable ASM performance year; and

(iv) Not eligible for the CMS-sponsored model arrangements and patient incentives safe harbor described in § 512.765 with respect to remuneration attributable to the applicable ASM performance year.

* * * * *

(c) *Exceptions to specific ASM performance requirements*—(1) *Exceptions.* CMS may in its sole discretion determine that an ASM participant who meets the requirements described in paragraph (c)(1)(i) or (ii) of this section is excepted from model requirements as described in paragraph (c)(2) of this section for the duration specified in paragraph (c)(3) of this section. CMS will provide notice, in the form and manner specified by CMS, to an ASM participant that an exception applies and specify the effective date of such exception. An ASM participant who meets the requirements of paragraph (c)(1)(i) or (ii) of this section may voluntarily provide written notice of the change to CMS in a form and manner determined by CMS and CMS will evaluate that notice to determine if an exception applies.

(i) *Exception based on change in TIN.* An ASM participant stops reassigning billing rights to the TIN that CMS used to select the ASM participant for the applicable ASM performance year.

(ii) *Exception based on ASM heart failure participant specialty type redesignation.* An ASM heart failure participant redesignates their primary specialty type through the applicable paper CMS–855 form or Internet-based PECOS before or during the applicable ASM performance year to any of the following specialty type redesignations for ASM heart failure participants:

(A) Cardiac Electrophysiology.

(B) Cardiac Surgery.

(C) Interventional Cardiology.

(D) Advanced Heart Failure and Transplant Cardiology.

(E) Adult Congenital Heart Disease.

(2) *Effect of exception.* If CMS determines an ASM participant meets an exception under paragraph (c)(1) of this section, the ASM participant is—

(i) Not subject to §§ 512.715, 512.720, and 512.745 for the ASM performance year;

(ii) Not subject to § 512.750 for the ASM payment year that corresponds to the ASM performance year specified in paragraph (c)(2)(i) of this section;

(iii) Not eligible for the waivers described in § 512.775 as of the date CMS specifies in its notice to the ASM participant that an exception applies; and

(iv) Not eligible for CMS-sponsored model arrangements and patient incentives safe harbor described at § 512.765 with respect to remuneration attributable to the period as of the date CMS specifies in its notice to the ASM participant that an exception applies.

(3) *Duration of exception.* (i) An exception under paragraph (c)(1)(i) of this section must remain in effect for each ASM performance year in the remainder of the ASM test period, as applicable, unless the ASM participant does all of the following:

(A) Reassigns billing rights to the TIN under which they received an exception based on a change in TIN.

(B) Meets the ASM participant eligibility criteria under the TIN described in paragraph (c)(3)(i)(A) of this section for a future ASM performance year.

(ii) An exception under paragraph (c)(1)(ii) of this section must remain in effect for each ASM performance year in the remainder of the ASM test period.

(d) * * *

(1) Heart failure specialty type—

* * * * *

(2) Low back pain specialty type—

* * * * *

(h) *Termination.* (1) CMS may in its sole discretion terminate an ASM participant's participation in the model immediately or upon advance notice if CMS determines:

(i) One or more grounds for remedial action described in § 512.160(a) have occurred with respect to the ASM participant; or

(ii) The ASM participant's continued participation would be inconsistent with the purposes of ASM, the requirements of this part, or applicable law.

(2) CMS will provide notice to the ASM participant specifying the grounds for termination and the effective date of such termination.

■ 104. Section 512.720 is amended by—

■ a. Revising paragraphs (a)(1)(i), (a)(ii)(B), and (e); and

■ b. Removing paragraph (f).

The revisions read as follows:

§ 512.720 Data submission requirements.

(a) * * *

(1) * * *

(i) * * *

(A) Include numerator and denominator data for at least one applicable quality measure described in § 512.725(b) or (c) that is not an administrative claims-based collection type and that meets the data completeness requirement as specified at § 512.725(f); and

(B) Except as provided in paragraph (a)(1)(i)(C) of this section, be submitted at the TIN/NPI level.

(C) An ASM participant who is in a small practice may submit quality ASM performance category data at either the TIN/NPI or the TIN level.

(ii) * * *

(B) Be submitted at either the TIN/NPI or TIN level;

* * * * *

(e) * * *

(1) *Quality ASM performance category.* (i) If CMS receives multiple data submissions in the quality ASM performance category in accordance with paragraph (a)(1)(i) of this section from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor) for an individual ASM participant, CMS scores each submission and assigns the highest score.

(ii) If CMS receives multiple data submissions for the quality ASM performance category in accordance with paragraph (a)(1)(i) of this section from one or more submitters in the same organization for an individual ASM participant, CMS scores the most recent submission and assigns that score.

(iii) If CMS receives a TIN-level data submission in the quality ASM performance category in accordance with paragraph (a)(1)(i) of this section for an ASM participant in a small practice, CMS scores the TIN-level submission and assigns that score to all individual ASM participants in the small practice, regardless of any TIN/NPI-level submission(s) received for one or more of those ASM participants.

(2) *Improvement activities ASM performance category.* (i) If CMS receives multiple data submissions in the improvement activities ASM

performance category in accordance with paragraph (a)(1)(ii) of this section from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor) for an individual ASM participant, CMS scores each submission and assigns the highest score.

(ii) If CMS receives multiple data submissions in the improvement activities ASM performance category in accordance with paragraph (a)(1)(ii) of this section from one or more submitters in the same organization for an individual ASM participant, CMS scores the most recent submission and assigns that score.

(3) *Promoting Interoperability ASM performance category.* (i) For multiple data submissions received for the Promoting Interoperability ASM performance category in accordance with paragraph (a)(1)(iii) of this section, CMS calculates a score for each submission and assigns the highest of the scores.

* * * * *

■ 105. Section 512.725 is amended by—

■ a. Revising paragraph (c)(4);

■ b. Adding paragraphs (c)(5), (e)(3)(i), and adding and reserving paragraph (e)(3)(ii);

■ c. Revising paragraphs (f)(3), (h)(1)(i), (h)(2) introductory text, and (h)(2)(i) introductory text;

■ d. Removing paragraph (h)(2)(iii);

■ e. Redesignating paragraph (h)(2)(iv) as paragraph (h)(2)(iii); and

■ f. Adding new paragraphs (h)(2)(iv) and (i).

The revisions and additions read as follows:

§ 512.725 Quality ASM performance category.

* * * * *

(c) * * *

(4) Functional Outcome Assessment (MIPS Q182).

(5) Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM).

* * * * *

(e) * * *

(3) * * *

(i) For ASM participants in small practices, CMS scores all administrative claims-based quality measures at the TIN/NPI level according to the measure specifications for the applicable ASM performance year.

(ii) [Reserved]

* * * * *

(f) * * *

(3) CMS excludes from an ASM participant's total measure achievement points and total available measure achievement points any measure required under paragraph (b) or (c) of this section that meets the respective measure's data completeness requirement but does not have a benchmark.

* * * * *

(h) * * *

(1) * * *

(i) For each ASM performance year, an ASM participant receives between 1 and 10 measure achievement points (including partial points) for each measure specified in paragraph (b) or (c) of this section that satisfies the requirements described in paragraph (h)(1)(i)(A) or (h)(1)(i)(B) of this section, as applicable.

(A) For each measure other than an administrative claims-based quality measure under the quality ASM performance category on which data is submitted in accordance with paragraph (e) of this section, the measure must do all of the following:

(*1*) Have a benchmark specified in paragraph (h)(2) of this section.

(*2*) Meet the case minimum requirements specified in paragraph (g) of this section.

(*3*) Meet the data completeness criteria specified in paragraph (f) of this section.

(B) For each administrative claims-based quality measure calculated by CMS under the quality ASM performance category, the measure must have a benchmark as specified in paragraph (h)(2) of this section and meet the case minimum requirements specified in paragraph (g) of this section.

* * * * *

(2) *Benchmarks for quality ASM performance category.* (i) CMS bases benchmarks on an ASM participant's performance by collection type, from one of the following data sources:

* * * * *

(iv) CMS excludes from an ASM participant's total measure achievement points and total available measure achievement points any measure required under paragraphs (b) or (c) of this section that does not have a benchmark.

* * * * *

■ 106. Section 512.740 is amended by—

■ a. Revising paragraphs (b) introductory text (b)(2)(ii), (b)(2)(iv), and (b)(3)(i)(C);

■ b. Removing paragraph (b)(3)(ii);

■ c. Redesignating paragraph (b)(3)(iii) as paragraph (b)(3)(ii);

■ d. Removing paragraph (b)(4)(i);

■ e. Redesignating paragraph (b)(4)(ii) as paragraph (b)(4)(i) and reserving paragraph (b)(4)(ii);

■ f. Revising newly redesignated paragraph (b)(4)(i) and paragraph (c) introductory text;

■ g. Redesignating paragraph (c)(2) as paragraph (c)(3); and

■ h. Adding new paragraph (c)(2) and paragraph (d).

The revisions and additions read as follows:

§ 512.740 Promoting Interoperability ASM performance category.

* * * * *

(b) *Reporting for the Promoting Interoperability ASM performance category beginning in the 2028 ASM performance year.* Beginning in the 2028 ASM performance year, to earn an ASM performance category score greater than zero for the Promoting Interoperability ASM performance category for inclusion in the final score, an ASM participant must be a meaningful EHR user and meet the following criteria:

(2) * * *

(i) v

(ii) An ASM participant must fulfill the Health Information Exchange objective through the following:

(A) Report one of the following options:

(*1*) Support Electronic Referral Loops by Sending Health Information (Measure ID # PI_HIE_1) and Support Electronic Referral Loops by Receiving and Reconciling Health Information (Measure ID # PI_HIE_4).

(*2*) Health Information Exchange (HIE) Bi-Directional Exchange (Measure ID # PI_HIE_5).

(*3*) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) (Measure ID # PI_HIE_6).

(B) Report both measures described in paragraphs (b)(2)(ii)(B)(*1*) and (b)(2)(ii)(B)(*2*) of this section, report one measure and claim one exclusion, or claim exclusions to both measures:

(*1*) Electronic Prior Authorization (Measure ID # PI_HIE_7).

(*2*) Electronic Prior Authorization for Prescription Drugs (Measure ID # PI_HIE_8).

* * * * *

(iv) An ASM participant must fulfill the Public Health and Clinical Data Exchange objective by reporting both measures described in paragraphs (b)(2)(iv)(A) and (b)(2)(iv)(B) of this section, reporting one measure and claiming one exclusion, or claiming exclusions to both measures:

(A) Immunization Registry Reporting (Measure ID # PI_PHCDRR_1).

(B) Electronic Case Reporting (Measure ID # PI_PHCDRR_3).

* * * * *

(3) * * *

(i) * * *

(C) An exclusion for each measure that includes an option for an exclusion.

(ii) Submit an affirmative attestation regarding the ASM participant's completion of the annual self-assessment checklist under the MIPS Promoting Interoperability High Priority Practices Guide of the SAFER Guides measure (Measure ID# PI_PPHI_2) within the calendar year of the ASM performance year.

(4) * * *

(i) *Actions to limit or restrict the compatibility or interoperability of CEHRT.* To fulfill ASM requirements for activities related to limiting or restricting the compatibility or interoperability of CEHRT, an ASM participant must not knowingly and willfully take action, such as disabling functionality, to limit or restrict the compatibility or interoperability of CEHRT.

(ii) [Reserved]

* * * * *

(c) *Scoring the Promoting Interoperability ASM performance category beginning in the 2028 ASM performance year*

(2) *Promoting Interoperability measure suppression.* If certain circumstances occur that impact CMS' assessment of the performance of ASM participants on a measure specified for the Promoting Interoperability ASM performance category, CMS may in its sole discretion suppress the affected measure by excluding it from CMS' assessment of ASM participant performance while allocating the maximum points available or providing full credit for the affected measure as long as the affected measure is reported, resulting in a suppressed measure contributing to the Promoting Interoperability ASM performance category objective score under paragraph (c)(3) of this section; or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. CMS determines whether certain circumstances exist that warrant suppression of a measure based on CMS' consideration of one or more of the following factors:

(i) The nature, breadth, and duration of the circumstances' effect on ASM participants' ability to fulfill the measure requirement.

(ii) The availability of certified health IT modules to fulfill the measure.

(iii) The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance.

(iv) Out-of-date or conflicting technical standards.

(v) Technical and operational capacity of required partners.

(vi) Other factors as determined by CMS.

(d) *Transition year policy for the 2027 ASM performance year.* (1) Notwithstanding paragraphs (b) and (c) of this section and § 512.720(a)(1)(iii)(A)(*1*) and (*2*), for the 2027 ASM performance year only, an ASM participant satisfies the performance requirements for the Promoting Interoperability ASM performance category by using CEHRT as defined at *§ 414.1305* and submitting, in accordance with § 512.720(a)(1)(iii)(A)(*3*) and (*4*), both of the following:

(i) The CEHRT ID from the CHPL for the CEHRT used by the ASM participant; and

(ii) The start date and end date of the applicable performance period used by the ASM participant as set forth in paragraph (a) of this section.

(2) CMS assigns a Promoting Interoperability ASM performance category score of 100 percent to an ASM participant that satisfies paragraph (d)(1) of this section. The Promoting Interoperability ASM performance category score cannot exceed 100 percent.

(3) An ASM participant may, but is not required to, report the measures and attestations described in paragraph (b) of this section.

* * * * *

■ 107. Section 512.745 is amended by—

■ a. Revising paragraph (a) introductory text and paragraph (a)(2)(iii)(B);

■ b. Redesignating paragraph (a)(5) as paragraph (a)(6);

■ c. Adding new paragraph (a)(5);

■ d. Revising newly redesignated paragraph (a)(6);

■ e. Revising paragraphs (b)(4) through (b)(6); and

■ f. Adding paragraphs (b)(7).

The revisions and additions read as follows:

§ 512.745 Final scoring.

(a) *Final score calculation.* CMS calculates a final score of zero to 100 points using the formula specified at paragraph (a)(6) of this section for each ASM participant that meets the requirements to receive a final score as specified in paragraph (a)(2) of this section.

* * * * *

(2) * * *

(iii) * * *

(B) Do not receive either a—

(*1*) Quality ASM performance category score under § 512.725(h)(4)(iii); or

(*2*) Cost ASM performance category score under § 512.730(e)(3)(i).

* * * * *

(5) *Rural scoring adjustment*—(i) *Scoring adjustment for an ASM participant in a rural area.* CMS adds 5 points to the final score of an ASM participant who is in a rural area as defined at § 512.705 and meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section for an applicable ASM performance year.

(ii) [Reserved]

(6) *Final score formula.* Final score = [(quality ASM performance category score × quality ASM performance category weight) + (cost ASM performance category score × cost ASM performance category weight)] × 100 + improvement activities ASM performance category scoring adjustment + Promoting Interoperability ASM performance category scoring adjustment + complex patient scoring adjustment + small practice scoring adjustment + rural scoring adjustment. The final score cannot be below zero points or exceed 100 points.

(b) * * *

(2) The ASM participant's complex patient scoring adjustment under paragraph (a)(3) of this section, as applicable.

(3) The ASM participant's small practice or solo practitioner scoring adjustment under paragraph (a)(4) of this section, as applicable.

(4) The ASM participant's rural scoring adjustment under paragraph (a)(5) of this section, as applicable.

(5) The ASM participant's final score, as applicable.

(6) The ASM payment adjustment factor under § 512.750(c)(1).

(7) The ASM payment multiplier under § 512.750(c).

* * * * *

■ 108. Section 512.750 is amended by revising paragraphs (c)(1)(i), (f)(1), and (f)(2) to read as follows:

§ 512.750 Payment adjustment.

* * * * *

(c) * * *

(1) * * *

(i) *ASM risk level.* CMS sets an ASM risk level that is the magnitude of the maximum downside and upside risk to which an ASM participant is subject to during an ASM payment year.

(A) For the 2029 ASM payment year, the ASM risk level is 9 percent.

(B) For the 2030 ASM payment year, the ASM risk level is 9 percent.

(C) For the 2031 ASM payment year, the ASM risk level is 10 percent.

(D) For the 2032 ASM payment year, the ASM risk level is 11 percent.

(E) For the 2033 ASM payment year, the ASM risk level is 12 percent.

* * * * *

(f) * * *

(1) If an NPI submits Part B covered professional service claims during an ASM payment year under a different TIN than the TIN CMS selected them as an ASM participant for that same ASM performance year and to which the NPI began assigning billing rights after the applicable ASM performance year but before the end of the corresponding ASM payment year, CMS multiplies the amount otherwise paid under Part B for covered professional services to the different TIN by the ASM payment multiplier calculated for the ASM participant based on their performance in the corresponding ASM performance year.

(2) CMS multiplies the amount otherwise paid under Part B for covered professional services by the highest ASM payment multiplier calculated for an NPI who meets all the following:

(i) Is an ASM participant under multiple TINs for a given ASM performance year.

(ii) Submits Part B covered professional service claims during an ASM payment year under a TIN by which CMS did not select the NPI as an ASM participant and to which the ASM participant began reassigning billing rights after the applicable ASM performance year but before the end of the corresponding ASM payment year.

* * * * *

■ 109. Section 512.765 is amended by adding paragraph (c) to read as follows:

§ 512.765 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

* * * * *

(c) *Scope.* The CMS-sponsored model arrangements and patients incentives safe harbor described in paragraphs (a) and (b) of this section is available only with respect to remuneration exchanged or furnished in connection with an ASM participant's performance under the model and does not apply with respect to remuneration attributable to any ASM performance year for which CMS determines the ASM participant does not meet ASM participant eligibility criteria under § 512.710(a)(2) or with respect to an ASM participant to whom an exception under § 512.710(c)(1) applies, the period described in § 512.710(c)(2)(iv).

■ 110. Section 512.771 is amended by—

■ a. Revising paragraphs (a)(1), (a)(2), (a)(5), and (a)(6);

■ b. Redesignating paragraphs (a)(7) and (a)(8) as paragraphs (d)(2) and (d)(3), respectively.

■ c. Redesignating paragraphs (a)(9) through (13) as (a)(7) through (11), respectively.

■ d. Revising newly redesignated paragraphs (a)(7) and (a)(9); and

■ e. Adding paragraph (d).

The revisions and additions read as follows:

§ 512.771 Collaborative care arrangements.

(a) * * *

(1) The collaborative care arrangement must be in writing, signed by all parties, specify the effective date, and be exclusively between an ASM participant, or one or more ASM participants who reassign billing rights through the same TIN, and a primary care practice.

(2) The primary care practice party must share one or more patients who are ASM beneficiaries with at least one ASM participant party to the collaborative care arrangement.

* * * * *

(5) All parties to the collaborative care arrangement must comply with the provisions of this section and all other applicable statutes, regulations, and guidance.

(6) Neither the opportunity to enter into a collaborative care arrangement nor remuneration given or received under a collaborative care arrangement may be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business generated by, between, or among the parties to the collaborative care arrangement or any other person. A selection criterion that considers whether an ASM participant and primary care practice share one or more ASM beneficiaries for the purpose of satisfying the requirement set forth in paragraph (a)(2) of this section will be deemed not to violate the volume or value standard of this section if the purpose of the criterion is to further the purpose of the collaborative care arrangement.

(7) All parties to the collaborative care arrangement must retain the ability to make decisions in the best interests of ASM beneficiaries, including the selection of clinicians, devices, supplies, and treatments.

* * * * *

(9) An ASM participant must maintain contemporaneous documentation, in accordance with § 512.135, regarding all collaborative care arrangements entered into, including the following:

(i) The relevant written agreements.

(ii) Records of all remuneration exchanged, if any, for each ASM participant party to a collaborative care arrangement, including, at a minimum, all of the following:

(A) A description of the remuneration.

(B) The value of remuneration.

(C) The methodology for determining the value of any in-kind remuneration in accordance with paragraph (d)(2)(ii) of this section, if applicable.

(D) The date on which the remuneration was exchanged.

(iii) The identity of each ASM participant who is a party to the collaborative care arrangement.

* * * * *

(d) *Remuneration under a collaborative care arrangement.* If the parties to a collaborative care arrangement elect to include terms allowing for the exchange of remuneration under the collaborative care arrangement, the parties must also comply with all of the following:

(1) The purpose of the exchange of remuneration under the collaborative care arrangement must be reasonably related to the purpose of the collaborative care arrangement, consistent with the requirements of paragraph (a)(3) of this section.

(2) The total amount of any remuneration exchanged under a collaborative care arrangement in a given ASM performance year must not exceed an amount equal to the ASM participant's ASM payment adjustment factor for the applicable ASM performance year multiplied by the amount otherwise paid to the ASM participant by CMS under Part B for covered professional services during the applicable ASM performance year.

(i) The collaborative care arrangement must specify a methodology for the parties to identify and calculate the total amount of remuneration exchanged under such arrangement in the ASM performance year for each ASM participant and determine within a reasonable amount of time after the information necessary to make the calculation in paragraph (d)(2) of this section becomes available whether the total amount of remuneration exceeds the limitation in paragraph (d)(2) of this section.

(ii) For in-kind remuneration, the value of remuneration exchanged for the purpose of this section is determined based on the offeror's cost for the remuneration, using any reasonable accounting methodology, or the fair market value of the in-kind remuneration.

(iii) The collaborative care arrangement must require the parties to reconcile any remuneration exchanged by each ASM participant under the arrangement in the ASM performance

year after the limitation in paragraph (d)(2) of this section is determined.

(iv) If the total amount of remuneration received by a party in the ASM performance year exceeds the limitation in paragraph (d)(2) of this section, the collaborative care arrangement must require the party that received the excess amount to repay the excess amount to the other party within a reasonable amount of time after the reconciliation.

(3) Any remuneration exchanged under a collaborative care arrangement must be solely between the parties to the arrangement. To the extent that remuneration exchanged is monetary, any payment between the parties must be made by check, electronic funds transfer, or another traceable cash transaction.

* * * * *

§ 512.775 [Amended]

■ 111. Section 512.775 is amended in paragraph (a) by removing the reference ''§ 512.710(a)(2)'' and adding in its place the phrase ''§ 512.710(a)(2) or (c)''.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

The following Appendices will not appear in the **Code of Federal Regulations**.

APPENDIX 1: MIPS QUALITY MEASURES

NOTE: Except as otherwise noted in this final rule, previously finalized measures and specialty sets will continue to apply for the CY 2027 performance period/2029 MIPS payment year and future years. Previously finalized measures and specialty sets are in the CY 2017 through CY 2026 PFS final rules: 81 FR 77558 through 77816, 82 FR 53966 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, 87 FR 70250 through 70633, 88 FR 79556 through 79964, 89 FR 98599 through 98957, and 90 FR 50036 through 50353. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a Consensus-Based Entity (CBE) are shown in Table A of this Appendix as follows: CBE # / eCQM CBE #.

NOTE: In section IV.A.4.d.(1)(c)(i) of this final rule, we finalized to implement MIPS core measures for traditional MIPS and MVP reporting which are identified in the tables in this Appendix. In addition, in section IV.A.4.d.(1)(c)(ii) of this final rule, we finalized to remove the high priority designation from MIPS quality measures and therefore, we removed the high priority indicator across all tables in this Appendix.

Table Group A: New MIPS Quality Measures Finalized and Finalized with Modification for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

Note: Proposed specialty sets for new measures are indicated under Table Group A of this Appendix within the last row of each A table. Commenters who requested additions of the new quality measures to specific specialty sets should use the Stakeholder Solicitation for Specialty Sets process as these updates must be proposed through rulemaking.

We requested comments on these new measures and the applicable specialty sets.

We received a few public comments asking for updates to the proposed new measures. We note that we would need to go through rulemaking in the future to make any substantive changes to the new measures. Section 1848(q)(2)(D)(i)(II)(cc) of the Act requires all substantive measure changes to be proposed and identified through notice-and-comment rulemaking. We have previously established criteria that apply when we consider making substantive changes to a quality measure (81 FR 77137 and 86 FR 65441 through 65442). On an annual basis, we review the established MIPS quality measure inventory to identify appropriate updates to the measures, based on, but not limited to, interested party feedback, known issues, and clinical guideline updates, for measure steward consideration. The measure steward is responsible for the maintenance of a measure and serves as the primary contact for any suggested revisions for possible implementation in future years. Measure steward contact information will be available in the 2027 MIPS Quality Measures List in the Measure Steward Contacts tab once posted on the QPP website (*https://qpp.cms.gov*) for CY 2027.

A.1. Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	517
Description:	Percentage of patients aged 18 years and older with clinical atherosclerotic cardiovascular disease (ASCVD) who received a low-density lipoprotein cholesterol (LDL-C) test via lipid panel and achieved an LDL-C of <70mg/dL on the most recent test during the performance period.
Measure Steward:	American Heart Association
Numerator:	Numerator 1: Patients with clinical atherosclerotic cardiovascular disease (ASCVD) who had a low-density lipoprotein cholesterol (LDL-C) tested via a lipid panel. Numerator 2: Patients aged 18 years and older with clinical ASCVD and a completed lipid panel during the performance period who achieved an LDL-C of <70 mg/dL on the most recent test.
Denominator:	Denominator 1: All patients aged 18 years and older diagnosed with clinical atherosclerotic cardiovascular disease (ASCVD). Denominator 2: All patients aged 18 years and older with clinical ASCVD who had a low-density lipoprotein cholesterol (LDL-C) tested via a lipid panel during the measurement period.

Category	Description
Exclusions:	Pregnancy, ESRD, hospice, over age 66+ with advanced illness, frailty, or dementia medications
Measure Type:	Intermediate Outcome
MIPS Core Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A
Rationale:	We proposed this intermediate outcome measure because it addresses appropriate care for adult patients with clinical atherosclerotic cardiovascular disease (ASCVD), ensuring patients diagnosed with this condition are annually tested for LDL-C and achieve a desired level. Studies support that elevated LDL-C levels contribute to ASCVD and once identified can be addressed via lipid management. Lowering LDL-C produces a marked reduction in clinical ASCVD and evidence shows that lower LDL-C levels are associated with better outcomes.[428] This measure ensures that patients receiving cholesterol lowering treatment, such as statin therapy, achieve a reduction in LDL-C, which in turn reduces risk of ASCVD and other patient outcomes, such as hospitalizations and cardiovascular death.[429] This measure is based on peer-reviewed evidence demonstrating that, for adults 20 years of age or older and not on lipid-lowering therapy, measurement of either a fasting or non-fasting plasma lipid profile is effective in estimating ASCVD risk and documenting baseline LDL-C.[430] This measure will expand on current MIPS measure Q438: *Statin Therapy for the Prevention and Treatment of Cardiovascular Disease*, which focuses on appropriate statin treatment of patients at high risk for cardiovascular events. While measure Q438 assesses for the prescribing of statin therapy, this new measure will build on measure Q438 by assessing the outcome of LDL-C treatment, through achievement of reaching a desired LDL-C level. The Pre-Rulemaking Measure Review (PRMR) Clinician Recommendation Committee reached consensus agreement to recommend the measure. Testing indicated good reliability based on signal to noise ratio and adequate face validity. Testing of measure performance indicated a gap in care with a mean performance rate of 46.8 percent for the first criteria and 64.9 percent for the second criteria. This demonstrates that there is room for improvement among clinicians treating this patient population. This measure is not currently CBE endorsed. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidence-based. This measure could be added to multiple MVPs in the future, including the proposed Hypertension MVP, Advancing Care for Heart Disease MVP, and Value in Primary Care MVP. We proposed adding this measure to applicable specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2026-02/Final-2025-2026-MUC-Recommendations-Report-508.pdf.*
Measure Proposed for Addition to the Following Specialty Sets:	Cardiology, Endocrinology, Family Medicine, Geriatrics, Internal Medicine, Nephrology, Neurology, Obstetrics/Gynecology, Preventive Medicine, Vascular Surgery

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed addition of the *Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management* measure. Commenters said that using meaningful, guideline-based outcome measures is key to changing clinician and patient behavior and improving chronic disease outcomes. A few commenters highlighted the disconnect between the current MIPS measure Q438: *Statin Therapy for the Prevention and Treatment of Cardiovascular Disease* and LDL-C

[428] Grundy, S. M., Stone, N. J., Bailey, A. L., Beam, C., Birtcher, K. K., Blumenthal, R. S., Braun, L. T., de Ferranti, S., Faiella-Tommasino, J., Forman, D. E., Goldberg, R., Heidenreich, P. A., Hlatky, M. A., Jones, D. W., Lloyd-Jones, D., Lopez-Pajares, N., Ndumele, C. E., Orringer, C. E., Peralta, C. A., Saseen, J. J., … Yeboah, J. (2019). 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation, 139(25), e1082–e1143. https://doi.org/10.1161/CIR.0000000000000625.

[429] See footnote Grundy et al., 2019.

[430] See footnote Grundy et al., 2019.

control, noting that the proposed new measure as an intermediate outcome measure addresses this gap and represents a significant step forward in care for patients with ASCVD, better reflects meaningful reductions in cardiac and stroke events, and is critical to improving cardiovascular health and reducing cardiovascular-related morbidity.

One commenter urged CMS to ensure the measure accounts for patients with familial hypercholesterolemia, noting the condition is often underdiagnosed and undertreated and requires combination lipid-lowering therapy beyond statins alone to reach recommended LDL-C levels. Another commenter supported this new measure and its inclusion across multiple specialty sets.

Response: We thank the commenters for supporting this new measure in MIPS. We encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years. Measure steward contact information will be available in the 2027 MIPS Quality Measures List in the Measure Steward Contacts tab once posted on the QPP website (*https://qpp.cms.gov*) for CY 2027. Any potential new substantive changes need to go through notice and comment rulemaking.

Comment: One commenter strongly supported finalizing the new *LDL-C Monitoring and Management* measure, stating that measure Q438 only rewards statin prescribing and cannot detect undertreatment. The commenter stated that a threshold-based LDL-C measure would better align with trial evidence and the 2026 ACC/AHA Guideline for the Management of Dyslipidemia,[431] which uses numeric LDL-C goals, and would incentivize appropriate retesting and treatment intensification. In addition to finalizing the measure, the commenter urged CMS to align LDL-C thresholds with the guideline's risk-based targets, allow a 4–12-week retesting window, include exceptions for statin intolerance and shared decision-making, and retain measure Q438 during a transition period. A second commenter recommended allowing denominator exceptions for documented intolerance, patient refusal, limited life expectancy, and pregnancy. They also suggested using non-HDL-C or apolipoprotein as alternative numerators when LDL-C is unreliable and stratifying the measure by social risk. A third commenter asked CMS to keep this measure aligned with current cholesterol guidelines and they emphasized the need for clear exclusions, exceptions, attribution rules, and practical implementation across settings.

Response: We thank the commenters for supporting this new measure in MIPS. We note that measure Q438 was not proposed for removal from MIPS. We encourage the commenters to reach out to the new proposed measure's steward to discuss revisions for possible implementation in future years. As we are finalizing CY2027 proposals, it is not possible to substantively change the measure nor to hold for testing as this was required at the time of submission for consideration for implementation in MIPS. However, as currently specified, the measure is still aligned with current guidelines in assessing for the most current health outcome. In addition to capturing and maintaining public comment, we review each measure annually to create recommendations for potential measure updates for future performance periods for measure steward consideration. The measure developer did not recommend risk adjustment or stratification at this time as the existing denominator exclusions, outlined in Table A.1 of this Appendix, are intended to address concerns regarding case-mix through appropriate patient exclusion criteria.

Comment: One commenter supported this new measure and noted that it must go beyond simply documenting that a lipid-lowering medication was prescribed and instead assess whether LDL-C is adequately controlled. Because lower LDL-C levels maintained over time reduce cardiovascular risk, quality measures should focus on LDL-C response to therapy, appropriate follow-up, and treatment intensification to reach evidence-based LDL-C goals. This approach would better align CMS quality reporting with contemporary cardiovascular prevention and the outcomes that matter most to patients, such as preventing heart attack and stroke. The commenter stated that CMS can improve the measure by shifting from "Was a medication prescribed?" to "Was the patient's LDL-C adequately treated to reduce cardiovascular risk?"

Another commenter stated that no disease status is as common and more dangerous than heart disease, and LDL cholesterol is a major driving factor for cardiovascular risk. The commenter indicated it is important that MIPS quality measures are clinically relevant and make sense. Targeting use of "statins" does not align with the lipid lowering therapy goals that are currently in the guidelines.

Response: We thank the commenters for supporting this new measure in MIPS. This new measure will go beyond ensuring medication prescription; it aims to assess whether patients aged 18 years and older with clinical ASCVD achieved an LDL-C of <70 mg/dL on their most recent test. This new measure builds upon the current MIPS measure Q438 by assessing the outcome of lipid management with the goal of reduction in LDL-C which in turn reduces risk of ASCVD. The proposed measure as currently specified is based on established clinical guidelines and while the new guidelines[432] released this spring have a lower recommended LDL-C value for high-risk patients, the current quality action would allow for assessing compliance across a broader range of patients without stratifying by risk factors. As with all MIPS quality measures, the measure steward will continue evaluating potential future updates to the measure.

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[431] Blumenthal, R. S., Morris, P. B., Gaudino, M., Johnson, H. M., Anderson, T. S., Bittner, V. A., Blankstein, R., Brewer, L. C., Cho, L., de Ferranti, S. D., Gianos, E., Gluckman, T. J., Gradney, K. F., Isiadinso, I., Lloyd-Jones, D. M., Marrs, J. C., Martin, S. S., McLain, K. H., Mehta, L. S., Mora, S., … Wilkins, J. T. (2026). 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Journal of the American College of Cardiology*, *87*(19), 2624–2757. https://doi.org/10.1016/j.jacc.2025.11.016.

[432] See footnote Blumenthal et al., 2026.

Comment: A few commenters supported the measure but recommended specific modifications to strengthen its impact and feasibility.

- One commenter noted that medication cost, access to specialty drugs, patient adherence, and social factors can limit patients' ability to reach LDL-C targets even with good care. The commenter recommended that CMS monitor how the measure performs and allow flexibility for patients who improve their LDL-C substantially but do not reach a strict threshold.
- One commenter requested that CMS consider adding LDL targets <70 achieved to help close the care gap and save lives. The commenter stated that measuring LDL-C is part of the solution, but CMS needs clear goals for health care clinicians to take action and to reduce cardiovascular events/mortality.
- One commenter asked that CMS add the following language to the measure specification in the final rule: A qualifying lipid panel may be performed using serum, plasma, capillary whole blood, or venous whole blood when the testing system is authorized or appropriately validated for the specimen type used, the system produces a valid and reportable LDL-C result, and testing is performed according to the manufacturer's instructions and applicable laboratory requirements.

Response: Thank you for the comments. We encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years. As currently specified, the measure is aligned with current guidelines in assessing for the most current health outcome for a broad patient population. In addition to capturing and maintaining public comment, CMS reviews each measure annually to develop recommendations for potential measure updates for future performance periods for measure steward consideration.

Comment: One commenter did not support this new measure. The commenter supported evidence-based lipid-lowering and prevention of recurrent events but cautioned that a uniform LDL-C target tied to quality or payment should preserve clinical discretion for patients who develop ASCVD despite untreated or presenting LDL-C ≤70 mg/dL.

The commenter requested that CMS:

1. Preserve pathways for documented shared decision-making and medically justified exceptions to LDL-C thresholds.
2. Do not financially penalize clinicians when patients miss LDL-C <70 mg/dL despite documented, appropriate care.
3. Promote prospective study of ASCVD in patients with untreated or presenting LDL-C ≤70 mg/dL, including Major Adverse Cardiovascular Events (MACE), mortality, and safety outcomes.
4. Distinguish, when appropriate, between low LDL-C from treatment and low LDL-C present before treatment or ASCVD onset.
5. Evaluate residual-risk mechanisms (e.g., lipoprotein (a), apolipoprotein B particles, insulin resistance, hypertension, inflammation) rather than relying on LDL-C alone.

The commenter expressed that the solution is not less lipid management but better evidence, better phenotyping, and preservation of individualized clinician–patient decision-making. The commenter asked CMS to build clinical flexibility into this measure and to promote prospective study of ASCVD in patients with already-low untreated LDL-C.

Response: We thank the commenter for their suggestions and encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Currently all MIPS eligible clinicians have choice in what measures they choose to report; therefore, if this measure does not reflect the patient population for which they care for, they can choose a different measure. The current measure is based on established clinical guidelines and while the new guidelines[433] released this spring have a lower recommended LDL-C value for high-risk patients, the current quality action would allow for compliance with a broader range of patients without stratifying by risk factors. As with all MIPS quality measures, the measure steward will continue evaluating potential future updates to the measure. Regarding differentiation between low LDL-C values from treatment and at ASCVD onset, the measure looks at patients with ASCVD and an LDL-C test via lipid panel to ensure the most recent test was less than 70 mg/dL; therefore, patients without an ASCVD diagnosis would not qualify for the denominator and would not be included in the performance data.

Comment: As this new measure was one of 10 new proposed Clinical Quality Measures (CQMs), one commenter asked why CMS would consider new CQM measures that are not Fast Healthcare Interoperability Resources (FHIR)-based with a transition to FHIR-based reporting in the next 2-3 years. The commenter said that CMS should place a moratorium on consideration and approval of any non-FHIR-based measures. After a review of these proposed CQMs, it is also unclear why they are not being proposed and written in an electronic CQM (eCQM) format at a minimum.

Response: We thank the commenter for sharing their concerns. We are advancing quality measurement by transitioning existing quality measures and reporting processes to FHIR-based digital approaches. Subject to future notice and comment rulemaking, we are developing a phased 2-year transition period beginning with the CY 2028 performance period/2030 MIPS payment year. During this period, existing CQM and eCQM collection types, including eCQM reporting via Quality Reporting Data Architecture (QRDA) files, would continue to be available while FHIR-based digital quality measures (dQM) options are introduced for selected new and existing measures. Under this plan, we may still propose non-FHIR MIPS CQMs in the interim.

[433] See footnote Blumenthal et al., 2026.

We are encouraging measure stewards to begin reviewing their measures against current FHIR-based standards and assessing their measures for updates necessary to support the digital transition. Currently, it is at the discretion of the measure steward to determine which collection types are developed and available when submitting to the Annual Call for Quality Measures. See the Measures Under Consideration Entry/Review Information Tool (MERIT) login page for more information on timelines to submit measures for consideration by CMS (*https://cmsmerit.cms.gov/merit/#/login*).

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44305 through 44306), we are finalizing the *Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management* measure as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

A.2. Functional Improvement for Patients with Neck Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	518
Description:	Percentage of patients aged 18 years and older with a neck impairment that met the risk-adjusted Predicted Moderate Clinical Improvement (P-MCI) on the PROMIS Pain Interference (PPI) or the alternative (legacy) patient-reported outcome measure (PROM), the Neck Disability Index (NDI).
Measure Steward:	Limber Health, Inc. and Patient360, LLC
Numerator:	Patients with a completed episode of care whose most recent PPI score beyond the baseline score meets or exceeds the P-MCI at the time of the completed episode of care.
Denominator:	All patients aged 18 years or older at the start of the episode of care with a neck impairment who completed a baseline PPI.
Exclusions:	Pre-operative Care: Patients who are being seen for pre-operative care and/or have surgery for the neck impairment within 30 days after the initial assessment, documented in the medical record. Cognitive Deficit: A significant mental or cognitive impairment. Hospice or Palliative Care: Patient is in hospice care or receiving palliative care for terminal illness, as documented in the medical record. Active Cancer Treatment: Patient is in active treatment for cancer AND the goal of MSK care is primarily to avoid or minimize decline in function, documented in the medical record. Maintenance Therapy: Patient is receiving maintenance therapy.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We proposed this current QCDR patient-reported outcome-based performance measure to replace current MIPS quality measure Q478: *Functional Status Change for Patients with Neck Impairments*. This new measure will address the same clinical topic as measure Q478; however, it allows for broader implementation by including widely available, non-proprietary tools to assess physical function improvement. Additionally, this measure's analytic allows independent calculation of performance by the clinician, or easy and free collaboration with the steward, which supports clinicians reporting this important aspect of rehabilitative care. This measure utilizes the PROMIS® Pain Interference tool, which was developed using item response theory (IRT) methods. Evidence indicates that the PROMIS-PI items constitute a psychometrically sound item bank for assessing the negative effects of pain on functioning across the range commonly experienced by people who have pain.[434] It allows clinician flexibility in administration as it uses computer adaptive testing (CAT) or a fixed-length short form. This measure also allows utilization of the Neck Disability Index (NDI), which is a commonly used tool for neck pain with established reliability and validity.[435] [436] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Rehabilitative Support for Musculoskeletal Care MVP (proposed to be renamed as the Rehabilitative Support MVP under Appendix 3: MVP Inventory, Table B.24). We proposed adding this measure to the Chiropractic Medicine and Physical Therapy/Occupational Therapy specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Chiropractic Medicine, Physical Therapy/Occupational Therapy

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Many commenters strongly supported adding the proposed new functional improvement quality measures for patients with neck, upper extremity, back, lower extremity, and knee impairments under Table A.2 through A.6 of this Appendix. These measures focus on patients' ability to function safely and independently. Because physical therapists routinely use standardized outcome measures to track progress, these metrics better capture the value rehabilitation professionals provide than process-based measures alone. A few other commenters supported this new measure and other new functional measures, because they better reflect current rehabilitative practice, let reporting clinicians calculate performance independently, and reduce administrative burden.

One commenter supported the new functional measures and urged CMS and stakeholders to pay close attention to the specific implementation guidance and operational details in the full measure specifications for these new measures.

Response: We thank the commenters for supporting this new measure in MIPS. We agree with the recommendation that we and the stakeholders review the full measure specifications for the functional improvement measures once posted for CY 2027.

Comment: Several commenters supported CMS' introduction of PROMIS measures. One of these commenters stated these changes are a positive step toward making quality reporting more relevant to clinical practice, but additional reforms are needed to ensure that physical therapists can participate meaningfully and efficiently. Another commenter supported the expanded use of the functional rehabilitation measures within MIPS and future MVP development and encouraged development of additional rehabilitation-focused outcome measures incorporating PROMIS methodologies and other validated functional outcome tools. The commenter urged CMS to recognize the operational and financial resources required to collect and report functional and

[434] Amtmann, D., Cook, K. F., Jensen, M. P., Chen, W. H., Choi, S., Revicki, D., Cella, D., Rothrock, N., Keefe, F., Callahan, L., & Lai, J. S. (2010). Development of a PROMIS Item Bank to Measure Pain Interference. *Pain*, *150*(1), 173–182. https://doi.org/10.1016/j.pain.2010.04.025.

[435] Young, I. A., Dunning, J., Butts, R., Mourad, F., & Cleland, J. A. (2019). Reliability, Construct Validity, and Responsiveness of the Neck Disability Index and Numeric Pain Rating Scale in Patients with Mechanical Neck Pain Without Upper Extremity Symptoms. *Physiotherapy Theory and Practice*, *35*(12), 1328–1335. https://doi.org/10.1080/09593985.2018.1471763.

[436] MacDermid, J. C., Walton, D. M., Avery, S., Blanchard, A., Etruw, E., McAlpine, C., & Goldsmith, C. H. (2009). Measurement Properties of the Neck Disability Index: A Systematic Review. *The Journal of Orthopaedic and Sports Physical Therapy*, *39*(5), 400–417. https://doi.org/10.2519/jospt.2009.2930.

patient-reported outcome measures, emphasizing that many outpatient rehabilitation providers depend on third-party platforms with per-provider subscription models that create significant costs, particularly for small and mid-sized independent practices.

Response: We thank the commenters for supporting the new functional status measures in MIPS. The proposed functional measures allow use of PROMIS tools which are publicly available at no cost for non-electronic surveys. For additional flexibility, the measures also allow for the use of legacy tools specified within each measure which are publicly available at no cost. We recognize the effort required to collect and score the surveys for these measures; however, these patient-reported outcome (PROM) based measures are critical for assessing quality outcomes. Third party platforms are not a CMS requirement to report these functional improvement measures and clinicians are not currently required to report these measures and may select measures that best fit their clinical workflow and scope of practice. The current Physical Therapy Specialty Measure Set contains 23 measures, only 5 of which are the new PRO-PMs, allowing clinicians to submit those measures that are meaningful to their scope of care with sufficient choice to meet the quality reporting requirements.

Comment: One commenter expressed the following concerns on this new measure (with the same concerns for the other functional improvement measures under Tables A.3, A.4, A.5, and A.6 of this Appendix):

- The P-MCI methodology lacks sufficient public detail for independent implementation.
- Registries may need licensing agreements to calculate or validate the measures and proprietary platforms may be needed.
- Practices may face additional financial, technical, and administrative burdens to implement the measures.
- Missing public specifications prevent transparent auditing and reproducibility.
- Smaller practices may be unable to report the measures.
- Conversion of scores across multiple approved instruments remains unclear.

The commenter made the following recommendations to CMS:

- Require stewards to publish a validated, publicly available crosswalk for all approved assessments.
- Require full publication of the P-MCI methodology, including the risk-adjustment model, coefficients, required data elements, episode definitions, missing-data rules, and numerator/denominator logic.
- Offer a publicly accessible calculator or API as an alternative that any reporting entity could use without relying on Limber Health or Patient360.
- Not finalize the measures for broad reporting if the methodology and crosswalk cannot be made public and independently implementable.

A second commenter did not support the new functional measures in MIPS until detailed measure specification and testing information is made available on the feasibility, reliability, and validity of these measures.

Response: Thank you for the comments and recommendations. We appreciate the concerns raised and note that the complete measure specifications will be publicly posted after publication of the final rule. The eligible tools and calculations necessary for reporting the measures will be publicly available at no cost and are included in the measure specifications. We are aware of the concerns and acknowledge they may stem from the current functional outcome measures; however, the proposed measures are intended to mitigate those concerns and reduce reporting burden. These measures were fully developed and tested as QCDR measures in accordance with § 414.1400(b)(4)(iii)(A)(3), which follow the same requirements as those submitted through Call for Measures.

Comment: One commenter expressed concern about the addition of the new functional measures because PROMs can be difficult and resource-intensive to collect and report.

Response: We thank the commenter for their comment. The proposed functional measures allow use of PROMIS tools which are publicly available at no cost for non-electronic surveys, in addition to the use of legacy tools specified within each measure to allow for increased implementation flexibility. We recognize the effort that may be required to collect and submit data for these measures for some clinicians; however, these patient-reported outcome-based measures are critical for assessing quality outcomes. Reporting these functional measures are not required by MIPS, and clinicians have many alternative measures to select if they determine that the reporting burden is too high. We also note that these measures would be optional to report, as clinicians have choice of which MIPS quality measures they choose to report.

Comment: One commenter asked if the Limber Health platform will be required to report the functional improvement measures and asked if this would add financial and other burdens to the clinician and subsequently to the patient.

Response: Thank you for the comment. The eligible tools and calculations necessary for reporting the measure will be publicly available at no cost and are included in the measure specifications. Clinicians who choose to report these measures will not be required to utilize Limber Health and its platform.

Comment: One commenter questioned why the new functional measures in Tables A.2, A.3, A.4, A.5, and A.6 of this Appendix were not proposed for the Physical Medicine specialty set.

Response: We thank the commenter for this comment, and we will consider inclusion of the new functional measures in other relevant specialty sets in future years as we continue to evaluate measure performance, clinical workflows, and stakeholder

feedback.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44307 through 44308), we are finalizing the *Functional Improvement for Patients with Neck Impairments* measure as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

A.3. Functional Improvement for Patients with Upper Extremity Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	519
Description:	Percentage of patients aged 18 years and older with an upper extremity impairment that met the risk-adjusted Predicted Moderate Clinical Improvement (P-MCI) on the PROMIS Upper Extremity (PUE) or the alternative (legacy) patient-reported outcome measure (PROM), the Quick Disabilities of the Arm, Shoulder, & Hand (QDASH).
Measure Steward:	Limber Health, Inc. and Patient360, LLC
Numerator:	Patients with a completed episode of care whose most recent PUE score beyond the baseline score meets or exceeds the P-MCI at the time of the completed episode of care.
Denominator:	All patients aged 18 years or older at the start of the episode of care with an upper extremity impairment who completed a baseline PUE.
Exclusions:	Pre-operative Care: Patients who are being seen for pre-operative care and/or have surgery for upper extremity impairment within 30 days after the initial assessment, documented in the medical record. Cognitive Deficit: A significant mental or cognitive impairment. Hospice or Palliative Care: Patient is in hospice care or receiving palliative care for terminal illness, as documented in the medical record Active Cancer Treatment: Patient is in active treatment for cancer AND the goal of MSK care is primarily to avoid or minimize decline in function, documented in the medical record. Maintenance Therapy: Patient is receiving maintenance therapy.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We proposed this current QCDR patient-reported outcome-based performance measure to replace current MIPS quality measure Q221: *Functional Status Change for Patients with Shoulder Impairments* and Q222: *Functional Status Change for Patients with Elbow, Wrist or Hand Impairments*. This new measure will address the same clinical topics as measures Q221 and Q222; however, it allows for broader implementation by including widely available, non-proprietary tools to assess physical function improvement. Additionally, this measure's analytic allows independent calculation of performance by the clinician, or easy and free collaboration with the steward, which supports clinicians reporting this important aspect of rehabilitative care. This measure utilizes the PROMIS® Upper Extremity tool, which was developed using item response theory (IRT) methods and evidence supports high reliability and validity[437]. It allows clinician flexibility in administration as it uses computer adaptive testing (CAT) or a fixed-length short form. This measure also allows use of the Quick Disabilities of the Arm, Shoulder, and Hand (QuickDASH) tool, which has also shown to be highly reliable and valid for use in patients with upper extremity musculoskeletal disorders.[438] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Rehabilitative Support for Musculoskeletal Care MVP (proposed to be renamed as the Rehabilitative Support MVP under Appendix 3: MVP Inventory, Table B.24). We proposed adding this measure to the Chiropractic Medicine and Physical Therapy/Occupational Therapy specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Chiropractic Medicine, Physical Therapy/Occupational Therapy

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table A.2 of this Appendix, many commenters strongly supported adding the functional improvement quality measures for patients with neck, upper extremity, back, lower extremity, and knee impairments.

Response: We thank the commenters for supporting this new measure in MIPS.

Comment: One commenter supported the move toward validated functional-improvement measures and specifically supported addition of a measure addressing upper extremity impairment. The commenter recommended ensuring that the measure applied to neurologic rehabilitation as well as orthopedic diagnoses, rather than being limited to strictly orthopedic conditions or short outpatient therapy episodes.

Response: We thank the commenter for their suggestion and encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Measure steward contact information will be available in the 2027 MIPS Quality Measures List in the Measure Steward Contacts tab once posted to the QPP website (*https://qpp.cms.gov*) for CY 2027. Any potential new substantive changes need to go through notice and comment rulemaking.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44309 through 44310), we are finalizing the *Functional Improvement for Patients with Upper Extremity Impairments* measure as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

A.4. Functional Improvement for Patients with Back Impairments

[437] Hung, M., Voss, M. W., Bounsanga, J., Crum, A. B., & Tyser, A. R. (2017). Examination of the PROMIS Upper Extremity Item Bank. *Journal of Hand Therapy: Official Journal of the American Society of Hand Therapists*, *30*(4), 485–490. https://doi.org/10.1016/j.jht.2016.10.008.

[438] Chao, Z., & Guo, H. (2023). Reliability and Validity of Quick Disabilities of the Arm, Shoulder, and Hand Questionnaire in Taiwan. *Archives of Physical Medicine and Rehabilitation*, *104*(3), e49. https://doi.org/10.1016/j.apmr.2022.12.142.

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	520
Description:	Percentage of patients aged 18 years and older with a back impairment that met the risk-adjusted Predicted Moderate Clinical Improvement (P-MCI) on the PROMIS Pain Interference (PPI) or the alternative (legacy) patient-reported outcome measure (PROM), the Modified Low Back Disability Questionnaire (MDQ).
Measure Steward:	Limber Health, Inc. and Patient360, LLC
Numerator:	Patients with a completed episode of care whose most recent PPI score beyond the baseline score meets or exceeds the P-MCI at the time of the completed episode of care.
Denominator:	All patients aged 18 years or older at the start of the episode of care with a back impairment who completed a baseline PPI.
Exclusions:	Pre-operative Care: Patients who are being seen for pre-operative care and/or have surgery for the back impairment within 30 days after the initial assessment, documented in the medical record. Cognitive Deficit: A significant mental or cognitive impairment. Hospice or Palliative Care: Patient is in hospice care or receiving palliative care for terminal illness, as documented in the medical record. Active Cancer Treatment: Patient is in active treatment for cancer AND the goal of MSK care is primarily to avoid or minimize decline in function, documented in the medical record. Maintenance Therapy: Patient is receiving maintenance therapy.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
MIPS Core Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A
Rationale:	We proposed this current QCDR patient-reported outcome-based performance measure to replace current MIPS quality measure Q220: *Functional Status Change for Patients with Low Back Impairments*. This new measure will address the same clinical topic as measure Q220; however, it allows for broader implementation by including widely available, non-proprietary tools to assess physical function improvement. Additionally, this measure's analytic allows independent calculation of performance by the clinician, or easy and free collaboration with the steward, which supports clinicians reporting this important aspect of rehabilitative care. This measure utilizes the PROMIS® Pain Interference tool, which was developed using item response theory (IRT) methods. Evidence indicates that the PROMIS-PI items constitute a psychometrically sound item bank for assessing the negative effects of pain on functioning across the range commonly experienced by people who have pain.[439] It allows clinician flexibility in administration as it uses computer adaptive testing (CAT) or a fixed-length short form. This measure also allows utilization of the Modified Low Back Disability Questionnaire (MDQ), which has shown to be a valid, reliable, and responsive condition-specific assessment tool that is suited for use in clinical practice.[440] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Rehabilitative Support for Musculoskeletal Care MVP (proposed to be renamed as the Rehabilitative Support MVP under Appendix 3: MVP Inventory, Table B.24). We proposed adding this measure to the Chiropractic Medicine and Physical Therapy/Occupational Therapy specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.

[439] See footnote Amtmann et al., 2010.

[440] Vianin M. (2008). Psychometric Properties and Clinical Usefulness of the Oswestry Disability Index. *Journal of Chiropractic Medicine*, *7*(4), 161–163. https://doi.org/10.1016/j.jcm.2008.07.001.

Category	Description
Measure Proposed for Addition to the Following Specialty Sets:	Chiropractic Medicine, Physical Therapy/Occupational Therapy

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table A.2 of this Appendix, many commenters strongly supported adding the functional improvement quality measures for patients with neck, upper extremity, back, lower extremity, and knee impairments.

Response: We thank the commenters for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44311 through 44312), we are finalizing the *Functional Improvement for Patients with Back Impairments* measure as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

A.5. Functional Improvement for Patients with Lower Extremity Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	521
Description:	Percentage of patients aged 18 years and older with a lower extremity impairment—not including knee impairments—that met the risk-adjusted Predicted Moderate Clinical Improvement (P-MCI) on the PROMIS Physical Function (PPF) or alternative (legacy) patient-reported outcome measure (PROM), the Lower Extremity Functional Scale (LEFS).
Measure Steward:	Limber Health, Inc. and Patient360, LLC
Numerator:	Patients with a completed episode of care whose most recent PPF score beyond the baseline score meets or exceeds the P-MCI at the time of the completed episode of care.
Denominator:	All patients aged 18 years or older at the start of the episode of care with a non-knee impairment who completed a baseline PPF.
Exclusions:	Pre-operative Care: Patients who are being seen for pre-operative care and/or have surgery for the non-knee lower extremity impairment within 30 days after the initial assessment, documented in the medical record. Cognitive Deficit: A significant mental or cognitive impairment. Hospice or Palliative Care: Patient is in hospice care or receiving palliative care for terminal illness, as documented in the medical record. Active Cancer Treatment: The patient is in active treatment for cancer AND the goal of MSK care is primarily to avoid or minimize decline in function, documented in the medical record. Maintenance Therapy: Patient is receiving maintenance therapy.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We proposed this current QCDR patient-reported outcome-based performance measure to replace current MIPS quality measures Q218: *Functional Status Change for Patients with Hip Impairments* and Q219: *Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments*. This new measure will address the same clinical topics as measures Q218 and Q219; however, it allows for broader implementation by including widely available, non-proprietary tools to assess physical function improvement. Additionally, this measure's analytic allows independent calculation of performance by the clinician, or easy and free collaboration with the steward, which supports clinicians reporting this important aspect of rehabilitative care. This measure utilizes the PROMIS® Physical Function (PPF) tool, which was developed using item response theory (IRT) methods and has demonstrated reliability, convergent and known-groups discriminant validity, and responsiveness in a sample of patients with a lower extremity orthopedic trauma injury.[441] This measure also allows utilization of the Lower Extremity Functional Scale (LEFS). Evidence supports the reliability, validity, and responsiveness of LEFS scores for assessing functional impairment in a wide array of patient groups with lower extremity musculoskeletal conditions.[442] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Rehabilitative Support for Musculoskeletal Care MVP (proposed to be renamed as the Rehabilitative Support MVP under Appendix 3: MVP Inventory, Table B.24). We proposed adding this measure to the Chiropractic Medicine and Physical Therapy/Occupational Therapy specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Chiropractic Medicine, Physical Therapy/Occupational Therapy

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table A.2 of this Appendix, many commenters strongly supported adding the functional improvement quality measures for patients with neck, upper extremity, back, lower extremity, and knee impairments.

Response: We thank the commenters for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44313 through 44314), we are finalizing the *Functional Improvement for Patients with Lower Extremity Impairments* measure as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

[441] Rothrock, N. E., Kaat, A. J., Vrahas, M. S., O'Toole, R. V., Buono, S. K., Morrison, S., & Gershon, R. C. (2019). Validation of PROMIS Physical Function Instruments in Patients With an Orthopaedic Trauma to a Lower Extremity. *Journal of Orthopaedic Trauma*, *33*(8), 377–383. https://doi.org/10.1097/BOT.0000000000001493.

[442] Mehta, S. P., Fulton, A., Quach, C., Thistle, M., Toledo, C., & Evans, N. A. (2016). Measurement Properties of the Lower Extremity Functional Scale: A Systematic Review. *The Journal of Orthopaedic and Sports Physical Therapy*, *46*(3), 200–216. https://doi.org/10.2519/jospt.2016.6165.

A.6. Functional Improvement for Patients with Knee Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	522
Description:	Percentage of patients aged 18 years and older with a knee impairment that met the risk-adjusted Predicted Moderate Clinical Improvement (P-MCI) on the PROMIS Physical Function (PPF) or the alternative (legacy) patient-reported outcome measure (PROM), the Knee Outcome Survey (KOS).
Measure Steward:	Limber Health, Inc. and Patient360, LLC
Numerator:	Patients with a completed episode of care whose most recent PPF score beyond the baseline score meets or exceeds the P-MCI at the time of the completed episode of care.
Denominator:	All patients aged 18 years or older at the start of the episode of care with a knee impairment who completed a baseline PPF.
Exclusions:	Pre-operative Care: Patients who are being seen for pre-operative care and/or have surgery for the knee impairment within 30 days after the initial assessment, documented in the medical record. Cognitive Deficit: A significant mental or cognitive impairment. Hospice or Palliative Care: Patient is in hospice care or receiving palliative care for terminal illness, as documented in the medical record. Active Cancer Treatment: Patient is in active treatment for cancer AND the goal of MSK care is primarily to avoid or minimize decline in function, documented in the medical record. Maintenance Therapy: Patient is receiving maintenance therapy.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A
Rationale:	We proposed this current QCDR patient-reported outcome-based performance measure to replace current MIPS quality measure Q217: *Functional Status Change for Patients with Knee Impairments*. This new measure will address the same clinical topic as measure Q217; however, it allows for broader implementation by including widely available, non-proprietary tools to assess physical function improvement. Additionally, this measure's analytic allows independent calculation of performance by the clinician, or easy and free collaboration with the steward, which supports clinicians reporting this important aspect of rehabilitative care. This measure utilizes the PROMIS® Physical Function (PPF) tool, which was developed using item response theory (IRT) methods and has demonstrated reliability, convergent and known-groups discriminant validity, and responsiveness in a sample of patients with a lower extremity orthopedic trauma injury.[443] This measure also allows utilization of the Knee Outcome Survey (KOS). Evidence shows it is a reliable, valid, and responsive instrument for the assessment of functional limitations that result from a wide variety of pathological disorders and impairments of the knee.[444] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Rehabilitative Support for Musculoskeletal Care MVP (proposed to be renamed as the Rehabilitative Support MVP under Appendix 3: MVP Inventory, Table B.24). We proposed adding this measure to the Chiropractic Medicine and Physical Therapy/Occupational Therapy specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.

[443] See footnote Rothrock et al., 2019.

[444] Irrgang, J. J., Snyder-Mackler, L., Wainner, R. S., Fu, F. H., & Harner, C. D. (1998). Development of a Patient-Reported Measure of Function of the Knee. *The Journal of Bone and Joint Surgery. American volume*, *80*(8), 1132–1145. https://doi.org/10.2106/00004623-199808000-00006.

Category	Description
Measure Proposed for Addition to the Following Specialty Sets:	Chiropractic Medicine, Physical Therapy/Occupational Therapy

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table A.2 of this Appendix, many commenters strongly supported adding the functional improvement quality measures for patients with neck, upper extremity, back, lower extremity, and knee impairments.

Response: We thank the commenters for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44315 through 44316), we are finalizing the *Functional Improvement for Patients with Knee Impairments* measure as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

A.7. Age-Related Hearing Loss: Comprehensive Audiometric Evaluation

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	523
Description:	Percentage of patients aged 50 years and older who failed a hearing screening and/or who report suspected hearing loss or tinnitus who were ordered or referred for a comprehensive audiometric evaluation on the day of diagnosis/office visit OR received a comprehensive audiometric evaluation within 4 weeks of the office visit.
Measure Steward:	American Academy of Otolaryngology - Head and Neck Surgery Foundation
Numerator:	Patients were ordered or referred for a comprehensive audiometric evaluation on the day of diagnosis/office visit OR received a comprehensive audiometric evaluation within 4 weeks of the office visit.
Denominator:	All patients aged 50 years and older who failed a hearing screening and/or who report suspected hearing loss or tinnitus.
Exclusions:	None
Measure Type:	Process
MIPS Core Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We proposed this current QCDR measure as it fills a gap in the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP. It is specific to audiology and ensures that patients suspected of having age-related hearing loss, either identified through a failed hearing screen or diagnosis, are referred for or receive a comprehensive audiometric evaluation. Implementation of this measure as a MIPS CQM will allow wider availability for reporting by MIPS eligible clinicians. The objective of auditory assessment is to diagnose the type and magnitude of hearing loss and the need for treatment, including candidacy for amplification. Age-related hearing loss (ARHL), despite being the most common sensory deficit seen in the older population, remains an underdiagnosed and undertreated condition among individuals aged 50 years and above.[445] Identifying ARHL in early stages could prevent its known adverse outcomes, such as lower quality of life and ability to function.[446] [447] Undertreatment may lead to associated health risks, including dementia, depression, cardiovascular disease, and falls.[448] This measure is based on clinical guidelines intended to inform the practice of hearing care professionals involved in the audiological management of adults with severe to profound hearing loss.[449] Additionally, the guidelines identify quality improvement opportunities and evidence-based recommendations regarding the identification and management of ARHL.[450] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. We proposed adding this measure to the Audiology and Otolaryngology specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Audiology, Otolaryngology

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed addition of the *Age-Related Hearing Loss: Comprehensive Audiometric Evaluation* measure in MIPS. Another commenter recommended adding this measure to the Family Medicine, Internal Medicine, and Geriatrics specialty sets, explaining that these specialties typically perform the Initial Preventive Physical Examination, where hearing screening was expected, and that appropriate screenings should lead directly to the follow-up actions reflected in the measure numerator. The commenter noted that audiology and otolaryngology generally receive patients who have already been identified as needing a comprehensive audiometric evaluation.

Response: We thank the commenters for supporting this new measure in MIPS. We will consider inclusion of this measure in other relevant specialty sets, such as Family Medicine, Internal Medicine, and Geriatrics, in future years as we continue to evaluate measure performance, clinical workflows, and stakeholder feedback.

Comment: A few commenters stated that the proposed measure is not feasible for inclusion in the Audiology specialty set because it is limited to clinicians eligible to bill Evaluation and Management (E/M) codes. They noted that, although the measure

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[445] Tsai Do, B. S., Bush, M. L., Weinreich, H. M., Schwartz, S. R., Anne, S., Adunka, O. F., Bender, K., Bold, K. M., Brenner, M. J., Hashmi, A. Z., Keenan, T. A., Kim, A. H., Moore, D. J., Nieman, C. L., Palmer, C. V., Ross, E. J., Steenerson, K. K., Zhan, K. Y., Reyes, J., & Dhepyasuwan, N. (2024). Clinical Practice Guideline: Age-Related Hearing Loss. *Otolaryngology--Head and Neck Surgery: Official Journal of American Academy of Otolaryngology-Head and Neck Surgery*, *170 Suppl 2*, S1–S54. https://doi.org/10.1002/ohn.750.

[446] Zazove, P., Plegue, M. A., McKee, M. M., DeJonckheere, M., Kileny, P. R., Schleicher, L. S., Green, L. A., Sen, A., Rapai, M. E., & Mulhem, E. (2020). Effective Hearing Loss Screening in Primary Care: The Early Auditory Referral-Primary Care Study. *Annals of Family Medicine*, *18*(6), 520–527. https://doi.org/10.1370/afm.2590.

[447] Chou, R., Dana, T., Bougatsos, C., Fleming, C., & Beil, T. (2011). Screening Adults Aged 50 Years or Older for Hearing Loss: A Review of the Evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*, *154*(5), 347–355. https://doi.org/10.7326/0003-4819-154-5-201103010-00009.

[448] See footnote Zazove et al., 2020.

[449] Turton, L., Souza, P., Thibodeau, L., Hickson, L., Gifford, R., Bird, J., Stropahl, M., Gailey, L., Fulton, B., Scarinci, N., Ekberg, K., & Timmer, B. (2020). Guidelines for Best Practice in the Audiological Management of Adults with Severe and Profound Hearing Loss. *Seminars in Hearing*, *41*(3), 141–246. https://doi.org/10.1055/s-0040-1714744.

[450] See footnote Tsai et al., 2024.

may conceptually involve audiology, its structure does not support participation by audiologists who cannot bill E/M services. The commenters also indicated that while audiologists can identify when an audiologic evaluation is clinically necessary, they cannot independently issue the required order or referral, meaning they would not be able to meet the measure's 4-week timeframe. The commenters suggested that this measure could potentially be adapted for audiology in the future with modifications.

Response: We thank the commenters for their feedback regarding the new measure. Based on the concerns cited, and coding finalization, we are not finalizing this new measure for inclusion in the Audiology specialty set.

After consideration of public comments, we are finalizing the *Age-Related Hearing Loss: Comprehensive Audiometric Evaluation* measure with modification. We are finalizing the measure for MIPS and the Otolaryngology specialty set as proposed for the CY 2027 performance period/2029 MIPS payment year and future years. However, we are not finalizing the measure in the Audiology specialty set based on the considerations stated above and coding finalization.

A.8. Patient-Reported Experience with Anesthesia

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	524
Description:	Percentage of patients, aged 18 and older, who were surveyed on their patient experience and satisfaction with anesthesia care and who reported a positive experience.
Measure Steward:	American Society of Anesthesiologists Anesthesia Quality Institute
Numerator:	Numerator 1. Patients who received a valid survey within 30 days of the procedure to assess their experience and satisfaction with anesthesia. Numerator 2. Patients who reported a positive experience with anesthesia care within 60 days of receipt of the survey.
Denominator:	Denominator 1. Patients aged 18 and older, who undergo a procedure under anesthesia during the denominator identification period. Denominator 2. All patients from Submission Criteria 1 who complete a survey on their patient experience and satisfaction with anesthesia care within 60 days of receipt of the survey.
Exclusions:	Organ Donors as designated by American Society of Anesthesiologists (ASA) Physical Status 6[451] Patient died within 30 days of the procedure Patients who did not complete the mandatory anesthesia satisfaction question within 60 days of receipt of the survey
Measure Type:	Patient-Reported Outcome-Based Performance Measure
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	A minimum of 20 completed surveys required to be eligible to report Denominator 2
Rationale:	We proposed this current QCDR patient-reported outcome-based performance measure as it fills a gap in the Anesthesiology specialty set. It will be the only patient experience of care measure for that specialty and is reported for each procedure. The measure assesses for patients that receive a valid survey and report a positive experience with their anesthesia care. The assessment of patient satisfaction with anesthesia care provides important feedback allowing clinicians to improve the quality-of-care delivery.[452] There are a variety of surveys available for practices and clinicians to implement based upon local patient populations, such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS): Patients' Perspectives of Care Survey[453] and Outpatient and Ambulatory Surgery CAHPS.[454] However, the measure will not require the use of a specific survey to collect patient feedback. Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Patient Safety and Support of Positive Experiences with Anesthesia MVP. We proposed adding this measure to the Anesthesiology specialty set based on available coding and because the clinical quality action is within the scope of care for anesthesiologists.
Measure Proposed for Addition to the Following Specialty Sets:	Anesthesiology

[451] American Society of Anesthesiologists (ASA) Physical Status 6 is defined as a declared brain-dead patient whose organs are being removed for donor purposes.
ASA. (2026). American Society of Anesthesiologists Statement on ASA Physical Status Classification System. *Anesthesiology Open, 1*(1), e0002. https://doi.org/10.1097/ao9.0000000000000002.
[452] Agency for Healthcare Research and Quality. (2013). Guide to Patient and Family Engagement in Hospital Quality and Safety. https://psnet.ahrq.gov/issue/guide-patient-and-family-engagement-hospital-quality-and-safety.
[453] CMS. (2025). HCAHPS: Patients' Perspectives of Care Survey. https://www.cms.gov/data-research/research/consumer-assessment-healthcare-providers-systems/hospital-cahps-hcahps.
[454] CMS. (2026). Outpatient and Ambulatory Surgery CAHPS (OAS CAHPS). https://www.cms.gov/data-research/research/consumer-assessment-healthcare-providers-systems/outpatient-and-ambulatory-surgery-cahps.

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: Two commenters supported the proposed addition of the *Patient-Reported Experience with Anesthesia* measure for use in MIPS. One of the commenters noted that the measure, already used by QCDRs and included in the Anesthesia MVP, is an important way for anesthesiologists to understand patients' perceptions of their care. The commenter stated that anesthesiology groups use these survey results to improve patient-centered perioperative care.

Response: We thank the commenters for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44319), we are finalizing the *Patient-Reported Experience with Anesthesia* measure as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

A.9. Intraoperative Hypotension (IOH) Among Non-Emergent Noncardiac Surgical Cases

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	525
Description:	Percentage of general, neuraxial, or regional anesthesia care cases performed during the performance period in which the mean arterial pressure (MAP) fell below 65 mmHg for a cumulative total of 15 minutes or more.
Measure Steward:	Anesthesia Quality Registry (AQR QCDR) in Collaboration with Anesthesia Quality Institute (AQI) and American Society of Anesthesiologists (ASA)
Numerator:	Patients who have a MAP below 65 mmHg that exceeds the cumulative length of 15 minutes during the performance period.
Denominator:	All cases in which adults (ages 18 and older) with non-cardiac, non-emergency surgery requires general, neuraxial, or regional anesthesia care during the performance period.
Exclusions:	Patients with a baseline MAP below 65 mmHg Patients with surgeries where anesthesia is complicated by utilization of controlled hypotension during the primary anesthesia procedure Patients with American Society of Anesthesiologists (ASA) Physical Status Classification of 1, 5 or 6[455] Emergency cases Patients who are undergoing cardiac, cataract, obstetric non-operative, or liver/lung transplant procedures
Measure Type:	Intermediate Outcome
MIPS Core Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A
Rationale:	We proposed this current QCDR measure as it fills a gap in the Anesthesiology specialty set. This inverse, intermediate outcome measure ensures mean arterial pressure (MAP) does not fall below 65mmHg for greater than 15 minutes during a procedure as it could be associated with adverse outcomes, such as acute kidney injury (AKI) or myocardial injury.[456] Evidence indicates a MAP below absolute thresholds of 65 mmHg or relative thresholds of 20 percent was progressively related to both myocardial and kidney injury. Prolonged exposure below the threshold was also associated with increased risk. Noncardiac surgery patients are at increased risk of AKI when their cumulative time below a MAP of 65 mmHg reaches or exceeds 13 minutes. When patients fall further below 65 mmHg, even shorter durations are associated with increased risk of AKI.[457] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Patient Safety and Support of Positive Experiences with Anesthesia MVP. We proposed adding this measure to the Anesthesiology specialty set based on available coding and because the clinical quality action is within the scope of care for anesthesiologists.

[455] ASA Physical Status 1 is defined as a normal healthy patient. Physical Status 5 is defined as a moribund patient who is not expected to survive without the operation. Physical Status 6 is defined as a declared brain-dead patient whose organs are being removed for donor purposes.
See footnote ASA, 2026.

[456] Walsh, M., Devereaux, P. J., Garg, A. X., Kurz, A., Turan, A., Rodseth, R. N., Cywinski, J., Thabane, L., & Sessler, D. I. (2013). *Relationship Between Intraoperative Mean Arterial Pressure and Clinical Outcomes After Noncardiac Surgery*. Anesthesiology, 119(3), 507–515. https://doi.org/10.1097/ALN.0b013e3182a10e26.

[457] Salmasi, V., Maheshwari, K., Yang, D., Mascha, E. J., Singh, A., Sessler, D. I., & Kurz, A. (2017). Relationship between Intraoperative Hypotension, Defined by Either Reduction from Baseline or Absolute Thresholds, and Acute Kidney and Myocardial Injury after Noncardiac Surgery: A Retrospective Cohort Analysis. *Anesthesiology*, *126*(1), 47–65. https://doi.org/10.1097/ALN.0000000000001432.

Category	Description
Measure Proposed for Addition to the Following Specialty Sets:	Anesthesiology

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed addition of the *Intraoperative Hypotension (IOH) Among Non-Emergent Noncardiac Surgical Cases* measure in MIPS. The commenter noted that the measure, already used by QCDRs, is an important intermediate outcome for anesthesiologists and the anesthesia care team. IOH has long been a clinical concern, and advances in monitoring technology now enable more proactive blood pressure management. This measure allows anesthesiologists to track IOH and understand its impact on patient outcomes, and the commenter stated that anesthesiologists use it intraoperatively to better predict and plan for potential postoperative complications.

Response: We thank the commenter for supporting this new measure in MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44320 through 44321), we are finalizing the *Intraoperative Hypotension (IOH) Among Non-Emergent Noncardiac Surgical Cases* measure as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

A.10. SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	526
Description:	The percentage of patients aged 18 years and older with chronic kidney disease (CKD) stages 2 and 3 who are prescribed an SGLT2 inhibitor during the performance period.
Measure Steward:	A Value-Based Care Registry
Numerator:	Patients who were prescribed or were currently taking an SGLT2 inhibitor during the performance period.
Denominator:	All patients aged 18 years and older diagnosed with chronic kidney disease (CKD) stages 2-3 during the performance period.
Exclusions:	Patients with Type 1 Diabetes Mellitus Diabetic Ketoacidosis
Measure Type:	Process
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We proposed this current QCDR measure as it fills a gap in the MIPS quality measure inventory, ensuring the appropriate, evidence-based treatment of patients diagnosed with CKD with SGLT2 inhibitors. Evidence demonstrates that SGLT2 inhibitors slow the progression of CKD and reduce cardiovascular events in this patient population.[458] [459] [460] As a result, SGLT2 inhibitors have become a key disease-modifying therapy to prevent CKD progression. These medications prevent decline in kidney function through reduction in glomerular hypertension, independent of their effect on glycemic control. This has expanded the approved clinical indications for these medications beyond patients with diabetes.[461] Current clinical and practice guidelines also recommend use of SGLT2 inhibitors to slow CKD progression in patients with or without type 2 diabetes.[462] [463] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. We proposed adding this measure to multiple applicable specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Cardiology, Endocrinology, Family Medicine, Geriatrics, Internal Medicine, Nephrology

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed addition of the *SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus* measure in MIPS. One commenter supported the addition of this optional measure within Family Medicine, Cardiology, Endocrinology, Geriatrics, Internal Medicine and Nephrology specialty sets in MIPS. The commenter agreed with the goal of this new measure; however, they stressed that successful implementation depends on patients having affordable and reliable access to the medications needed to meet the measure. The commenter urged CMS to ensure these therapies are well covered under Medicare, included on affordable formularies, and available to beneficiaries without excessive cost-sharing or administrative hurdles. Another commenter requested that this measure reflect current guidelines and promote equitable medication access across diverse practice settings.

Response: We thank the commenters for supporting this new measure in MIPS. We will continue to monitor implementation of this measure for adherence to clinical guidelines and addition to appropriate specialty measure sets.

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[458] Heerspink, H. J. L., Stefánsson, B. V., Correa-Rotter, R., Chertow, G. M., Greene, T., Hou, F. F., Mann, J. F. E., McMurray, J. J. V., Lindberg, M., Rossing, P., Sjöström, C. D., Toto, R. D., Langkilde, A. M., Wheeler, D. C., & DAPA-CKD Trial Committees and Investigators (2020). Dapagliflozin in Patients with Chronic Kidney Disease. *The New England Journal of Medicine*, *383*(15), 1436–1446. https://doi.org/10.1056/NEJMoa2024816.

[459] Perkovic, V., Jardine, M. J., Neal, B., Bompoint, S., Heerspink, H. J. L., Charytan, D. M., Edwards, R., Agarwal, R., Bakris, G., Bull, S., Cannon, C. P., Capuano, G., Chu, P. L., de Zeeuw, D., Greene, T., Levin, A., Pollock, C., Wheeler, D. C., Yavin, Y., Zhang, H., … CREDENCE Trial Investigators (2019). Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy. *The New England Journal of Medicine*, *380*(24), 2295–2306. https://doi.org/10.1056/NEJMoa1811744.

[460] The EMPA-KIDNEY Collaborative Group, Herrington, W. G., Staplin, N., Wanner, C., Green, J. B., Hauske, S. J., Emberson, J. R., Preiss, D., Judge, P., Mayne, K. J., Ng, S. Y. A., Sammons, E., Zhu, D., Hill, M., Stevens, W., Wallendszus, K., Brenner, S., Cheung, A. K., Liu, Z. H., Li, J., … Haynes, R. (2023). Empagliflozin in Patients with Chronic Kidney Disease. *The New England Journal of Medicine*, *388*(2), 117–127. https://doi.org/10.1056/NEJMoa2204233.

[461] Yau, K., Dharia, A., Alrowiyti, I., & Cherney, D. Z. I. (2022). Prescribing SGLT2 Inhibitors in Patients With CKD: Expanding Indications and Practical Considerations. *Kidney International Reports*, *7*(7), 1463–1476. https://doi.org/10.1016/j.ekir.2022.04.094.

[462] Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. (2022). *KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease*. *Kidney International, 102*(5S), S1–S127. https://doi.org/10.1016/j.kint.2022.06.008.

[463] American Diabetes Association Professional Practice Committee. (2024). *11. Chronic Kidney Disease and Risk Management: Standards of Care in Diabetes—2024*. *Diabetes Care, 47*(Suppl. 1), S219–S230. https://doi.org/10.2337/dc24-S011.

Comment: One commenter supported adding the measure to the Geriatrics specialty set but stated it would be strengthened by adding denominator exceptions for clinical contraindication or intolerance, documenting patient preference, and considering advanced illness, frailty, hospice, polypharmacy, and limited expected benefit. Another commenter supported the addition of this measure and recommended setting a uACR threshold of at least 200 mg/g for stage 2–3 CKD to ensure clinical appropriateness. With this change, the commenter supported adding the measure across multiple specialty sets and emphasized its alignment with guidelines and its kidney and cardiovascular benefits.

Response: We thank the commenters for supporting this new measure in MIPS. We encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter did not support including this new measure in MIPS until detailed measure specification and testing information is made available. The commenter was unable to find the detailed measure specifications or the results on the feasibility, reliability, and validity testing of this measure. It would also be important to know the process by which this measure was developed, including whether a technical expert panel was convened, which specialties and experts were included, and other important details relevant to the development and testing process.

Response: We appreciate the concerns raised and note that this measure was previously available for MIPS reporting as a QCDR measure. As a QCDR measure, the same requirements for being fully developed and tested would apply (§ 414.1400(b)(4)(iii)(A)(3)). The complete measure specification will be publicly posted after publication of the final rule.

Comment: One commenter asked who a Value-Based Care Registry is as the measure steward.

Response: The Value-Based Care Registry is a MIPS Qualified Clinical Data Registry (QCDR); as the author/owner of the measure, they are responsible for the ongoing development and maintenance of the measure specifications. Measure steward contact information will be available in the 2027 MIPS Quality Measures List in the Measure Steward Contact tab once posted on the QPP website (*https://qpp.cms.gov*) for CY 2027.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44321 through 44322), we are finalizing the *SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus* measure as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

Table Group AA: New MIPS Quality Measures Finalized for the CY 2028 Performance Period/2030 MIPS Payment Year and Future Years

In addition to the new quality measures proposed in Table Group A of this Appendix, we proposed adding one eCQM for the 2028 performance period/2030 MIPS payment year and future years to allow clinicians sufficient time to adapt their workflows prior to implementation within MIPS. We requested comments on this new measure.

AA.1. Rate of Timely Follow-up on Abnormal Screening Mammograms for Breast Cancer Detection

Category	Description
CBE # / eCQM CBE #:	N/A / 4700e
Quality #:	527
Description:	This electronic clinical quality measure (eCQM) reports the percentage of female patients aged 40 to 75 years with at least one abnormal screening (BI-RADS 0) or screening-to-diagnostic (BI-RADS 4, 5) mammogram during the measurement period (i.e., calendar year) who received timely diagnostic resolution defined as either follow-up imaging with negative/benign/probably benign results or a breast biopsy within 60 days after their index (i.e., first) abnormal screening mammogram.
Measure Steward:	Brigham and Women's Hospital
Numerator:	Patients in the denominator population who received timely diagnostic resolution defined as negative/benign/probably benign follow-up imaging (BI-RADS 1, 2, 3) or breast biopsy within 60 days after the date of their index (i.e., first) abnormal screening (BI-RADS 0) or screening-to-diagnostic (BI-RADS 4, 5) mammogram.
Denominator:	Female patients aged 40 to 75 years with an abnormal screening (BI-RADS 0) or screening-to-diagnostic (BI-RADS 4, 5) mammogram during the measurement period (i.e., calendar year). Only the first abnormal screening or screening-to-diagnostic mammogram (i.e., index screening test) is included in the measure calculation.
Exclusions:	N/A
Measure Type:	Process
MIPS Core Measure	No
Collection Type:	eCQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We proposed this eCQM because it addresses timely follow up of diagnostic testing for patients with an abnormal mammogram. Additionally, it fills a gap in the Diagnostic Radiology specialty set with potential for inclusion in an MVP. Breast cancer is the second most common cause of cancer deaths among women in the United States[464] and survival is dependent upon cancer stage at diagnosis. Breast cancer mainly occurs in middle-aged and older women, with the median age at the time of diagnosis being 62 years.[465] Noninvasive mammographic screening is the primary screening modality used to detect breast cancer. Studies show that between 27 to 72 percent of women did not receive appropriate follow-up within 6 months of an abnormal mammogram.[466] Delays in diagnostic follow-up after abnormal mammographic screening results increase the risk of diagnosing cancer at a more advanced stage.[467] Timely follow-up is essential to facilitate early-stage detection and improve overall survival outcomes. The Pre-Rulemaking Measure Review (PRMR) Clinician Recommendation Committee did not reach consensus on this measure; however, the majority (71 percent) of the committee expressed support for use of the measure. The measure is CBE endorsed with conditions of continued monitoring of performance and additional data element validity testing of other electronic health records (EHRs). We proposed this measure with a one-year delay in implementation to allow time for clinicians to adapt their workflows and therefore ensure greater feasibility of reporting within MIPS. If finalized as proposed, this measure will be available for reporting for the CY 2028 performance period/2030 MIPS payment year. We proposed adding this measure to the Diagnostic Radiology specialty set for the CY 2028 performance period/2030 MIPS payment year based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Diagnostic Radiology

We received public comments on this proposed measure. The following is a summary of the comments we received and our responses.

Comment: One commenter was pleased this proposed measure is an eCQM. Another commenter supported the delay of this new measure until CY 2028. This additional lead time will allow organizations to address potential gaps and challenges before reporting becomes required, ultimately supporting a smoother transition and more successful adoption of the measure.

Response: We thank the commenters for supporting eCQM measures and this measure in MIPS. Accordingly, this measure is not required for reporting. Clinicians have the flexibility to choose which measures to report based upon the appropriateness of the measure to their scope of care.

Comment: One commenter opposed using this measure for clinician- or group-level MIPS reporting at this time, emphasizing that it was designed for facility and system accountability and has been tested only in limited settings. The commenter was concerned the measure would hold radiologists responsible for scheduling, patient delays, navigation barriers, workforce constraints, and care delivered by others, and noted that BI-RADS data are often stored in unstructured reports without consistent extraction tools across vendors—issues that could especially burden small or rural practices and distort performance and payment. The commenter urged CMS not to finalize the measure for clinician- or group-level MIPS reporting in 2028. The commenter recommended it remain at the facility level or be delayed until robust multi-TIN, varied practice-type testing confirms reliable performance and confirms accurate attribution when clinicians do not control the full care pathway. They also recommended CMS ensure that eCQM data are available in standardized, interoperable formats, provide clear extraction tools and vendor guidance, and establish safeguards for follow-up care outside the reporting entity's control.

If CMS proceeds with the measure, the commenter recommended using 2028 and later for voluntary, non-scored testing in varied practice and technology settings, releasing detailed specifications and standardized BI-RADS extraction tools early, and including exclusions for factors outside clinicians' control plus support for resource-limited sites. They also advised starting with

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[464] American Cancer Society (ACS). (2024). Key Statistics for Breast Cancer. https://www.cancer.org/cancer/types/breast-cancer/about/how-common-is-breast-cancer.html.

[465] See footnote ACS, 2024.

[466] Reece, J. C., Neal, E. F. G., Nguyen, P., et al. (2021). Delayed or Failure To Follow-up Abnormal Breast Cancer Screening Mammograms in Primary Care: A Systematic Review. *BMC Cancer, 21*, 373. https://doi.org/10.1186/s12885-021-08100-3.

[467] McCarthy, A. M., Kim, J. J., Beaber, E. F., Zheng, Y., Burnett-Hartman, A., Chubak, J., Ghai, N. R., McLerran, D., Breen, N., Conant, E. F., Geller, B. M., Green, B. B., Klabunde, C. N., Inrig, S., Skinner, C. S., Quinn, V. P., Haas, J. S., Schnall, M., Rutter, C. M., Barlow, W. E., … PROSPR consortium (2016). Follow-Up of Abnormal Breast and Colorectal Cancer Screening by Race/Ethnicity. *American Journal of Preventive Medicine*, *51*(4), 507–512. https://doi.org/10.1016/j.amepre.2016.03.017.

confidential feedback only (no payment or public reporting impact) and moving to full implementation only after proving interoperability, data completeness, reliable attribution, and no harm to breast imaging access.

A few additional commenters expressed similar concerns to above. This measure, if finalized, would be the only breast imaging measure in MIPS. One of the commenters urged CMS not to finalize inclusion of this measure in MIPS until further testing is conducted. Another commenter recommended this measure should also be reportable as a MIPS CQM.

Response: Thank you for the comments, suggestions, and concerns raised. Testing for reliability and validity was completed at the individual clinician level, in accordance with requirements outlined in Pre-Rulemaking: The Measure Submission Period and the Measures Under Consideration (MUC) List - 2026 Frequently Asked Questions.[468] Reliability testing at the individual clinician level indicated a median Signal to Noise Ratio (SNR) was 0.962 for 99 clinicians. With regards to attribution, as an important measure concept we agree that radiologists and radiology practices retain meaningful influence over scheduling and operational prioritization (e.g., adding late-day slots, advocating within hospital operations), and therefore share responsibility for timely follow-up. Published literature shows that long wait times to diagnostic evaluation are associated with increased tumor size and lymph node metastases in patients with delays exceeding 12 weeks.[469] [470] [471] BI-RADS data is available in discrete fields within major electronic health records, such as Epic and Oracle Health (Cerner), and while it may not be available in some facilities, multi-site testing showed string-search/natural language processing (NLP) methods achieved accurate extraction where structured fields were not consistently used, as demonstrated within the measure steward's submitted material. We encourage the commenters to reach out to the measure steward to discuss collection type expansion for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44323 through 44324), we are finalizing the *Rate of Timely Follow-up on Abnormal Screening Mammograms for Breast Cancer Detection* measure as proposed for the CY 2028 performance period/2030 MIPS payment year and future years.

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[468] CMS. (2026). Pre-Rulemaking: The Measure Submission Period and the Measures Under Consideration (MUC) List - 2026 Frequently Asked Questions. https://mmshub.cms.gov/sites/default/files/Pre-Rulemaking-FAQ-20261-v3.pdf.

[469] Olivotto, I. A., Gomi, A., Bancej, C., Brisson, J., Tonita, J., Kan, L., Mah, Z., Harrison, M., & Shumak, R. (2002). Influence of Delay to Diagnosis on Prognostic Indicators of Screen-Detected Breast Carcinoma. *Cancer*, 94(8), 2143–2150. https://doi.org/10.1002/cncr.10453.

[470] Ganry, O., Peng, J., & Dubreuil, A. (2004). Influence of Abnormal Screens on Delays and Prognostic Indicators of Screen-Detected Breast Carcinoma. *Journal of Medical Screening*, 11(1), 28–31. https://doi.org/10.1177/096914130301100107.

[471] Doubeni, C. A., Gabler, N. B., Wheeler, C. M., McCarthy, A. M., Castle, P. E., Halm, E. A., Schnall, M. D., Skinner, C. S., Tosteson, A. N. A., Weaver, D. L., Vachani, A., Mehta, S. J., Rendle, K. A., Fedewa, S. A., Corley, D. A., & Armstrong, K. (2018). Timely Follow-Up of Positive Cancer Screening Results: A Systematic Review and Recommendations from the PROSPR Consortium. CA: *A Cancer Journal for Clinicians*, 68(3), 199–216. https://doi.org/10.3322/caac.21452.

Table Group B: Modifications to Previously Finalized Specialty Sets Finalized and Finalized with Modification for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

In the CY 2027 PFS proposed rule (91 FR 44325), we proposed modifying the previously finalized specialty sets based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and feedback provided by specialty societies and other interested parties. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D of this Appendix.

We use the following symbols in the Indicator column in the Table Group B tables below:

- Existing quality measures with substantive changes described in Table Group D of this Appendix are identified with an asterisk (*).
- Quality measures designated as MIPS core measures are identified with an exclamation point (!). As discussed in section IV.A.4.d.(1)(c)(i) of this final rule, we finalized implementation of the MIPS core measure designation for traditional MIPS and MVP reporting.
- Quality measures finalized for addition to a specialty set are identified with a plus sign (+).

Additionally, measures that are endorsed by a CBE are shown in Table Group B of this Appendix as follows: CBE # / eCQM CBE #.

In the proposed rule (91 FR 44325), we updated the format of the specialty set tables to reflect what the specialty set will be for the CY 2027 performance period, if finalized as proposed. Measures proposed for addition to the specialty sets were added to applicable tables and are noted with a plus sign (+) in the Indicator column. See Table Group A of this Appendix for rationales for proposed new measures. Existing measures proposed for addition to a specific specialty set are also indicated with a plus sign (+) and were included in the introductory paragraphs of the specialty set, as applicable. If the measure was not finalized for addition in the CY 2027 PFS final rule, it would have been removed from the specialty set table. For proposed new measures, the reason for its removal from the specialty set would have been addressed under Table Group A of this Appendix.

Measures proposed for removal were removed from each specialty set, as applicable. See Table Group C of this Appendix for rationales for proposed measure removals from MIPS. Specialty-specific measure removals were also noted in the introductory paragraphs of the specialty set, as applicable. If a measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back to the specialty set table. For proposed measure removals from MIPS, the reason for its retention would have been addressed under Table Group C of this Appendix.

NOTE:

- Updates to measure titles and/or measure descriptions under Table Group B in this final rule may or may not be considered substantive in nature, therefore may not be proposed or updated under Table Group D. If the change was considered substantive in nature, it was finalized under Table Group D.
- Under Table Group B, we responded to comments related to existing measures that were proposed for addition to a specific specialty, and/or specialty-specific measure removals, as applicable. Comments and responses pertaining to new measures that were proposed for addition to the specialty set can be found in Table Group A of this Appendix. Comments and responses pertaining to measures that were proposed for removal from MIPS, and therefore from the specialty set, can be found in Table Group C of this Appendix. Comments and responses pertaining to previously finalized measures that have substantive changes can be found in Table Group D of this Appendix. Any comments received on previously finalized measures that have no substantive changes are out of scope and not included in this final rule. Commenters who requested additions or removals of quality measures to specific specialty sets should use the Stakeholder Solicitation for Specialty Sets process as these updates must be proposed through rulemaking.
- For each specialty set, measures in the Finalized tables will be available for reporting in CY 2027.

We requested comments on proposed measure additions of previously finalized measures in six specialty sets in this Appendix: B.5, B.13, B.19, B.25. B.26, and B.38. Previously finalized measures that had no substantive changes were not open for comment under the proposed rule.

The following specialty set had no proposed modifications and no proposed substantive changes to previously finalized measures for the CY 2027 performance period/2029 MIPS payment year: Diagnostic Radiology.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.1. Allergy/Immunology

FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology – Head and Neck Surgery Foundation
!	N/A / N/A	338	CMS31 4v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration
	N/A / N/A	340	CMS11 57v3	eCQM, MIPS CQM	Process	HIV Annual Retention in Care	Health Resources and Services Administration
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance

B.1. Allergy/Immunology

FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.2. Anesthesiology

FINALIZED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	404	N/A	MIPS CQM	Intermediate Outcome	Anesthesiology Smoking Abstinence	American Society of Anesthesiologists
!	N/A / N/A	477	N/A	MIPS CQM	Process	Multimodal Pain Management	American Society of Anesthesiologists
+	N/A / N/A	524	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Patient-Reported Experience with Anesthesia	American Society of Anesthesiologists Anesthesia Quality Institute
+ !	N/A / N/A	525	N/A	MIPS CQM	Intermediate Outcome	Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases	Anesthesia Quality Registry (AQR QCDR) in Collaboration with Anesthesia Quality Institute (AQI) and American Society of Anesthesiologists (ASA)

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

Below will be the specialty set for this specialty for the CY 2027 performance period with modification. The *Age-Related Hearing Loss: Comprehensive Audiometric Evaluation* measure is not being finalized for the Audiology set as discussed under Table A.7 of this Appendix and therefore has been removed from the table below.

B.3. Audiology

FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	NA / NA	261	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness	Audiology Quality Consortium
* !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS139v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance

B.3. Audiology

FINALIZED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	2152/ N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.4a. Cardiology

FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0081 / 0081e	005	CMS13 5v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0083 / 0083e	008	CMS14 4v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	0066 / N/A	118	N/A	MIPS CQM	Process	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)	American Heart Association
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
	N/A / N/A	187	N/A	MIPS CQM	Process	Stroke and Stroke Rehabilitation: Thrombolytic Therapy	American Heart Association
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	236	CMS16 5v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Inter-mediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	0643 / N/A	243	N/A	MIPS CQM	Process	Cardiac Rehabilitation Patient Referral from an Outpatient Setting	American Heart Association

B.4a. Cardiology

FINALIZED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	344	N/A	MIPS CQM	Outcome	Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)	Society for Vascular Surgery
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	N/A / N/A	438	CMS347v10	eCQM, MIPS CQM	Process	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Centers for Medicare & Medicaid Services
* !	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)	Wisconsin Collaborative for Healthcare Quality
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665/ N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
+ !	N/A / N/A	517	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	526	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.4b. Electrophysiology Cardiac Specialist

FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	2474 / N/A	392	N/A	MIPS CQM	Outcome	Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation	American College of Cardiology Foundation
*	N/A / N/A	393	N/A	MIPS CQM	Outcome	Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision	American College of Cardiology Foundation

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Certified Nurse Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We also proposed adding one existing MIPS quality measure to this specialty set:

- **Q493:** *Adult Immunization Status*: This MIPS quality measure assesses whether adult patients are up-to-date with recommended routine immunizations. We agreed with interested parties' feedback that this measure is clinically relevant to this clinician type. Certified Nurse Midwives are advanced practice clinicians uniquely qualified to deliver comprehensive primary care, pregnancy care, and gynecological care. Their scope of practice often includes primary care services such as immunizations, especially in alignment with their focus on preventive care and wellness for women.[472] [473] Adding this measure will align the Certified Nurse Midwife specialty set with the Obstetrics and Gynecology specialty set, recognizing the similarities in care delivery between these specialties and ensuring consistency across specialty sets. Including this measure in the Certified Nursing Midwife specialty set acknowledges the important role they play in preventive care and primary health maintenance, as well as promoting consistent, high quality care delivery across patient populations. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received no public comments on the measure proposed for addition to this specialty set. For the reasons stated above and in the proposed rule (91 FR 44333), we are finalizing the *Certified Nurse Midwife Specialty Set* as proposed for the CY 2027 performance period/2029 MIPS payment year and future years. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.5. Certified Nurse Midwife

FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / N/A	335	N/A	MIPS CQM	Outcome	Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse)	Centers for Medicare & Medicaid Services

[472] American College of Nurse-Midwives. (2024). Discover Midwives: Certified Nurse-Midwives and Certified Midwives. https://midwife.org/wp-content/uploads/2024/11/2022_Discover-Midwives.pdf.

[473] American College of Nurse-Midwives. (2025). American College of Nurse-Midwives Statement on Maternal Immunization: Updated July 2025. https://midwife.org/american-college-of-nurse-midwives-statement-on-maternal-immunization-updated-july-2025/.

B.5. Certified Nurse Midwife

FINALIZED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	N/A / N/A	336	N/A	MIPS CQM	Process	Maternity Care: Postpartum Follow-up and Care Coordination	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	N/A / N/A	475	CMS349v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
+	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
	N/A / N/A	496	N/A	MIPS CQM	Process	Cardiovascular Disease (CVD) Risk Assessment Measure – Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument	University of California, Irvine
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
*	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Reduction in Suicidal Ideation or Behavior Symptoms	American Psychiatric Association

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.6. Chiropractic Medicine

FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
+	N/A / N/A	518	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Neck Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	519	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Upper Extremity Impairments	Limber Health, Inc. and Patient360, LLC
+ !	N/A / N/A	520	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Back Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	521	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Lower Extremity Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	522	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Knee Impairments	Limber Health, Inc. and Patient360, LLC

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.7. Clinical Social Work

FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v15	eCQM	Process	Dementia: Cognitive Assessment	American Academy of Neurology
!	N/A / N/A	282	N/A	MIPS CQM	Process	Dementia: Functional Status Assessment	American Academy of Neurology
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Academy of Neurology/ American Psychiatric Association
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
!	N/A / N/A	305	CMS13 7v15	eCQM	Process	Initiation and Engagement of Substance Use Disorder Treatment	National Committee for Quality Assurance
!	0710 / 0710e	370	CMS15 9v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	382	CMS177v15	eCQM	Process	Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment	Centers for Medicare & Medicaid Services
* !	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	Adherence to Antipsychotic Medications For Individuals with Schizophrenia	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder	American Psychiatric Association
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
*	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Reduction in Suicidal Ideation or Behavior Symptoms	American Psychiatric Association

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.8. Dentistry

FINALIZED MEASURES IN THE DENTISTRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	379	CMS 74v16	eCQM	Process	Primary Caries Prevention Intervention as Offered by Dentists	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.9. Dermatology

FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A/ N/A	176	N/A	MIPS CQM	Process	Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy	American College of Rheumatology
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
!	N/A / N/A	410	N/A	MIPS CQM	Intermediate Outcome	Psoriasis: Clinical Response to Systemic Medications	American Academy of Dermatology
* !	N/A / N/A	440	N/A	MIPS CQM	Process	Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician	American Academy of Dermatology
	N/A / N/A	485	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Psoriasis – Improvement in Patient-Reported Itch Severity	American Academy of Dermatology
!	N/A / N/A	486	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Dermatitis – Improvement in Patient-Reported Itch Severity	American Academy of Dermatology
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.9. Dermatology

FINALIZED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	N/A / N/A	509	N/A	MIPS CQM	Process	Melanoma: Tracking and Evaluation of Recurrence	American Academy of Dermatology

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set. This specialty set had no proposed changes for CY 2027.

We note the *Rate of Timely Follow-up on Abnormal Screening Mammograms for Breast Cancer Detection* measure finalized under Table AA.1 of this Appendix will be available for the CY 2028 performance period/2030 MIPS payment year.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	145	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy	American College of Radiology
!	N/A / N/A	360	N/A	MIPS CQM	Process	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies	American College of Radiology
	N/A / N/A	364	N/A	MIPS CQM	Process	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines	American College of Radiology
!	N/A / N/A	405	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Appropriate Follow-up Imaging for Incidental Abdominal Lesions	American College of Radiology
	N/A / N/A	406	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Appropriate Follow-up Imaging for Incidental Thyroid Nodules	American College of Radiology
	N/A / 3633e	494	CMS1056v4	eCQM	Intermediate Outcome	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Clinician Level)	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.11. Emergency Medicine

FINALIZED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	0069/ N/A	065	CMS15 4v15	eCQM, MIPS CQM	Process	Appropriate Treatment for Upper Respiratory Infection (URI)	National Committee for Quality Assurance
	N/A / N/A	066	CMS14 6v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
	N/A / N/A	187	N/A	MIPS CQM	Process	Stroke and Stroke Rehabilitation: Thrombolytic Therapy	American Heart Association
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology – Head and Neck Surgery Foundation
!	N/A / N/A	416	N/A	MIPS CQM	Efficiency	Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years	American College of Emergency Physicians

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.12. Endocrinology

FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	0059 / N/A	001	CMS122v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
	0055 / N/A	117	CMS131v15	eCQM, MIPS CQM	Process	Diabetes: Eye Exam	National Committee for Quality Assurance
	0066 / N/A	118	N/A	MIPS CQM	Process	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)	American Heart Association
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	236	CMS165v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
*	N/A / N/A	374	CMS50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services

B.12. Endocrinology

FINALIZED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance
*	N/A / N/A	438	CMS347v10	eCQM, MIPS CQM	Process	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Centers for Medicare & Medicaid Services
!	N/A / N/A	462	CMS645v10	eCQM	Process	Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy	Oregon Urology Institute
!	N/A / N/A	488	CMS951v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
+ !	N/A / N/A	517	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	526	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We also proposed adding two existing MIPS quality measures to this specialty set:

- **Q205**: *Sexually Transmitted Infection (STI) Testing for People with HIV*: This MIPS quality measure assesses appropriate screening of STIs for patients with HIV. We agreed with interested parties' feedback that this measure is clinically relevant to this clinician type and proposed adding this measure to the Family Medicine specialty set. Clinical guidelines, such as those from the Centers for Disease Control and Prevention (CDC), recommend regular screening for STIs in individuals with HIV.[474] Despite the high incidence of STIs among people with HIV, screening rates remain suboptimal.[475] Including this measure emphasizes adherence to established best practices in care provision within family medicine. This measure will allow clinicians and health systems to track and benchmark their performance in meeting preventive care goals for patients with HIV. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.
- **Q340**: *HIV Annual Retention in Care*: This MIPS quality measure promotes routine monitoring to track patient progress and ensure treatment efficacy. We agreed with interested parties' feedback that this measure is clinically relevant to this clinician type and proposed adding this measure to the Family Medicine specialty set. Incorporating this measure aligns with national goals such as the Ending the HIV Epidemic initiative, led by the CDC, which highlights retention and viral suppression as cornerstones for reducing transmission and new infections.[476] A study from the Centers for AIDS Research Network of Integrated Clinical Systems revealed that patients who missed more than two clinic visits over a two-year period had significantly higher mortality risks, even if they otherwise met institutional retention metrics.[477] These findings underscore the life-saving importance of retention in improving survival rates. By measuring and promoting retention in HIV care, the addition of this measure could drive system-wide improvements, support better patient outcomes, reduce preventable mortality, and contribute to public health efforts to end the HIV epidemic. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measures proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: Three commenters supported adding measures Q205: *Sexually Transmitted Infection (STI) Testing for People with HIV* and Q340: *HIV Annual Retention in Care* to this specialty set. Another commenter supported addition of measure Q205 specifically; however, they noted that because many patients receive HIV care from specialists or HIV clinics, CMS should ensure appropriate attribution and acknowledge that this measure has limited applicability across family medicine overall.

Response: We thank the commenters for supporting the addition of these measures to this specialty set and for recognizing the importance of routine STI screening for people with HIV. We will continue to consider issues of measure attribution and specialty-specific applicability as we evaluate the use and performance of this measure within the Family Medicine specialty set over time.

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[474] CDC. (2024a). Screening Recommendations and Considerations Referenced in Treatment Guidelines and Original Sources. https://www.cdc.gov/std/treatment-guidelines/screening-recommendations.htm.

[475] Gass, S. J., Chen, S., Zhang, J., Elliott, A. S., Wagner, K. D., White, K. P., & Magnus, M. (2025). Sexually Transmitted Infection (STI) Incidence and Risk Factors Among People with HIV (PWH): Insights From a 13-Year Cohort Study in South Carolina. *AIDS and Behavior, 29*, 2882–2890. https://doi.org/10.1007/s10461-025-04744-5.

[476] CDC. (2024b). About Ending the HIV Epidemic in the US. https://www.cdc.gov/ehe/php/about/index.html.

[477] Mugavero, M. J., Westfall, A. O., Cole, S. R., Geng, E. H., Crane, H. M., Kitahata, M. M., Mathews, W. C., Napravnik, S., Eron, J. J., Moore, R. D., Keruly, J. C., Mayer, K. H., Giordano, T. P., Raper, J. L., & Centers for AIDS Research Network of Integrated Clinical Systems (CNICS) (2014). Beyond Core Indicators of Retention in HIV Care: Missed Clinic Visits are Independently Associated with All-Cause Mortality. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, *59*(10), 1471–1479. https://doi.org/10.1093/cid/ciu603.

Comment: One commenter opposed adding measure Q340 to this specialty set. The commenter stated this measure is not broadly applicable to family medicine because many patients receive HIV-specific care from infectious disease specialists or dedicated HIV clinics, not family physicians. The commenter was concerned about attribution and said patients should be attributed to the clinician providing HIV care, so primary care physicians are not held accountable when they are not managing HIV treatment and follow-up. The commenter stated that specialty sets should focus on measures that are broadly relevant to family medicine and where physicians can meaningfully influence performance, rather than highly condition-specific measures with limited applicability.

Response: We thank the commenter for providing feedback on measure Q340. We acknowledge the commenter's concerns about the measure's applicability in the Family Medicine Specialty Set and the importance of attributing patients to clinicians responsible for managing HIV care. Clinicians have the flexibility to choose which measures to report based upon the appropriateness of the measure to their scope of care. Accordingly, this measure is not required for reporting; however, the addition of this measure enhances clinician choice on which measures to report. Currently, the Family Medicine Specialty Set contains 61 measures allowing clinicians to choose to submit those measures that are most meaningful to their scope of care.

For the reasons stated above and in the proposed rule (91 FR 44344), we are finalizing the *Family Medicine Specialty Set* as proposed for the CY 2027 performance period/2029 MIPS payment year and future years. Below will be the specialty set for this specialty for the CY 2027 performance period.

B.13. Family Medicine

FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	0059 / N/A	001	CMS1 22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
!	0081 / 0081e	005	CMS1 35v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0083 / 0083e	008	CMS1 44v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
	N/A / N/A	009	CMS1 28v15	eCQM	Process	Antidepressant Medication Management	National Committee for Quality Assurance
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance

B.13. Family Medicine

FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
	0069 / N/A	065	CMS1 54v15	eCQM, MIPS CQM	Process	Appropriate Treatment for Upper Respiratory Infection (URI)	National Committee for Quality Assurance
	N/A / N/A	066	CMS1 46v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
	0055 / N/A	117	CMS1 31v15	eCQM, MIPS CQM	Process	Diabetes: Eye Exam	National Committee for Quality Assurance
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
*	N/A / N/A	130	CMS6 8v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2 v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
* !	N/A / N/A	176	N/A	MIPS CQM	Process	Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy	American College of Rheumatology
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
+ !	N/A / 3755e	205	CMS1 188v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
* !	N/A / N/A	236	CMS1 65v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
!	0022 / N/A	238	CMS1 56v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	0643 / N/A	243	N/A	MIPS CQM	Process	Cardiac Rehabilitation Patient Referral from an Outpatient Setting	American Heart Association

B.13. Family Medicine

FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	305	CMS1 37v15	eCQM	Process	Initiation and Engagement of Substance Use Disorder Treatment	National Committee for Quality Assurance
	N/A / N/A	309	CMS1 24v15	eCQM	Process	Cervical Cancer Screening	National Committee for Quality Assurance
	0101 / N/A	318	CMS1 39v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement /Experience	CAHPS for MIPS Clinician/Group Survey	Centers for Medicare & Medicaid Services
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology – Head and Neck Surgery Foundation
!	N/A / N/A	338	CMS3 14v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration
+	N/A / N/A	340	CMS1 157v3	eCQM, MIPS CQM	Process	HIV Annual Retention in Care	Health Resources and Services Administration
!	0710 / 0710e	370	CMS1 59v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS5 0v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	N/A / N/A	377	CMS9 0v16	eCQM	Process	Functional Status Assessments for Heart Failure	Centers for Medicare & Medicaid Services
* !	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	Adherence to Antipsychotic Medications For Individuals with Schizophrenia	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQM	Process	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users	American Gastroenterological Association
	N/A / N/A	394	N/A	MIPS CQM	Process	Immunizations for Adolescents	National Committee for Quality Assurance
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
	N/A / N/A	400	N/A	MIPS CQM	Process	One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation	American Gastroenterological Association
	N/A / N/A	401	N/A	MIPS CQM	Process	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis	American Gastroenterological Association
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance

B.13. Family Medicine

FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	N/A / N/A	438	CMS347v10	eCQM, MIPS CQM	Process	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Centers for Medicare & Medicaid Services
* !	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)	Wisconsin Collaborative for Healthcare Quality
*	0657 / N/A	464	N/A	MIPS CQM	Process	Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	N/A / N/A	468	N/A	MIPS CQM	Process	Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)	University of Southern California
*	N/A / N/A	475	CMS349v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
*	N/A / N/A	476	CMS771v8	eCQM	Patient-Reported Outcome-Based Performance Measure	Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia	Large Urology Group Practice Association and Oregon Urology Institute
!	N/A / N/A	488	CMS951v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665/ N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
*	N/A / N/A	497	N/A	MIPS CQM	Process	Preventive Care and Wellness (composite)	Centers for Medicare & Medicaid Services
	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder	American Psychiatric Association
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.13. Family Medicine

FINALIZED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
*	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Reduction in Suicidal Ideation or Behavior Symptoms	American Psychiatric Association
	N/A / 3749e	514	CMS1 173v2	eCQM	Intermediate Outcome	Diagnostic Delay of Venous Thromboembolism in Primary Care	Brigham and Women's Hospital
	N/A / N/A	515	CMS1 154v2	eCQM	Process	Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes	American Medical Association
!	N/A / N/A	516	N/A	MIPS CQM	Outcome	Hepatitis C Virus (HCV): Sustained Virological Response (SVR)	American Gastroenterological Association
+ !	N/A / N/A	517	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	526	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.14. Gastroenterology

FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v 16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	NA / N/A	275	N/A	MIPS CQM	Process	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy	American Gastroenterological Association
* !	N/A / N/A	317	CMS22v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS50v 15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	N/A / N/A	401	N/A	MIPS CQM	Process	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis	American Gastroenterological Association
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.14. Gastroenterology

FINALIZED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	516	N/A	MIPS CQM	Outcome	Hepatitis C Virus (HCV): Sustained Virological Response (SVR)	American Gastroenterological Association

B.15. General Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.15. General Surgery

FINALIZED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	354	N/A	MIPS CQM	Outcome	Anastomotic Leak Intervention	American College of Surgeons
	N/A / N/A	355	N/A	MIPS CQM	Outcome	Unplanned Reoperation within the 30-Day Postoperative Period	American College of Surgeons
!	N/A / N/A	356	N/A	MIPS CQM	Outcome	Unplanned Hospital Readmission within 30 Days of Principal Procedure	American College of Surgeons
!	N/A / N/A	357	N/A	MIPS CQM	Outcome	Surgical Site Infection (SSI)	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.16. Geriatrics

FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138 v15	Medicare Part B Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS156 v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149 v15	eCQM	Process	Dementia: Cognitive Assessment	American Academy of Neurology
!	N/A / N/A	282	N/A	MIPS CQM	Process	Dementia: Functional Status Assessment	American Academy of Neurology

B.16. Geriatrics

FINALIZED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Academy of Neurology/ American Psychiatric Association
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
	0101 / N/A	318	CMS139 v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
!	0710 / 0710e	370	CMS159 v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Centers for Medicare & Medicaid Services
*	N/A / N/A	476	CMS771 v8	eCQM	Patient-Reported Outcome-Based Performance Measure	Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia	Large Urology Group Practice Association and Oregon Urology Institute
!	N/A / N/A	488	CMS951 v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
!	1662/ N/A	489	N/A	MIPS CQM	Process	Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy	Renal Physicians Association
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
+ !	N/A / N/A	517	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	526	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.17. Hospitalists

FINALIZED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0081 / 0081e	005	CMS13 5v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0083 / 0083e	008	CMS14 4v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.18. Infectious Disease

FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	0069 / N/A	065	CMS15 4v15	eCQM, MIPS CQM	Process	Appropriate Treatment for Upper Respiratory Infection (URI)	National Committee for Quality Assurance
	N/A / N/A	066	CMS14 6v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	176	N/A	MIPS CQM	Process	Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy	American College of Rheumatology
!	N/A / 3755e	205	CMS11 88v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / N/A	240	CMS11 7v15	eCQM	Process	Childhood Immunization Status	National Committee for Quality Assurance
!	NA / N/A	338	CMS31 4v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration
	N/A / N/A	340	CMS11 57v3	eCQM, MIPS CQM	Process	HIV Annual Retention in Care	Health Resources and Services Administration
	N/A / N/A	387	N/A	MIPS CQM	Process	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users	American Gastroenterological Association
	N/A / N/A	394	N/A	MIPS CQM	Process	Immunizations for Adolescents	National Committee for Quality Assurance
*	N/A / N/A	475	CMS34 9v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance

B.18. Infectious Disease

FINALIZED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
!	N/A / N/A	516	N/A	MIPS CQM	Outcome	Hepatitis C Virus (HCV): Sustained Virological Response (SVR)	American Gastroenterological Association

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We also proposed adding two existing MIPS quality measures to this specialty set:

- **Q205**: *Sexually Transmitted Infection (STI) Testing for People with HIV*: This MIPS quality measure assesses appropriate screening of STIs for patients with HIV. We agreed with interested parties' feedback that this measure is clinically relevant to this clinician type and proposed adding this measure to the Internal Medicine specialty set. Clinical guidelines, such as those from the CDC, recommend regular screening for STIs in individuals with HIV.[478] Despite the high incidence of STIs among people with HIV, screening rates remain suboptimal.[479] Including this measure emphasizes adherence to established best practices in care provision within family medicine. This measure will allow clinicians and health systems to track and benchmark their performance in meeting preventive care goals for patients with HIV. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.
- **Q340**: *HIV Annual Retention in Care*: This MIPS quality measure promotes routine monitoring to track patient progress and ensure treatment efficacy. We agreed with interested parties' feedback that this measure is clinically relevant to this clinician type and proposed adding this measure to the Internal Medicine specialty set. Incorporating this measure aligns with national goals such as the Ending the HIV Epidemic initiative, led by the CDC, which highlights retention and viral suppression as cornerstones for reducing transmission and new infections.[480] A study from the Centers for AIDS Research Network of Integrated Clinical Systems revealed that patients who missed more than two clinic visits over a two-year period had significantly higher mortality risks, even if they otherwise met institutional retention metrics.[481] These findings underscore the life-saving importance of retention in improving survival rates. By measuring and promoting retention in HIV care, the addition of this measure could drive system-wide improvements, support better patient outcomes, reduce preventable mortality, and contribute to public health efforts to end the HIV epidemic. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measures proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: Three commenters supported adding measures Q205: *Sexually Transmitted Infection (STI) Testing for People with HIV* and Q340: *HIV Annual Retention in Care* to this specialty set.

Response: We thank the commenters for supporting the addition of these two measures to this specialty set.

For the reasons stated above and in the proposed rule (91 FR 44357), we are finalizing the *Internal Medicine Specialty Set* as proposed for the CY 2027 performance period/2029 MIPS payment year and future years. Below will be the specialty set for this specialty for the CY 2027 performance period.

[478] See footnote CDC, 2024a.
[479] See footnote Gass et al., 2025.
[480] See footnote CDC, 2024b.
[481] See footnote Mugavero et al., 2014.

B.19. Internal Medicine

FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	0059 / N/A	001	CMS122v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
!	0081 / 0081e	005	CMS135v 15	eCQM, MIPS CQM	Process	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0083 / 0083e	008	CMS144 v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
	N/A / N/A	009	CMS128 v15	eCQM	Process	Antidepressant Medication Management	National Committee for Quality Assurance
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
	0055 / N/A	117	CMS131 v15	eCQM, MIPS CQM	Process	Diabetes: Eye Exam	National Committee for Quality Assurance
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
*	N/A / N/A	130	CMS68v 16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v1 6	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance

B.19. Internal Medicine

FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	N/A / N/A	176	N/A	MIPS CQM	Process	Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy	American College of Rheumatology
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
+ !	N/A / 3755e	205	CMS118 8v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
* !	N/A / N/A	236	CMS165 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
!	0022 / N/A	238	CMS156 v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	0643 / N/A	243	N/A	MIPS CQM	Process	Cardiac Rehabilitation Patient Referral from an Outpatient Setting	American Heart Association
	N/A / N/A	277	N/A	MIPS CQM	Process	Sleep Apnea: Severity Assessment at Initial Diagnosis	American Academy of Sleep Medicine
!	N/A / N/A	279	N/A	MIPS CQM	Process	Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy	American Academy of Sleep Medicine
!	N/A / N/A	305	CMS137 v15	eCQM	Process	Initiation and Engagement of Substance Use Disorder Treatment	National Committee for Quality Assurance
	N/A / N/A	309	CMS124 v15	eCQM	Process	Cervical Cancer Screening	National Committee for Quality Assurance
	0101 / N/A	318	CMS139 v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	CAHPS for MIPS Clinician/Group Survey	Centers for Medicare & Medicaid Services
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology – Head and Neck Surgery Foundation
!	N/A / N/A	338	CMS314 v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration
+	N/A / N/A	340	CMS115 7v3	eCQM, MIPS CQM	Process	HIV Annual Retention in Care	Health Resources and Services Administration
!	0710 / 0710e	370	CMS159 v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS50v 15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	N/A / N/A	377	CMS90v 16	eCQM	Process	Functional Status Assessments for Heart Failure	Centers for Medicare & Medicaid Services
* !	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	Adherence to Antipsychotic Medications For Individuals with Schizophrenia	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	387	N/A	MIPS CQM	Process	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users	American Gastroenterological Association
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
	N/A / N/A	400	N/A	MIPS CQM	Process	One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation	American Gastroenterological Association
	N/A / N/A	401	N/A	MIPS CQM	Process	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis	American Gastroenterological Association
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	N/A / N/A	438	CMS347 v10	eCQM, MIPS CQM	Process	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Centers for Medicare & Medicaid Services
* !	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)	Wisconsin Collaborative for Healthcare Quality
	N/A / N/A	468	N/A	MIPS CQM	Process	Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)	University of Southern California
*	N/A / N/A	475	CMS349 v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
*	N/A / N/A	476	CMS771 v8	eCQM	Patient-Reported Outcome-Based Performance Measure	Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia	Large Urology Group Practice Association and Oregon Urology Institute
!	N/A / N/A	488	CMS951 v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
*	N/A / N/A	497	N/A	MIPS CQM	Process	Preventive Care and Wellness (composite)	Centers for Medicare & Medicaid Services
	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder	American Psychiatric Association

B.19. Internal Medicine

FINALIZED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
	N/A / N/A	515	CMS115 4v2	eCQM	Process	Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes	American Medical Association
!	N/A / N/A	516	N/A	MIPS CQM	Outcome	Hepatitis C Virus (HCV): Sustained Virological Response (SVR)	American Gastroenterological Association
+ !	N/A / N/A	517	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	526	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.20. Interventional Radiology

FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
*	N/A / N/A	130	CMS 68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	145	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy	American College of Radiology
	N/A / N/A	355	N/A	MIPS CQM	Outcome	Unplanned Reoperation within the 30-Day Postoperative Period	American College of Surgeons
!	N/A / N/A	356	N/A	MIPS CQM	Outcome	Unplanned Hospital Readmission within 30 Days of Principal Procedure	American College of Surgeons
!	N/A / N/A	357	N/A	MIPS CQM	Outcome	Surgical Site Infection (SSI)	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS 50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
!	N/A / N/A	413	N/A	MIPS CQM	Intermediate Outcome	Door to Puncture Time for Endovascular Stroke Treatment	Society of Interventional Radiology
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance

B.20. Interventional Radiology

FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	420	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Varicose Vein Treatment with Saphenous Ablation: Outcome Survey	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQM	Process	Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal	Society of Interventional Radiology
	N/A / N/A	465	N/A	MIPS CQM	Process	Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries	Society of Interventional Radiology

B.21. Mental/Behavioral Health and Psychiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.21. Mental/Behavioral Health and Psychiatry

FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	009	CMS128v15	eCQM	Process	Antidepressant Medication Management	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149v15	eCQM	Process	Dementia: Cognitive Assessment	American Academy of Neurology
!	N/A / N/A	282	N/A	MIPS CQM	Process	Dementia: Functional Status Assessment	American Academy of Neurology
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Academy of Neurology/ American Psychiatric Association
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
!	N/A / N/A	305	CMS137v15	eCQM	Process	Initiation and Engagement of Substance Use Disorder Treatment	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	N/A / N/A	366	CMS136v16	eCQM	Process	Follow-Up Care for Children Prescribed ADHD Medication	National Committee for Quality Assurance
!	0710 / 0710e	370	CMS159v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	382	CMS177v15	eCQM	Process	Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment	Centers for Medicare & Medicaid Services
* !	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	Adherence to Antipsychotic Medications For Individuals with Schizophrenia	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
	N/A / N/A	468	N/A	MIPS CQM	Process	Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)	University of Southern California
	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder	American Psychiatric Association
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
*	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Reduction in Suicidal Ideation or Behavior Symptoms	American Psychiatric Association

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.22. Nephrology

FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	0059 / N/A	001	CMS12 2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS13 9v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
	N/A / N/A	400	N/A	MIPS CQM	Process	One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation	American Gastroenterological Association
!	N/A/ N/A	482	N/A	MIPS CQM	Intermediate Outcome	Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate	Centers for Medicare & Medicaid Services
!	N/A / N/A	488	CMS95 1v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
!	1662/ N/A	489	N/A	MIPS CQM	Process	Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy	Renal Physicians Association
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance

B.22. Nephrology

FINALIZED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performanc e Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	510	N/A	MIPS CQM	Process	First Year Standardized Kidney Transplant Waitlist Ratio (FYSWR)	Centers for Medicare & Medicaid Services
	N/A / N/A	511	N/A	MIPS CQM	Process	Percentage of Prevalent Patients Waitlisted for Kidney Transplant (PPPW) and Percentage of Prevalent Patients Waitlisted for Kidney Transplant in Active Status (aPPPW)	Centers for Medicare & Medicaid Services
	N/A / N/A	512	N/A	MIPS CQM	Process	Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR)	Centers for Medicare & Medicaid Services
+ !	N/A / N/A	517	N/A	MIPS CQM	Intermediat e Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	526	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.23. Neurology

FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / N/A	268	N/A	MIPS CQM	Process	Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy	American Academy of Neurology
	N/A / N/A	277	N/A	MIPS CQM	Process	Sleep Apnea: Severity Assessment at Initial Diagnosis	American Academy of Sleep Medicine
!	N/A / N/A	279	N/A	MIPS CQM	Process	Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy	American Academy of Sleep Medicine
	N/A / 2872e	281	CMS14 9v15	eCQM	Process	Dementia: Cognitive Assessment	American Academy of Neurology

B.23. Neurology

FINALIZED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / N/A	282	N/A	MIPS CQM	Process	Dementia: Functional Status Assessment	American Academy of Neurology
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Academy of Neurology/ American Psychiatric Association
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQM	Process	Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease	American Academy of Neurology
	N/A / N/A	293	N/A	MIPS CQM	Process	Rehabilitative Therapy Referral for Patients with Parkinson's Disease	American Academy of Neurology
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	N/A / N/A	386	N/A	MIPS CQM	Process	Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences	American Academy of Neurology
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
*	N/A / N/A	513	N/A	MIPS CQM	Process	Patient Reported Falls and Plan of Care	American Academy of Neurology
+ !	N/A / N/A	517	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.24. Neurosurgical

FINALIZED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
	N/A / N/A	187	N/A	MIPS CQM	Process	Stroke and Stroke Rehabilitation: Thrombolytic Therapy	American Heart Association
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	N/A / N/A	344	N/A	MIPS CQM	Outcome	Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)	Society for Vascular Surgery
!	N/A / N/A	413	N/A	MIPS CQM	Intermediate Outcome	Door to Puncture Time for Endovascular Stroke Treatment	Society of Interventional Radiology
!	N/A / N/A	459	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Back Pain After Lumbar Surgery	Minnesota Community Measurement
	N/A / N/A	461	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Leg Pain After Lumbar Surgery	Minnesota Community Measurement
	N/A / N/A	471	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Status After Lumbar Surgery	Minnesota Community Measurement

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We also proposed adding one existing MIPS quality measure to this specialty set:

- **Q317**: *Preventive Care and Screening*: Screening for High Blood Pressure and Follow-Up Documented: This MIPS quality measure supports screening for high blood pressure. We agreed with interested parties' feedback that adding this measure to this specialty set will help empower registered dietician nutritionists (RDNs) to meaningfully participate in quality programs and value-based care, ensuring patients receive high-value nutritional care. Hypertension (HTN) is among the leading global preventable risk factors for cardiovascular disease and premature mortality.[482] Early detection and effective management of HTN have demonstrated significant reductions in mortality, morbidity, and health care costs.[483] RDNs provide medical nutrition therapy, which has demonstrated effectiveness in improving outcomes such as blood pressure control and reducing cardiovascular risks.[484] Including this measure within the Nutrition/Dietician specialty set recognizes the critical role of RDNs in managing HTN and promotes team-based, whole-person care. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measure proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: One commenter supported adding measure Q317: *Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented* to this specialty set.

Response: We thank the commenter for supporting the addition of measure Q317 to this specialty set.

For the reasons stated above and in the proposed rule (91 FR 44372), we are finalizing the *Nutrition/Dietician Specialty Set* as proposed for the CY 2027 performance period/2029 MIPS payment year and future years. Below will be the specialty set for this specialty for the CY 2027 performance period.

B.25. Nutrition/Dietician

FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* !	0059 / N/A	001	CMS12 2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services

[482] Severin, R., Sabbahi, A., Albarrati, A., Phillips, S. A., & Arena, S. (2020). Blood Pressure Screening by Outpatient Physical Therapists: A Call to Action and Clinical Recommendations. Physical Therapy, 100(6), 1008–1019. https://doi.org/10.1093/ptj/pzaa034.

[483] See footnote Severin et al., 2020.

[484] Senkus, K. E., Dudzik, J. M., Lennon, S. L., DellaValle, D. M., Moloney, L. M., Handu, D., & Rozga, M. (2024). *Medical Nutrition Therapy Provided by a Dietitian Improves Outcomes in Adults With Prehypertension or Hypertension: A Systematic Review and Meta-Analysis*. *The American Journal of Clinical Nutrition, 119*(6), 1417–1442. https://doi.org/10.1016/j.ajcnut.2024.04.012.

B.25. Nutrition/Dietician

FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* !	NA / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / N/A	239	CMS155v15	eCQM	Process	Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents	National Committee for Quality Assurance
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
+ * !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We also proposed adding two existing MIPS quality measures to this specialty set:

- **Q205**: *Sexually Transmitted Infection (STI) Testing for People with HIV*: This MIPS quality measure assesses appropriate screening of STIs for patients with HIV. We agreed with interested parties' feedback that this measure is clinically relevant to this clinician type and proposed adding this measure to the Obstetrics/Gynecology specialty set. Clinical guidelines, such as those from the CDC, recommend regular screening for STIs in individuals with HIV.[485] Despite the high incidence of STIs among people with HIV, screening rates remain suboptimal.[486] Adding measure Q205 to this specialty set will help address critical screening gaps, ensuring sexual health services are consistently delivered in settings managing patients' reproductive health. This measure will allow clinicians and health systems to track and benchmark their performance in meeting preventive care goals for patients with HIV. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.
- **Q338**: *HIV Viral Suppression*: This MIPS quality measure promotes effective management of HIV viral load for patients diagnosed with HIV. We agreed with interested parties' feedback that this measure is clinically relevant to this clinician type and proposed adding this measure to the Obstetrics/Gynecology specialty set. This specialty plays an essential role in ensuring patients remain actively engaged in HIV care while accessing comprehensive prevention services that improve health outcomes. Viral suppression is widely recognized as the clinical goal of HIV treatment, reflecting successful management of the condition.[487] [488] Measuring viral suppression ensures clinicians are accountable for achieving this outcome across their patient population, which is directly linked to measurable preventive outcomes, such as reducing HIV transmission rates and decreasing HIV-related morbidity and mortality.[489] [490] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measures proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: Three commenters supported adding measures Q205: *Sexually Transmitted Infection (STI) Testing for People with HIV* and Q338: *HIV Viral Suppression* to this specialty set.

Response: We thank the commenters for supporting the addition of these two measures to this specialty set.

For the reasons stated above and in the proposed rule (91 FR 44374), we are finalizing the *Obstetrics/Gynecology Specialty Set* as proposed for the CY 2027 performance period/2029 MIPS payment year and future years. Below will be the specialty set for this specialty for the CY 2027 performance period.

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[485] See footnote CDC, 2024a.

[486] See footnote Gass et al., 2025.

[487] Panel on Antiretroviral Guidelines for Adults and Adolescents. (2025). Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. U.S. Department of Health and Human Services. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new.

[488] CDC. (2023). Treating HIV. https://www.cdc.gov/hiv/treatment/?CDC_AAref_Val=https://www.cdc.gov/hiv/basics/livingwithhiv/treatment.html.

[489] Crawford, T. N., & Thornton, A. (2017). Retention in Continuous Care and Sustained Viral Suppression. *Journal of the International Association of Providers of AIDS Care*, *16*(1), 42–47. https://doi.org/10.1177/2325957416678929.

[490] CDC. (2024c). Effectiveness of HIV Treatment in Preventing HIV Transmission. https://www.cdc.gov/hivpartners/php/hiv-treatment/?CDC_AAref_Val=https://www.cdc.gov/hiv/risk/art/index.html.

B.26. Obstetrics/Gynecology

FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
+ !	N/A / 3755e	205	CMS1188v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
* !	N/A / N/A	236	CMS165v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
	N/A / N/A	309	CMS124v15	eCQM	Process	Cervical Cancer Screening	National Committee for Quality Assurance
	N/A / N/A	310	CMS153v15	eCQM	Process	Chlamydia Screening in Women	National Committee for Quality Assurance
	N/A / N/A	335	N/A	MIPS CQM	Outcome	Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse)	Centers for Medicare & Medicaid Services
*	N/A / N/A	336	N/A	MIPS CQM	Process	Maternity Care: Postpartum Follow-up and Care Coordination	Centers for Medicare & Medicaid Services
+ !	N/A / N/A	338	CMS314v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration
*	N/A / N/A	374	CMS50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance
	2063 / N/A	422	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury	American Urogynecologic Society
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / N/A	432	N/A	MIPS CQM	Outcome	Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair	American Urogynecologic Society
	N/A / N/A	448	N/A	MIPS CQM	Process	Appropriate Workup Prior to Endometrial Ablation	Centers for Medicare & Medicaid Services
*	N/A / N/A	475	CMS349v 9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
	N/A / N/A	496	N/A	MIPS CQM	Process	Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument	University of California, Irvine
*	N/A / N/A	497	N/A	MIPS CQM	Process	Preventive Care and Wellness (composite)	Centers for Medicare & Medicaid Services
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
*	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Reduction in Suicidal Ideation or Behavior Symptoms	American Psychiatric Association
+ !	N/A / N/A	517	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.27a. Oncology/Hematology

FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
* !	N/A / N/A	102	CMS129v16	eCQM, MIPS CQM	Process	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Centers for Medicare & Medicaid Services
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
* !	0383 / N/A	144	N/A	MIPS CQM	Process	Oncology: Medical and Radiation – Plan of Care for Pain	American Society of Clinical Oncology
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS156v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
*	N/A / N/A	250	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Radical Prostatectomy Pathology Reporting	College of American Pathologists
* !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	CAHPS for MIPS Clinician/Group Survey	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance

B.27a. Oncology/Hematology

FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	1858 / N/A	450	N/A	MIPS CQM	Process	Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer	American Society of Clinical Oncology
!	1859 / N/A	451	N/A	MIPS CQM	Process	RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy	American Society of Clinical Oncology
*	0210 / N/A	453	N/A	MIPS CQM	Intermediate Outcome	Percentage of Patients who Died with Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)	American Society of Clinical Oncology
* !	0216 / N/A	457	N/A	MIPS CQM	Intermediate Outcome	Percentage of Patients who Died with Cancer Enrolled in Hospice For At Least 3 Days Immediately Before Death	American Society of Clinical Oncology
!	N/A / N/A	462	CMS645v10	eCQM	Process	Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy	Oregon Urology Institute
	N/A / N/A	490	N/A	MIPS CQM	Process	Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors	Society for Immunotherapy of Cancer (SITC)
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
!	N/A / N/A	506	N/A	MIPS CQM	Process	Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy	Society for Immunotherapy of Cancer (SITC)
*	N/A / N/A	507	N/A	MIPS CQM	Process	Appropriate Germline Testing for Ovarian Cancer Patients	American Society of Clinical Oncology

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.27b. Radiation Oncology

FINALIZED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* !	N/A / N/A	102	CMS 129v16	eCQM, MIPS CQM	Process	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Centers for Medicare & Medicaid Services
* !	0383 / N/A	144	N/A	MIPS CQM	Process	Oncology: Medical and Radiation – Plan of Care for Pain	American Society of Clinical Oncology
!	N/A / N/A	226	CMS 138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance

B.28. Ophthalmology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.28. Ophthalmology

FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / 0086e	012	CMS143v15	eCQM	Process	Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation	American Academy of Ophthalmology
	N/A / N/A	019	CMS142v15	eCQM	Process	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care	American Academy of Ophthalmology
	0055 / N/A	117	CMS131v15	eCQM, MIPS CQM	Process	Diabetes: Eye Exam	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	0563 / N/A	141	N/A	Medicare Part B Claims Measure, MIPS CQM	Outcome	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care	American Academy of Ophthalmology
*	0565 / 0565e	191	CMS133v15	eCQM, MIPS CQM	Outcome	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery	American Academy of Ophthalmology
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS156v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	N/A / N/A	303	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	American Academy of Ophthalmology
!	N/A / N/A	304	N/A	MIPS CQM	Patient Engagement/ Experience	Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery	American Academy of Ophthalmology

B.28. Ophthalmology

FINALIZED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
!	N/A / N/A	385	N/A	MIPS CQM	Outcome	Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery	American Academy of Ophthalmology
	N/A / N/A	389	N/A	MIPS CQM	Outcome	Cataract Surgery: Difference Between Planned and Final Refraction	American Academy of Ophthalmology
	N/A / N/A	499	N/A	MIPS CQM	Process	Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy	American Society of Retina Specialists
	N/A / N/A	500	N/A	MIPS CQM	Process	Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up	American Society of Retina Specialists
!	N/A / N/A	501	N/A	MIPS CQM	Process	Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up	American Society of Retina Specialists

B.29. Optometry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.29. Optometry

FINALIZED MEASURES IN THE OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	019	CMS142v15	eCQM	Process	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care	American Academy of Ophthalmology
	0055 / N/A	117	CMS131v15	eCQM, MIPS CQM	Process	Diabetes: Eye Exam	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS156v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
*	N/A / N/A	374	CMS50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.30. Orthopedic Surgery

FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
* !	N/A / N/A	178	N/A	MIPS CQM	Process	Rheumatoid Arthritis (RA): Functional Status Assessment	American College of Rheumatology
!	N/A / N/A	180	N/A	MIPS CQM	Process	Rheumatoid Arthritis (RA): Glucocorticoid Management	American College of Rheumatology
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS13 9v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance

B.30. Orthopedic Surgery

FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	351	N/A	MIPS CQM	Process	Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation	American Association of Hip and Knee Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	N/A / N/A	376	CMS56 v15	eCQM	Process	Functional Status Assessments for Total Hip Replacement	Centers for Medicare & Medicaid Services
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance
!	N/A / N/A	459	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Back Pain After Lumbar Surgery	Minnesota Community Measurement
	N/A / N/A	461	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Leg Pain After Lumbar Surgery	Minnesota Community Measurement
!	N/A / N/A	470	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Status After Primary Total Knee Replacement	Minnesota Community Measurement
	N/A / N/A	471	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Status After Lumbar Surgery	Minnesota Community Measurement
!	3493 / N/A	480	N/A	Administrative Claims	Outcome	Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)	Centers for Medicare & Medicaid Services

B.31. Otolaryngology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

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B.31. Otolaryngology

FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	066	CMS14 6v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQM	Process	Sleep Apnea: Severity Assessment at Initial Diagnosis	American Academy of Sleep Medicine
!	N/A / N/A	279	N/A	MIPS CQM	Process	Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy	American Academy of Sleep Medicine
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS13 9v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology-Head and Neck Surgery Foundation
	N/A / N/A	355	N/A	MIPS CQM	Outcome	Unplanned Reoperation within the 30-Day Postoperative Period	American College of Surgeons

B.31. Otolaryngology

FINALIZED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / N/A	357	N/A	MIPS CQM	Outcome	Surgical Site Infection (SSI)	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	0657 / N/A	464	N/A	MIPS CQM	Process	Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
+ !	N/A / N/A	523	N/A	MIPS CQM	Process	Age-Related Hearing Loss: Comprehensive Audiometric Evaluation	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.32. Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

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B.32. Pathology

FINALIZED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Barrett's Esophagus	College of American Pathologists
*	N/A / N/A	250	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Radical Prostatectomy Pathology Reporting	College of American Pathologists
*	N/A / N/A	395	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Lung Cancer Reporting (Biopsy/Cytology Specimens)	College of American Pathologists
* !	N/A / N/A	396	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Lung Cancer Reporting (Resection Specimens)	College of American Pathologists
*	N/A / N/A	397	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Melanoma Reporting	College of American Pathologists
* !	N/A / N/A	440	N/A	MIPS CQM	Process	Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician	American Academy of Dermatology
* !	3661 / N/A	491	N/A	MIPS CQM	Process	Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status	College of American Pathologists

B.33. Pediatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

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B.33. Pediatrics

FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0069 / N/A	065	CMS154v15	eCQM, MIPS CQM	Process	Appropriate Treatment for Upper Respiratory Infection (URI)	National Committee for Quality Assurance
	N/A / N/A	066	CMS146v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / 3755e	205	CMS1188v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / N/A	239	CMS155v15	eCQM	Process	Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents	National Committee for Quality Assurance
	N/A / N/A	240	CMS117v15	eCQM	Process	Childhood Immunization Status	National Committee for Quality Assurance
!	N/A / N/A	305	CMS137v15	eCQM	Process	Initiation and Engagement of Substance Use Disorder Treatment	National Committee for Quality Assurance
	N/A / N/A	310	CMS153v15	eCQM	Process	Chlamydia Screening in Women	National Committee for Quality Assurance
	N/A / N/A	366	CMS136v16	eCQM	Process	Follow-Up Care for Children Prescribed ADHD Medication	National Committee for Quality Assurance
!	0710 / 0710e	370	CMS159v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Centers for Medicare & Medicaid Services
	N/A / N/A	382	CMS177v15	eCQM	Process	Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment	Centers for Medicare & Medicaid Services
	N/A / N/A	394	N/A	MIPS CQM	Process	Immunizations for Adolescents	National Committee for Quality Assurance

B.33. Pediatrics

FINALIZED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
*	0657 / N/A	464	N/A	MIPS CQM	Process	Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.34. Physical Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.34. Physical Medicine

FINALIZED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS 68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS 138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS 22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS 50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
	N/A / N/A	468	N/A	MIPS CQM	Process	Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)	University of Southern California

B.35. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.35. Physical Therapy/Occupational Therapy

FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear	American Podiatric Medical Association
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v15	eCQM	Process	Dementia: Cognitive Assessment	American Academy of Neurology

B.35. Physical Therapy/Occupational Therapy

FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Academy of Neurology/ American Psychiatric Association
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQM	Process	Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease	American Academy of Neurology
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS13 9v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder	American Psychiatric Association
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
+	N/A / N/A	518	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Neck Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	519	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Upper Extremity Impairments	Limber Health, Inc. and Patient360, LLC
+ !	N/A / N/A	520	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Back Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	521	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Lower Extremity Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	522	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Knee Impairments	Limber Health, Inc. and Patient360, LLC

B.36. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.36. Plastic Surgery

FINALIZED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	N/A / N/A	355	N/A	MIPS CQM	Outcome	Unplanned Reoperation within the 30-Day Postoperative Period	American College of Surgeons
!	N/A / N/A	356	N/A	MIPS CQM	Outcome	Unplanned Hospital Readmission within 30 Days of Principal Procedure	American College of Surgeons
!	N/A / N/A	357	N/A	MIPS CQM	Outcome	Surgical Site Infection (SSI)	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons

B.37. Podiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.37. Podiatry

FINALIZED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear	American Podiatric Medical Association
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	226	CMS 138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS 22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS 139v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.38. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We also proposed adding two existing MIPS quality measures to this specialty set:

- **Q205**: *Sexually Transmitted Infection (STI) Testing for People with HIV*: This MIPS quality measure assesses appropriate screening of STIs for patients with HIV. We agreed with interested parties' feedback that this measure is clinically relevant to this clinician type and proposed adding this measure to the Preventive Medicine specialty set. Clinical guidelines, such as those from the CDC, recommend regular screening for STIs in individuals with HIV.[491] Despite the high incidence of STIs among people with HIV, screening rates remain suboptimal.[492] Including this measure emphasizes adherence to established best practices in care provision within preventive medicine. This measure will allow clinicians and health systems to track and benchmark their performance in meeting preventive care goals for patients with HIV. The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.
- **Q338**: *HIV Viral Suppression*: This MIPS quality measure promotes effective management of HIV viral load for patients diagnosed with HIV. We agreed with interested parties' feedback that this measure is clinically relevant to this clinician type and proposed adding this measure to the Preventive Medicine specialty set. This specialty plays an essential role in ensuring patients remain actively engaged in HIV care while accessing comprehensive prevention services that improve health outcomes. Viral suppression is widely recognized as the clinical goal of HIV treatment, reflecting successful management of the condition.[493] [494] Measuring viral suppression ensures clinicians are accountable for achieving this outcome across their patient populations, which is directly linked to measurable preventive outcomes, such as reducing HIV transmission rates and decreasing HIV-related morbidity and mortality.[495] [496] The measure being added to this specialty set was contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding was not included in the final specification, this measure would not have been finalized for inclusion within this specialty measure set.

We received public comments on the measures proposed for addition to this specialty set. The following is a summary of the comments we received and our responses.

Comment: Three commenters supported adding measures Q205: *Sexually Transmitted Infection (STI) Testing for People with HIV* and Q338: *HIV Viral Suppression* to this specialty set.

Response: We thank the commenters for supporting the addition of these two measures to this specialty set.

For the reasons stated above and in the proposed rule (91 FR 44396), we are finalizing the *Preventive Medicine Specialty Set* as proposed for the CY 2027 performance period/2029 MIPS payment year and future years. Below will be the specialty set for this specialty for the CY 2027 performance period.

[491] See footnote CDC, 2024a.
[492] See footnote Gass et al., 2025.
[493] See footnote Panel on Antiretroviral Guidelines for Adults and Adolescents, 2025.
[494] See footnote CDC, 2023.
[495] See footnote Crawford & Thornton, 2017.
[496] See footnote CDC, 2024c.

B.38. Preventive Medicine

FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* !	0059 / N/A	001	CMS122v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
+ !	N/A / 3755e	205	CMS1188v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
	0643 / N/A	243	N/A	MIPS CQM	Process	Cardiac Rehabilitation Patient Referral from an Outpatient Setting	American Heart Association
+ !	N/A / N/A	338	CMS314v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration

B.38. Preventive Medicine

FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	N/A / N/A	438	CMS34 7v10	eCQM, MIPS CQM	Process	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Centers for Medicare & Medicaid Services
*	N/A / N/A	475	CMS34 9v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
!	N/A / N/A	488	CMS95 1v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
*	N/A / N/A	497	N/A	MIPS CQM	Process	Preventive Care and Wellness (composite)	Centers for Medicare & Medicaid Services
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
+ !	N/A / N/A	517	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association

B.39. Pulmonology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.39. Pulmonology

FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
!	0102 / N/A	052	N/A	MIPS CQM	Process	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy	American Thoracic Society
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	236	CMS16 5v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQM	Process	Sleep Apnea: Severity Assessment at Initial Diagnosis	American Academy of Sleep Medicine
!	N/A / N/A	279	N/A	MIPS CQM	Process	Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy	American Academy of Sleep Medicine
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance

B.39. Pulmonology

FINALIZED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.40. Rheumatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.40. Rheumatology

FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	176	N/A	MIPS CQM	Process	Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy	American College of Rheumatology
	2523 / N/A	177	N/A	MIPS CQM	Process	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity	American College of Rheumatology
* !	N/A / N/A	178	N/A	MIPS CQM	Process	Rheumatoid Arthritis (RA): Functional Status Assessment	American College of Rheumatology
!	N/A / N/A	180	N/A	MIPS CQM	Process	Rheumatoid Arthritis (RA): Glucocorticoid Management	American College of Rheumatology
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	236	CMS16 5v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance

B.40. Rheumatology

FINALIZED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee Quality Assurance
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.41. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.41. Skilled Nursing Facility

FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0083 / 0083e	008	CMS1 44v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	0066 / N/A	118	N/A	MIPS CQM	Process	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)	American Heart Association
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0022 / N/A	238	CMS1 56v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS2 2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)

B.42. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.42. Speech Language Pathology

FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	N/A / N/A	282	N/A	MIPS CQM	Process	Dementia: Functional Status Assessment	American Academy of Neurology
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Academy of Neurology/ American Psychiatric Association
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQM	Process	Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease	American Academy of Neurology
	N/A / N/A	386	N/A	MIPS CQM	Process	Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences	American Academy of Neurology

B.43. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.43. Thoracic Surgery

FINALIZED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS 68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	0129 / N/A	164	N/A	MIPS CQM	Outcome	Coronary Artery Bypass Graft (CABG): Prolonged Intubation	Society of Thoracic Surgeons
*	0114 / N/A	167	N/A	MIPS CQM	Outcome	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure	Society of Thoracic Surgeons
*	0115 / N/A	168	N/A	MIPS CQM	Outcome	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration	Society of Thoracic Surgeons
!	N/A / N/A	226	CMS 138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	N/A / N/A	356	N/A	MIPS CQM	Outcome	Unplanned Hospital Readmission within 30 Days of Principal Procedure	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS 50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	0119 / N/A	445	N/A	MIPS CQM	Outcome	Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG)	Society of Thoracic Surgeons

B.44. Urgent Care

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.44. Urgent Care

FINALIZED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0069 / N/A	065	CMS15 4v15	eCQM, MIPS CQM	Process	Appropriate Treatment for Upper Respiratory Infection (URI)	National Committee for Quality Assurance
	N/A / N/A	066	CMS14 6v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	0657 / N/A	464	N/A	MIPS CQM	Process	Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use	American Academy of Otolaryngology – Head and Neck Surgery Foundation
!	N/A / N/A	488	CMS95 1v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation

B.45. Urology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.45. Urology

FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
* !	N/A / N/A	102	CMS129v16	eCQM, MIPS CQM	Process	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Centers for Medicare & Medicaid Services
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022/ N/A	238	CMS156v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	CAHPS for MIPS Clinician/Group Survey	Centers for Medicare & Medicaid Services

B.45. Urology

FINALIZED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
!	N/A / N/A	432	N/A	MIPS CQM	Outcome	Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair	American Urogyneco-logic Society
*	0210/ N/A	453	N/A	MIPS CQM	Intermediate Outcome	Percentage of Patients who Died with Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)	American Society of Clinical Oncology
* !	0216/ N/A	457	N/A	MIPS CQM	Intermediate Outcome	Percentage of Patients who Died with Cancer Enrolled in Hospice For At Least 3 Days Immediately Before Death	American Society of Clinical Oncology
!	N/A / N/A	462	CMS645v10	eCQM	Process	Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy	Oregon Urology Institute
*	N/A / N/A	476	CMS771v8	eCQM	Patient-Reported Outcome-Based Performance Measure	Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia	Large Urology Group Practice Association and Oregon Urology Institute
*	N/A/ N/A	481	CMS646v7	eCQM	Process	Intravesical Bacillus-Calmette -Guerin for Non-Muscle Invasive Bladder Cancer	Oregon Urology
!	N/A / N/A	488	CMS951v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.46. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this final rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications finalized for the CY 2027 performance period/2029 MIPS payment year.

Measures finalized for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures finalized for addition, are indicated by a + in the Indicator column, as applicable. Measures finalized for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below will be the specialty set for this specialty for the CY 2027 performance period as proposed.

B.46. Vascular Surgery

FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS 68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS 138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	236	CMS 165v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
	N/A / N/A	259	N/A	MIPS CQM	Outcome	Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2)	Society for Vascular Surgery
* !	N/A / N/A	317	CMS 22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	344	N/A	MIPS CQM	Outcome	Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)	Society for Vascular Surgery
!	N/A / N/A	357	N/A	MIPS CQM	Outcome	Surgical Site Infection (SSI)	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS 50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services

B.46. Vascular Surgery

FINALIZED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / N/A	420	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Varicose Vein Treatment with Saphenous Ablation: Outcome Survey	Society of Interventional Radiology
* !	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)	Wisconsin Collaborative for Healthcare Quality
+ !	N/A / N/A	517	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association

Table Group C: Previously Finalized Quality Measures Finalized for Removal for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

In this final rule, we are removing 20 previously finalized MIPS quality measures for the CY 2027 performance period/2029 MIPS payment year and future years. These measures are discussed in detail in the removal tables below. Note: Specialty sets impacted by each measure removal are indicated under Table Group C of this Appendix within the last row of each C table.

The CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) discuss our incremental approach to removing process measures. Further considerations are given in the evaluation of a measure's performance data to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), an additional criterion we use for the removal of measures includes extremely topped-out measures, which refers to measures topped out with an average (mean) performance rate between 98-100 percent. For a measure proposed for removal due to criteria relating to the benchmark and performance data, further information regarding 2025 MIPS benchmarking data can be located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks.*

As codified in the CY 2025 PFS final rule (89 FR 98561) at § 414.1330(c)(1), we list 12 criteria used to determine the removal of a quality measure.

(i) If the Secretary determines that the quality measure is no longer meaningful, such as measures that are topped out.
(ii) If a measure steward is no longer able to maintain the quality measure.
(iii) If the quality measure reached extremely topped out status.
(iv) If the quality measure does not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.
(v) If the quality measure is duplicative.
(vi) If the quality measure is not updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice.
(vii) If the quality measure is a process measure.
(viii) If the quality measure addresses a measurement gap.
(ix) If the quality measure is a patient-reported outcome.
(x) If the quality measure is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians.
(xi) The robustness of the quality measure.
(xii) Consideration of the quality measure in developing MIPS Value Pathways (MVPs).

Additionally, we codified at § 414.1330(c)(2) 6 instances when a quality measure that otherwise meets the criteria for removal in § 414.1330(c)(1) may nonetheless be retained based on the following considerations:

(i) Whether the removal of the process measure impacts the number of measures available for a specific specialty.
(ii) Whether the quality measure addresses a priority area.
(iii) Whether the quality measure promotes positive outcomes in patients.
(iv) Whether the quality measure is designated as high priority or not.
(v) Whether the quality measure has reached extremely topped out status.
(vi) Evaluation of the quality measure's performance data.

However, we note that in section IV.A.4.d.(1)(c)(ii) of this final rule we are finalizing to update the existing quality measure retention consideration at § 414.1330(c)(1)(iv) to state that we will consider whether the quality measure is designated as high priority or not through the CY 2026 performance period/CY 2028 MIPS payment year.

We requested comments on these measure removals and the impacted specialty sets.

C.1 Coronary Artery Disease (CAD): Antiplatelet Therapy

Category	Description
CBE # / eCQM CBE #:	0067 / N/A
Quality#:	006
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.
Measure Steward:	American Heart Association
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), at the measure steward's request because it will no longer be maintained for inclusion.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

We received no public comments on the proposed removal of this measure. For reasons stated above and in the proposed rule (91 FR 44412), we are finalizing the removal of measure Q006 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.2 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)

Category	Description
CBE # / eCQM CBE #:	0070 / 0070e
Quality#:	007
CMS eCQM ID:	CMS145v15
Collection Type:	eCQM / MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.
Measure Steward:	American Heart Association
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), at the measure steward's request because it will no longer be maintained for inclusion.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter requested that measure Q007: *Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)* be retained based on the measure's clinical relevance and inclusion in a number of specialty sets. The commenter requested the measure be retained for CY 2027 under topped-out status.

Response: We thank the commenter for their comment; however, as the measure steward is no longer supporting the measure, we are unable to continue implementation within MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44412), we are finalizing the removal of measure Q007 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.3 Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
CBE # / eCQM CBE #:	0384 / 0384e
Quality#:	143
CMS eCQM ID:	CMS157v15
Collection Type:	eCQM / MIPS CQM
Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Measure Steward:	American Society of Clinical Oncology
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. Topped-out process measures are those with a median performance rate of 95 percent or higher (81 FR 77286). This measure's continued topped-out status is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf*.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Oncology/Hematology, Radiation Oncology

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter urged CMS to implement a more thorough and thoughtful process based on specific criteria when identifying whether a measure is topped out and potentially considered for removal from MIPS. The commenter stated a recent review of reporting rates on MIPS topped out measures during the first 6 years of the program identified that, of the 137 topped out measures, the vast majority were not reported by a large percentage of clinicians and groups. In fact, the median reporting rate across those measures was not more than 5 percent.[497] Using data from the 2024 QPP Experience Public Use File (*https://data.cms.gov/quality-of-care/quality-payment-program-experience/data*), this measure was reported by just over 1,000 individuals and groups out of the more than 12,000 oncologists who reported at least one measure and over 40 percent were small practices and 30 percent served in a health professional shortage area.

Response: We thank the commenter for their feedback and acknowledge their concern regarding the removal of specialty measures. In developing this proposal, we sought to balance meaningful quality reporting with the resources and operational demands required to collect measures that may not meaningfully inform performance. Although topped-out measures may address important aspects of care, the underlying quality actions are generally considered standard practice and offer limited opportunity for further improvement in clinical outcomes. This measure has been topped out for 5 consecutive years, 9 total years, for the eCQM collection type and 9 consecutive years for the MIPS CQM collection type. While the measure was identified as being eligible for the defined topped-out benchmark and, therefore eligible to receive over 7 points, removing this process measure will better support the goal of prioritizing measures that improve patient outcomes and include robust quality actions that go beyond assessment of concerns.

Comment: A few commenters opposed the removal of measure Q143: *Oncology: Medical and Radiation – Pain Intensity Quantified* and noted that this measure operates as a paired measure with measure Q144: *Oncology: Medical and Radiation – Plan of Care for Pain.* Without the Pain Intensity Quantified measure, clinicians are unable to identify patients requiring a documented plan of care for pain. Pain management is paramount in oncology care, and existing metrics should not be dismantled without a sufficient replacement. One of the commenters recommended CMS work with the measure steward to combine measures Q143 and Q144, or alternatively adopt the existing QCDR measure PIMSH4 for broader use in MIPS prior to removing measure Q143.

Response: We acknowledge the commenters' concern regarding the removal of measure Q143; however, we determined that removal of this measure is necessary to promote meaningful and complete quality reporting, informing quality care for patients with pain receiving chemotherapy or radiation therapy. Measures Q143 and Q144 represent a single, unified quality action that requires both detection and an intervention; splitting this into two separate measures allows for reporting of one without the other and breaks up what should be a unified standard of care. We agree the measures should be combined; however, the measure steward has decided not to combine them. Measure Q143 is also topped out and while topped-out measures may still represent an important aspect of care, the associated quality actions are generally considered standard of practice and offer limited opportunity to further improve clinical outcomes.

[497] Chung, Y., Nicola, L. P., & Rula, E. Y. (2026). Reporting Rates of Topped-Out Merit-Based Incentive Payment System (MIPS) Quality Measures, 2017–2023. *Health Affairs Scholar*, *4*(4), qxag061. https://doi.org/10.1093/haschl/qxag061.

While we agree the concept is important to quality care, the removal of the measure does not preclude the quality action from continuing. Whether the clinician/group is being assessed for the quality action or not, it should still be completed as a matter of high-quality care. High measure performance suggests that assessment is happening already as standard of care.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44413), we are finalizing the removal of measure Q143 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.4 Functional Status Change for Patients with Knee Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	217
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Knee Impairments measure being finalized in Table A.6 of this Appendix. Measure Q217 is specific to knee impairments and restricts clinicians to using the proprietary tool FOTO LEPF PROM or a manual crosswalk for numerator assessment. The new measure in Table A.6 of this Appendix is a more comprehensive patient-reported outcome-based performance measure. The new measure allows the use of various validated assessments tools, including the Knee Outcome Survey, Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the Predicted Moderate Clinical Improvement (P-MCI), a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that will improve feasibility of reporting as all information to calculate performance will be provided by the measure steward.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to replace the FOTO functional status measures with the new functional improvement measures in Table A of this Appendix. One of the commenters highlighted the new measure set's broad use across major health systems, its whole-person, patient-centered design, and its flexibility across practice types and EHR systems. They also pointed to low-cost administration options and strong alignment with CMS' patient-centered MVP goals, particularly the emphasis on patient-reported outcomes. The commenter appreciated that adopting PROMIS would expand meaningful reporting opportunities for physical therapists. Another commenter supported the removal of these measures, noting that they are duplicative of the newly proposed functional improvement measures.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44413), we are finalizing the removal of measure Q217 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.5 Functional Status Change for Patients with Hip Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	218
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Lower Extremity Impairments measure being finalized in Table A.5 of this Appendix. Measure Q218 is specific to hip impairments and restricts clinicians to using the proprietary tool FOTO LEPF PROM or a manual crosswalk for numerator assessment. The new measure in Table A.5 of this Appendix is a more comprehensive patient-reported outcome-based performance measure that includes all lower extremity injuries. The new measure allows the use of various validated assessments tools, including the Lower Extremity Functional Scale (LEFS), PROMIS Physical Function, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that will improve feasibility of reporting as all information to calculate performance will be provided by the measure steward.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table C.4 of this Appendix, a few commenters supported the proposal to replace the FOTO functional status measures with the new functional improvement measures in Table A of this Appendix.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44414), we are finalizing the removal of measure Q218 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.6 Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	219
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Lower Extremity Impairments measure being finalized in Table A.5 of this Appendix. Measure Q219 is specific to lower leg, foot and ankle impairments and restricts clinicians to the use of the proprietary tool FOTO LEPF PROM or a manual crosswalk for numerator assessment. The new measure in Table A.5 of this Appendix is a more comprehensive patient-reported outcome-based performance measure that includes all lower extremity injuries. The new measure allows the use of various validated assessments tools, including the LEFS, PROMIS Physical Function, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that will improve feasibility of reporting as all information to calculate performance will be provided by the measure steward.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy, Podiatry

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table C.4 of this Appendix, a few commenters supported the proposal to replace the FOTO functional status measures with the new functional improvement measures in Table A of this Appendix.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44414), we are finalizing the removal of measure Q219 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.7 Functional Status Change for Patients with Low Back Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	220
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Back Impairments measure being finalized in Table A.4 of this Appendix. Measure Q220 is specific to low back impairments and restricts clinicians to the use of the proprietary tool FOTO Low Back FS PROM or a manual crosswalk for numerator assessment. The new measure in Table A.4 of this Appendix is a more comprehensive patient-reported outcome-based performance measure that includes all back impairments. The new measure allows the use of various validated assessment tools, such as the Modified Low Back Disability Questionnaire, PROMIS Pain Interference, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that will improve feasibility of reporting as all information to calculate performance will be provided by the measure steward.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table C.4 of this Appendix, a few commenters supported the proposal to replace the FOTO functional status measures with the new functional improvement measures in Table A of this Appendix.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44415), we are finalizing the removal of measure Q220 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.8 Functional Status Change for Patients with Shoulder Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	221
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Upper Extremity Impairments measure being finalized in Table A.3 of this Appendix. Measure Q221 is specific to shoulder impairments and restricts clinicians to the use of the proprietary tool FOTO Shoulder FS PROM or a manual crosswalk for numerator assessment. The new measure in Table A.3 of this Appendix is a more comprehensive patient-reported outcome-based performance measure that includes all upper extremity injuries. The new measure allows the use of various validated assessment tools, such as the Quick Disabilities of the Arm, Shoulder, & Hand (QDASH) and PROMIS Upper Extremity, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that will improve feasibility of reporting as all information to calculate performance will be provided by the measure steward.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table C.4 of this Appendix, a few commenters supported the proposal to replace the FOTO functional status measures with the new functional improvement measures in Table A of this Appendix.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44415), we are finalizing the removal of measure Q221 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.9 Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	222
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Upper Extremity Impairments measure being finalized in Table A.3 of this Appendix. Measure Q222 is specific to elbow, wrist and hand impairments and restricts clinicians to the use of the proprietary tool FOTO Elbow/Wrist/Hand FS PROM or a manual crosswalk for numerator assessment. The new measure in Table A.3 of this Appendix is a more comprehensive patient-reported outcome-based performance measure that includes all upper extremity injuries. The new measure allows the use of various validated assessment tools, such as QDASH and PROMIS Upper Extremity, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that will improve feasibility of reporting as all information to calculate performance will be provided by the measure steward.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table C.4 of this Appendix, a few commenters supported the proposal to replace the FOTO functional status measures with the new functional improvement measures in Table A of this Appendix.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44416), we are finalizing the removal of measure Q222 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.10 Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

Category	Description
CBE # / eCQM CBE #:	0658 / N/A
Quality#:	320
CMS eCQM ID:	N/A
Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Measure Description:	Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of 10 years for repeat colonoscopy documented in their colonoscopy report.
Measure Steward	American Gastroenterological Association
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. Topped-out process measures are those with a median performance rate of 95 percent or higher (81 FR 77286). This measure's continued topped-out status is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf*.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Gastroenterology

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the removal of measure Q320: *Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*, stating that there is no documented performance gap for screening patients over age 86, that peak colorectal cancer incidence occurs in patients aged 65–69, and that the measure lacks testing data at the individual or physician level to support its use.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: As indicated under Table C.3 of this Appendix, one commenter urged CMS to implement a more thorough and thoughtful process based on specific criteria when identifying whether a measure is topped out and potentially considered for removal from MIPS. Using data from the 2024 QPP Experience Public Use File (*https://data.cms.gov/quality-of-care/quality-payment-program-experience/data*), just over 800 individuals and groups out of the more than 7,000 gastroenterologists reported this measure and 33 percent were small practices.

Response: We thank the commenter for their feedback and acknowledge their concern regarding the removal of measure Q320: *Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*. In developing this proposal, we sought to balance meaningful quality reporting with the resources and operational demands required to collect measures that may not meaningfully inform performance. Although topped-out measures may address important aspects of care, the underlying quality actions are generally considered standard practice and offer limited opportunity for further improvement in clinical outcomes. Measure adoption is a statistic reviewed when identifying quality measures for removal and is included as part of the overarching criteria used for quality measure inventory refinements. Communication of procedure results and recommended follow-up should be a standard of care, which is reflected in the current MIPS data that shows that both collection types have been topped out for 10 years. We continue to encourage the development of new quality measures to fill important gaps in quality care that continue to drive high-quality outcomes.

Comment: One commenter supported removing measure Q320 from facility-based reporting programs because it inappropriately attributes clinician decisions to facilities. However, the commenter did not support removing the measure from MIPS because scores do not reflect true gastroenterology performance, it is the only colonoscopy-specific measure outside a QCDR, and it helps align quality with the Surveillance/Screening Colonoscopy episode-based cost measure. The commenter echoed the previous commenter above about experience data on reporting of this measure. The commenter stated that if CMS removes measure Q320 from MIPS, gastroenterologists who don't use a QCDR would lose the only colonoscopy-specific measure reportable via claims and MIPS CQM collection type. It would also reduce access to a widely available clinician-level colorectal cancer prevention quality measure while keeping the related cost accountability. This commenter and another commenter urged CMS to maintain topped-out or standard of care, GI-relevant measures when measure choice is limited and no clinically superior replacements are available using defined topped-out measure benchmarks where appropriate.

Response: We thank the commenters for their feedback and acknowledge the concern regarding the removal of measure Q320. We acknowledge the measure's role in supporting clear communication of follow-up intervals in adherence to USPSTF recommendations, promoting avoidance of unnecessary procedures and costs; however, the measure doesn't assess for

compliance. Therefore, the clinician may meet numerator compliance for all denominator eligible patients, but this would not indicate future appropriate use and screening. We acknowledge the commenters' concerns that measure Q320 is currently the only colonoscopy-specific quality measure reportable outside a QCDR. Although topped-out measures address important aspects of care, the underlying quality actions are generally considered standard practice and offer limited opportunity for further improvement in clinical outcomes. Removal of the measure does not preclude continuation of the underlying quality actions. While the measure was identified as being eligible for the defined topped-out benchmark and, therefore eligible to receive over 7 points, the measure's consistently high performance indicates little variability in completion of this quality action. Please note that measure Q113: *Colorectal Cancer Screening* is available for the Medicare Part B Claims collection type for MVP reporting and assesses appropriate colorectal cancer screening at the clinician-level. We continue to encourage the development of new quality measures to fill important gaps in quality care that continue to drive high-quality outcomes.

Comment: Two commenters opposed removal of measure Q320, stating that the measure ensures adherence to USPSTF recommendations for a 10-year follow-up interval after a normal, high-quality colonoscopy in average-risk adults and promotes clear communication of follow-up recommendations to patients and referring clinicians and is appropriately attributed at the individual clinician level within MIPS. They noted that this measure is also included in the CQMC Gastroenterology core measure set.

Response: We thank the commenters for their feedback and acknowledge the concern regarding the removal of measure Q320. We acknowledge the measure's role in supporting clear communication of follow-up intervals in adherence to USPSTF recommendations, promoting avoidance of unnecessary procedures and costs; however, the measure doesn't assess for compliance. Therefore, the clinician may meet numerator compliance for all denominator eligible patients, but this would not indicate future appropriate use and screening. We endeavor to maintain alignment in measures across programs; however, for the purposes of MIPS, reporting this measure doesn't produce meaningful benchmarks allowing for distinctions in quality of care.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44416), we are finalizing the removal of measure Q320 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.11 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	326
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Measure Steward	American Heart Association
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), at the measure steward's request because it will no longer be maintained for inclusion.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: Two commenters opposed removal of measure Q326: *Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy* because this measure would result in only one atrial fibrillation-related measure in the MIPS quality measure inventory, measure Q392: *Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation*, which focuses on adverse events for an atrial fibrillation procedure that is only relevant to a subset of the overall atrial fibrillation population. One of these commenters suggested that CMS retain measure Q326 until CMS adopts a clinically appropriate successor measure focused on stroke risk reduction.

Response: We thank the commenters for their feedback. We acknowledge the concern that removal of measure Q326 would leave only one atrial fibrillation-related measure (Q392) in the MIPS quality inventory and that measure Q392 applies only to a subset of the atrial fibrillation population. However, as the measure steward is no longer supporting Q326, we are unable to continue implementation within MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44416 through 44417), we are finalizing the removal of measure Q326 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.12 Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	332
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.
Measure Steward	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF)
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative in clinical topic of measure Q331: *Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)*. Measure Q331 assesses patients with a diagnosis of acute viral sinusitis for receipt of antibiotics within 10 days of symptoms onset, highlighting inappropriate use of antibiotics in eligible patients. Measure Q331 is broader than measure Q332 as it encourages avoidance of prescribing any antibiotic for viral illnesses, capturing the patient populations found in both measures. Measure Q332 is narrower in scope, focusing only on patients with bacterial sinusitis appropriately receiving an antibiotic, impacting a smaller proportion of sinusitis cases.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Allergy/Immunology, Emergency Medicine, Family Medicine, Internal Medicine, Otolaryngology, Urgent Care

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the removal of measure Q332: *Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)*, stating that its narrow scope limits meaningful reporting for many otolaryngology practices. The commenter encouraged CMS to retain measure Q331 as a more broadly relevant alternative.

Response: We thank the commenter for supporting the removal of this measure from MIPS. We note that measure Q331 was not proposed for removal from MIPS.

Comment: One commenter strongly opposed removal of measure Q332 because it is a key tool for antimicrobial stewardship and resistance prevention. The commenter disagreed that measure Q332 is duplicative of measure Q331, noting that measure Q331 addresses whether to prescribe antibiotics at all for viral sinusitis, while measure Q332 addresses which antibiotic to prescribe for bacterial sinusitis, representing two distinct clinical decisions in mutually exclusive patient populations. The commenter argued that removing measure Q332 would create a critical stewardship gap by failing to address inappropriate broad-spectrum antibiotic use in patients who genuinely need treatment, particularly given that acute sinusitis is a common source of overly broad outpatient antibiotic prescribing. The commenter urged CMS to retain measure Q332 or clearly identify replacement measures that will promote appropriate outpatient antibiotic selection, and more broadly to preserve and expand antimicrobial stewardship–relevant measures to support national efforts by HHS and CDC to combat antimicrobial resistance.

Response: We agree that appropriate antibiotic prescribing is essential, and MIPS will continue assessing overuse through measure Q331. To maintain a streamlined yet robust measure set, we are retaining this overuse measure as a critical first element. Per AAO-HNSF guidelines, only about 50 percent of clinically diagnosed acute bacterial rhinosinusitis (ABRS) cases have positive bacterial cultures, and many resolve spontaneously, making randomized controlled trial (RCT)-based efficacy difficult to determine.[498] Amoxicillin (with or without clavulanate) is recommended for its safety, efficacy, low cost, narrow spectrum, and alignment with antimicrobial stewardship principles, rather than RCT outcomes. As this measure targets a subpopulation already covered by measure Q331, we maintain that these actions would be part of the same episode of care given that the choice of antibiotic would follow the decision to treat with an antibiotic. We therefore proposed its removal, while encouraging the measure steward to incorporate this aspect into measure Q331 for a more comprehensive assessment of appropriate ABRS care.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44417), we are finalizing the removal of measure Q332 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

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[498] Payne, S. C., McKenna, M., Buckley, J., Colandrea, M., Chow, A., Detwiller, K., Donaldson, A., Dubin, M., Finestone, S., Filip, P., Khalid, A., Peters, A. T., Rosenfeld, R., Akrami, Z., & Dhepyasuwan, N. (2025). Clinical Practice Guideline: Adult Sinusitis Update. *Otolaryngology–Head and Neck Surgery, 173*, S1–S56. https://doi.org/10.1002/ohn.1344.

C.13 Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	350
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.
Measure Steward	American Association of Hip and Knee Surgeons
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because it is a process measure. Removing this process measure will support the goal of prioritizing measures that improve patient outcomes and have meaningful impact. Additionally, this measure is not prescriptive to conservative therapy utilization; therefore, it only assesses for informed consent, which is a standard of care for any clinician. In the CY 2019 (83 FR 59763 through 59765) and CY 2020 (84 FR 62957) PFS final rules, we communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 QPP final rule (81 FR 77101), we explained that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality-of-care patients receive. In the CY 2025 PFS final rule (89 FR 98561), we codified under § 414.1330(c)(1)(vii) that CMS uses the following criteria to determine the removal of a quality measure: If the quality measure is a process measure.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Orthopedic Surgery

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter indicated that measure Q350: *Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy* was reported primarily through MVPs with more than 2,500 of the over 4,000 reporting groups using the MVP reporting option. As indicated under Table C.3 of this Appendix, the commenter expressed concerns about the topped-out methodology as the basis for removing measures from MIPS. Similarly, a second commenter requested CMS retain this measure and apply the defined topped out benchmark.

Another commenter opposed removal of measure Q350, stating that it promotes meaningful shared decision-making and that removing it would further limit MIPS CQM options, particularly within the Improving Care for Lower Extremity Joint Repair MVP. The commenter noted that reducing measure availability disproportionately harms clinicians without CEHRT and specialists with few applicable measures.

Response: We thank the commenters for their feedback and acknowledge their concern regarding this measure. In developing this proposal, we sought to balance meaningful quality reporting with the resources and operational demands required to collect measures that may not meaningfully inform performance. Although topped-out measures may address important aspects of care, the underlying quality actions are generally considered standard practice and; therefore, represent a relatively low bar for measuring quality performance, offering limited opportunity to drive or discern improvement in clinical outcomes. We appreciate the commenters' input on measure Q350. While the measure was identified as being eligible for the defined topped-out benchmark and, therefore eligible to receive over 7 points, removing this process measure will better support the goal of prioritizing measures that improve patient outcomes.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44418), we are finalizing the removal of measure Q350 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.14 Children Who Have Dental Decay or Cavities

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	378
CMS eCQM ID:	CMS75v15
Collection Type:	eCQM
Measure Description:	Percentage of children, 1 - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.
Measure Steward:	Centers for Medicare & Medicaid Services
Measure Type:	Outcome
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), due to the robustness of the measure. This measure lacks a quality action that can be attributed to the clinicians reporting it, and as a result, the current scoring methodology for determination of measure achievement points for this measure is not a reflection of the quality of care provided. This measure focuses on incidence of tooth decay or cavities rather than the quality of care delivered, as patients will be attributed to clinicians based on encounter and not whether they have been involved in the patient's care. Therefore, it is likely they had no impact on the outcome being assessed. While tracking the incidence of tooth decay or cavities identifies the prevalence of the issue, it is not a reflection of the quality of care given, as currently specified, and does not promote meaningful dental care interventions that will drive improvements in oral health outcomes. The lack of an actionable quality assessment reduces the overall robustness of the measure.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Dentistry

We received no public comments on the proposed removal of this measure. For the reasons stated above and in the proposed rule (91 FR 44418), we are finalizing the removal of measure Q378 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.15 Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	384
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.
Measure Steward:	American Academy of Ophthalmology
Measure Type:	Outcome
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. This measure's continued topped-out status is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf.*
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Ophthalmology

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table C.3 of this Appendix, one commenter urged CMS to implement a more thorough and thoughtful process based on specific criteria when identifying whether a measure is topped out and potentially considered for removal from MIPS. Using data from the 2024 QPP Experience Public Use File (*https://data.cms.gov/quality-of-care/quality-payment-program-experience/data*), this measure only had 154 individuals and groups out of the more than 11,000 ophthalmologists reporting the measure, with almost half classified as a small practice. A few commenters opposed removal based on topped-out status and stated there are limited measures in the Complete Ophthalmologic Care MVP and that retinal specialists face limited measure choice.

Response: We thank the commenters for their feedback and acknowledge the concern regarding the removal of measure Q384: *Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery* due to the topped-out lifecycle of the measure; however, in developing this proposal, we sought to balance meaningful quality reporting with the resources and operational demands required to collect measures that may not meaningfully inform performance. Measure adoption is a statistic reviewed when identifying quality measures for removal and is included as part of the overarching criteria used for quality measure inventory refinements. Given the measure's current performance data, no meaningful comparisons can be made to drive quality improvement, which is MIPS goal. The Complete Ophthalmologic Care MVP for 2027 will have 8 MIPS quality measures available for reporting across the Retinal Disease (5 measures), Advancing Health and Wellness (2 measures), and Experience of Care (1 measure) clinical groupings.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44418 through 44419), we are finalizing the removal of measure Q384 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.16 Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	415
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.
Measure Steward:	American College of Emergency Physicians
Measure Type:	Efficiency
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. This measure's continued topped-out status is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf.*
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Emergency Medicine

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table C.3 of this Appendix, one commenter urged CMS to implement a more thorough and thoughtful process based on specific criteria when identifying whether a measure is topped out and potentially considered for removal from MIPS. Using data from the 2024 QPP Experience Public Use File (*https://data.cms.gov/quality-of-care/quality-payment-program-experience/data*), just under 2,000 out of the more than 25,000 emergency medicine physicians reported this measure with roughly 30 percent of them serving within a health professional shortage area; a similar percentage were also classified with safety-net status and a quarter were rural. A second commenter did not support removal of Q415 based on topped-out status.

Response: We thank the commenters for their feedback and acknowledge the concern regarding the removal of measure Q415: *Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older* due to the topped-out lifecycle of the measure. While this measure was identified as being eligible for the defined topped-out benchmark and may still represent an important aspect of care, the associated quality actions are generally considered a standard of practice, presenting limited opportunity to further improve clinical outcomes. Measure adoption is a statistic reviewed when identifying quality measures for removal and is included as part of the overarching criteria used for quality measure inventory refinements. Removing this measure will better support the goal of prioritizing measures that promote meaningful quality reporting showing improvement in clinical quality care. The Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP for 2027 will have 6 MIPS quality measures available for reporting by emergency medicine clinicians.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44419), we are finalizing the removal of measure Q415 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.17 Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy

Category	Description
CBE # / eCQM CBE #:	N/A /N/A
Quality#:	430
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively and/or intraoperatively.
Measure Steward:	American Society of Anesthesiologists
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. The average performance for this measure, 99.34 percent, is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance rate is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks.* For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf.*
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Anesthesiology

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter opposed removal of measures Q430: *Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy* and Q463: *Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics)* from MIPS, emphasizing the measures capture most anesthesia patients and reflect a core, clinically integrated component of anesthesia care. The commenter noted that PONV remains a common, clinically significant, and preventable complication that affects patient comfort, satisfaction, recovery, and resource use, and stated that high MIPS scores should not be interpreted as evidence that the underlying quality gap has been eliminated or that performance is uniform across the broader clinical population. The commenter indicated that their submissions showed far fewer facilities achieving very high performance compared with CMS data, suggesting discrepancies in measure definition, implementation, and data capture.

The commenter stated that removing measures Q430 and Q463 would increase administrative burden because the measures are already embedded in existing data-capture systems and workflows, while adopting the newly proposed Patient-Reported Experience with Anesthesia and IOH measures would require significant vendor engagement, system updates, and workflow changes over several months. They argued that inclusion of these new measures should not be viewed as replacing measures Q430 and Q463 and encouraged CMS to maintain the existing measures until anesthesia groups can transfer to reporting the two newly proposed measures. To ensure continuity and reporting flexibility as clinicians move from traditional MIPS to MVPs, the commenter encouraged CMS to retain measure Q430 either within traditional MIPS or, at a minimum, as an MVP-only measure in the Anesthesia MVP.

A second commenter opposed removal of measure Q430 because it would eliminate an anesthesia measure and create a significant and inequitable barrier to successful MIPS participation for anesthesia clinicians and groups. This would impact the number of quality measures available in the Patient Safety and Support of Positive Experiences with Anesthesia MVP and would result in a practice needing to use a QCDR measure to satisfy the reporting requirement.

Response: We thank the commenters for their feedback and acknowledge their concern regarding the removal of anesthesia measures. In developing this proposal, we sought to balance meaningful quality reporting with the resources and operational demands required to collect measures that may not meaningfully inform performance. Although topped-out measures address important aspects of care, the underlying quality actions are generally considered standard practice; the continued high-performance rates don't allow for meaningful benchmarking, offering limited opportunity for further improvement in clinical outcomes. We appreciate the commenter's input on measures Q430 and Q463. While the measures were identified as being eligible for the defined topped-out benchmark and, therefore eligible to receive over 7 points, the measures' consistently high performance indicates little variability in completion of this quality action across reporting within MIPS. We recognize changes to the measure inventory may lead to system rework and updating; however, we don't want to maintain measures in MIPS that are no longer showing actionable data to drive quality care. To support continued robust anesthesia-related reporting, as the commenter stated above, we have proposed two new MIPS CQMs under Tables A.8 (*Patient-Reported Experience with Anesthesia*) and A.9 (*Intraoperative Hypotension (IOH) Among Non-Emergent Noncardiac Surgical Cases*) of this Appendix, maintaining the current number of four available MIPS CQMs.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44420), we are finalizing the removal of measure Q430 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.18 Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	463
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.
Measure Steward:	American Society of Anesthesiologists
Measure Type:	Process
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2018 Quality Payment Program final rule (82 FR 53966 through 53975), because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. The average performance for this measure, 98.99 percent, is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance rate is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks.* For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf.*
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Anesthesiology

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter opposed removal of measure Q463: *Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics)* because it would eliminate an anesthesia measure and create a significant and inequitable barrier to successful MIPS participation for anesthesia clinicians and groups. This commenter also opposed removal of measure Q430: *Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy* with full comments under Table C.17 of this Appendix. This measure's removal would impact the number of quality measures available in the Patient Safety and Support of Positive Experiences with Anesthesia MVP and would result in a practice needing to use a QCDR measure to satisfy the reporting requirement. This commenter and a second commenter recommended maintaining measures Q430 (under Table C.17 of this Appendix) and Q463 as MVP-only measures.

Response: We thank the commenters for their feedback and acknowledge their concern regarding the removal of anesthesia measures. In developing this proposal, we sought to balance meaningful quality reporting with the resources and operational demands required to collect measures that may not meaningfully inform performance. Although topped-out measures address important aspects of care, the associated quality actions are generally considered standard practice and offer limited opportunity to further improve clinical outcomes. While the measures were identified as being eligible for the defined topped-out benchmark and, therefore eligible to receive over 7 points, the measure's consistent high performance indicates little variability in completion of this quality action. The removal of the measure does not preclude continuation of the underlying quality actions. To support continued robust anesthesia-related reporting, we are finalizing two new anesthesia measures under Tables A.8 and A.9 of this Appendix, maintaining the current number of 4 available MIPS CQMs.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44420), we are finalizing the removal of measure Q463 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.19 Functional Status Change for Patients with Neck Impairments

Category	Description
CBE # / eCQM CBE #:	3461 / N/A
Quality#:	478
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2020 Quality Payment Program final rule (84 FR 63205 through 63213), because this measure is duplicative of the Functional Improvement for Patients with Neck Impairments measure being finalized in Table A.2 of this Appendix. Measure Q478 is specific to neck impairments and restricts clinicians to the use of the proprietary tool FOTO Neck FS PROM or a manual crosswalk for numerator assessment. The new measure in Table A.2 of this Appendix is a more comprehensive patient-reported outcome-based performance measure. The new measure allows the use of various validated assessment tools, such as the Neck Disability Index, PROMIS Pain Interference, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that will improve feasibility of reporting as all information to calculate performance will be provided by the measure steward.
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: As indicated under Table C.4 of this Appendix, a few commenters supported the proposal to replace the FOTO functional status measures with the new functional improvement measures in Table A of this Appendix.

Response: We thank the commenters for supporting the removal of this measure from MIPS.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44421), we are finalizing the removal of measure Q478 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

C.20 Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM)

Category	Description
CBE # / eCQM CBE #:	3568 / N/A
Quality#:	483
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items - to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.
Measure Steward:	The American Board of Family Medicine
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We proposed the removal of this quality measure from MIPS, finalized in the CY 2020 Quality Payment Program final rule (84 FR 63205 through 63213), because the limited adoption of this quality measure does not allow for the creation of a benchmark after being in the program for two consecutive CY performance periods. For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf*. The current 2026 MIPS benchmarking data is located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks.*
In the Circumstance the Measure Was Retained:	There were no substantive changes for this measure. If the measure was not finalized for removal in the CY 2027 PFS final rule, it would have been added back into the applicable finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would have been addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Family Medicine, Internal Medicine

We received public comments on the proposed removal of this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported removing measure Q483: *Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM)*, noting concerns about whether the measure would meaningfully lead to improvements in care, a lack of evidence to demonstrate such improvement, and the instrument lacking face validity. The commenter stated that the measure is burdensome to implement in a general internal medicine practice.

Response: We thank the commenter for supporting the removal of this measure from MIPS.

Comment: Many commenters opposed removing measure Q483, noting that CMS already uses alternative approaches that could achieve benchmarking goals without eliminating this measure. They emphasized that the PCPCM PRO-PM aligns with the rule's focus on prevention, chronic disease management, longitudinal relationships, and outcomes-based, prospective payment, and that its removal would create a critical gap just as payment reforms most need this tool.

The commenters noted no concerns about the PCPCM's validity, reliability, clinical relevance, or patient burden. The commenters cited the measure is included in the Value in Primary Care MVP and primary care specialty sets, and the ACO Primary Care Flex Model. The measure is CBE-endorsed and a high-priority measure.

They also observed that limited adoption and missing benchmarks are common early on. Over 30 percent of current MIPS measures lack national benchmarks. CMS can use performance-period benchmarks, and scoring floors encourage reporting before benchmarks form; removing the broader 3-point floor in 2023 may have dampened adoption and slowed benchmark development. One commenter urged CMS to retain this measure and consider alternative scoring approaches such as a scoring floor.

The National Academies of Sciences, Engineering, and Medicine (NASEM) Standing Committee on Primary Care calls for metrics on core primary care functions (access, continuity, comprehensiveness, coordination, person-centeredness). PCPCM is the only validated, low-burden patient-reported measure of these kind and commenters believed its removal would undercut the "Redesigning Primary Care to Make America Healthy Again" initiative. The commenters recommended CMS retain measure Q483, apply a defined scoring floor for 2 performance periods, and keep it in the Value in Primary Care MVP and primary care specialty sets.

Response: We appreciate the commenters' feedback. While we agree that the measure concept is clinically relevant and aligned with core primary care functions important to the provision of high-quality person-centered care, removal of the measure does not preclude continuation of the underlying quality actions. Regardless of whether a clinician or group is formally assessed on this aspect of care, it should continue to be performed as a component of high-quality care. While commenters suggest relying on performance-period benchmarks and defined scoring floors to encourage ongoing reporting, further continuation of this measure

under the current conditions would prolong reporting burden without reasonable assurance that adequate adoption and benchmarking will be achieved. In addition, the implementation and reporting burden for both clinicians and patients, as well as the measure's non-proportional analytic, can make it challenging to assess performance consistently across all clinician types. We also note that removal would maintain alignment across CMS reporting programs as this measure has been removed from the ACO Primary Care Flex Model.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44421), we are finalizing the removal of measure Q483 from MIPS and applicable specialty sets as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

Table Group D: Finalized and Finalized with Modification Substantive Changes to Previously Finalized MIPS Quality Measures for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

The D Tables within this final rule provide the substantive changes finalized for the MIPS quality measures for CY 2027. We requested comments on these substantive changes. Two measures have finalized substantive changes that will result in a new benchmark. All measures with substantive changes are discussed in detail in the tables below. In addition, measures that are endorsed by a CBE are shown in Table Group D of this Appendix as follows: CBE # / eCQM CBE #.

We note that some MIPS quality measures available in traditional MIPS and MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP), specifically the inclusion of such measures in the APP Plus measure set, as finalized in the CY 2025 PFS final rule (89 FR 98363 through 98371). For such measures, the collection types solely applicable for purposes of the APP Plus measure set (Medicare Clinical Quality Measures for Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Medicare CQMs) collection type and newly finalized Medicare Electronic Clinical Quality Measures for ACOs Participating in the Medicare Shared Savings Program (Medicare eCQMs) collection type as described in section IV.A.4.d.(1)(c)(v) of this final rule) are also specified as a collection type available for such relevant measures described in Table Group D.

Changes made to denominator code sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2027 may not be identified within this final rule due to their later publication. Coding revisions to the denominator may be postponed until CY 2028, if measure steward review and their ability to implement the coding changes are impacted due to the timing of 2027 CPT and ICD-10 updates. The 2027 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types on the QPP website at *https://qpp.cms.gov*.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes will expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2027 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has been added to all quality measure specifications in the form of a revised 'Instructions Note' to clearly identify if telehealth encounters are allowed for denominator eligibility regardless of changes in coding or billing practices that may occur. Eligibility of telehealth encounters will be based on the intent of the measure and those settings that are appropriate for inclusion.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the substantive changes, there may be revisions within the logic that are not considered substantive in nature; however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow for the most accurate implementation.

As indicated in the introduction to Table Group B of this Appendix, comments on measures that have substantive changes that are not related to what was proposed are considered out of scope and are not included in this final rule. In addition, requested changes on previously finalized measures that were not proposed under the CY 2027 PFS proposed rule are also out of scope to this final rule.

Section 1848(q)(2)(D)(i)(II)(cc) of the Act requires all substantive measure changes to be proposed and identified through notice-and-comment rulemaking. We have previously established criteria that will apply when we are considering making substantive changes to a quality measure (81 FR 77137 and 86 FR 65441 through 65442). On an annual basis, we review the established MIPS quality measure inventory to identify appropriate updates to the measures, based on, but not limited to, interested party feedback, known issues, and clinical guideline updates, for measure steward consideration. The measure steward is responsible for the maintenance of a measure and serves as the primary contact for suggested revisions for possible implementation in future years.

Commenters who requested clarifications on how to implement previously finalized quality measures should contact the QPP Service Center by emailing QPP@cms.hhs.gov, submitting a QPP Service Center ticket, or calling 1-866-288-8292 (Monday-Friday, 8 a.m. – 8 p.m. ET).

D.1 Diabetes: Glycemic Status Assessment Greater Than 9%

Category	Description
CBE # / eCQM CBE #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure, eCQM, Medicare CQM, MIPS CQM, Medicare eCQM collection types. **Updated logic: For the eCQM collection type: Revised:** to prioritize identifying numerical glycemic status results over null values.
Measure Steward:	National Committee for Quality Assurance
MIPS Core Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the logic of the eCQM collection type to ensure clinically meaningful data is prioritized for inclusion in the measure, better aligning with the measure intent. We also proposed to update the collection types available for this measure to include the Medicare eCQM collection type to allow choice in submission method for Medicare Shared Savings Program ACOs reporting the APP Plus measure set. See section IV.A.4.d.(1)(c)(v) of this final rule for further information on the Medicare eCQM collection type.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the substantive changes to measure Q001: *Diabetes: Glycemic Status Assessment Greater Than 9%* to prioritize numerical glycemic status results over null values.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44422), we are finalizing the changes to measure Q001 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.2 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	102
CMS eCQM ID:	CMS129v16
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.
Substantive Change:	**Updated measure logic and logic definitions: For the eCQM collection type: Added:** Gleason Grade Group and anatomical site specificity for tumor staging. **Updated value set/coding: For the eCQM collection type: Added:** two direct reference codes representing Gleason Grade Group and value set 'Prostate Anatomical Site' (2.16.840.1.113762.1.4.1248.411). **Updated definition: For the MIPS CQM collection type**: **Added:** PET/CT, Ga-68 PSMA-11, F-18 flotufolastat PSMA PET/CT, PET/MRI (full body imaging) to 'Bone Scan'.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	For the eCQM collection type, we proposed the addition of Gleason Grade Group and anatomical site specificity for tumor staging to facilitate the capture of low or very low risk of prostate cancer. With this addition to the eCQM, we also proposed revising the measure logic to include coding that will capture Gleason Grade Group as an option for assessing prostate cancer risk, as well as the addition of value set 'Prostate Anatomical Site,' which will ensure anatomical site specificity for tumor staging. For the MIPS CQM collection type, we proposed the addition of PET/CT, Ga-68 PSMA-11, F-18 flotufolastat PSMA PET/CT imaging, and PET/MRI (full body imaging) to the measure, to align with guideline-directed avoidance of advanced imaging related to low or very low risk prostate cancer.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported reducing low-value imaging but opposed including these newer molecular imaging modalities in measure Q102: *Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients* at this time because their role in evaluating prostate cancer is still evolving. Labeling these tools as overuse now could discourage clinically appropriate imaging for select low-risk patients who may still have metastatic disease and require individualized assessment. The commenter urged CMS to delay including PSMA PET and other advanced imaging in measure Q102 until there is stronger clinical consensus and clearer guidance to avoid penalizing appropriate patient care.

Response: We thank the commenter for their feedback. We acknowledge the commenter's request that the PSMA PET[499] and other advanced imaging be removed; however, the measure steward refined the list to include appropriate imaging for clarity and purposes of reporting this measure. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44423), we are finalizing the changes to measure Q102 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

[499] Fendler, W. P., Eiber, M., Beheshti, M., et al. (2017). 68Ga-PSMA PET/CT: Joint EANM and SNMMI Procedure Guideline for Prostate Cancer Imaging: Version 1.0. *European Journal of Nuclear Medicine and Molecular Imaging, 44*, 1014–1024. https://doi.org/10.1007/s00259-017-3670-z.

D.3 Documentation of Current Medications in the Medical Record

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	130
CMS eCQM ID:	CMS68v16
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Substantive Change:	**Updated value set/coding**: **For the eCQM collection type: Revised:** Direct Reference Code (DRC) "Acute health crisis (finding)" (SNOMEDCT Code (705016005)) to value set 'Acute Health Crisis' (OID: 2.16.840.1.113762.1.4.1248.429) to allow for additional conditions to qualify for the exception. **Updated value set/coding**: **For the eCQM collection type: Revised:** 'Encounter to Document Medications' (2.16.840.1.113883.3.600.1.1609) to remove CPT code 99211 and add CPT code 92622 as outlined in the previous EKI.[500]
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the coding for the eCQM collection type to ensure the measure includes additional coding for the denominator exception, aligning with measure intent and allowing for mapping to equivalent appropriate clinical circumstances. Additionally, the encounter coding has been revised to ensure the appropriate patient population is being captured in the denominator for assessment.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the substantive changes to measure Q130: *Documentation of Current Medications in the Medical Record* to expand the SNOMEDCT code set to allow for the additional exceptions. One commenter supported the substantive changes and continued to recommend that we define "Acute Health Crisis" clearly due to the importance of accurate medication reconciliation for patients with multimorbidity and polypharmacy.

Response: We thank the commenters for supporting the substantive changes to this measure. We acknowledge the request for a clearer definition of "acute health crisis" and will review and discuss this revision for possible implementation in future years. The value sets within the measure specification will contain all coding applicable to each measure component.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44424), we are finalizing the changes to measure Q130 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

[500] See eCQM Known Issue (EKI) #39 at https://oncprojectracking.healthit.gov/support/browse/EKI-39.

D.4 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	134
CMS eCQM ID:	CMS2v16
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure, eCQM, Medicare CQM, MIPS CQM, Medicare eCQM collection types. **The measure description is revised to read: For the eCQM collection type:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented from the date of the screening to two days after the date of the qualifying encounter or an active depression medication or active depression management intervention was active or prescribed at any time on the date of qualifying encounter. **Updated definition: For the eCQM collection type: Added:** Active Depression Medication or Active Depression Management Intervention Documentation that patient is actively receiving interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options. **Updated guidance: For the eCQM collection type: Added:** clarifying language on screening tool to be used for screening a 17-year-old, and which screening should be used to satisfy the numerator. **The measure numerator is revised to read: For the eCQM collection type:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented from the date of the screening to two days after the date of the qualifying encounter or an active depression medication or active depression management intervention was active or prescribed at any time during the qualifying encounter. **Updated numerator definition: For the MIPS CQM, Medicare CQM, and the Medicare Part B Claims Measure collection types: Added:** Prior screening within performance period: Patient previously screened by another clinician using an age-appropriate standardized depression screening tool with documented results within the performance period AND if positive, a follow-up plan is documented. **Updated denominator exception: For the MIPS CQM, Medicare CQM, and the Medicare Part B Claims Measure collection types: Added:** Screening for depression not completed, previous patient screening with results documented within performance period.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	For the eCQM collection type, we proposed to expand the numerator so that an active depression medication or depression management intervention that is prescribed or in place at any time on the date of the qualifying encounter may meet the numerator quality action.[501] We proposed to revise the language in the description, definitions, and numerator statement to reflect the proposed revision and align with measure logic. We also proposed clarifying the screening tools that may be used to satisfy the measure for patients who are 17 years old at the start of the measurement period, as this age group may fall into a transitional category requiring unique considerations for tool selection. For the MIPS CQM, Medicare CQM, and Medicare Part B Claims Measure collection types, we proposed adding a new denominator exception for patients with documentation of being previously screened, with a follow-up care plan documented if appropriate, in accordance with the measure requirements, by another clinician within the performance period to enhance team-based, coordinated, and patient-centered care processes between clinicians.[502]

[501] Zuckerbrot, R. A., Cheung, A., Jensen, P. S., Stein, R. E. K., Laraque, D., GLAD-PC Steering Group, Levitt, A., Birmaher, B., Campo, J., Clarke, G., Emslie, G., Kaufman, M., Kelleher, K. J., Kutcher, S., Malus, M., Sacks, D., Waslick, B., & Sarvet, B. (2018). Guidelines for Adolescent Depression in Primary Care (GLAD-PC): Part I. Practice Preparation, Identification, Assessment, and Initial Management. *Pediatrics*, *141*(3), e20174081. https://doi.org/10.1542/peds.2017-4081.

[502] Department of Veterans Affairs, & Department of Defense. (2022). VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder (Version 4.0). https://www.healthquality.va.gov/guidelines/MH/mdd/VADODMDDCPGFinal508.pdf.

Category	Description
	We also proposed to update the collection types available for this measure to include the Medicare eCQM collection type to allow choice in submission method for Medicare Shared Savings Program ACOs reporting the APP Plus measure set. See section IV.A.4.d.(1)(c)(v) of this final rule for further information on the Medicare eCQM collection type.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the substantive changes to measure Q134: *Preventive Care and Screening: Screening for Depression and Follow-Up Plan* but expressed concern that differences between the eCQM and MIPS CQM requirements create unnecessary documentation burden and introduce performance variation unrelated to care quality. One of the commenters supported the proposed denominator exception for a patient that was previously screened within the same performance year but noted that it was not proposed for the eCQM collection type. Another commenter indicated the eCQM allows an active depression medication or an active depression management intervention to satisfy the follow-up requirement, while the MIPS CQM accepts only documentation of a follow-up plan. Commenters recommended aligning the eCQM and MIPS CQM criteria to reduce burden, improve consistency, and better represent real clinical pathways for depression identification and management.

Response: We thank the commenters for supporting the substantive changes to this measure. We reviewed and discussed this revision for all collection types; however, these revisions are unnecessary for the eCQM collection type, where the measure logic, and patient-based structure, already address and resolve the issue. The additional language and measure component are needed for appropriate implementation of the MIPS CQM, Medicare CQM, and the Medicare Part B Claims Measure collection types as they don't contain the same measure logic as the eCQM collection type. Therefore, differences in measure specification language and requirements between collection types reflect nuances in implementation within MIPS and address the abilities and constraints specifically inherent to each collection type.

Comment: One commenter appreciated CMS' proposed denominator exception for depression screening but stated it does not fully fix implementation problems for ACOs, especially when aggregating data across multiple practices and EHRs. The commenter recommended clarifying across all reporting options that one depression screen with follow-up (if positive) at any time in the performance period is sufficient, using the most recent screen if multiple exist, which would eliminate the need for the denominator exception. Similarly, another commenter stated the denominator exception for prior screenings within the performance period adds unnecessary complexity and instead recommended updating the numerator to: "Patients screened for depression during the measurement period using an age-appropriate standardized tool and if positive, a follow-up plan is documented on the date of or up to two days after the positive screening." The commenter also requested removal of the requirement that screening occur on the date of the encounter or up to 14 days prior, because tying screening to denominator-eligible encounters relies on billing rules rather than clinical relevance and penalizes clinicians when screening is done at non-eligible encounters despite meeting best practices.

Response: We thank the commenters for their feedback. We will review and discuss this revision for possible implementation in future years as it would be substantive in nature and would need to go through public notice and comment. Regarding implementation at the ACO level, measure Q134 has explicitly defined the timeframe and quality actions necessary to meet the numerator for this once per performance period patient level measure to ensure screenings, results, and care plans are appropriately aligned with best practices. As each collection type may have slight nuances in implementation, this revision has created harmonized specifications and clear guidance on handling multiple encounters and multiple screenings.

Comment: One commenter thanked CMS for expanding the eCQM numerator criteria for measure Q134 by making active depression or active depression management intervention active or prescribed. However, the commenter asked CMS to continue looking at adding CPT codes for measure qualifying encounter expansion. The commenter asked CMS through help desk tickets to consider post-partum visit codes for inclusion. The commenter further asked CMS to consider expanding screening exclusions or exceptions for patients that are unable to be screened as they may be cognitively impaired, non-verbal, or have other disabilities that may prevent them from accurate depression screening. Another commenter supported the substantive changes and requested CMS add CPT code 97168 to the denominator, noting that occupational therapy re-evaluations may identify functional or psychosocial changes that warrant depression screening and follow-up.

Response: We thank the commenters for supporting the substantive changes to this measure. We will review and discuss this revision for possible implementation in future years as it would be substantive in nature and would need to go through public notice and comment. We note this measure contains other occupational therapy codes within the measure's denominator eligible encounters. Therefore, patients being reevaluated should already be found within the denominator and assessed for depression screening; however, this doesn't preclude the quality action from being completed as a matter of high-quality care based on clinician judgement at any encounter.

Comment: One commenter did not support the proposed eCQM requirement that depression medication or depression management be active or prescribed only on the date of the qualifying encounter and instead recommended allowing documentation on or before that date to avoid unnecessary re-documentation that does not improve care. The commenter requested clarification of what qualifies as an "active depression management intervention" within the eCQM and recommended that a referral for behavioral health evaluation count as an appropriate intervention when clinically indicated. The commenter also

noted that requiring a behavioral health evaluation within 2 days of the encounter is often impractical due to cross-organization care and scheduling limitations and therefore requested clear and flexible eCQM documentation requirements that accommodate care delivered across multiple organizations.

Response: We thank the commenter for their feedback. We encourage the commenter to view the revised measure specification on the eCQI Resource Center (*https://ecqi.healthit.gov/*) for specific information; however, we note that the measure was updated to include a definition for 'Active Depression Medication or Active Depression Management Intervention' as noted in the Substantive Change row in Table D.4 above. We will review and discuss suggested revisions and clarifications for possible implementation in future years as it would be substantive in nature and would need to go through public notice and comment.

Comment: One commenter requested clarification regarding whether and how the exception for patients with documentation of being previously screened would be applied within the Medicare CQM collection methodology.

Response: As stated in the Substantive Change row in Table D.4 above, the numerator definition and denominator exception will be updated within the Medicare CQM collection type. Measure specifications will be posted prior to January 1, 2027.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44425 through 44426), we are finalizing the changes to measure Q134 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.5 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care

Category	Description
CBE # / eCQM CBE #:	0563 / N/A
Quality#:	141
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period.
Substantive Change:	**Measure description revised to read: For all collection types:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within 7 days after the patient encounter when IOP was assessed. **Updated denominator exclusions: For all collection types: Added:** 1. Eyes with absolute glaucoma blindness 2. Pre-existing visual acuity findings include: Count fingers (CF or FC), Hand motion (HM), Light perception (LP), No light perception (NLP) **Updated numerator: For all collection types: Added:** a plan of care was documented within 7 days after the patient encounter when IOP was assessed. **Updated numerator definition**: **For all collection types: Revised:** definition for Plan of Care to include: The plan of care must be documented within 7 days after the patient encounter when IOP was assessed. **Updated numerator options: For all collection types: Revised:** **Performance Met:** Glaucoma plan of care documented within 7 days after the patient encounter when IOP was assessed
Measure Steward:	American Academy of Ophthalmology
MIPS Core Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update multiple components of the measure for all collection types to align with the added numerator definition that specifies the timing of when the plan of care must be documented in the patient's medical record after the IOP is assessed. This will ensure timely and optimal patient care across clinicians for measure performance, as well as reduce variability in how the measure is applied. We proposed adding denominator exclusions for patients with absolute glaucoma blindness or specific visual acuity findings because they represent end-stage clinical conditions characterized by absolute blindness or profound vision loss, in which further IOP reduction is unlikely to provide meaningful benefit in preserving visual function or slowing glaucoma progression. The exclusions will align with the intent of the measure to assess IOP management in support of preserving remaining visual function and limiting disease progression and will refine the denominator to reflect patients who may reasonably benefit from vision-preserving IOP management and related care planning.[503]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed modification to require a glaucoma plan of care to be documented within 7 days after the patient encounter when IOP was assessed for measure Q141: *Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care*. One commenter supported the substantive changes to the denominator exclusion.

Response: We thank the commenters for supporting the substantive changes to this measure.

Comment: One commenter supported the substantive changes for measure Q141, but requested clarification on whether the exclusion criteria must be met in both eyes.

Response: We thank the commenter for supporting the substantive changes to this measure. For implementation purposes, it would be expected to assess each patient for eligibility and numerator compliance based upon each eye in accordance with the intent to maintain the IOP within a range to ensure any visual field loss is unlikely to significantly reduce a patient's health-related quality of life. Therefore, if a patient meets denominator eligibility based on one or both eyes, it would be expected that

[503] Kastner, A., & King, A. J. (2020). Advanced Glaucoma at Diagnosis: Current Perspectives. *Eye (London, England)*, *34*(1), 116–128. https://doi.org/10.1038/s41433-019-0637-2.

they are assessed for the quality action at that level (one or both eyes); ensuring the patient has received appropriate and complete care for their eyes.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44427), we are finalizing the changes to measure Q141 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.6 Oncology: Medical and Radiation - Plan of Care for Pain

Category	Description
CBE # / eCQM CBE #:	0383 / N/A
Quality#:	144
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Substantive Change:	**Updated denominator note: For Submission Criteria 2: Added:** definition for lookback period in the instance a code has a billing date different from the face-to-face encounter.
Measure Steward:	American Society of Clinical Oncology
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We proposed adding a defined look-back window to identify the encounter at which the plan of care to address pain should be documented for numerator assessment. This will clarify implementation of the numerator assessment, which will ensure reporting is appropriate and consistent across clinician submissions. Addressing treatment-induced pain improves patients' health, quality of life, and long-term survival,[504] and reduces interruption in radiation therapy due to pain, thereby ensuring treatment compliance.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44428), we are finalizing the changes to measure Q144 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

[504] Konopka-Filippow, M., Polityńska, B., Wojtukiewicz, A. M., & Wojtukiewicz, M. Z. (2025). Cancer Pain: Radiotherapy as a Double-Edged Sword. *International Journal of Molecular Sciences*, *26*(11), 5223. https://doi.org/10.3390/ijms26115223.

D.7 Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure

Category	Description
CBE # / eCQM CBE #:	0114 / N/A
Quality#:	167
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older undergoing isolated coronary artery bypass graft (CABG) surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.
Substantive Change:	**Updated definitions: Added:** **Denominator:** **Baseline serum creatinine** – Most recent creatinine level obtained prior to the operating room entry **Numerator:** **Postoperative period** – Period begins upon operating room exit and continues to discharge from the hospital after cardiac surgery.
Measure Steward:	Society of Thoracic Surgeons
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We proposed adding two definitions to clarify implementation of the denominator exclusion for documented history of baseline serum creatinine and the numerator assessment timeframe for patients who develop postoperative renal failure or require dialysis. The first definition (baseline serum creatinine) will ensure the denominator eligible patient population is appropriately identified, and the second definition (postoperative period) will clarify the numerator assessment timeframe. These additions will ensure appropriate and consistent implementation across clinician submissions.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter strongly supported the substantive changes to measure Q167: *Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure*. The commenter explained these changes were intended to provide greater clarity and promote consistent implementation across clinician submissions. The proposed definitions for baseline serum creatinine and the postoperative period more clearly define the appropriate patient populations and assessment timeframes while maintaining the measure's clinical intent.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44429), we are finalizing the changes to measure Q167 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.8 Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration

Category	Description
CBE # / eCQM CBE #:	0115 / N/A
Quality#:	168
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older undergoing isolated coronary artery bypass graft (CABG) surgery who require a return to the operating room (OR) for mediastinal bleeding with or without tamponade, unplanned coronary artery intervention (native vessel, graft or both), valve dysfunction, aortic reintervention or other cardiac reason during the current hospitalization.
Substantive Change:	**Updated definition: Added:** **Postoperative period –** Period for surgical re-exploration begins upon OR exit and continues to discharge from the hospital after cardiac surgery.
Measure Steward:	Society of Thoracic Surgeons
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We proposed adding a definition of postoperative period to clarify the numerator assessment timeframe, which will ensure appropriate and consistent implementation across clinician submissions.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter strongly supported the substantive changes to measure Q168: *Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration.*

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44429), we are finalizing the changes to measure Q168 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.9 Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	176
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**The measure numerator is revised to read:** Patients for whom any record of TB testing is documented or performed (PPD, Tspot or QuantiFERON-TB Gold Plus) in the medical record in the 12 months preceding the biologic and/or immune response modifier prescription.
Measure Steward:	American College of Rheumatology
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We proposed changes to the measure numerator to clarify the appropriate tests for TB screening to meet the numerator quality action. This revision will ensure the intent of the measure was met and numerator compliance is consistently assessed across all clinician submissions.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the substantive changes to measure Q176: *Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy*. The commenter supported CMS' proposed clarification of which TB tests count toward the numerator, so that only validated tests are recognized, performance is measured consistently, and clinicians using guideline-concordant screening are appropriately credited. The commenter recommended that both the Interferon-Gamma Release Assay (IGRA) and Tuberculin Skin Test (TST) remain specified as acceptable tests and urged CMS to maintain the measure's clinical integrity and support appropriate pre-treatment TB screening.

Response: We thank the commenter for their feedback. We acknowledge the commenter's request that the final specifications fully capture that both IGRA and TST remain specified as acceptable tests; however, the measure steward refined the list to include appropriate TB screenings for clarity and purposes of reporting this measure. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Any potential new substantive changes need to go through notice and comment rulemaking.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44430), we are finalizing the changes to measure Q176 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.10 Rheumatoid Arthritis (RA): Functional Status Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	178
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period.
Substantive Change:	**The measure title is revised from Rheumatoid Arthritis (RA): Functional Status Assessment to:** Rheumatic Disease: Functional Status Assessment. **The measure description is revised to read:** Percentage of patients aged 18 years and older with two or more encounters with a diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA), or systemic lupus erythematosus (SLE) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period. **Updated intent and clinical applicability: Revised:** to include PsA and SLE. **The measure denominator is revised to read:** Patients aged 18 years and older with two or more RA, PsA, or SLE diagnoses documented at least 90 days apart with at least one encounter with an RA, PsA, or SLE diagnosis occurring during the performance period and an additional encounter with an RA, PsA or SLE diagnosis occurring in the performance period or prior performance period. **Updated denominator criteria: Revised:** to include diagnosis coding for PsA and SLE. Added PsA and SLE to the additional encounter criteria. **Updated denominator definition: Revised:** definition for additional encounter to include PsA and SLE. **Updated numerator definition: Revised:** definition for functional status assessment to include PsA and SLE.
Measure Steward:	American College of Rheumatology
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise multiple components of this measure by adding psoriatic arthritis (PsA) or systemic lupus erythematosus (SLE) to ensure that all patients diagnosed with rheumatic disease are included in the measure's denominator. The addition of PsA and SLE to the RA measure improves the comprehensiveness of the measure, aligns with shared disease characteristics and treatment approaches, and ensures appropriate care across rheumatic diseases. In the event the proposed substantive change(s) were finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for the creation of a performance period benchmark, a new benchmark will be used for scoring.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44431), we are finalizing the changes to measure Q178 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.11 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
CBE # / eCQM CBE #:	0565 / 0565e
Quality#:	191
CMS eCQM ID:	CMS133v15
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated value set/coding**: **For the eCQM collection type: Updated:** to a single value set for significant ocular conditions denominator exclusion.
Measure Steward:	American Academy of Ophthalmology
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We proposed to replace the individual condition specific value sets for the ocular conditions denominator exclusion with a single value set of significant ocular conditions to streamline implementation.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44431), we are finalizing the changes to measure Q191 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.12 Controlling High Blood Pressure

Category	Description
CBE # / eCQM CBE #:	NA / N/A
Quality#:	236
CMS eCQM ID:	CMS165v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure, eCQM, Medicare CQM, MIPS CQM, Medicare eCQM collection types.
Measure Steward:	National Committee for Quality Assurance
MIPS Core Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the collection types available for this measure to include the Medicare eCQM collection type to allow choice in submission method for Medicare Shared Savings Program ACOs reporting the APP Plus measure set. See section IV.A.4.d.(1)(c)(v) of this final rule for further information on the Medicare eCQM collection type.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44432), we are finalizing the changes to measure Q236 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.13 Radical Prostatectomy Pathology Reporting

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	250
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.
Substantive Change:	**Updated denominator exclusion**: **For all collection types: Removed:** Specimen site other than anatomic location of prostate. **Updated denominator exception: For all collection types: Added:** Specimen site other than anatomic location of prostate.
Measure Steward:	College of American Pathologists
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to move the denominator exclusion for "Specimen site other than anatomic location of prostate" to the numerator options as a denominator exception. Moving this criteria from a denominator exclusion to a denominator exception will allow for more automated capture of the relevant cases for the measure with less manual intervention required for measure reporting.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44432), we are finalizing the changes to measure Q250 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.14 Dementia: Education and Support of Caregivers for Patients with Dementia

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	288
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
Substantive Change:	**The measure description is revised to read:** Percentage of patients with dementia whose caregiver(s), who are not part of the licensed care team, were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months. **Updated intent and clinician applicability: Added:** whose caregiver(s), who are not part of the licensed care team, were provided with education on dementia disease. **The measure numerator is revised to read:** Patients with dementia whose caregiver(s), who are not part of the licensed care team, were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
Measure Steward:	American Academy of Neurology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of this measure to clarify that the education and support required as part of the numerator quality action is intended for caregivers who are not part of the licensed clinical care team. Consistent with the measure's intent, educating caregivers that are not part of the licensed care team recognizes their essential role in patient care, improves patient-centered care outcomes, enhances caregiver well-being, and strengthens the overall continuity of care across both formal and informal settings.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the substantive changes to measure Q288: *Dementia: Education and Support of Caregivers for Patients with Dementia.* One commenter stated that the measure revisions further recognize unpaid caregivers' essential role in patient care and was grateful for this update. One of the commenters recommended clarifying who is considered an unlicensed caregiver and encouraged future inclusion of multicomponent caregiver supports such as counseling, training, and connections to community services.

Response: We thank the commenters for supporting the substantive changes to this measure. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Any potential new substantive changes need to go through notice and comment rulemaking.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44433), we are finalizing the changes to measure Q288 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.15 Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	291
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for physical therapy.
Measure Steward:	American Academy of Neurology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed adding physical therapy coding as part of the denominator criteria for this measure as it is clinically appropriate for this clinician type to assess patients with a diagnosis of PD for cognitive impairment or dysfunction. Physical therapists play a critical role in identifying functional limitations linked to cognitive decline and tailoring interventions accordingly. These codes recognize that cognitive dysfunction significantly influences physical function and safety, and they integrate the expertise of physical therapists into the multidisciplinary care of PD.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter urged CMS to ensure that expanding clinician eligibility to physical therapists does not blur distinctions between cognitive screening and specialized cognitive interventions for measure Q291: *Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease*. The commenter stated that such interventions require training and expertise not typically covered in physical therapist education and encouraged CMS to consider safeguards that maintain discipline-appropriate care and scope-of-practice standards.

Response: We thank the commenter for the feedback on this measure and for highlighting the importance of maintaining clear distinctions between cognitive screening and specialized cognitive interventions. We acknowledge the commenter's concerns regarding scope of practice and the need to ensure that clinicians performing specialized cognitive interventions have appropriate training and expertise; however, clinicians reporting this measure would need to meet all requirements as specified for numerator compliance. The measure steward has approved inclusion of all added physical therapy coding for this measure, allowing for it to be at the clinician's discretion to choose to report the measure based upon applicability to their scope of care. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Any potential new substantive changes need to go through notice and comment rulemaking.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44433), we are finalizing the changes to measure Q291 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.16 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	317
CMS eCQM ID:	CMS22v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / MIPS CQM
Current Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for physical and occupational therapy.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator criteria to include coding for physical and occupational therapy (PT/OT) as it is clinically appropriate for these clinician types to assess for high blood pressure. By adding PT/OT professionals in this measure, healthcare organizations can help ensure a more inclusive, proactive, and effective approach to managing cardiovascular health in patients aged 18 and older, while also capitalizing on all patient touchpoints to achieve comprehensive wellness and improved health outcomes.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported adding physical therapy and occupational therapy coding, noting that occupational therapy practitioners routinely identify health risks and play an underrecognized role in addressing chronic conditions.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44434), we are finalizing the changes to measure Q317 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.17 Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	336
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breastfeeding evaluation and education, postpartum depression screening, intimate partner violence screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.
Substantive Change:	**The measure numerator is revised to read:** Patients receiving the following at a postpartum visit: • Evaluating the physical recovery from birth, including pain and incontinence • Evaluating and counseling for sleep hygiene and fatigue • Breastfeeding evaluation and education, including patient-reported breastfeeding • Postpartum depression and anxiety screening • Intimate partner violence screening • Postpartum glucose screening for gestational diabetes patients • Family and contraceptive planning counseling, including same-day placement of a long-acting reversible contraceptive (LARC) if desired • Tobacco use screening and cessation education • Substance use disorder /opioid use disorder screening • Physical activity and exercise counseling • Immunization review and update **Updated definitions: Added:** **Evaluating Physical Recovery From Birth –** Patients who were evaluated for physical recovery from birth, including pain and incontinence, with referral as indicated (e.g., to physical therapy, urogynecology). **Evaluating and Counseling for Sleep Hygiene and Fatigue –** Patients were evaluated for sleep hygiene and fatigue and clinicians discussed coping options for fatigue and sleep disruption. **Substance Use Disorder/Opioid Use Disorder Screening –** Patients were screened for substance use/opioid use and referred to postpartum psychosocial support services, including substance use disorder treatment and relapse prevention programs. **Revised:** **Physical Activity and Exercise Counseling –** Patients with uncomplicated pregnancies who were encouraged to undertake regular physical activity and/or to engage in aerobic and strength-conditioning exercises (of any intensity) after pregnancy, as part of efforts to recommend and reinforce a healthy lifestyle. **Postpartum Depression and Anxiety Screening –** added anxiety screening via a self-reported validated anxiety tool. **Updated Numerator Instructions: Revised:** to include evaluating for physical recovery from birth, including pain and incontinence; evaluating and counseling for sleep hygiene and fatigue; postpartum anxiety screening; same-day placement of a long-acting reversible contraceptive (LARC) if desired; substance use disorder /opioid use disorder screening; and physical activity and exercise counseling.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure numerator by adding evaluations for physical recovery from birth, including pain and incontinence; evaluations and counseling for sleep hygiene and fatigue; postpartum anxiety screening; same-day placement of a long-acting reversible contraceptive (LARC) if desired; substance use disorder /opioid use disorder screening; and physical activity and exercise counseling as recommended by The American College of Obstetricians and Gynecologists (ACOG).[505] The additional evaluations provide significant added value to postpartum care by addressing broader aspects of maternal health that may impact recovery, well-being, and long-term outcomes. Additionally, we proposed to reflect this revision in the definitions and numerator instructions sections of the measure to ensure appropriate assessment of quality actions and consistent implementation across clinician submissions.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the substantive changes to measure Q336: *Maternity Care: Postpartum Follow-up and Care Coordination* to include physical activity and exercise counseling.

[505] American College of Obstetricians and Gynecologists. (2018). ACOG Committee Opinion No. 736: Optimizing Postpartum Care. *Obstetrics & Gynecology, 131*(5), e140–e150. https://doi.org/10.1097/AOG.0000000000002633.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44435), we are finalizing the changes to measure Q336 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.18 Closing the Referral Loop: Receipt of Specialist Report

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	374
CMS eCQM ID:	CMS50v15
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.
Substantive Change:	**Updated guidance: For the eCQM collection type: Added:** If two or more referrals have the same date/time stamp and are captured in the denominator as "first" referral, a consultant report for any of these "first" referrals will qualify the patient for the numerator. **Updated denominator criteria: For all collection types: Added:** coding for audiology visits. **Updated logic: For the eCQM collection type: Revised:** numerator logic to capture the 'first referral' when multiple instances of a "first referral" with the same date/time stamp are present.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator criteria to include audiology visits as this measure is applicable to their scope of care. By including audiology visits in the measure, it will ensure that referrals made by audiologists are tracked, especially as specialization continues to increase in the provision of patient care, facilitating better coordination of care. Additionally, we proposed to update the measure guidance and logic for the eCQM collection type to clarify implementation when multiple referrals are received and ensure the logic is aligned. This will ensure consistent reporting across clinician submitters.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44435 through 44436), we are finalizing the changes to measure Q374 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.19 Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
CBE # / eCQM CBE #:	1879 / N/A
Quality#:	383
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.
Substantive Change:	**Updated denominator: Revised:** (Table 1) added oral antipsychotic medications: - pimavanserin - pimozide - olanzapine-fluoxetine - xanomeline-tropisum chloride
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the list of medications used to identify denominator eligible patients by adding four oral antipsychotic medications to the existing list in the denominator. This expansion will provide an up-to-date list of appropriate oral antipsychotic medications that clinicians may have prescribed for their patients, thereby ensuring that as many of the appropriate patients are identified in the denominator of this measure as possible.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44436), we are finalizing the changes to measure Q383 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.20 Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation

Category	Description
CBE # / eCQM CBE #:	2474 / N/A
Quality#:	392
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and sex. • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older
Substantive Change:	**Updated reporting frequency and implementation considerations: Revised:** measure is to be submitted each time a denominator eligible procedure is performed.
Measure Steward:	American College of Cardiology Foundation
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We proposed to update the measure submission frequency to each time a denominator eligible procedure is performed as cardiac tamponade is a life-threatening emergency.[506] Requiring this measure to be submitted for each procedure will ensure MIPS eligible clinicians are monitoring and assessing patients for all instances of cardiac tamponade and/or pericardiocentesis occurring within 30 days following atrial fibrillation ablation, as well as adhering to evidence-based practices, which will improve clinical outcomes for patients. This change reflects a transition towards higher standards of care, increased accountability, and greater alignment with the goals of modern healthcare delivery systems.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44437), we are finalizing the changes to measure Q392 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

[506] Khan Z. (2023). Cardiac Tamponade During Catheter Atrial Fibrillation Ablation: A Life-Threatening Complication. *Cureus*, *15*(9), e44989. https://doi.org/10.7759/cureus.44989.

D.21 Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	393
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Infection rate following CIED device implantation, replacement, or revision.
Substantive Change:	**Updated reporting frequency and implementation considerations: Revised:** measure is to be submitted each time a denominator eligible procedure is performed. **The measure denominator is revised to read:** **For Submission Criteria 1:** All patients with a new CIED from January July 1, 2026, through June 30, 2027, of the performance period. **For Submission Criteria 2:** All patients with replacement or revision of a CIED from July 1, 2026, through June 30, 2027, of the performance period. **Updated denominator definition: Added:** Denominator Identification Period – The twelve month period in which eligible patients have a procedure. The "denominator identification period" includes dates of procedure 7/1/2026 to 6/30/2027.
Measure Steward:	American College of Cardiology Foundation
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We proposed to update the measure submission frequency to each time a denominator eligible procedure is performed as infections resulting from implantable cardiac devices are associated with substantial morbidity. Requiring this measure to be submitted for each procedure will ensure MIPS eligible clinicians are monitoring and assessing patients for all instances of an infection requiring device removal or surgical revision within 180 days following CIED implantation, replacement, or revision, as well as adhering to evidence-based practices, which will improve clinical outcomes for patient. This change reflects a transition towards higher standards of care, increased accountability, and greater alignment with the goals of modern healthcare delivery systems.[507] We also proposed to lengthen the denominator identification period from July of the previous year through June of the measurement period to allow for a full year of denominator eligibility, ensuring the denominator eligible patient population being assessed for the numerator action is complete.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44438), we are finalizing the changes to measure Q393 with modification for the CY 2027 performance period/2029 MIPS payment year and future years. There is a typographical error in the dates given for Submission Criteria 1 denominator, which will be revised to read, "All patients with a new CIED from July 1, 2026, through June 30, 2027, of the performance period."

[507] Lakkireddy, D. R., Rao, A., Theriot, P., Darden, D., Pothineni, N. V. K., Ram, R., Gao, Y. R., Cheung, J. W., & Birgersdotter-Green, U. (2023). Contemporary Management of Cardiac Implantable Electronic Device Infection: The American College of Cardiology COGNITO Survey. *JACC. Advances*, *3*(2), 100773. https://doi.org/10.1016/j.jacadv.2023.100773.

D.22 Lung Cancer Reporting (Biopsy/Cytology Specimens)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	395
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.
Substantive Change:	**Updated denominator exclusion: For all collection types: Removed:** Specimen site other than anatomic location of lung or is not classified as primary non-small cell lung cancer. **Updated denominator exception: For all collection types: Added:** Specimen site other than anatomic location of lung or is not classified as primary non-small cell lung cancer.
Measure Steward:	College of American Pathologists
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to move the denominator exclusion for "specimen site other than anatomic location of lung or is not classified as primary non-small cell lung cancer" to the numerator options as a denominator exception. Moving this criteria from a denominator exclusion to a denominator exception will allow for more automated capture of the relevant cases for the measure with less manual intervention required for measure reporting.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44439), we are finalizing the changes to measure Q395 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.23 Lung Cancer Reporting (Resection Specimens)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	396
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.
Substantive Change:	**Updated denominator exclusion: For all collection types: Removed:** Specimen site other than anatomic location of lung OR classified as non-small cell lung cancer, not otherwise specified (NSCLC-NOS). **Updated denominator exception: For all collection types: Added:** Specimen site other than anatomic location of lung OR classified as NSCLC-NOS.
Measure Steward:	College of American Pathologists
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to move the denominator exclusion for "Specimen site other than anatomic location of lung OR classified as NSCLC-NOS" to the numerator options as a denominator exception. Moving this criteria from a denominator exclusion to a denominator exception will allow for more automated capture of the relevant cases for the measure with less manual intervention required for measure reporting.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44439), we are finalizing the changes to measure Q396 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.24 Melanoma Reporting

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	397
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.
Substantive Change:	**The measure description is revised to read**: **For all collection types:** Pathology reports for primary malignant cutaneous melanoma that include the thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors, and for excisions, pT category. **Updated intent and applicability: For all collection types: Revised:** to clarify pT category reporting is only required for excisions. **Updated denominator instructions: For the MIPS CQM collection type: Removed**: instructions moved to the numerator. **Updated denominator exclusion: For all collection types: Removed:** Specimen site other than anatomic cutaneous location. **The measure numerator is revised to read: For all collection types:** Pathology reports for primary malignant cutaneous melanoma that include the thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors, and in excisions, pT Category. **Updated numerator instructions: For all collection types: Revised:** to clarify pT category reporting is only required for excisions. **Updated numerator options: For all collection types: Revised:** to clarify pT category reporting is only required for excisions. **Updated denominator exception: For all collection types: Added:** Specimen site other than anatomic cutaneous location.
Measure Steward:	College of American Pathologists
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise multiple components of the measure to align with the College of American Pathologists 2025 Protocols[508] [509] and improve the quality of care for melanoma patients by mandating the inclusion of specific, evidence-based pathological parameters in all reports. We are specifically requiring pT category reporting for excisions only. By standardizing and ensuring completeness in pathology reporting, clinicians will significantly enhance diagnostic accuracy, treatment planning, and patient outcomes. Additionally, we proposed to move the denominator exclusion for "Specimen site other than anatomic cutaneous location" to the numerator options as a denominator exception. Moving this criteria from a denominator exclusion to a denominator exception will allow for more automated capture of the relevant cases for the measure with less manual intervention required for measure reporting.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44440), we are finalizing the changes to measure Q397 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

[508] College of American Pathologists. (2025). Protocol for the Examination of Excision Specimens from Patients with Invasive Melanoma of the Skin. https://documents.cap.org/documents/New-Cancer-Protocols-March-2025/Skin.Inv_Melanoma.Res_1.2.0.0.REL.CAPCP.pdf.

[509] College of American Pathologists. (2025). Protocol for the Examination of Biopsy Specimens from Patients with Invasive Melanoma of the Skin. https://documents.cap.org/documents/New-Cancer-Protocols-March-2025/Skin.Inv_Melanoma.Bx_1.1.0.0.REL.CAPCP.pdf.

D.25 Optimal Asthma Control

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	398
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.
Substantive Change:	**Updated numerator and component options: For Submission Criteria 1: Component 1: Removed:** Asthma control Questionnaire (ACQ) **Added:** Asthma Impairment and Risk Questionnaire (AIRQ) and Pediatric Asthma Impairment and Risk Questionnaire (Peds-AIRQ) **Updated numerator note: For Submission Criteria 1: Component 2: Revised:** to base exacerbation on one of two methods. **Added:** Method 2: Asthma Impairment and Risk Questionnaire (AIRQ) result of 0 or 1 – ages 12 and older Pediatric Asthma Impairment and Risk Questionnaire (Peds-AIRQ) result of 0 or 1 – ages 5 – 11 **Updated component options: For Submission Criteria 1: Component 2: Added:** **Performance Met:** Not at elevated risk of exacerbation based on AIRQ or Peds-AIRQ score and results documented **Performance Not Met:** At elevated risk of exacerbation based on AIRQ or Peds-AIRQ score and results documented OR specified asthma control tool not used, reason not given **Updated numerator and component options: For Submission Criteria 2: Component 1: Removed:** Asthma control Questionnaire (ACQ) **Added:** Asthma Impairment and Risk Questionnaire (AIRQ) **Updated numerator note: For Submission Criteria 2: Component 2: Revised:** to base exacerbation on one of two methods. **Added:** Method 2: Asthma Impairment and Risk Questionnaire (AIRQ) result of 0 or 1 – ages 12 and older **Updated component options: For Submission Criteria 2: Component 2: Added:** **Performance Met:** Not at elevated risk of exacerbation based on AIRQ score and results documented **Performance Not Met:** At elevated risk of exacerbation based on AIRQ score and results documented OR specified asthma control tool not used, reason not given
Measure Steward:	Minnesota Community Measurement
MIPS Core Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to remove ACQ tools from the list of acceptable patient-reported outcome tools for all submission criteria. We proposed adding the AIRQ (both submission criteria) and Peds-AIRQ (Submission Criteria 1 only) tools for COMPONENT 1: Asthma well-controlled. Additionally, we proposed adding the AIRQ (both submission criteria) and Peds-AIRQ (Submission Criteria 1 only) tools as a second method for determining exacerbation risk for COMPONENT 2: Patient not at elevated risk of exacerbation. These changes will ensure that the tools used are better suited to current evidence-based practices for asthma management.[510] The AIRQ and Peds-AIRQ tools support the shift toward standardization, accuracy, and relevance in clinical decision-making.[511]

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the substantive changes to measure Q398: *Optimal Asthma Control* to update the list of acceptable patient-reported outcome tools.

Response: We thank the commenter for supporting the substantive changes to this measure.

[510] Murphy, K. R., Chipps, B., Lanz, M. J., Bacharier, L. B., Guilbert, T. W., George, M., Mohammad, A., Winders, T., LeNoir, M., Gilbert, I. A., Eudicone, J. M., Coyne, K. S., Harding, G., & Zeiger, R. S. (2025). Pediatric Asthma Impairment and Risk Questionnaire: A Control Assessment for Children Aged 5 to 11 years. *The Journal of Allergy and Clinical Immunology: In Practice, 13*(10), 2659–2671. https://doi.org/10.1016/j.jaip.2025.06.039.

[511] AstraZeneca. Pediatric Asthma Impairment and Risk Questionnaire. https://www.asthmaresourcecenter.com/home/peds_airq_studies.html.

Comment: One commenter supported the substantive changes to measure Q398 and stated that adding AIRQ and Peds-AIRQ as accepted instruments for both Component 1 (asthma control) and Component 2 (exacerbation risk) directly addresses a gap that the commenter previously raised with QPP's Service Center. The commenter had two clarifications before this change is finalized. First, the commenter wanted to confirm that the AIRQ tool as proposed reflects the same instrument its clients and members are already using in practice, since a mismatch in tool version or scoring methodology at this stage could recreate the same reporting gap in a different form. Second, the commenter also wanted to confirm if CMS is proposing to remove ACQ entirely, not just add AIRQ alongside it, which means practices currently reporting Component 1 or Component 2 using ACQ will need to transition to AIRQ, Peds-AIRQ, or one of the remaining accepted tools (ACT, C-ACT, ATAQ) by the time this change takes effect.

Response: We thank the commentor for the support and feedback on this measure. We are unable to verify alignment with specific instruments used in individual practices. Clinicians should refer to the official AIRQ and Peds-AIRQ materials[512] to ensure they are using the correct versions and scoring methodology. We did propose to remove ACQ entirely. Retiring ACQ in favor of AIRQ/Peds-AIRQ and other validated tools keeps measure Q398 aligned with current clinical science and measurement best practices, improving the measure's ability to capture clinically meaningful asthma control.[513] The measure steward's workgroup determined the AIRQ tools had several advantages including availability and ease of workflow incorporation, as well as accuracy and both risk and impairment assessment ability, which should help with the transition between tools by the time this measure change goes into effect. Eliminating ACQ rather than maintaining multiple overlapping tools also reduces measurement variability and ensures more consistent, interpretable data across clinicians and practices reporting measure Q398.[514]

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44441), we are finalizing the changes to measure Q398 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

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[512] AstraZeneca. Asthma Impairment and Risk Questionnaire. https://www.asthmaresourcecenter.com/.

[513] Murphy, K. R., Chipps, B., Beuther, D. A., Wise, R. A., McCann, W., Gilbert, I., Eudicone, J. M., Gandhi, H. N., Harding, G., Coyne, K. S., Zeiger, R. S., & US PRECISION Advisory Board (2020). Development of the Asthma Impairment and Risk Questionnaire (AIRQ): A Composite Control Measure. *The Journal of Allergy and Clinical Immunology. In Practice*, *8*(7), 2263–2274.e5. https://doi.org/10.1016/j.jaip.2020.02.042.

[514] Streiner, D. L., Norman, G. R., & Cairney, J. (2014). Health Measurement Scales: A Practical Guide to Their Development and Use (5th ed.). Oxford University Press. https://doi.org/10.1093/med/9780199685219.001.0001.

D.26 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v10
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • Patients ≥18 years of age who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent. **Updated rate aggregation: For eCQM collection type: Revised: For Population 1:** Patients greater than or equal to 18 years of age at the beginning of the measurement period were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure before the end of the measurement period. **Updated measure strata and performance rates: For MIPS CQM collection type: Revised: For Submission Criteria 1**: Patients ≥ 18 years of age at the beginning of the performance period and reporting timeframe for diagnosis of clinical ASCVD, including ASCVD procedure. **Updated guidance: For the eCQM collection type: Revised:** age for initial patient population 1 to greater than or equal to 18 years. **Updated initial patient population: For the eCQM collection type: Revised: For population 1:** age greater than or equal to 18 years. **The measure denominator is revised to read: For the MIPS CQM collection type: For Submission Criteria 1:** Patients ≥18 years of age who were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure. **Updated denominator criteria: For the MIPS CQM collection type:** **Revised: For Submission Criteria 1:** age ≥ 18 years at the beginning of the performance period and reporting timeframe for diagnosis of clinical ASCVD, including ASCVD procedure. **Removed**: **For Submission Criteria 3:** presymptomatic diabetes codes. **Updated denominator exclusion: For all collection types: Added: For all Submission Criteria:** Patients who are pregnant at any time during the performance period.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise Patient Population 1 / Submission Criteria 1 for the eCQM and MIPS CQM collection types, to include patients 18 years of age and older who were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure before the end of the performance period to align with the intent of the measure and current guidelines for adults.[515] [516] In addition, we proposed to update

[515] de Ferranti, S. D., Steinberger, J., Ameduri, R., Baker, A., Gooding, H., Kelly, A. S., Mietus-Snyder, M., et al. (2019). Cardiovascular Risk Reduction in High-Risk Pediatric Patients: A Scientific Statement From the American Heart Association. *Circulation, 139*(13). https://doi.org/10.1161/CIR.0000000000000618.

[516] Blumenthal, R., Morris, P., Gaudino, M., et al. (2026). 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on

Category	Description
	the rate aggregation and guidance for the eCQM collection type to align with the updated Patient Population 1. For the MIPS CQM collection type, we are updating the denominator criteria for Submission Criteria 1 with the updated age criteria. These updates aim to refine the population targeted by the measure and enhance alignment with clinical guidelines.[517] Additionally, we proposed to remove patients with presymptomatic diabetes from the denominator of Patient Population 3 / Submission Criteria 3 to focus on patients with established clinical diagnoses rather than those at risk or presymptomatic. Evidence suggests that use of statins may increase the risk of progression of prediabetes to type 2 diabetes.[518] Excluding these patients from Submission Criteria 3 will allow clinicians to use their clinical judgement and appropriately prescribe statin therapy to those patients who will benefit most without affecting their performance on the measure. We also proposed to add patients who are pregnant to the denominator exclusions, for all collection types, to align with current recommendations. It is recommended that patients stop statin therapy as soon as pregnancy is discovered.[519] Excluding pregnant patients will allow clinicians to align with evidence-based practices, ensuring safe and appropriate care for this patient population, without affecting their performance on the measure. We proposed to revise the measure description for all collection types, to improve the clarity, clinical utility, and applicability of the measure by explicitly defining high-risk patient populations. These enhancements aim to ensure more accurate identification of eligible patients, assess appropriate use of statin therapy, and ultimately drive improvements in cardiovascular health outcomes.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the substantive changes to measure Q438: *Statin Therapy for the Prevention and Treatment of Cardiovascular Disease*. One of the commenters requested that CMS ensure the final specifications capture the full range of clinical ASCVD recognized in current guidelines, including coronary, cerebrovascular, and peripheral arterial disease, while preserving shared decision-making and clinical judgment. Another commenter asked if CMS would look at denominator exception criteria logic that is not dependent on a specific statin or statin level for exception from the measure.

Response: We thank the commenters for supporting the substantive changes to this measure. We acknowledge the commenter's request that the final specifications fully capture the range of clinical ASCVD recognized in current guidelines (including coronary, cerebrovascular, and peripheral arterial disease) while preserving shared decision-making and clinical judgment. We will review and discuss revisions to the denominator exception for possible implementation in future years as it would be substantive in nature and would, therefore, need to go through public notice and comment.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44442 through 44443), we are finalizing the changes to measure Q438 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

Clinical Practice Guidelines. *Journal of the American College of Cardiology*, 0(0). https://doi.org/10.1016/j.jacc.2025.11.016.

[517] See footnote Blumenthal et al., 2026.

[518] See footnote Blumenthal et al., 2026.

[519] See footnote Blumenthal et al., 2026.

D.27 Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	440
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.
Substantive Change:	**The measure description is revised to read:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 5 business days from the time when the tissue specimen was received by the pathologist. **The measure numerator is revised to read:** Number of final pathology reports diagnosing cutaneous basal cell carcinoma or squamous cell carcinoma or melanoma (to include in situ disease) sent from the Pathologist/Dermatopathologist to the biopsying clinician for review within 5 business days from the time when the tissue specimen was received by the pathologist. **Updated the numerator option**: **Revised:** to within 5 business days.
Measure Steward:	American Academy of Dermatology
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We proposed revising multiple components of this measure to clarify the timing of when a pathologist must communicate the results to the biopsying clinician. Reporting the results within 5 business days will enable clinicians to make timely decisions regarding patient management, scheduling surgeries or therapies, and planning follow-up consultations.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the substantive change to measure Q440: *Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician*, agreeing that the updated timeframe to 5 business days enables timely care decisions and aligns with an existing QCDR measure, AAD6: *Skin Cancer: Biopsy Reporting Time – Clinician to Patient.*

Response: We thank the commenter for supporting the substantive change to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44444), we are finalizing the changes to measure Q440 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.28 Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	441
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 130/80 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • High Intensity Statin Use Unless Contraindicated
Substantive Change:	**Updated the measure strata and performance rates: Revised:** a patient will only be included in Submission Criteria 2 of the measure if they meet the denominator criteria for both Submission Criteria 1 and Submission Criteria 2.
Measure Steward:	Wisconsin Collaborative for Healthcare Quality
MIPS Core Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to revise the measure strata and performance rates to clarify how to handle scenarios in which the patient meets denominator criteria for both Submission Criteria 1 and Submission Criteria 2. This change will ensure consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44444), we are finalizing the changes to measure Q441 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.29 Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)

Category	Description
CBE # / eCQM CBE #:	0210 / N/A
Quality#:	453
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.
Substantive Change:	**The measure title is revised from 'Percentage of Patients who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)' to:** Percentage of Patients who Died with Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better) **The measure description is revised to read:** Percentage of patients, aged 18 years and older, who died with cancer receiving systemic cancer-directed therapy in the last 14 days of life. **Updated intent and clinician applicability: Revised:** patients aged 18 years and older. **Updated Implementation Considerations: Revised:** Measure type revised to Intermediate Outcome. **Updated denominator note: Revised:** The patient must have two encounters during the performance period and both eligible encounters must include a diagnosis of cancer. **The measure denominator is revised to read:** Patients, aged 18 years and older, who died with cancer. **Updated denominator criteria:** **Revised:** Patients aged ≥ 18 years and Diagnosis for cancer during the encounter. **Added:** Patients who died during performance period. **Removed:** Patients who died from cancer. **Updated denominator exclusion: Added:** Patients given hydroxyurea or bruton tyrosine kinase (BTK) inhibitors. **Updated numerator definition: Revised:** **Systemic Cancer-directed Therapy –** Includes: ▪ Cytotoxic chemotherapy ▪ Drugs and biologics which activate or inhibit the hallmarks of cancer (e.g., kinase inhibitors) ▪ Antineoplastic Agents • Alkylating agents (id: L01A) • Antimetabolites (id: L01B) • Cytotoxic antibiotics and related substances (id: L01D) • Monoclonal antibodies and antibody drug conjugates (id: L01F) • Other antineoplastic agents (id: L01X) • Plant alkaloids and other natural products (id: L01C) • Protein kinase inhibitors (id: L01E) o Exclude: Cyclin-dependent kinase (CDK) inhibitors (id: L01EF) ▪ Immunostimulants (Includes only those that apply to cancer) • Interferons (id: L03AB) o Include only: interferon alfa-2b, ropeginterferon alfa-2b, and ropeginterferon alfa-2b-njft • Interleukins (id: L03AC) o Include only: aldesleukin • Other immunostimulants (id: L03AX) o Include only: sipuleucel-T ▪ Immunosuppressants (Includes only those that apply to cancer) • Selective immunosuppressants (id: L04AA) o Include only: alemtuzumab, everolimus, and sirolimus • Other immunosuppressants (id: L04AX) o Include only: lenalidomide, pomalidomide, and thalidomide Excludes: • Hormones and hormone antagonists • Red Blood Cell (RBC) growth factors used to treat chemotherapy-induced anemia • White Blood Cell (WBC) growth factors used to treat chemotherapy-induced neutropenia • Bisphosphonates and biologics used to treat osteopenia or osteoporosis • Antiemetics and antinauseants • Pain medications Example: Drugs and biologics under the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification "Antineoplastic Agents" and select "Immunostimulants" and "Immunosuppressants".

Category	Description
	"Antineoplastic and Immunomodulating Agents" Drug Classes and Identifiers: Note: To find the drug members under each class, go to https://mor.nlm.nih.gov/RxClass/ and enter the class name or ID on the "Search" field of the RxClass browser. **Updated numerator instructions: Added:** • Receipt of systemic cancer-directed therapy in the last 14 days of life can be calculated as follows: • (Date of death minus Most Recent Systemic cancer-directed therapy Administration Date or Date Filled) < 14 days. **Updated numerator note: Added:** The measure includes intramuscular, intravenous, oral, and subcutaneous routes of administration of systemic cancer-directed therapy. Oral systemic cancer-directed therapy is oral prescription of extension of same oral drug or prescription of new oral drug. The measure is limited to medications approved by the United States Food and Drug Administration (FDA). Patients that are given bridging chemotherapy and other cancer-directed therapies while awaiting transplant or chimeric antigen receptor T-cell therapy (CAR T-cell therapy) should be reported as a denominator exception. For patients given Hydroxyurea and bruton tyrosine kinase (BTK) inhibitors, it may be inappropriate to withdraw at the end of life and/or are used for palliative purposes. For the purposes of reporting this inverse quality measure, this scenario is considered "performance not met" only in the absence of other systemic therapies. **Updated denominator exception: Added:** Patient received systemic cancer-directed therapy due to 1) receipt or in process of receipt of bone marrow or peripheral blood stem cell transplant (transplant status) in the last 60 days of life, or 2) receipt or in process of receipt of CAR T-cell therapy in the last 60 days of life. **Updated numerator options: Added:** **Performance Not Met:** Patients given hydroxyurea or BTK inhibitors.
Measure Steward:	American Society of Clinical Oncology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of this measure to ensure the appropriate patient population is identified by including an age, defined encounter eligibility, and additional guidance for defining the eligible patient population. We proposed revising the measure type to intermediate outcome to be reflective of the quality action. Additionally, we proposed adding a denominator exclusion for common drugs given for palliation or to prevent rapid disease acceleration at the end of life as recommended by ASCO's End of Life Technical Expert Panel as this conflicts with the measure's intent. We proposed adding further clarification and granularity to the numerator definition of systemic cancer-directed therapy to ensure numerator assessment is consistent across clinician submissions. Additionally, we proposed adding a denominator exception to remove patients receiving bone marrow or peripheral blood stem cell transplant, or CAR T-cell therapy as these patients are appropriately given bridging chemotherapy and other types of cancer-directed therapy beforehand. We proposed these changes to better align with the intent of the measure and to ensure consistent implementation across submissions. In the event the proposed substantive change(s) were finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for the creation of a performance period benchmark, a new benchmark will be used for scoring.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed denominator exceptions to measure Q453: *Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)* and encouraged CMS to periodically reassess these specifications as cell-therapy technologies evolve to ensure that quality measures do not become inadvertently tethered to an outdated description of the relevant therapeutic modalities. Another commenter urged CMS to consider adding a secondary 30-day measurement period in addition to the existing 14-day period, stating that a 30-day measure could more effectively prompt timely transitions to palliative care, support improved symptom management, and provide a more complete picture of end-of-life care for patients dying of cancer.

Response: We thank the commenters for supporting the substantive changes to this measure. We encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years. In addition, we complete measure analysis to evaluate measure performance, identify potential unintended consequences, assess alignment with current clinical guidelines and evidence, and determine whether technical or substantive updates are needed for future performance periods, which we recommend to measure stewards for their consideration. Any potential new substantive changes need to go through notice and comment rulemaking.

After consideration of public comments, we are finalizing the changes to measure Q453 with modification for the CY 2027 performance period/2029 MIPS payment year and future years. The proposal to "**Updated denominator exclusion: Added:** Patients given hydroxyurea or bruton tyrosine kinase (BTK) inhibitors" is duplicative of the proposed numerator revision **"Updated numerator options: Added: Performance Not Met:** Patients given hydroxyurea or BTK inhibitors." While administration of these drugs appears discordant with the measure intent, it may be inappropriate to withdraw at the end of life. Therefore, it would be appropriate to include patients receiving these medications in the eligible patient population to ensure they are assessed for utilization of other systemic therapies. For this inverse measure, appropriate use of hydroxyurea or BTK inhibitors would be reported as Performance Not Met, indicating better quality care.

D.30 Percentage of Patients who Died from Cancer Admitted to Hospice for less than 3 Days (lower score – better)

Category	Description
CBE # / eCQM CBE #:	0216 / N/A
Quality#:	457
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of Patients who Died from Cancer Admitted to Hospice for less than 3 Days (lower score – better)
Substantive Change:	**The measure title is revised from Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better) to:** Percentage of Patients who Died with Cancer Enrolled in Hospice For At Least 3 Days Immediately Before Death. **The measure description is revised to read:** Percentage of patients, aged 18 years and older, who died with cancer and were enrolled in hospice for at least 3 days immediately before and on date of death. **Updated Implementation Considerations: Revised:** Measure analytic to no longer be inverse and measure type to Intermediate Outcome. **The measure denominator is revised to read:** Patients, aged 18 years and older, who died with cancer. **Updated denominator note: Revised:** The patient must have two encounters during the performance period and both eligible encounters must include a diagnosis of cancer. **Updated denominator criteria:** **Revised:** Patients aged ≥ 18 years and Diagnosis for cancer during the encounter. **Removed:** Patients enrolled in hospice and Patients who died from cancer. **Added:** Patients who died during performance period. **The measure numerator is revised to read:** Patients enrolled in hospice for at least 3 days immediately before and on the date of death. **Updated numerator instructions: Removed:** Inverse measure analytic **Added:** • Patients should be currently enrolled in hospice on date of death to meet the numerator. • Enrolled in hospice for at least 3 days immediately before death can be calculated as follows: • (Date of death minus Most Recent Date of Hospice Admission) ≥ 3 days **Updated numerator note: Added:** • Receipt of or in the process of receipt of bone marrow transplant, peripheral blood stem cell transplant, or CAR T-cell therapy are typically not covered in hospice but may be appropriate for select patients at the end of life. In these scenarios, the denominator exception should be reported. • It may be inappropriate to withdraw Hydroxyurea and bruton tyrosine kinase (BTK) inhibitors at the end of life and/or are used for palliative purposes, however these treatments are not covered by hospice. In this situation, the denominator exception should be reported. **The measure numerator options are revised to read**: **Performance Met:** Patient enrolled in hospice for at least 3 days immediately before and on the date of death. **Denominator Exception:** Patient not enrolled in hospice due to 1) receipt or in process of receipt of bone marrow or peripheral blood stem cell transplant (transplant status) in the last 60 days of life, or 2) receipt or in process of receipt of CAR T-cell therapy in the last 60 days of life. **Denominator Exception:** Patients given hydroxyurea or BTK inhibitors. **Performance Not Met:** Patient enrolled in hospice less than 3 days immediately before death or on date of death.
Measure Steward:	American Society of Clinical Oncology
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the measure type to intermediate outcome and to allow for a proportional non-inverse analytic for the purpose of determining measure performance. We proposed these changes to better align with the intent of the measure and to provide a performance rate reflective of appropriate resource utilization. We proposed to update multiple components of this measure to ensure the appropriate patient population is identified by including an age, defined encounter eligibility, and additional guidance for defining the eligible patient population. We also proposed to update the numerator options to align with a proportional non-inverse measure analytic such that a higher score indicates better quality care; and add denominator exceptions to remove patients 1) receiving bone marrow or peripheral blood stem cell transplant, or CAR T-cell therapy or 2) receiving drugs for palliation or to prevent rapid disease acceleration at the end of life as recommended by ASCO's End Of Life Technical Expert Panel. We proposed these changes to better align with the intent of the measure and to ensure consistent implementation across clinician submissions.

Category	Description
	In the event the proposed substantive change(s) are finalized, the substantive changes will not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for the creation of a performance period benchmark, a new benchmark will be used for scoring.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposed denominator exceptions to measure Q457: *Percentage of Patients who Died from Cancer Admitted to Hospice for less than 3 Days (lower score – better)* and encouraged CMS to periodically reassess these specifications as cell-therapy technologies evolve to ensure that quality measures do not become inadvertently tethered to an outdated description of the relevant therapeutic modalities. Another commenter urged CMS to extend the measurement window to include hospice lengths of stay of less than seven days, noting that the current three-day window captures only the most extreme cases of late referrals. The commenter stated that evidence consistently shows longer hospice stays are associated with improved symptom control, higher patient and family satisfaction, fewer in-hospital deaths, and lower end-of-life expenditures, while shorter stays are a marker of poorer-quality care.

Response: We thank the commenters for supporting the substantive changes to the measure. We encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years. In addition, we complete measure analysis to evaluate measure performance, identify potential unintended consequences, assess alignment with current clinical guidelines and evidence, and determine whether technical or substantive updates are needed for future performance periods, which we recommend to measure stewards for their consideration. Any potential new substantive changes need to go through notice and comment rulemaking.

Comment: One commenter indicated that the revisions to measure Q457 are substantial enough to limit comparability with historical performance. The commenter noted that changes to the measure name, type, denominator specifications, denominator exceptions, and directionality would affect interpretation, scoring, benchmarking, and communication to clinicians. They recommended that CMS treat measure Q457 as a new measure for the 2027 performance year and apply the corresponding new-measure policies for benchmarking and scoring.

Response: We thank the commenter for their feedback and acknowledge that the data would not be comparable to previous years; therefore, we will remove the historical benchmark. While the analytic of the measure has changed, the intent and quality action being assessed remains consistent and doesn't constitute a need to classify this as a new quality measure. In addition, as this measure concept has shown sufficient adoption in MIPS, the new measure benchmarking and scoring would not be appropriate.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44447 through 44448), we are finalizing the changes to measure Q457 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.31 Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use

Category	Description
CBE # / eCQM CBE #:	0657 / N/A
Quality#:	464
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.
Substantive Change:	**The measure description is revised to read**: Percentage of patients aged 2 months through 12 years with a diagnosis of otitis media with effusion (OME) who were not prescribed systemic antimicrobials within 3 months of diagnosis. **Updated implementation and considerations: Revised:** 90 days to 3 months. **The measure numerator is revised to read:** Patients who were not prescribed systemic antimicrobials within 3 months of diagnosis. **Updated numerator options**: **Revised:** to include timeframe of within 3 months of diagnosis.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of the measure by adding "within 3 months of diagnosis" to clarify the timeframe during which systemic antimicrobials were not prescribed to patients. This clarification, based on AAO-HNS's Clinical Practice Guideline on Otitis Media with Effusion (Update),[520] will ensure the numerator quality action is appropriately and consistently assessed.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter did not support the substantive change modifying the timeframe from 90 days to 3 months, stating that the current 90-day period is clearer and supports consistent interpretation for measure Q464: *Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use*.

Response: We thank the commenter for the feedback on the substantive change to the measure. The language change from 90 days to 3 months is in accordance with current clinical practice guidelines,[521] where they recommend watchful waiting for 3 months after onset/diagnosis, ensuring the patient population is consistently and appropriately assessed for numerator compliance. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Any potential new substantive changes need to go through notice and comment rulemaking.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44449), we are finalizing the changes to measure Q464 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

[520] Rosenfeld, R. M., Shin, J. J., Schwartz, S. R., Coggins, R., Gagnon, L., Hackell, J. M., Hoelting, D., Hunter, L. L., Kummer, A. W., Payne, S. C., Poe, D. S., Veling, M., Vila, P. M., Walsh, S. A., & Corrigan, M. D. (2016). Clinical Practice Guideline: Otitis Media with Effusion (Update). *Otolaryngology--Head and Neck Surgery: Official Journal of American Academy of Otolaryngology-Head and Neck Surgery*, *154*(1 Suppl), S1–S41. https://doi.org/10.1177/0194599815623467.

[521] See footnote Rosenfeld et al., 2016.

D.32 HIV Screening

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	475
CMS eCQM ID:	CMS349v9
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human immunodeficiency virus (HIV).
Substantive Change:	**Updated initial patient population: Removed:** without an HIV diagnosis prior to the start of the measurement period.
Measure Steward:	Centers for Disease Control and Prevention
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the initial patient population language to better align with the logic of the measure as this patient population is removed by the denominator exclusion: Patients diagnosed with HIV prior to the day of the start of the measurement period.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter urged CMS not to remove the exclusion for patients with a prior HIV diagnosis, since screening measures are intended to identify undiagnosed infection and it is clinically inappropriate to "screen" patients already known to have HIV. The commenter was concerned that this change would misalign the measure with guideline-defined screening populations, distort performance results, and could drive redundant testing of patients already in HIV care without improving detection of new infections. The commenter recommended retaining the current exclusion and, if CMS seeks to achieve a different objective (such as targeted testing in specific groups), developing a separate measure designed for that purpose, while ensuring any changes keep measure Q475: *HIV Screening* aligned with screening guidelines and strengthen its role in promoting broad, guideline-concordant HIV screening.

Response: We thank the commentor for their feedback on the substantive change and note this revision addresses duplicative criteria but doesn't change the patient population being assessed. This change does not modify the denominator exclusion, rather it removes the redundancy from the initial population. The denominator exclusion already ensures all patients being assessed don't have an HIV diagnosis and will remain as "Patients diagnosed with HIV prior to the day of the start of the measurement period" within the measure specifications.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44450), we are finalizing the changes to measure Q475 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.33 Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	476
CMS eCQM ID:	CMS771v8
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Substantive Change:	**The measure description is revised to read:** Percentage of patients with an office visit during the measurement period and a new diagnosis of clinically significant benign prostatic hyperplasia (BPH) who have International Prostate Symptom Score (IPSS) or American Urological Association Symptom Index (AUA-SI) documented within one month of diagnosis and again 6-12 months after diagnosis, with an improvement of at least 3 points. **The measure numerator is revised to read:** Patients with an improvement of at least 3 points in their IPSS or AUA-SI urinary symptom score from baseline to the 6-12 month follow-up assessment.
Measure Steward:	Large Urology Group Practice Association and Oregon Urology Institute
MIPS Core Measure:	No
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to revise both the description of the measure and the numerator to include specific timeframes for completion of the assessments. By explicitly detailing timeframes (baseline within one month of diagnosis and follow-up assessment within 6–12 months) and the outcome metric (3-point improvement), the measure reduces ambiguity in performance measurement and ensures consistency in reporting.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter encouraged CMS to consider allowing the documentation of patient preference when symptoms are stable and treatment escalation is not desired to ensure goal concurrent care.

Response: We thank the commenter for their feedback on this measure. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Any potential new substantive changes need to go through notice and comment rulemaking.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44450), we are finalizing the changes to measure Q476 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.34 Hospital-wide, 30-day, All-cause Unplanned Readmission (HWR) Rate for the Merit-based Incentive Payment System (MIPS) Groups

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	479
CMS eCQM ID:	N/A
Current Collection Type:	Administrative Claims
Current Measure Description:	This measure is a re-specified version of the measure, "Risk-adjusted readmission rate (RARR) of unplanned readmission within 30 days of hospital discharge for any condition" (NQF 1789), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to MIPS participating clinician groups and assesses each group's readmission rate. The measure comprises a single summary score, derived from the results of five models, one for each of the following specialty cohorts (groups of discharge condition categories or procedure categories): medicine, surgery/gynecology, cardio-respiratory, cardiovascular, and neurology.
Substantive Change:	**Updated denominator exclusion: Removed:** With a principal or a secondary diagnosis code of COVID-19 coded as present on admission (POA) on the index admission claim.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We proposed to remove the exclusion for admissions with either a principal or secondary diagnosis of COVID–19 present on admission from the measure denominator due to the end of the public health emergency. This change will align this measure with language finalized under the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule (90 FR 36948 through 36950).

We received public comments on the substantive change proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the substantive change to measure Q479: *Hospital-wide, 30-day, All-cause Unplanned Readmission (HWR) Rate for the Merit-based Incentive Payment System (MIPS) Groups*, stating that the change will improve consistency in specifications and enhance comparability of performance results across MIPS groups.

Response: We thank the commenter for supporting the substantive change to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44451), we are finalizing the change to measure Q479 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.35 Intravesical Bacillus-Calmette-Guerin for Non-Muscle Invasive Bladder Cancer

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	481
CMS eCQM ID:	CMS646v7
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.
Substantive Change:	**Measure description is revised to read:** Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of initial diagnosis of bladder cancer. **Updated denominator exclusion: Revised:** timing is centered around diagnosis. **Updated numerator: Revised:** timing is centered around diagnosis. **Updated denominator exception: Revised:** timing is centered around diagnosis. **Updated logic and logic definitions: Revised:** timing is centered around diagnosis.
Measure Steward:	Oregon Urology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to update multiple components of the measure to clarify that the timing for receipt of intravesical BCG is based on the initial diagnosis of bladder cancer and not staging. The revision to base the timing of intravesical BCG administration on the initial diagnosis of bladder cancer enhances clinical clarity, promotes consistency in care measurement and measure reporting, and encourages more timely treatment, all of which contributes to improved patient care.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44451), we are finalizing the changes to measure Q481 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.36 Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status

Category	Description
CBE # / eCQM CBE #:	3661 / N/A
Quality#:	491
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both.
Substantive Change:	**Updated denominator criteria: Added:** coding to diagnosis criteria for genetic susceptibility.
Measure Steward:	College of American Pathologists
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We proposed adding additional codes to the denominator criteria for genetic susceptibility as it will ensure better targeting of high-risk populations, optimize resources, and contribute to improved patient outcomes and data reliability for cancer care.[522]

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44452), we are finalizing the changes to measure Q491 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

[522] Robson, M. E., Storm, C. D., Weitzel, J., Wollins, D. S., & Offit, K. (2015). American Society of Clinical Oncology Policy Statement Update: Genetic and Genomic Testing for Cancer Susceptibility. *Journal of Clinical Oncology, 33*, 3660–3667. https://doi.org/10.1200/JCO.2015.63.0996.

D.37 Preventive Care and Wellness (composite)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	497
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).
Substantive Change:	**Updated numerator definition: For Submission Criteria 3: Added: Reviewed** – to meet the quality action, there must be documentation in the medical record that the clinician reviewed the mammography report. The mammography report may also be provided by the patient for the clinician's review during the visit and should be documented in the medical record. **Updated numerator definition: For Submission Criteria 4: Added: Reviewed** – to meet the quality action, there must be documentation in the medical record that the clinician reviewed the colorectal screening report. The colorectal screening report may also be provided by the patient for the clinician's review during the visit and should be documented in the medical record. **Updated denominator criteria: For Submission Criteria 7: Added:** coding for physical and occupational therapy.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure numerator definition for Submission Criteria 3 and 4, the medical record must document the clinician's review of the mammography or colorectal screening report, whether obtained directly or provided by the patient, during the visit. By specifying that the review should be documented in the medical record, the measure ensures clinicians are confirming review of mammography and colorectal screening results, not just receipt, and the measure encourages standardization in documentation practices across different clinical settings, which promotes care coordination and appropriate patient follow-up if needed. We also proposed to update the denominator criteria for Submission Criteria 7 with physical and occupational therapy codes to align with the eCQM measure specifications. By adding PT/OT coding in this measure, healthcare organizations can help ensure a more inclusive, proactive, and effective approach to managing cardiovascular health, while also capitalizing on all patient touchpoints to achieve comprehensive wellness and improve health outcomes.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the substantive changes to measure Q497: *Preventive Care and Wellness (composite)*, Submission Criteria 4, noting the changes align with those made to measure Q113: *Colorectal Cancer Screening*. The commenter noted, however, that the measure did not recognize all FDA-approved, Medicare-covered colorectal cancer screening options, specifically blood-based tests and stool RNA tests. The commenter recommended that CMS work with NCQA to ensure that colorectal cancer screening quality measures used across CMS programs incorporate all FDA-authorized, Medicare-covered screening tests. A second commenter noted that the measure still relies on an outdated definition of "appropriate" screening based on old USPSTF recommendations that exclude newer FDA-approved, Medicare-covered tests and recommended updating measures Q497 and Q113 to reflect current coverage and clinical practice guidelines.

Response: We thank the commenters for supporting the substantive changes to this measure. We will review and discuss this revision for possible implementation in future years as it would be substantive in nature and would therefore need to go through public notice and comment. We encourage the commenter to reach out to the measure steward of measure Q113 to discuss revisions for possible implementation and application to measure Q497 in future years.

Comment: Two commenters opposed the proposed updates to the numerator definitions for Submission Criteria 3 (Breast Cancer Screening) and 4 (Colorectal Cancer Screening). They emphasized that adding a requirement for explicit documentation that the clinician "reviewed" the mammography or colorectal cancer screening report would create additional administrative burden without meaningful clinical benefit. Commenters noted that when screening results are already available in the electronic health record, reviewing those results is part of routine clinical workflow. Introducing a separate attestation or specific notation of review solely for reporting purposes adds unnecessary documentation steps for clinicians and staff. Commenters also expressed concern that expanding the numerator definition beyond the original intent of the measure could lead to unintended consequences. Because the lookback period for colorectal cancer screening can extend up to 10 years, commenters cautioned that it is unlikely prior reviews and discussions are documented in an accessible way. As a result, clinicians may feel compelled to order repeat mammograms or colorectal screenings not because they are clinically indicated, but to satisfy measure requirements. They noted that this could lead to overuse of screening procedures, patient confusion, and unnecessary alarm, especially if

physicians must discuss old test results ordered or reviewed by other providers. Lastly, one of the commenters recommended that CMS consider including patient refusal as an exception in the future.

Response: We appreciate the feedback on measure Q497 on Submission Criteria 3 and 4. The added definition of "reviewed" is intended to clarify, not expand, the original measure intent by specifying that review of a mammography or colorectal cancer screening report includes documenting that review in the medical record, consistent with usual clinical practice. There are a multitude of benefits for both the patient and provider in having a clinician review, discuss, and document the results/findings and discussion, including but not limited to, supporting shared decision-making[523] and ensuring continuity of care.[524] Screening decisions should continue to be based on clinical judgment, evidence-based guidelines, and patient preferences. While in healthcare it is standard practice to document care provided to a patient, including documenting a discussion upon the review of results/findings of a medical test or exam, the measure specification does not dictate the format or structure of such documentation. We encourage the commenters to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44453), we are finalizing the changes to measure Q497 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

[523] Schrager, S. B., Phillips, G., & Burnside, E. (2017). A Simple Approach to Shared Decision Making in Cancer Screening. *Family Practice Management, 24*(3), 5–10. https://pmc.ncbi.nlm.nih.gov/articles/PMC5697707/.
[524] National Comprehensive Cancer Network. (2025). NCCN Guidelines for Patients®: Breast Cancer Screening and Diagnosis (Version 2.2025). https://www.nccn.org/patients/guidelines/content/PDF/breastcancerscreening-patient.pdf.

D.38 Reduction in Suicidal Ideation or Behavior Symptoms

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	505
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.
Substantive Change:	**The measure description is revised to read**: The percentage of patients aged 12 years and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale 'Screen Version' or 'Since Last Visit' (C-SSRS), or other clinician rating tools such as the Clinician Rating of Potential Suicide Risk (CRPSR) or the Suicide Assessment Five-step Evaluation & Triage (SAFE-T) protocol with C-SSRS, within 120 days after an index assessment. **The measure denominator is revised to read**: Patients aged 12 and older with a mental and/or substance use disorder with an index assessment completed who were identified as having suicidal ideation and/or behavior symptoms as determined by a non-zero score on the patient-rated C-SSRS OR deemed a suicide risk based on their clinician's evaluation using a clinician rating tool such as the CRPSR or the SAFE-T protocol with C-SSRS during the denominator identification period. **Updated denominator definitions: Revised:** **Suicide risk based on clinician rating tool –** clarified suicide risk to be based on a clinician-rating tool, which may be C-SSRS or other. **Denominator Identification Period** and **Index Assessment –** updated to reflect use of other clinician-rating tools. **Updated the denominator criteria: Revised:** age to 12 **Removed:** 'Suicidal Ideation and/or Behavior Symptoms based on the C-SSRS' and 'Suicide risk based on their clinician's evaluation or a clinician-rated tool' **Revised:** index assessment criteria to reflect use of other clinician-rating tools. **The measure numerator is revised to read**: Patients who demonstrated a reduction in suicidal ideation and/or behavior symptoms as demonstrated by results of a follow-up assessment using the patient-rated C-SSRS OR reduction in suicide risk based on their clinician's evaluation using a clinician rating tool such as the CRPSR or the SAFE-T protocol with C-SSRS, within 120 days after the index assessment during the measurement period. **Updated numerator definitions: Revised:** **Reduction –** to account for use of other clinician-rating tools. **Follow-up Assessment –** to account for use of other clinician-rating tools and require consistency in index and follow-up assessment.
Measure Steward:	American Psychiatric Association
MIPS Core Measure:	No
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We proposed to update multiple components of the measure to lower the denominator eligible age to 12 years and older and expand the denominator requirements to allow use of other clinician-rating tools for the index assessment and follow-up, to ensure inclusion of a critical demographic group in suicide prevention and substance use disorder interventions. This measure enhances alignment with CMS' mental health priorities, leverages validated tools like the C-SSRS and promotes actionable insights into improved care outcomes for a vulnerable population. We also proposed to update the numerator definition to clarify that the same patient-rated C-SSRS or clinician rating tool must be used at a follow-up encounter after the index assessment. This will ensure consistent implementation and ensure direct comparability of data between assessments.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter encouraged CMS and the measure steward to reevaluate whether the current methodology for defining improvement accurately reflects clinically meaningful changes in suicide risk for measure Q505: *Reduction in Suicidal Ideation or Behavior Symptoms*.

The measure defines improvement as any reduction in the total C-SSRS score, calculated as the sum of all Yes/No responses (Yes = 1, No = 0), with performance met when the follow-up score is lower than the index score. However, in clinical practice, clinicians primarily rely on the C-SSRS to assess and interpret suicide risk rather than to calculate or trend a total numerical score. As a result, clinicians and health IT systems may not routinely display, track, or act upon changes in the cumulative score required for measure reporting. The commenter encouraged CMS and the measure steward to consider whether future

refinements should incorporate changes in clinically validated risk categories, item-level weighting, or other approaches that better reflect meaningful changes in suicide risk. At a minimum, CMS should evaluate whether the current score-based methodology accurately captures the measure's stated intent of reducing suicidal ideation and behavior symptoms while maintaining consistency with real-world clinical workflows and suicide risk assessment practices.

Response: We thank the commentor for their feedback regarding the substantive changes to this measure. The intent of the measure was not changed with these revisions; rather, we streamlined and clarified the components to support more consistent and efficient implementation. We also considered the need for the measure to be feasible within the program's reporting structure and to generate meaningful, actionable metrics. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. In addition, we complete measure analysis to evaluate measure performance, identify potential unintended consequences, assess alignment with current clinical guidelines and evidence, and determine whether technical or substantive updates are needed for future performance periods, which we recommend to measure stewards for their consideration. Any potential new substantive changes will need to go through notice and comment rulemaking.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44454), we are finalizing the changes to measure Q505 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.39 Appropriate Germline Testing for Ovarian Cancer Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	507
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients, aged 18 and older, diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of diagnosis.
Substantive Change:	**Updated denominator criteria**: **Removed:** Audio only Telehealth codes.
Measure Steward:	American Society of Clinical Oncology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove audio only visits from the denominator criteria because they lack the visual assessment necessary to confirm a patient's physical condition (e.g., performance status; physical signs of toxicity, pain, and distress) and the physical assessment required by the clinician providing the care and responsible for conducting germline testing.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the substantive changes to measure Q507: *Appropriate Germline Testing for Ovarian Cancer Patients*.

Response: We thank the commenter for supporting the substantive changes to this measure.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44455), we are finalizing the changes to measure Q507 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.40 Melanoma: Tracking and Evaluation of Recurrence

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	509
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who had an excisional surgery for melanoma or melanoma in situ with initial American Joint Committee on Cancer (AJCC) staging of 0, I, or II, in the past 5 years in which the operating provider examines and/or diagnoses the patient for recurrence of melanoma.
Substantive Change:	**The measure description is revised to read**: Percentage of patients who had an excisional surgery for melanoma or melanoma in situ with initial American Joint Committee on Cancer (AJCC) staging of 0, I, or II, in the past 5 years for whom the clinician or practice responsible for longitudinal care documents examination and/or diagnosis for recurrence of melanoma during the performance period. **Updated intent and clinician applicability: Revised:** The examination for recurrence may be performed by any qualified clinician, provided that the clinician or practice reporting the measure documents that the examination occurred in the medical record. **Updated denominator note**: **Added**: The excisional surgery may have been performed by any clinician or practice, provided documentation of the qualifying procedure and staging is present in the medical record of the clinician or practice reporting the measure.
Measure Steward:	American Academy of Dermatology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed revising this measure to address instances where one clinician may perform the excision and another performs the subsequent skin examinations. This measure revision will ensure inclusiveness, continuity, and accuracy in reporting excisional surgery outcomes by allowing documentation from any qualified clinician or practice, as is common in clinical practice.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the substantive changes to measure Q509: *Melanoma: Tracking and Evaluation of Recurrence* and requested information on the examination and how to implement the measure.

Response: We thank the commenter for supporting the substantive changes to this measure. The examination for recurrence may be performed by any qualified clinician, allowing for care coordination and continuity. Please see the measure specification, once posted by January 1, 2027, for specific reporting requirements.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44455), we are finalizing the changes to measure Q509 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

D.41 Patient Reported Falls and Plan of Care

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	513
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients (or caregivers as appropriate) with an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke who reported a fall occurred and those that fell had a plan of care for falls documented at every visit.
Substantive Change:	**Updated denominator criteria: Removed: For all Submission Criteria:** diagnosis coding not specific to an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke. **Updated definitions: For all Submission Criteria: Added:** **Last Visit –** if the patient is established, this would be since the last visit with the same clinician/group. If the patient is new, it would be since the patient's last visit with any clinician. **Updated denominator**: **For Submission Criteria 2: Added**: Patient reported a fall since last visit OR Accidental Fall **Updated numerator note: For Submission Criteria 1: Added:** Denominator Exception medical reason(s) should be documented at the time of the denominator eligible encounter. **Updated numerator options: For Submission Criteria 2: Revised:** **Performance Met:** Patients that reported a fall occurred who had a plan of care for falls documented **Performance Not Met:** Patients that had a fall who did not have a plan of care for falls documented **Removed:** Denominator Exception
Measure Steward:	American Academy of Neurology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise multiple components of this measure to ensure alignment with intent and clinical workflow. We proposed to remove coding that is broad in nature and not specific to the diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke. Removal will ensure the denominator does not include patients beyond those in neurology with symptomology who will not be appropriate for assessment of the quality action. While patient safety in context of falls is important in all patients, the quality action for this measure is specific for the patient population intended and may not be appropriate for any falls patient. For clarity we proposed adding a definition for 'Last Visit' so that all clinicians reporting are following the same timeline, ensuring consistent implementation across clinician submissions. Additionally, we proposed adding to the Submission Criteria 1 numerator note to clarify that the medical reason should be documented as active or present on the day of the denominator eligible encounter. This will ensure that regardless of condition, whether it be chronic or acute, active or historical, it will be attributable to that interaction. Finally, we proposed to revise Submission Criteria 2 to focus on those patients who reported a fall since their last visit as this is the at-risk patient population requiring the quality action; plan of care for falls. This revision aligns with measure intent as well as the structure of other screening measures in MIPS for better consistency.

We received public comments on the substantive changes proposed for this measure. The following is a summary of the comments we received and our responses.

Comment: One commenter opposed limiting measure Q513: *Patient Reported Falls and Plan of Care* to a narrow set of diagnoses, stating that fall assessment is important for a broader patient population and noting concerns about further reducing measure choice for clinicians. The commenter requested CMS expand the numerator to include all patients for whom fall risk assessment and appropriate follow-up are clinically important.

Response: We thank the commenter for the feedback on the substantive changes to this measure. Limiting the diagnosis will ensure the denominator does not include patients beyond those in neurology with symptomology who will not be appropriate for assessment of the quality action. In addition, there are two alternative quality measures that address falls within MIPS that are age-based as opposed to diagnosis-based. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. Any potential new substantive changes need to go through notice and comment rulemaking.

After consideration of public comments, and for the reasons stated above and in the proposed rule (91 FR 44456), we are finalizing the changes to measure Q513 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

Table Group DD: Finalized Substantive Changes to Previously Finalized MIPS Quality Measures Available Only for Use in Relevant MVPs for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

As finalized for the CY 2024 performance period/2026 MIPS payment year and future years, the following three MIPS quality measures were retained for utilization in MVPs only while removed from traditional MIPS: Q112**:** *Breast Cancer Screening*, Q113: *Colorectal Cancer Screening*, and Q128**:** *Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan* (88 FR 79897 through 79902). We note that measures Q112 and Q113 available only in MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP), specifically for inclusion in the APP Plus measure set, as finalized in the CY 2025 PFS final rule (89 FR 98363 through 98371). For such measures, the collection types solely applicable for purposes of the APP Plus measure set (Medicare Clinical Quality Measures for Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Medicare CQMs) collection type and newly finalized Medicare Electronic Clinical Quality Measures for ACOs Participating in the Medicare Shared Savings Program (Medicare eCQMs) collection type as described in section IV.A.4.d.(1)(c)(v) of this final rule) are also specified as a collection type available for such relevant measures described in Table Group DD of this Appendix.

Table Group DD within this final rule provides substantive changes finalized for the CY 2027 performance period/2029 MIPS payment year for MIPS quality measures available only in a relevant MVP. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2027 may not be identified within this final rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2027 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2028. The 2027 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov*.

Measures that are endorsed by a CBE are shown in Table Group DD of this Appendix as follows: CBE # / eCQM CBE #.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but it is important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes will expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2027 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the finalized substantive changes, there may be revisions within the logic that are not considered substantive in nature; however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

There were no proposed substantive changes for measure Q128. We requested comments on the substantive changes for the other measures outlined below.

DD.1 Breast Cancer Screening

Category	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of women 40-74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure, eCQM, Medicare CQM, MIPS CQM, Medicare eCQM collection types.
Measure Steward:	National Committee for Quality Assurance
Core Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the collection types available for this measure to include the Medicare eCQM collection type to allow choice in submission method for Medicare Shared Savings Program ACOs reporting the APP Plus measure set. See section IV.A.4.d.(1)(c)(v) of this final rule for further information on the Medicare eCQM collection type.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44458), we are finalizing the changes to measure Q112 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

DD.2 Colorectal Cancer Screening

Category	Description
CBE # / eCQM CBE #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure, eCQM, Medicare CQM, MIPS CQM, Medicare eCQM collection types.
Measure Steward:	National Committee for Quality Assurance
Core Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the collection types available for this measure to include the Medicare eCQM collection type to allow choice in submission method for Medicare Shared Savings Program ACOs reporting the APP Plus measure set. See section IV.A.4.d.(1)(c)(v) of this final rule for further information on the Medicare eCQM collection type.

We received no public comments on the substantive changes proposed for this measure. For the reasons stated above and in the proposed rule (91 FR 44458), we are finalizing the changes to measure Q113 as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

APPENDIX 2: IMPROVEMENT ACTIVITIES

In the CY 2027 PFS proposed rule (90 FR 44143), we proposed, for the CY 2027 performance period/2029 MIPS payment year and future years, to add **six** new improvement activities, modify **five** previously finalized improvement activities, and remove **eleven** previously finalized improvement activities. These proposals are discussed in section IV.A.4.d.(3).(b). of this final rule and in more detail below. We solicited comment on our proposals. Overall, we received comments sharing support, concerns, and suggestions. Many of the comments focused on specific proposed improvement activity additions, modifications, and removals, which are detailed below. Generally, comments addressed the safety of AI use for clinicians and patients and offered suggestions for developing additional activities in the future to support health initiatives aimed at reducing cardiovascular disease risk and preventing HIV.

TABLE F-B1: New Improvement Activities

New Improvement Activity	
Proposed Activity ID:	**IA_CC_20**
Proposed Subcategory:	Care Coordination
Proposed Activity Title:	Use of Data to Improve Practice Workflows
Proposed Activity Description:	MIPS-eligible clinicians collaborate to design, implement, and continuously refine evidence based utilization pathways and clinical workflows that support the integration of current research and clinical guidelines into everyday practice. Eligible activities include the creation or maintenance of any algorithm, clinical pathway, process, or order set that is grounded in established clinical practice guidelines and/or peer reviewed literature. Actions that fulfill this activity may include: • Collecting and analyzing clinical data to identify the need for a new or revised pathway, order set, or process • Developing and deploying the updated pathway, order set, or process within clinical operations • Evaluating adoption, effectiveness, and clinical impact through ongoing monitoring and feedback. Additional qualifying activities may include, for example, conducting annual reviews of existing pathways or algorithms by a pathology group and/or in collaboration with ordering clinician, developing and disseminating educational materials, and identifying or engaging new stakeholders to support pathway improvement and implementation.
Rationale:	Promoting uptake of best clinical practices from guidelines and other resources is critical for improving quality of patient care. However, translating recommendation statements into action can be challenging for individual practices due to resource constraints. Clinical pathways and algorithms are effective ways to encourage implementation of guidelines.[525] Development of such pathways requires clinical expertise and time, although a 10-step process has been established by other organizations.[526] By including a multi-disciplinary team in pathway development, care coordination can be maximized and all stakeholders can ensure that the pathway is feasible to implement. Such guidance requires regular review as new clinical practice statements become available, especially if the pathway includes multiple specialties (e.g., oncology, radiology, pathology, pain management, etc.).

[525] Fiordalisi, C., Borsky, A., Chang, S., & Guise, J.-M. (2019). AHRQ EPC Series on Improving Translation of Evidence into Practice for the Learning Health System: Introduction. Journal on Quality and Patient Safety, 45(8), 558-565. doi: 10.1016/j.jcjq.2019.05.006

[526] Flores, E. J., Jue, J. J., Giradi, G., Schoelles, K., Mull, N. K., & Umscheid, C. A. (2019). AHRQ EPC series on improving translation of evidence: use of a clinical pathway for C. Difficile treatment to facilitate the translation of research findings into practice. The Joint Commission Journal on Quality and Patient Safety, 45(12), 822-828. doi: 10.1016/j.jcjq.2019.10.002.

	Therefore, the effort involved in this activity is ongoing and requires input from many members of the care team.
Comment & Response:	*Comment*: We received several comments in support of finalizing this new activity. *Response*: We thank commenters for their support of this new activity.
Final Action:	After consideration of public comments, we are finalizing this new activity as proposed.
New Improvement Activity	
Proposed Activity ID:	**IA_CC_21**
Proposed Subcategory:	Care Coordination
Proposed Activity Title:	Understand and Improve Diagnostic Performance
Proposed Activity Description:	This activity aims to improve patient safety by reducing diagnostic safety events, including delayed, inaccurate, or missed diagnoses, as well as failures to communicate correct diagnoses to patients and their families. This activity should support diagnostic transparency, build staff competency through training, and improve the completeness and accuracy of patient data. Understanding and improving diagnostic performance includes establishing a standardized process to monitor diagnostic discrepancies, diagnostic safety events, near misses, and miscommunications. Key components of this activity may include: • Identifying a metric to track (e.g., frozen section discrepancy rate) • Implementing a consistent tracking mechanism • Conducting ongoing monitoring • Initiating mitigation or education efforts when needed. Processes must incorporate both routine tracking and root cause analysis, followed by appropriate corrective actions such as workflow changes, education, and/or targeted training for individuals and/or groups.
Rationale:	Accurate and timely diagnosis is the cornerstone of effective patient care. Diagnostic performance directly influences treatment decisions, patient outcomes, and healthcare resource utilization. Recent studies have emphasized the importance of addressing diagnostic safety events in clinical settings.[527] A deeper understanding of diagnostic processes--including cognitive, systemic, and technological factors--enables healthcare providers to identify gaps, implement targeted interventions, and promote a culture of continuous learning and accountability. As healthcare becomes increasingly data-driven, integrating diagnostic improvement efforts with quality metrics, patient feedback, and interdisciplinary collaboration ensures that care is not only clinically sound but also patient-centered.
Comment & Response	*Comment*: We received several comments in support of finalizing this new activity. *Response*: We thank commenters for their support of this new activity.
Final Action:	After consideration of public comments, we are finalizing this new activity as proposed.
New Improvement Activity	
Proposed Activity ID:	**IA_AHW_2**
Proposed Subcategory:	Advancing Health and Wellness
Proposed Activity Title:	Systematic Screening and Intervention for Nutrition and other Health-Impacting, Non-Clinical Issues
Proposed Activity Description:	This activity supports the implementation of standardized health-related, non-clinical issues screening tools and workflows to identify and address wellness-impacting factors such as poor nutrition, housing instability, transportation barriers, and financial strain. It may include: • Training staff on screening protocols • Embedding validated screening tools into the electronic health record (EHR)

[527] Auerbach, A. D., Lee, T. M., Hubbard, C. C., Ranji, S. R., Raffel, K., Valdes, G., ... & Schnipper, J. L. (2024). Diagnostic errors in hospitalized adults who died or were transferred to intensive care. JAMA Internal Medicine, 184(2), 164-173.

	• Establishing referral pathways to community-based resources • Tracking follow-up and resolution of identified needs.
Rationale:	This activity addresses a gap for a nutrition-focused improvement activity. It aligns with CMS's focus on wellness and whole-person care, and supports Enhancing Oncology Model (EOM) and MVP efforts by integrating health-related, non-clinical issues into quality improvement strategies. This activity builds on existing patient navigation and care coordination activities but focuses specifically on upstream factors.
Comment & Response:	*Comment*: We received several comments in support of finalizing this new activity. *Response*: We thank commenters for their support of this new activity.
Final Action:	After consideration of public comments, we are finalizing this new activity as proposed.
New Improvement Activity	
Proposed Activity ID:	**IA_AHW_3**
Proposed Subcategory:	Advancing Health and Wellness
Proposed Activity Title:	Advance Care Planning Conversations to Support Patient Wellness and Care Preferences
Proposed Activity Description:	MIPS-eligible clinicians engage patients and their caregivers in structured, proactive discussions about end-of-life preferences, advance care planning (ACP), and palliative care options as part of comprehensive wellness and care management. This activity integrates conversations about goals of care, symptom management, and quality of life into routine encounters with patients who have serious or life limiting illness. CMS reminds clinicians that they must not attempt to influence the ACP-related decisions of their patients. Participating clinicians must document: • Use of standardized communication tools or frameworks (e.g., Serious Illness Conversation Guide, Practitioner Orders for Life Sustaining Treatment (POLST)) to support consistent, high quality discussions; • Inclusion of wellness oriented topics, such as symptom relief, emotional wellbeing, social supports, and patient identified priorities; • Coordination and alignment of care plans across specialties, including primary care, palliative care, behavioral health, and other involved clinicians; and • Regular review and updates of advance directives or care preferences to ensure they remain accurate and reflective of the patient's evolving goals and clinical status.
Rationale:	End-of-life care planning discussions contribute to improved patient and caregiver well-being by reducing stress, enhancing understanding of care options, and ensuring treatment aligns with patient goals. Integrating these conversations into wellness and/or chronic care management visits supports a holistic approach to health, one that prioritizes quality of life, emotional and physical comfort, and patient autonomy. Evidence indicates that patients who engage in structured end-of-life care planning experience better symptom control, higher satisfaction, and reduced hospitalizations, aligning with MIPS goals of improved care coordination and patient-centered outcomes.
Comment & Response:	*Comment*: We received several comments in support of finalizing this new activity. One commenter recommended encouraging clinicians to assess existing ACP documents, verifying that patient preferences remain current, and promoting availability and exchange of ACP information across care settings. *Response:* We thank commenters for sharing their support and suggestions for this new activity. While we appreciate the recommendations, we believe these aspects are already incorporated into the activity.
Final Action:	After consideration of public comments, we are finalizing this new activity as proposed.
New Improvement Activity	
Proposed Activity ID:	**IA_AHW_4**
Proposed Subcategory:	Advancing Health and Wellness
Proposed Activity Title:	Clinician Use of Artificial Intelligence (AI) to Improve Patient Care

Proposed Activity Description:	MIPS-eligible clinicians implement and participate in structured organizational initiatives that improve patient care through the responsible and transparent use of artificial intelligence (AI) in clinical and operational workflows. This activity supports the safe adoption of AI-enabled technologies while encouraging the development, evaluation, and refinement of AI resources designed to improve patient outcomes, care-team efficiency, and population health management. As part of this activity, participating clinicians and organizations must: • Establish and maintain organizational policies and procedures for AI use in healthcare settings that guide the evaluation, deployment, and monitoring of AI-enabled tools ○ These policies incorporate key AI model characteristics including fairness, appropriateness, validity, and effectiveness as foundational criteria for assessing model performance, identifying event patterns, and determining appropriate risk-mitigation and escalation actions and • Engage in or support innovative initiatives that encourage the creation, piloting, and/or enhancement of AI-enabled tools, workflows, and/or resources ○ Examples include developing risk-stratification models, AI-supported clinical decision support (CDS), predictive analytics for chronic-disease management, and/or tools that expand patient access, wellness interventions, and/or care-coordination capabilities. Additional examples include using AI tools to summarize medical literature for clinical decision making, support documentation (e.g., generate notes with AI for clinician review), and/or support population health management by identifying care gaps, determining patient eligibility for clinical trials, or generating draft responses to patient questions for clinician review.
Rationale:	The rapid expansion of artificial intelligence (AI) in healthcare presents significant opportunities to improve clinical outcomes, reduce clinician burden, and enhance population health management. However, realizing these benefits requires deliberate, responsible, and transparent implementation practices that ensure AI tools are safe, fair, reliable, and aligned with evidence-based care. This improvement activity encourages MIPS-eligible clinicians to adopt AI in a structured, governance-driven manner that promotes innovation while safeguarding patient well-being. Establishing organizational policies and procedures for AI use provides an essential foundation for ensuring that deployed tools are evaluated using key model characteristics (fairness, appropriateness, validity, and effectiveness). By incentivizing participation in innovation initiatives such as developing or piloting new AI-enabled tools and workflows, this activity further advances the field of applied clinical AI, encouraging clinicians and practices to collaborate in the creation and refinement of AI resources. This activity also aligns with the AI-related goals of the CMS ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model, a 10-year voluntary Medicare program testing outcome-aligned payments to expand technology-supported chronic care for common conditions.[528]
Comment & Response:	*Comment*: We received many comments related to this new activity. The majority of comments shared support for finalizing the new activity with some offering suggestions on additional protections or technologies to include within the activity. One commenter opposed AI in medicine and asked to delay the integration of AI into the Improvement Activities Inventory. *Response*: We thank commenters for expressing their support, concerns, and suggestions for this activity. We will continue to track the progression of AI technology and tools, best practices, and safeguards. We note that the activity requires participating clinicians and organizations to: "Establish and maintain organizational policies and procedures for AI use in healthcare settings that guide the evaluation, deployment, and monitoring of AI-enabled tools." We will continue to make modifications and additions to the Improvement Activity Inventory as needed. We welcome collaboration with interested parties on this topic.
Final Action:	After consideration of public comments, we are finalizing this new activity as proposed.
New Improvement Activity	

[528] Centers for Medicare and Medicaid Services. (n.d). ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model. https://www.cms.gov/priorities/innovation/innovation-models/access.

Proposed Activity ID:	**IA_AHW_5**
Proposed Subcategory:	Advancing Health and Wellness
Proposed Activity Title:	Lifestyle Approaches to Diabetes Remediation
Proposed Activity Description:	MIPS-eligible clinicians engage patients and their caregivers in structured, evidence-based lifestyle interventions to support the treatment and management of diabetes. Clinicians use the American College of Lifestyle Medicine's (ACLM) Lifestyle Empowerment Approach for Diabetes Remission (LEADR) or a similar diabetes-focused lifestyle program to help patients address modifiable behavioral factors and improve overall health status. These programs provide education, coaching, and support across key lifestyle domains such as nutrition, physical activity, sleep, stress management, and reducing harmful behaviors. Participating clinicians may use one or more of the following evidence-based programs and resources: • ACLM Lifestyle Empowerment Approach for Diabetes Remission (LEADR)[529] • Diabetes Self-Management Education and Support (DSMES)[530] • American Diabetes Association Institute of Learning – Hands On Webinar: Diet, Lifestyle, Medicine, and Beyond—CardioKidneyMetabolic Strategies for Managing Obesity in People with Type 2 Diabetes[531] Use of each resource includes participating in the LEADR and/or Hands on Webinar programs and implementing learnings into practice with patients as clinically appropriate or referring patients when clinically appropriate to a DSMES program in-house or externally.
Rationale:	This activity aligns with CMS's focus on wellness and whole-person care and supports MVP efforts by integrating health-related, non-clinical issues into quality improvement strategies.
Comment & Response:	*Comment*: Several commenters expressed support for finalizing this activity. Commenters shared how this activity aligns with evidence-based approaches to managing diabetes. Some commenters suggested adding more information to the activity description to explain how each resource should be used. *Response*: We thank the commenters for sharing their support and suggestions for this activity.
Final Action:	We have made minor edits to this activity description accordingly and are otherwise finalizing this new activity as proposed.

In this proposed rule, we are proposing to modify **five** previously finalized improvement activities for the CY 2027 performance period/2029 MIPS payment year and future years. These

[529] American College of Lifestyle Medicine. (n.d.). Research and innovation. https://lifestylemedicine.org/about-aclm/research-innovation/.
[530] Association of Diabetes Care & Education Specialists. (n.d.). Diabetes self-management education and support. https://www.adces.org/diabetes-education-dsmes.
[531] American Diabetes Association. (n.d.). Hands On: Diet, Lifestyle, Medicine, and Beyond CardioKidneyMetabolic Strategies for Managing Obesity in People with Type 2 Diabetes https://professionaleducation.diabetes.org/ProductInfo/HandsOnFeb25OD.

proposed changes are discussed in section IV.A.4.d.(3)(b)(IV) of this proposed rule and in more detail below.

TABLE F-B2: Modifications to Previously Finalized Improvement Activities

Current Improvement Activity	
Current Activity ID:	**IA_PSPA_16**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
Current Activity Description:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools—and standardized treatment protocols to manage workflow on the care team to meet patient needs. Clinicians should focus on utilizing open-source, freely available, interoperable CDS in completing the requirements of this activity.
Proposed Change and Rationale:	Stakeholder comments on the CY 2026 PFS NPRM supported stronger oversight of clinical AI, including monitoring, root cause analysis, and mitigation of AI-related diagnostic safety events and near-misses. This activity, IA_PSPA_16, already contains core patient safety elements, making it a strong candidate for modification to explicitly include AI-enabled decision support, aligned with the Office of the National Coordinator for Health Information Technology (ONC) definition of predictive decision-support interventions in 45 CFR 170.102 and stakeholder concerns about safety, liability, and governance.
Revised Activity Title:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools, including AI-enabled predictive decision-support interventions—and standardized treatment protocols to manage workflow on the care team to meet patient needs
Revised Activity Description:	MIPS-eligible clinicians use platform-agnostic, interoperable clinical decision support (CDS) tools—including artificial intelligence (AI)-enabled predictive decision-support interventions—to guide care-team workflow and support evidence-based, patient-centered decision-making. As part of this activity, clinicians prioritize open-source or freely available CDS tools where feasible and implement organizational policies to ensure the safe, appropriate, and effective use of these technologies. This activity may include: • Use of interoperable CDS tools, including AI-enabled technologies that meet the ONC definition of predictive decision-support interventions in 45 CFR 170.102: "technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis"[532] • Organizational policies for safe CDS and AI use, including processes to identify, review, and mitigate AI-related adverse events or near-misses, and to address clinician concerns about liability, model reliability, and appropriate use • Evaluation of AI-enabled CDS tools using the following quality principles: ○ Fairness: outputs free from bias or undue risk ○ Appropriateness: relevance to the clinical context ○ Validity: accurate and reliable predictions or recommendations ○ Effectiveness: demonstrated benefit in real-world use • Workflow integration practices showing that CDS recommendations—whether originally human-curated or AI-generated—are applied consistently in treatment planning, patient counseling, and follow-up • Periodic review and updating of CDS tools and related protocols to maintain alignment with best practices, organizational policies, and patient-safety standards.

[532] Office of the National Coordinator for Health IT. (2026). *45 CFR 170.315: ONC certification criteria for Health IT*. U.S. Code of Federal Regulations. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-C/section-170.315.

Comment & Response:	*Comment*: We received several comments related to the modification of this activity. All comments shared support for finalizing the modification with some suggesting additional requirements to include within the activity. *Response*: We thank commenters for expressing their support and suggestions for this activity modification. We will continue to track the progression of AI technology and tools, best practices, and safeguards. We will propose further modifications to this activity as needed in the future. We welcome collaboration with interested parties on this topic.
Final Action:	After consideration of public comments, we are finalizing this activity modification as proposed
Current Improvement Activity	
Current Activity ID:	**IA_BMH_4**
Current Subcategory:	Behavioral And Mental Health
Current Activity Title:	Depression screening
Current Activity Description:	Depression screening and follow-up plan: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including depression screening and follow-up plan (refer to NQF #0418) for patients with co-occurring conditions of behavioral or mental health conditions
Proposed Change and Rationale:	IA_BMH_4 and IA_BMH_5 contain similar elements that could be combined into one, more robust activity.
Proposed Revised Activity Title:	Depression Screening, Treatment, and Prevention
Proposed Revised Activity Description:	MIPS-eligible clinicians or groups regularly engage in integrated screening, treatment, and/or prevention interventions for patients with behavioral or mental health conditions, with a focus on early identification and coordinated management of major depressive disorder and associated risks. This activity includes systematic depression screening and follow-up planning, along with suicide risk assessment for individuals at elevated risk. Clinicians participating in this activity should implement and document: • Use of validated depression screening tools administered at appropriate intervals for patients • Completion of suicide risk assessments when clinically indicated, using standardized tools for patients who screen positive for depression or exhibit mental-illness warning signs • Development and execution of evidence-based follow-up plans, including safety planning, symptom management, referral to behavioral health specialists, and monitoring of treatment response • Integrated, team-based coordination of care between primary care, behavioral health, psychiatry, and other relevant specialties to support continuity, patient safety, and positive patient outcomes • Routine monitoring and reassessment, including documentation of treatment adjustments, patient (and/or family/caregiver) engagement, and adherence to follow-up intervals consistent with clinical guidelines.
Comment & Response:	*Comment*: We received some comments specifically related to the modification of this activity. One comment shared support for finalizing the modification and suggested adding "evidence-based depression treatment" to the activity. Another comment shared concern that the combination of two depression-related improvement activities could diminish the visibility of depression management. *Response*: We thank commenters for expressing their support, concern, and suggestions for this activity modification. We believe that language relating to evidence-based depression treatment is already incorporated into the activity description sufficiently. The combination of depression-related improvement activities will not lessen focus on depression management. This modification is aimed at reducing duplicative activities to reduce administrative effort.
Final Action:	After consideration of public comments, we are finalizing this activity modification as proposed.
Current Improvement Activity	

Current Activity ID:	**IA_CC_8**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of documentation improvements for practice/process improvements
Current Activity Description:	Implementation of practices/processes that document care coordination activities (e.g., a documented care coordination encounter that tracks all clinical staff involved and communications from date patient is scheduled for outpatient procedure through day of procedure).
Proposed Change and Rationale:	IA_CC_8, IA_CC_10, IA_CC_11, and IA_CC_12 all contain similar elements that could be combined into one, more robust activity.
Proposed Revised Activity Title:	Implementation of Documentation and/or Operational Improvements for Practice/Process Improvements
Proposed Revised Activity Description:	This activity aims to strengthen communication, transparency, and patient-centered care across all transitions—outpatient, inpatient, specialty, and community settings. It seeks to promote clinicians' proactively coordinating care, tracking patient progress, documenting actions taken, and maintaining clear, structured processes that reduce fragmentation and improve clinical outcomes. This activity may include: • Documentation of care coordination encounters that track all clinical staff involved, communication steps, and handoffs from the time a patient is scheduled for an outpatient procedure or referral through completion of the episode of care • Systematic tracking of patients referred to consultants or specialists, including confirmation that the referral was received, appointments were completed, and recommendations were integrated into the plan of care • Documentation of care transition practices reflecting a patient-centered action plan aligned with the patient's values, preferences, and social context • Implementation of care coordination agreements with frequently used consultants or facilities that set expectations for timely, bidirectional information sharing and clearly define responsibilities across settings.
Comment & Response:	We did not receive public comment specifically on this modification.
Final Action:	We are finalizing this activity modification as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_CC_9**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of practices/processes for developing regular individual care plans
Current Activity Description:	Implementation of practices/processes, including a discussion on care, to develop regularly updated individual care plans for at-risk patients that are shared with the beneficiary or caregiver(s). Individual care plans should include consideration of a patient's goals and priorities, as well as desired outcomes of care.
Proposed Change and Rationale:	IA_CC_9 and IA_BE_15 contain similar elements that could be combined into one, more robust activity.
Proposed Activity Title:	Implementation of Practices/Processes for Developing Regular Individual Care Plans
Proposed Revised Activity Description:	Implementation of practices/processes, including a discussion about care goals and preferences, to develop regularly updated individual care plans for at-risk patients that are developed and shared with the beneficiary and family and/or caregiver(s). Individual care plans should include consideration of a patient's (and family/caregiver's, as appropriate) goals and priorities, as well as desired outcomes of care.
Comment & Response:	*Comment*: We received some comments specifically related to the modification of this activity. One commenter supports the modification of this activity and its consolidation with IA_BE_15. However, a commenter also expressed concern that beneficiary-engagement activities previously recognized under IA_BE_15 may be excluded if the modification is finalized. Another commenter requested that this activity retain references to family and caregivers. *Response*: We thank commenters for expressing their support and concern with this activity modification. We do not believe that beneficiary-engagement activities will be diminished by combining these activities. The revised activity is intended to recognize care coordination and individualized care planning activities in partnership with

	patients' goals. Beneficiary engagement remains an important element of this activity because effective individualized care plans depend on engaging patients, family, and caregivers in developing a care plan and prioritizing their goals. This modification aims to reduce redundancy in the Inventory and administrative effort for clinicians. References to family and caregivers remain in this activity description post-modification. We also note that fifteen activities will remain in the Inventory in the Beneficiary Engagement subcategory.
Final Action:	After consideration of public comments, we are finalizing this activity modification as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_PM_4**
Current Subcategory:	Population Management
Current Activity Title:	Glycemic management services
Current Activity Description:	For outpatient Medicare beneficiaries with diabetes and who are prescribed antidiabetic agents (e.g., insulin, sulfonylureas), MIPS eligible clinicians and groups must attest to having: For the first performance year, at least 60 percent of medical records with documentation of an individualized glycemic treatment goal that: a) Considers patient-specific factors, including, at least 1) age, 2) comorbidities, and 3) risk for hypoglycemia, and b) Is reassessed at least annually. The performance threshold will increase to 75 percent for the second performance year and onward. Clinician would attest that, 60 percent for first year, or 75 percent for the second year, of their medical records that document individualized glycemic treatment represent patients who are being treated for at least 90 days during the performance period.
Proposed Change and Rationale:	IA_PM_4, IA_PM_19, and IA_PM_20 all contain similar elements that could be combined into one, more robust activity.
Proposed Revised Activity Title:	Glycemic Screening, Referral, and Management
Proposed Revised Activity Description:	For outpatient Medicare beneficiaries, MIPS-eligible clinicians and groups must attest to having: For the first performance year, at least 60 percent of medical records with documentation of screening patients for abnormal blood glucose, referring eligible patients with prediabetes to a CDC-recognized diabetes prevention program, and developing individualized glycemic treatment plans that: a) Consider patient-specific factors, including, at least 1) age, 2) comorbidities, and 3) risk for hypoglycemia, and b) Are reassessed at least annually. The performance threshold will increase to 75 percent for the second performance year and onward. Clinicians must attest that 60 percent (for the first year) and 75 percent (for the second year and beyond) of their medical records include documentation of screening patients for abnormal blood glucose according to current US Preventive Services Task Force (USPSTF) and/or American Diabetes Association (ADA) guidelines. Clinicians must attest that 60 percent (for the first year) and 75 percent (for the second year and beyond) of their medical records include documentation of referring eligible patients with prediabetes to a CDC-recognized diabetes prevention program operating under the framework of the National Diabetes Prevention Program. Clinicians must attest that 60 percent (for the first year) and 75 percent (for the second year and beyond) of their medical records document individualized glycemic treatment

	plans representing patients who are being seen for at least 90 days during the performance period.
Comment & Response:	*Comment*: We received some comments related to the modification of this activity, including expressions of support. A specific comment suggested recognizing nutrition-risk and food-access assessments, coordinating glycemic and nutrition intervention, longitudinal follow up, and referrals within this activity. *Response*: We thank commenters for expressing their support and providing suggestions for this activity modification. We believe that this activity as modified already includes follow up and referral. We will continue to monitor the implementation of this activity, and make further modifications to this activity as needed. We welcome collaboration with interested parties on this topic. We are finalizing this activity as proposed, and will carefully monitor its implementation..
Final Action:	After consideration of public comments, we are finalizing this activity modification as proposed.

In this proposed rule, we are proposing to remove **eleven** previously finalized improvement activities beginning with the CY 2027 performance period/2029 MIPS payment year. These changes are discussed in section IV.A.4.d.(3)(b)(V) of this proposed rule and in more detail below; activity removal factors are discussed in the CY 2020 PFS final rule (84 FR 62568 through 63563).

TABLE F-B3: Improvement Activities Being Removed

Current Improvement Activity	
Current Activity ID:	**IA_BMH_5**
Current Subcategory:	Behavioral And Mental Health
Current Activity Title:	MDD prevention and treatment interventions
Current Activity Description:	Major depressive disorder: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including suicide risk assessment (refer to NQF #0104) for mental health patients with co-occurring conditions of behavioral or mental health conditions.
Removal Rationale:	Proposed removal to combine with IA_BMH_4; Factor 1, activity is duplicative
Comment & Response:	*Comment*: We received some comments related to the removal of this activity. One specific comment shared support for finalizing this removal. Another comment shared concern that the combination of two depression-related improvement activities could diminish the visibility of depression management. *Response*: We thank commenters for expressing their support and concern regarding this activity removal. We believe that the combination of depression-related improvement activities will not lessen focus on depression management. This removal is aimed at reducing duplicative activities to reduce administrative effort.
Final Action:	After consideration of public comments, we are finalizing this activity removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_CC_10**
Current Subcategory:	Care Coordination
Current Activity Title:	Care transition documentation practice improvements
Current Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must document practices/processes for care transition with documentation of how a MIPS eligible clinician or group carried out an action plan for the patient with the patient's preferences in mind (that is, a "patient-centered" plan) during the first 30 days following a discharge. Examples of these practices/processes for care transition include: staff involved in the care transition; phone calls conducted in support of transition; accompaniments of patients to appointments or other navigation actions; home visits; patient information access to their medical records; real time communication between PCP and consulting clinicians; PCP included on specialist follow-up or transition communications.
Removal Rationale:	Proposed removal to combine with IA_CC_8; Factor 1, activity is duplicative
Comment & Response:	*Comment*: We received some comments related to the removal of this activity. One specific comment shared concern that removing IA_CC_10, IA_CC_11, and IA_CC_12 could inadvertently reduce recognition of the care transition and coordination activities performed by clinicians, particularly infectious disease physicians whose patients regularly move across care settings.

	Response: We thank commenters for sharing their concern and emphasizing the importance of care transitions and care coordination for patients with complex conditions. Proposed removals are aimed at reducing duplication within the Inventory while maintaining recognition of the importance of care transitions and care coordination. We note that--with ten activities remaining in the Care Coordination subcategory--the Improvement Activities Inventory will continue to recognize care transitions, care coordination, and information-sharing practices and give clinicians credit for this work.
Final Action:	After consideration of public comments, we are finalizing this activity removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_CC_11**
Current Subcategory:	Care Coordination
Current Activity Title:	Care transition standard operational improvements
Current Activity Description:	Establish standard operations to manage transitions of care that could include one or more of the following: • Establish formalized lines of communication with local settings in which empaneled patients receive care to ensure documented flow of information and seamless transitions in care; and/or • Partner with community or hospital-based transitional care services.
Removal Rationale:	Proposed removal to combine with IA_CC_8; Factor 1, activity is duplicative
Comment & Response:	*Comment*: We received some comments related to the removal of this activity. One specific comment shared concern that removing IA_CC_10, IA_CC_11, and IA_CC_12 could inadvertently reduce recognition of the care transition and coordination activities performed by clinicians, particularly infectious disease physicians whose patients regularly move across care settings. *Response*: We thank commenters for sharing their support and concern and emphasizing the importance of care transitions and care coordination for patients with complex conditions. Proposed removals are aimed at reducing duplication within the Inventory while maintaining recognition of the importance of care transitions and care coordination. We note that--with ten activities remaining in the Care Coordination subcategory--the Improvement Activities Inventory will continue to recognize care transitions, care coordination, and information-sharing practices and give clinicians credit for this work.
Final Action:	After consideration of public comments, we are finalizing this activity removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_CC_12**
Current Subcategory:	Care Coordination
Current Activity Title:	Care coordination agreements that promote improvements in patient tracking across settings
Current Activity Description:	Establish effective care coordination and active referral management that could include one or more of the following: • Establish care coordination agreements with frequently used consultants that set expectations for documented flow of information and MIPS eligible clinician or MIPS eligible clinician group expectations between settings. Provide patients with information that sets their expectations consistently with the care coordination agreements; • Track patients referred to specialist through the entire process; and/or • Systematically integrate information from referrals into the plan of care.
Removal Rationale:	Proposed removal to combine with IA_CC_8; Factor 1, activity is duplicative

Comment & Response:	*Comment*: We received some comments related to the removal of this activity. One commenter shared concern that removing IA_CC_10, IA_CC_11, and IA_CC_12 could inadvertently reduce recognition of the care transition and coordination activities performed by clinicians, particularly infectious disease physicians whose patients regularly move across care settings. *Response*: We thank commenters for their support and for sharing concern and emphasizing the importance of care transitions and care coordination for patients with complex conditions. Proposed removals are aimed at reducing duplication within the Inventory while maintaining recognition of the importance of care transitions and care coordination. We note that--with ten activities remaining in the Care Coordination subcategory--the Improvement Activities Inventory will continue to recognize care transitions, care coordination, and information-sharing practices and give clinicians credit for this work.
Final Action:	After consideration of public comments, we are finalizing this activity removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_2**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in MOC Part IV
Current Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must participate in Maintenance of Certification (MOC) Part IV. Maintenance of Certification (MOC) Part IV requires clinicians to perform monthly activities across practice to regularly assess performance by reviewing outcomes addressing identified areas for improvement and evaluating the results. Some examples of activities that can be completed to receive MOC Part IV credit are: the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program, National Cardiovascular Data Registry (NCDR) Clinical Quality Coach, Quality Practice Initiative Certification Program, American Board of Medical Specialties Practice Performance Improvement Module or American Society of Anesthesiologists (ASA) Simulation Education Network, for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program; specialty- specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE); American Psychiatric Association (APA) Performance in Practice modules.
Removal Rationale:	Many physicians are already required (e.g., by states) to participate in MOC; therefore, this activity is not likely to be driving additional meaningful clinical care improvement; Factors 1 & 7, activity is duplicative and/or obsolete
Comment & Response:	*Comment*: We received one comment specifically related to this activity removal. This commenter opposed this removal, stating that the MOC Part IV activity incentivizes clinician education and practical quality improvement. *Response*: We thank the commenter for sharing their opposition to this activity removal. We believe that MOC Part IV participation is standard practice and/or required and is therefore unlikely to be driving additional meaningful clinical care improvement.
Final Action:	After consideration of public comments, we are finalizing this activity removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_CC_16**
Current Subcategory:	Care Coordination
Current Activity Title:	Primary Care Physician and Behavioral Health Bilateral Electronic Exchange of Information for Shared Patients
Current Activity Description:	The primary care and behavioral health practices use the same electronic health record system for shared patients or have an established bidirectional flow of primary care and behavioral health records.

Removal Rationale:	Given advancements in EHR adoption and data-sharing practices, this activity is no longer likely driving additional meaningful clinical care improvement; Factor 7, activity is obsolete.
Comment & Response:	*Comment*: We received some comments specifically related to the removal of this activity. One comment opposed the removal of this improvement activity, stating that information exchange between primary care and behavioral health providers remains inconsistent and that this activity would continue to incentivize information exchange. *Response*: We thank commenters for sharing their concern and emphasizing the importance of information exchange between primary care and behavioral health providers. We agree that information exchange is important, but believe this activity is unlikely to drive additional meaningful clinical care improvement because EHR adoption and data sharing has advanced significantly since the creation of this activity. Also, please see existing IA_CC_13, Practice improvements to align with OpenNotes principles; and IA_BE_4, Engagement of Patients through Implementation of New Patient Portal.
Final Action:	After consideration of public comments, we are finalizing this activity removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_BE_15**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
Current Activity Description:	Engage patients, family, and caregivers in developing a plan of care and prioritizing their goals for action, documented in the electronic health record (EHR) technology.
Removal Rationale:	Proposed removal to combine with IA_CC_9; Factor 1, activity is duplicative
Comment & Response:	*Comment*: We received some comments related to the removal of this activity, including the expression of support. However, a specific comment also expressed concern that beneficiary-engagement activities previously recognized under IA_BE_15 will be excluded if the removal is finalized. *Response*: We thank commenters for expressing their support and concern with this activity removal. We do not believe that beneficiary-engagement activities will be diminished by this activity's removal, which is intended to reduce redundancy in the Inventory and administrative effort for clinicians. Beneficiary engagement remains an important element of the modified activity because effective individualized care plans depend on engaging patients, family, and caregivers in developing a care plan and prioritizing their goals. We also note that fifteen activities will remain in the Inventory in the Beneficiary Engagement subcategory.
Final Action:	After consideration of public comments, we are finalizing this activity removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_PM_19**
Current Subcategory:	Population Management
Current Activity Title:	Glycemic Screening Services
Current Activity Description:	For at-risk outpatient Medicare beneficiaries, individual MIPS eligible clinicians and groups must attest to implementation of systematic preventive approaches in clinical practice for at least 60 percent for the 2018 performance period and 75 percent in future years, of electronic medical records with documentation of screening patients for abnormal blood glucose according to current US Preventive Services Task Force (USPSTF) and/or American Diabetes Association (ADA) guidelines.
Removal Rationale:	Proposed removal to be combined with IA_PM_4; Factor 1, activity is duplicative

Comment & Response:	We did not receive public comments specifically on this removal.
Final Action:	We are finalizing this removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_PM_20**
Current Subcategory:	Population Management
Current Activity Title:	Glycemic Referring Services
Current Activity Description:	For at-risk outpatient Medicare beneficiaries, individual MIPS eligible clinicians and groups must attest to implementation of systematic preventive approaches in clinical practice for at least 60 percent for the CY 2018 performance period and 75 percent in future years, of medical records with documentation of referring eligible patients with prediabetes to a CDC-recognized diabetes prevention program operating under the framework of the National Diabetes Prevention Program.
Removal Rationale:	Proposed removal to be combined with IA_PM_4; Factor 1, activity is duplicative
Comment & Response:	We did not receive public comments specifically on this removal.
Final Action:	We are finalizing this removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_EPA_4**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Additional improvements in access as a result of QIN/QIO TA
Current Activity Description:	As a result of Quality Innovation Network (QIN)-Quality Improvement Organization (QIO) technical assistance, performance of additional activities that improve access to services or improve care coordination (for example, investment of on-site diabetes educator).
Removal Rationale:	This activity is one of several focused on improvements that can be supported and/or driven by QIN/QIOs. This particular activity could be attested to with relatively low levels of effort and without a need to measure specific outcomes. If this concept is important to eligible clinicians, they can attest to IA_PSPA_19. Other QIN/QIO-relevant activities will remain in the Inventory. Factor 2; There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. Factor 7; Activity is obsolete.
Comment & Response:	We did not receive public comments specifically on this removal.
Final Action:	We are finalizing this removal as proposed.
Current Improvement Activity	
Current Activity ID:	**IA_PM_2**
Current Subcategory:	Population Management
Current Activity Title:	Anticoagulant management improvements
Current Activity Description:	Individual MIPS eligible clinicians and groups who prescribe anti-coagulation medications (including, but not limited to oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors) must attest that for 75 percent of their ambulatory care patients receiving these medications are being managed with support from one or more of the following improvement activities:

	• Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program); • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Removal Rationale:	Direct oral anticoagulant medications (DOACs) have dramatically changed clinical practice, with significantly decreased use of warfarin over the last decade. Despite these changes, there are still specific circumstances that require use of warfarin, including the presence of prosthetic valves, antiphospholipid syndrome, and a high risk of bleeding complications, particularly gastrointestinal bleeding. This activity drives 'classic' quality actions related to the use of warfarin. Given the transition away from warfarin's common use, removing this activity is likely appropriate. We acknowledge the ongoing importance of medication management and will work to ensure that, going forward, improvement activities that support continued enhancement and maintenance of anticoagulation medication management are reflected in MIPS. Factor 7; activity is obsolete.
Comment & Response:	Comment: We received some comments related to the removal of IA_PM_2. One commenter opposed the removal of IA_PM_2 and recommended maintaining the activity within the inventory. Response: We thank commenters for their feedback. However, this activity no longer reflects current anticoagulation practice broadly. To ensure improvement activities remain strongly and widely clinically relevant, we will finalize the removal of this activity. We will continue to consider opportunities to develop future activities that reflect current approaches to anticoagulation management.
Final Action:	After consideration of public comments, we are finalizing this activity removal as proposed.

APPENDIX 3: MVP INVENTORY

MVP Development: Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), the CY 2022 PFS final rule (86 FR 65998 through 66031), and the CY 2023 PFS final rule (87 FR 70210 through 70211) we finalized a set of criteria to use in the development of MVPs. These criteria include MVP reporting requirements, MVP maintenance, and the selection of measures and activities within an MVP.

This appendix includes three groups of finalized MVP tables: Table 1 covers the MVP Foundational Layer, Group A presents 3 finalized new MVPs, and Group B outlines finalized modifications to 27 previously finalized MVPs.

Each MVP is composed of measures and activities from the quality, improvement activities, and cost performance categories relevant to the clinical specialty of the MVP. Additionally, every MVP includes a foundational layer which consists of population health measures and Promoting Interoperability performance category objectives and measures. The foundational layer is consistent across all MVPs and is detailed in Table 1: MVP Foundational Layer.

When applicable and substantive, we included a brief overview of the planned modifications to QCDR measures within relevant MVPs. Although QCDR measures are exempt from public notice and comment, providing this overview ensures transparency and offered interested parties the opportunity to provide comment on all aspects of each MVP prior to finalization. Final decisions regarding modifications to QCDR measure specifications are made by QCDR measure stewards independently of the rulemaking process, though these modifications may have influenced the decisions in this final rule.

IA_PCMH: Electronic submission of Patient Centered Medical Home Accreditation is not listed in the finalized MVP tables. In accordance with § 414.1380(b)(3)(ii), MIPS eligible clinicians in practices certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, may attest to this activity and receive an improvement activities performance category score of 100 percent (81 FR 77179 through 77180).

MVP Development: Performance Category Sources

Table 1, Group A, and Group B MVP tables include foundational measures and sets of MIPS quality measures, QCDR measures (as applicable), improvement activities, and cost measures organized around clinical topics. For further reference, the sources for the measures and activities included in the MVP tables can be found on the Quality Payment Program website, as detailed below:

- Existing MIPS quality measures are included in the 2026 MIPS Quality Measures List.[533] For details on finalized changes, refer to Appendix 1: MIPS Quality Measures in this final rule, which outlines the following: finalized additions (Table Group A), finalized removals (Table Group C), and finalized modifications to existing quality measures (Table Groups D and DD).

[533] See the 2026 MIPS Quality Measures List: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3570/2026-MIPS-Quality-Measures-List.xlsx.*

● Existing QCDR measures are derived from the latest publication of the 2026 QCDR Measure Specification file.[534] We anticipate updating the list of 2027 QCDR measures in December 2026.

● Existing improvement activities are included in the 2026 Improvement Activities Inventory and the 2026 MIPS Data Validation Criteria.[535] For details on finalized changes, refer to Appendix 2: Improvement Activities in this final rule, which outlines the following: finalized additions (Table Group A), finalized modifications to existing improvement activities (Table Group B), and finalized removals (Table Group C).

● Existing cost measures are included in the 2026 Cost Measures Inventory.[536] There were no proposed changes to cost measures included in the finalized CY 2027 MVPs.

● Existing Promoting Interoperability measures and attestations, adopted in prior rulemaking and included in the foundational layer, can be found on the Quality Payment Program website.[537] For details on finalized proposals to the Promoting Interoperability performance category, we refer readers to section IV.A.4.d.(4) of this final rule. Finalized proposals include a modification to the definition of CEHRT, a reduction in requirements, and the following: A modification to the PI_HIE_7: Electronic Prior Authorization measure, which changed the measure from being a required measure to an optional measure for the CY 2027 performance period/2029 MIPS payment year (measure was previously finalized as a required measure in the CMS Interoperability and Prior Authorization final rule (89 FR 8915 through 8927); and the addition of a new measure, Electronic Prior Authorization for Prescription Drugs (PI_HIE_8), which would be a required measure starting with the CY 2028 performance period/2030 MIPS payment year.

● For more information on the population health measures, attributed to the quality performance category and included in the foundational layer, refer to the CY 2022 PFS final rule (86 FR 65408 through 65409).

MVP Development: Measure and Improvement Activity Updates

● Group A and Group B MVPs include an additional table, identifying the finalized MIPS core measures within each MVP. For details on the finalized MIPS core measure proposal and selection criteria for MVPs refer to section IV.A.4.d.(1)(c) of this final rule.

● Refer to Appendix 1: MIPS Quality Measures (Table Group C) in this final rule for details on the removal of MIPS quality measures.

● Refer to Appendix 2: Improvement Activities (Table Group C) in this final rule for details on the removal of improvement activities.

● Refer to section IV.A.4.d.(4) Promoting Interoperability Performance Category measures in this final rule for details on the removal of Promoting Interoperability Performance Category measures. The following Promoting Interoperability measures, previously included in the foundational layer of MVPs, were finalized for removal from MIPS: **PI_PPHI_1:** Security Risk Analysis, **PI_ONCDIR_1:** ONC Direct Review Attestation, and **PI_ONCACB_1:** ONC-ACB Surveillance Attestation (Optional).

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[534] See the 2026 QCDR Measure Specification file: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3573/2026_QCDR_Measure_Specifications.xlsx* for QCDR measures.

[535] See the 2026 Improvement Activities Inventory: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3567/2026-Improvement-Activities-Inventory.zip* and 2026 MIPS Data Validation Criteria: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3574/2026-MIPS-Data-Validation-Criteria.zip*.
for improvement activity details.

[536] See the 2026 Cost Measures Inventory: *https://qpp.cms.gov/reporting-requirements/measures-activities/explore?tab=costMeasures&py=2026.*

[537] See the 2026 Promoting Interoperability Measure Specifications: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3566/2026-MIPS-Promoting-Interoperability-Measure-Specifications.zip* for Promoting Interoperability measure details.

MVP Symbol Information and Definitions

Please note the following symbols and definitions used within the MVP tables in this appendix:

- Quality measures finalized as MIPS core measures in an MVP are identified with a single exclamation point (!).
- Quality measures, improvement activities, cost measures, and Promoting Interoperability measures finalized for addition to a previously finalized MVP are identified with a plus sign (+).
- Finalized new MIPS quality measures, improvement activities, and Promoting Interoperability measures included in an MVP beginning with the CY 2027 performance period/2029 MIPS payment year and future years are identified with a caret symbol (^). See Appendix 1: MIPS Quality Measures: Table Group A, Appendix 2: Improvement Activities: Table Group A, and section IV.A.4.d.(4) of this final rule for further information regarding new MIPS quality measures, improvement activities and Promoting Interoperability measures.
- Existing measures and improvement activities with finalized revisions are identified with a single asterisk (*). For further information regarding finalized revisions see Appendix 1: MIPS Quality Measures: Tables Group D and DD for revisions to MIPS quality measures, Appendix 2: Improvement Activities: Table Group B for revisions to improvement activities, and section IV.A.4.d.(4) for revisions to Promoting Interoperability measures. Unless changes were required to continue to meet programmatic standards for inclusion, we included existing measures or activities with proposed revisions in MVPs (as applicable) regardless of whether the proposed revisions were finalized beginning with the CY 2027 performance period/2029 MIPS payment year.
- QCDR measures finalized with modifications by the QCDR measure stewards are identified in this appendix with a single asterisk (*). When applicable and substantive in nature, we provide a brief overview of the planned modifications within applicable MVPs. Since QCDR measures are exempt from public notice and comment, this overview allowed for transparency with interested parties and an opportunity to comment on all aspects of each MVP prior to finalization. Final decisions to modify QCDR measure specifications are determined by QCDR measure stewards, separate from rulemaking, but may impact decisions as finalized in the final rule.
- Quality measures and improvement activities identified with a double asterisk (**) can only be submitted when included in an MVP.
- Improvement activities that include an advancing health and wellness component are identified with a double exclamation point (!!).
- Quality measure collection types are identified in parentheses after each quality measure title.

Foundational Layer

Each MVP contains a foundational layer, which includes the entire set of Promoting Interoperability performance category measures and two population health measures. The foundational layer is the same for all MVPs, as listed in Table 1.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.

TABLE 1: MVP Foundational Layer

Population Health Measures	Promoting Interoperability Measures
(*) Q479: Hospital-wide, 30-Day, All-cause Unplanned Readmission (HWR) Rate for the Merit-based Incentive Payment System (MIPS) Groups (Collection Type: Administrative Claims) **Q484:** Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MCC) (Collection Type: Administrative Claims)	**PI_PPHI_2:** High Priority Practices Safety Assurance Factors for EHR Resilience (SAFER) Guide **PI_EP_1:** e-Prescribing **PI_EP_2:** Query of Prescription Drug Monitoring Program (PDMP) **PI_PEA_1:** Provide Patients Electronic Access to Their Health Information **PI_HIE_1:** Support Electronic Referral Loops By Sending Health Information AND **PI_HIE_4:** Support Electronic Referral Loops By Receiving and Reconciling Health Information OR **PI_HIE_5:** Health Information Exchange (HIE) Bi-Directional Exchange OR **PI_HIE_6:** Enabling Exchange Using the Trusted Exchange Framework and Common Agreement (TEFCA) **(+)(*) PI_HIE_7:** Electronic Prior Authorization (Optional) **PI_PHCDRR_1:** Immunization Registry Reporting **PI_PHCDRR_2:** Syndromic Surveillance Reporting (Optional) **PI_PHCDRR_3:** Electronic Case Reporting **PI_PHCDRR_4:** Public Health Registry Reporting (Optional) **PI_PHCDRR_5:** Clinical Data Registry Reporting (Optional) **PI_PHCDRR_6:** Public Health Reporting Using TEFCA (Optional) **PI_INFBLO_1:** Actions to Limit or Restrict Compatibility or Interoperability of CEHRT Attestation

Group A: New MVPs Proposed for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

A.1 Diabetic Disease MVP

In the CY 2027 PFS proposed rule (91 FR 43842), we proposed and solicited comments on the Diabetic Disease MVP. The proposed Diabetic Disease MVP assesses meaningful outcomes in diabetic disease care. This MVP would be most applicable to clinicians who provide diabetic disease patient care, including primary care, endocrinology, ophthalmology, podiatry, and nonphysician practitioners (NPPs) such as nurse practitioners, clinical nurse specialists, and

physician assistants. The summary of the public comments received and our responses to this MVP are included immediately after Table A.1b and the list of improvement activities.

Quality Measures

We proposed to include 11 MIPS quality measures and 2 QCDR measures within the quality performance category of this MVP, which are relevant to the clinical topic of diabetic disease care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2026 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

For the reasons stated in the introduction of this appendix,[538] we proposed the following measures as MIPS core measures for the Diabetic Disease MVP:

- **Q001**: Diabetes: Glycemic Status Assessment Greater Than 9%
- **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
- **Q317**: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented
- **Q488**: Kidney Health Evaluation

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in diabetic disease care:

- **Q001**: Diabetes: Glycemic Status Assessment Greater Than 9%: This inverse outcome MIPS quality measure assesses patients diagnosed with diabetes mellitus for poor control of their HbA1c.
- **Q019**: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: This MIPS quality measure focuses on the communication between the primary physician managing ongoing care and the physician performing the dilated macular or fundus exam on patients with diabetic retinopathy.
- **Q117**: Diabetes: Eye Exam: This MIPS quality measure supports eye screening for diabetic retinal disease.
- **Q126**: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation: This MIPS quality measure ensures patients diagnosed with diabetes mellitus have a lower extremity neurological exam performed at least once every 12 months.
- **Q127**: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear: This MIPS quality measure ensures patients diagnosed with diabetes mellitus are evaluated for proper footwear and sizing at least once every 12 months.
- **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients for a documented BMI with a follow-up plan documented if their most recent documented BMI was outside of normal parameters
- **Q317**: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: This MIPS quality measure ensures all adult patients are screened for high blood pressure at each visit and have a recommended follow-up plan if blood pressure is elevated or hypertensive.
- **Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: This MIPS quality measure identifies patients at high risk of cardiovascular events and ensures they are prescribed or currently on a statin therapy.

[538] See MVP Development: Quality Measure and Improvement Activity Updates

- **Q488**: Kidney Health Evaluation: This MIPS quality measure ensures patients with diabetes receive a kidney health evaluation including both an estimated glomerular filtration rate (eGFR) and a urine albumin-creatinine ratio (uACR).
- **IRIS58**: Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days: This QCDR measure assesses success of vitrectomy procedures in patients with diabetic retinopathy by reviewing patients for complications within 120 days of the procedure.
- **USWR35**: Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer: This QCDR measure assesses for adequate off-loading for diabetic foot ulcers during patient visits, which supports positive outcomes of Diabetic Foot Ulcer (DFU) healing.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in diabetic disease care. The quality measures below assess for screenings and follow-up actions for select measures:

- **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for those patients who screen positive.
- **Q226**: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 13 improvement activities that reflect actions and processes undertaken by clinicians who specialize in diabetic disease care, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision-making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities were proposed for inclusion in this MVP:

- **IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_AHW_5:** Lifestyle Approaches to Diabetes Remediation
- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_3:** Engagement with QIN-QIO to implement self-management training programs
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_19:** Use group visits for common chronic conditions (e.g., diabetes)
- **IA_BE_23:** Integration of patient coaching practices between visits
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_4:** Glycemic management services
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

Cost Measures

We proposed to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of diabetes. We reviewed the MIPS cost measure inventory and considered feedback received during the 2026 MVP candidate feedback period to

determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in diabetic care and align with other measures and activities within this MVP:

- **COST_D_1**: Diabetes: This MIPS cost measure applies to clinicians providing diabetic care.
- **TPCC_1:** Total Per Capita Cost (TPCC): This MIPS cost measure assesses the overall cost of care delivered to a Medicare patient with a focus on the primary care the patient receives from their providers.

Symbol Key:
Single exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): finalized new measure or improvement activity.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE A.1a: Diabetic Disease MVP MIPS Core Measures

Diabetic Disease MVP MIPS Core Measures
Q001: Diabetes: Glycemic Status Assessment Greater Than 9%
Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented
Q488: Kidney Health Evaluation

TABLE A.1b: Diabetic Disease MVP Clinical Groupings

Diabetic Disease MVP		
Clinical Grouping	**Quality**	**Cost**
Ophthalmology	**Q019:** Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (Collection Type: eCQM)	**N/A**
	Q117: Diabetes: Eye Exam (Collection Type: eCQM, MIPS CQM)	
	IRIS58: Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days (Collection Type: QCDR)	
Podiatry	**Q126:** Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (Collection Type: MIPS CQM)	**N/A**
	Q127: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear (Collection Type: MIPS CQM)	
	USWR35: Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer (Collection Type: QCDR)	

Diabetic Disease MVP		
Clinical Grouping	**Quality**	**Cost**
Multispecialty	**(!)(*) Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: eCQM, MIPS CQM, Medicare Part B Claims)	**COST_D_1:** Diabetes **TPCC_1:** Total Per Capita Cost
	(*) Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	
	(!) Q488: Kidney Health Evaluation (Collection Type: eCQM, MIPS CQM)	
Advancing Health and Wellness	**(!)(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: eCQM, MIPS CQM, Medicare Part B Claims)	**COST_D_1:** Diabetes **TPCC_1:** Total Per Capita Cost
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: eCQM, MIPS CQM, Medicare Part B Claims)	
	(!)(*) Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented (Collection Type: eCQM, MIPS CQM, Medicare Part B Claims)	

Diabetic Disease Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **(^)(!!) IA_AHW_5:** Lifestyle Approaches to Diabetes Remediation
- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_3:** Engagement with QIN-QIO to implement self-management training programs
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_19:** Use group visits for common chronic conditions (e.g., diabetes)
- **(!!) IA_BE_23:** Integration of patient coaching practices between visits
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(*)(!!) IA_PM_4:** Glycemic management services
- **IA_PM_16:** Implementation of medication management practice improvements
- **(!!) IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported this new MVP.

Response: We thank the commenters for their support.

Comment: A few commenters recognized the importance of this MVP for assessing diabetes care once traditional MIPS sunsets, but believed its current measures are too narrowly focused on glycemic thresholds and disease control rather than disease reversal and complexity. They noted that the central HbA1c poor control measure rewards staying below a high threshold, often through medication intensification, without recognizing substantial improvement, remission, or reduction in medications (for example, a patient lowering A1c from 8.5% to 5.6% off medications is treated similarly to a patient with an A1c of 6.8% on multiple drugs). Commenters also urged that the MVP be designed with type 1 diabetes (T1D) in mind, explaining that most existing measures are built around type

2 diabetes and do not reflect key T1D realities: lifelong insulin dependence from diagnosis, continuous hypoglycemia risk, and routine use of devices as standard care. They cautioned that measures based solely on glycemic thresholds could systematically disadvantage clinicians caring for the most complex T1D patients and, in a workforce-strained field, might discourage clinicians from accepting high-need beneficiaries. They therefore recommended incorporating measures that better capture disease reversal, lifestyle-driven improvement, and the distinct risks and care patterns in T1D.

Another commenter believed this MVP fails to reflect the full value of podiatric clinicians, who manage complex interactions among chronic lower-extremity conditions to prevent infection, hospitalization, and amputation. As a result, the commenter believed that for CY2028–CY2029 there is no MVP that accurately measures the work of clinicians providing chronic lower-extremity and complex-comorbidity care. The commenter recommended that podiatric and other lower-extremity chronic-disease measures—such as diabetic foot risk stratification, offloading, and amputation-prevention outcomes—be incorporated into any diabetes-related or chronic-care MVP.

Additional commenters focused on broadening participation and emphasizing meaningful outcomes. One commenter requested that the MVP include measures and activities that would allow pharmacists to participate, including medication-specific quality measures (for example, medication optimization, adherence, reconciliation, and comprehensive medication management) that capture the impact of pharmacist-led services on outcomes and costs, particularly for chronic conditions commonly addressed in the Quality Payment Program. Another commenter emphasized that the value of this MVP depends on its measure composition and urged that we prioritize outcome measures, such as rates of achieved disease control across a clinician's panel, rather than process attestations, noting that documenting counseling without improving control does not deliver value to the public. Finally, a couple of commenters recommended adding Q517: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management to this MVP.

Response: We thank the commenters for their feedback and may consider modifications to this MVP, including the addition of quality measures, through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter opposed this MVP, arguing it duplicates existing MVPs and should be folded into the Value in Primary Care MVP. They noted that diabetes care is often delivered by primary care providers, so a separate MVP is unnecessary and would increase administrative complexity. Another commenter appreciated the proposal to include this new MVP concept but stated that, as designed, it is not representative of comprehensive diabetes care. The commenter noted that the MVP identifies primary care, endocrinology, ophthalmology, podiatry, and nonphysician clinicians such as nurse practitioners, clinical nurse specialists, and physician assistants as the clinicians for whom this MVP would be most applicable. However, while these specialties participated in diabetes care, they were not responsible for diabetes care as a whole. For example, ophthalmologists and podiatrists address diabetes-related issues affecting the eyes and feet, respectively, but did not manage overall diabetes care.

Response: While we recognize that primary care clinicians often manage diabetes care, this MVP is designed to support clinicians who focus on diabetes management and the continuum of care, to provide meaningful performance measurement across this patient population. The Value of Primary Care MVP is most applicable to clinicians who specialize in preventive, internal, or family medicine or geriatrics, inclusion of these measures would pull in specialties beyond its intended scope. We acknowledge that there may be overlap between MVPs; however, our goal with offering disease-specific MVPs is to increase flexibility allowing clinicians to report on the MVP most relevant to their patient population and scope of care.

Comment: A commenter noted that although many quality measures in this MVP apply to all people with diabetes, Type 1 diabetes differs fundamentally from Type 2 diabetes. Because of these differences, the commenter recommended that the quality measures included in this MVP recognize these differences and support clinicians caring for people with Type 1 diabetes and others who require intensive insulin management. The commenter further recommended considering additional measures that better reflect high-quality diabetes care than A1C alone. Specifically, they suggested that quality measures should recognize the following: improvement over time; prevention of severe hypoglycemia and diabetic ketoacidosis; appropriate use of diabetes technology; individualized treatment plans; patient education and shared decision-making; and continuity and coordination of care.

Response: We appreciate the commenter's observations about the fundamental differences between Type 1 and Type 2 diabetes and the need for measures that support clinicians caring for patients who require intensive insulin

management. We agree that the current quality measure set does not fully capture high-quality diabetes care and encourage the commenter to work with measure developers and stewards to develop and submit measures that address these aspects of care through the Call for Measures process; such as improvement over time, prevention of complications, individualized treatment plans, patient education and shared decision-making, and continuity and coordination of care.

As we continue to refine the diabetes MVP, we will consider whether additional or alternative measures can better reflect these elements of high-quality diabetes care. Finalized MVPs are reviewed annually, and we may consider the addition of new quality measures through the MVP Maintenance Process and future rulemaking. Guidance on submitting recommended changes to an MVP is available on the Quality Payment Program website, and we will evaluate all recommendations to determine whether they are appropriate and aligned with the broader vision for the MVP.

Comment: A couple of commenters supported this MVP in concept but recommended revising to focus on the core elements of diabetes care and patient health conditions rather than medical specialties. Another commenter recommended the addition of the Adult Immunization Status measure. One commenter recommended the MVP include at least one prevention-focused concept measure, emphasizing identification and intervention for prediabetes rather than focusing exclusively on glycemic control and management of already diagnosed diabetes. A commenter recommended the addition of measures recognizing appropriate diagnostic testing, timely diagnosis, and follow-up based on test results in this MVP. Another commenter recommended anchoring MVP performance metrics in this MVP in objective, laboratory confirmed results, such as glycemic status assessment, kidney health evaluation, and lipid management. Another commenter was concerned that the MVP is overly broad and that its groupings are organized by specialty. One commenter expressed concern that the MVP does not adequately account for the foundational role Registered Dietitian Nutritionists (RDNs) play in chronic disease detection and intervention, including for the medical conditions associated with this MVP. The commenter recommended incorporating additional nutrition-related measures in this MVP that reflect the full scope of an RDN's role in preventing, managing, and treating such conditions as part of team-based, high-value care, and requested that RDNs be listed as an applicable clinician type for this MVP. A commenter recommended this MVP include at least one concept addressing prevention of diabetes onset rather than management of diagnosed disease alone.

Response: We appreciate the commenter's feedback. We encourage interested parties to submit potential new measures that will align with current program goals and priorities and fill these identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS during the annual Call for Measures. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A couple of commenters supported this MVP. A commenter requested clarification that reporting of Q117: Diabetes: Eye Exam can be any clinician who participates in this MVP.

Response: We thank the commenters for their support. For measure requested clarifications please contact the QPP Service Center by emailing QPP@cms.hhs.gov, submitting a QPP Service Center ticket, or calling 1-866-288-8292 (Monday-Friday, 8 a.m. – 8 p.m. ET).

Comment: A commenter requested the removal of the Total Per Capita Cost (TPCC) measure from this MVP, noting that a diabetes-specific episode cost measure already exists and is more appropriate. They stated that TPCC is fundamentally flawed because it holds physicians accountable for costs related to conditions they did not treat, decisions made by other providers, and spending they cannot influence (such as drug price changes and coverage for high-cost supplies). Since TPCC captures all Medicare Part A and B spending, it offers little actionable information for physicians to reduce costs or for patients to lower out-of-pocket expenses or choose clinicians, making it unsuitable for inclusion in this MVP.

Response: We consider TPCC an appropriate measure for use in this MVP, for reasons outlined in the CY 2027 PFS proposed rule (91 FR 43842). The costs of primary care services captured by the TPCC measure may be related to diabetic care management. Clinicians or groups who choose to report the Diabetic Disease MVP may be scored on the TPCC measure if they meet the established case minimum. We recognize that a portion of a patient's total cost of care may reflect services furnished or ordered by other providers. The measure's revised attribution methodology, specialty exclusion criteria, risk adjustment model, and payment standardization are all elements of the measure construction that help TPCC assess costs within a clinician's influence. We continue to consider potential updates for the TPCC measure and ways to enhance the actionability of the measure for attributed clinicians. We may

consider the addition or removal of cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Diabetic Disease MVP* as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

A.2 Hospitalist MVP

In the CY 2027 PFS proposed rule (91 FR 43842), we proposed and solicited comments on the Hospitalist MVP. The proposed Hospitalist MVP assesses meaningful outcomes for patients receiving care provided by hospitalists. This MVP would be most applicable to hospitalists, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. The summary of the public comments received and our responses to this MVP are included immediately after Table A.2b and the list of improvement activities.

Quality Measures

We proposed to include four MIPS quality measures and five QCDR measures within the quality performance category of this MVP, which are relevant to care provided by hospitalists. We reviewed the MIPS quality measure inventory and considered feedback received during the 2026 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

For the reasons stated in the introduction of this appendix,[539] we proposed the following measures as MIPS core measures for the Hospitalist MVP:

- **Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- **Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- **Q047:** Advance Care Plan

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for hospitalists:

- **Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD): This MIPS quality measure ensures patients diagnosed with heart failure and a left ventricular ejection fraction of less than or equal to 40% are prescribed an ACE inhibitor, ARB or ARNI therapy.
- **Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): This MIPS quality measure ensures patients diagnosed with heart failure and a left ventricular ejection fraction of less than or equal to 40% are prescribed beta-blocker therapy.
- **Q238:** Use of High-Risk Medications in Older Adults: This inverse MIPS quality measure supports patient safety by assessing high-risk medication utilization in the older adult population.
- **ECPR51:** Discharge Prescription of Naloxone after Opioid Poisoning or Overdose: This QCDR measure ensures patients treated for opioid poisoning in the acute care setting are prescribed naloxone and receive education on its proper use before discharge.

[539] See MVP Development: Quality Measure and Improvement Activity Updates

- **HCPR24:** Appropriate Utilization of Vancomycin for Cellulitis: This QCDR measure ensures the appropriate use of vancomycin for patients diagnosed with cellulitis in the hospital setting, whether admitted or under observation.
- **HCPR25:** Physician's Orders for Life-Sustaining Treatment (POLST) Form: This QCDR measure ensures patients with advanced illness have a completed POLST form during their hospitalization.
- **HCPR27:** Point-of-Care Ultrasound: Evaluation for Pneumothorax after Central Venous Catheter (CVC) Placement: This QCDR measure ensures patients undergoing CVC placement receive appropriate pneumothorax evaluation using point-of-care ultrasound.
- **HCPR30**: Avoidance of Sliding-Scale Insulin Monotherapy for Admitted Diabetic Patients: This QCDR measure ensures patients admitted to the hospital with a diagnosis of diabetes mellitus receive an order for basal insulin therapy.

The following broadly applicable MIPS quality measure is relevant to clinicians who specialize in hospitalist care.

- **Q047:** Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker.

Modifications were considered for the following QCDR measure:

- **ECPR51:** Discharge Prescription of Naloxone after Opioid Poisoning or Overdose: This QCDR measure is undergoing modifications to expand the measure to include the treatment for opioid withdrawal in additional care settings.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 12 improvement activities that reflect actions and processes undertaken by hospitalists, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision-making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities were proposed for inclusion in this MVP:

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BMH_12:** Promoting Clinician Well-Being
- **IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults
- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_8:** Use of patient safety tools
- **IA_PSPA_15:** Implementation of an ASP
- **IA_PSPA_21:** Implementation of fall screening and assessment programs

Cost Measures

We proposed to include one MIPS cost measure within the cost performance category of this MVP, which applies to hospitalists. We reviewed the MIPS cost measure inventory and considered feedback received during the 2026 MVP candidate feedback period to determine the

set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for hospitalists and aligns with other measures and activities within this MVP:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to hospitalists.

Symbol Key:
Single exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE A.2a: Hospitalist MVP MIPS Core Measures

Hospitalist MVP MIPS Core Measures
Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
Q047: Advance Care Plan

TABLE A.2b: Hospitalist MVP Clinical Groupings

Hospitalist MVP		
Clinical Grouping	**Quality**	**Cost**
Medication	**(!) Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM^^, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM^^, MIPS CQM)	
	(*) ECPR51: Discharge Prescription of Naloxone after Opioid Poisoning or Overdose (Collection Type: QCDR)	
	HCPR24: Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	
General Clinical Care	**HCPR27:** Point-of-Care Ultrasound: Evaluation for Pneumothorax after Central Venous Catheter (CVC) Placement (Collection Type: QCDR)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	HCPR30: Avoidance of Sliding-Scale Insulin Monotherapy for Admitted Diabetic Patients (Collection Type: QCDR)	
Advancing Health and Wellness	**Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	

Hospitalist MVP		
Clinical Grouping	**Quality**	**Cost**
	HCPR25: Physician's Orders for Life-Sustaining Treatment (POLST) Form (Collection Type: QCDR)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

^^Please note this collection type does not include inpatient coding and may not be applicable.

Hospitalist Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BMH_12:** Promoting Clinician Well-Being
- **(!!) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults
- **(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_8:** Use of patient safety tools
- **(!!) IA_PSPA_15:** Implementation of an ASP
- **(!!) IA_PSPA_21:** Implementation of fall screening and assessment programs

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported this new MVP. A commenter supported the designation of the three MIPS core measures in this MVP.

Response: We thank the commenters for their support.

Comment: A commenter appreciated the recognition of hospitalists through a proposed Hospitalist MVP but believed its four non-QCDR measures do not reflect the full scope of the specialty. They argued the MVP should include at least eight non-QCDR measures and a broader range beyond heart failure, given hospitalists care for patients across many service lines (e.g., cardiology, pulmonology, nephrology, oncology). They concluded that this MVP should only be finalized if at least four additional, relevant non-QCDR quality measures are added. Another commenter encouraged the identification of alternate measures that would remain meaningful for hospitalists should Q005: Heart Failure: Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker Therapy for Left Ventricular Systolic Dysfunction, and Q008: Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction become retired.

Response: We acknowledge that there are a limited number of quality measures included in this MVP and appreciate the commenter's feedback that the hospitalist clinician type represents a gap for quality measurement. We encourage the commenters to reach out to measure developers and stewards to develop applicable and meaningful measures for hospitalists for submission to the Call for Measures for possible future implementation. Finalized MVPs are reviewed annually to determine if additional updates are needed to meet the needs of the MVP and program requirements.

Comment: A few commenters requested the inclusion of Q130: Documentation of Current Medications in this MVP. They noted that Q130 had long been part of the Hospitalists Specialty Measure Set, is clinically relevant, and aligned with core responsibilities in the hospitalist setting. They also emphasized that Q130 was operationally feasible and already integrated into clinical workflows, unlike Q238.

Response: We may consider the addition of quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter stated that including Q047: Advance Care Plan as a MIPS core measure creates redundant reporting and unnecessary administrative burden because the same information is already captured through the

hospital inpatient eCQM CMS1317v1. The commenter questioned the rationale for maintaining two separate measures that collect the same content in the same setting for a subset of clinicians and urged alignment of advance care planning measures across clinician and hospital programs to reduce duplicative workflows, lessen documentation burden, and support consistent digital quality measurement.

Response: We thank the commenter for their feedback. We acknowledge there may be redundancy between clinical topics across programs; however, to be considered for purposes of reporting as a MIPS core measure, it must be proposed and finalized for MIPS. As each program has unique reporting requirements and nuances, the specification must be developed for that program to ensure feasible implementation. Currently, the hospital inpatient measure is not a part of the MIPS quality measure inventory. We will continue to work towards program alignment as applicable.

Comment: A couple of commenters appreciated both the proposal to include a Hospitalist MVP and the modifications made in response to stakeholder input, including the decision not to blend hospitalists and critical care intensivists into a single MVP. However, the commenters believed additional changes are needed. They stated that this MVP is specialty-based rather than focused on patient conditions and that categories such as "Medications" and "General Clinical Care" do not meaningfully distinguish the diverse patient populations and complications hospitalists manage. A commenter noted that many quality measures apply only to a small subset of patients (for example, heart failure measures for a minority of hospitalist cases) and that most measures are QCDR or eCQM measures that require extraction of data from hospital EHR systems. They explained that hospitalists cannot seamlessly aggregate EHR or registry data, and that hospital EHRs are certified and configured for hospital-level, not clinician-level, eCQMs. The commenters also expressed concern that there were only three eCQM reporting options despite related eCQMs having been adopted in other facility-based reporting programs.

Response: We appreciate the commenter's feedback. We acknowledge limitations to MVP development based upon the current MIPS quality measure inventory. Therefore, we had to balance clinical grouping identification based on selected measures that are meaningful and cover care assessment in alignment with the MVP intent. We encourage interested parties to submit potential new measures that will align with current program goals and priorities and fill these identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS during the annual Call for Measures. As each program has unique reporting requirements and nuances, the specification has to be developed for that program to ensure feasible implementation; then it must be proposed and finalized for MIPS. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Hospitalist MVP* as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

A.3 Hypertension MVP

In the CY 2027 PFS proposed rule (91 FR 43842), we proposed and solicited comments on the Hypertension MVP. The proposed Hypertension MVP assesses meaningful outcomes for patients receiving care for hypertension and appropriate preventive interventions for those considered high-risk. This MVP would be most applicable to clinicians who treat patients at risk for hypertension and with a hypertension diagnosis, including cardiology, family medicine, geriatrics, internal medicine, nutrition and dietician, preventive medicine, and NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. The summary of the public comments received and our responses to this MVP are included immediately after Table A.3b and the list of improvement activities.

Quality Measures

We proposed to include 13 MIPS quality measures within the quality performance category of this MVP, which are specific to the clinical topic of hypertension. We reviewed the MIPS quality measure inventory and considered feedback received during the 2026 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

For the reasons stated in the introduction of this appendix,[540] we proposed the following measures as MIPS core measures for the Hypertension MVP:

- **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
- **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
- **Q236:** Controlling High Blood Pressure

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in the treatment of hypertension:

- **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients for a documented BMI with a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- **Q236:** Controlling High Blood Pressure: This intermediate outcome MIPS quality measure assesses patients diagnosed with hypertension for adequately controlled blood pressure.
- **Q239:** Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents: This MIPS quality measure ensures that patients aged 3-17 years have a BMI recorded with appropriate nutrition and physical activity counseling.
- **Q317:** Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: This MIPS quality measure ensures all adult patients are screened for high blood pressure at each visit and have a recommended follow-up plan if blood pressure is elevated or hypertensive.
- **Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control): This intermediate outcome MIPS quality measure ensures optimal control of patients with IVD by assessing goals for blood pressure management, smoking cessation, antiplatelet use, and high intensity statin use.
- **Q489:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy: This MIPS quality measure ensures patients diagnosed with chronic kidney disease and proteinuria are prescribed an ACE inhibitor or ARB therapy.
- **Q517:** Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management: This proposed intermediate outcome MIPS quality measure ensures lipid monitoring in patients with atherosclerotic cardiovascular disease (ASCVD) and achieving the target goal of an LDL-C less than 70mg/dL.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in the treatment of hypertension. The quality measures below assess for age-specific screenings and follow-up actions for select measures:

- **Q047:** Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decision maker.
- **Q130:** Documentation of Current Medications in the Medical Record: This MIPS quality measure assesses for review and documentation of all current medications at each visit.
- **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- **Q374:** Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures that the referring

[540] See MVP Development: Quality Measure and Improvement Activity Updates

clinician receives a report from the clinician to whom the patient was referred, therefore closing the communication loop.

- **Q431:** Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: This MIPS quality measure screens patients for unhealthy alcohol use. Any patients that screen positive for unhealthy alcohol use should receive brief counseling.
- **Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We proposed to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in the treatment of hypertension, as well as activities that promote advancing health and wellness, engagement and patient-centeredness, shared decision-making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities were proposed for inclusion in this MVP:

- **IA_AHW_1:** Chronic care and preventative care management for empaneled patients
- **IA_AHW_5:** Lifestyle Approaches to Diabetes Remediation
- **IA_BE_16:** Promote Self-management in Usual Care
- **IA_BMH_2:** Tobacco use
- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_4:** Glycemic management services
- **IA_PM_5:** Engagement of community for health status improvement
- **IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk
- **IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

Cost Measures

We proposed to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of hypertension. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for clinicians who care for patients with hypertension:

- **TPCC_1:** Total Per Capita Cost (TPCC): This MIPS cost measure assesses the overall cost of care delivered to a Medicare patient with a focus on the primary care the patient receives from their providers.

Symbol Key:

Single exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): finalized new measure or improvement activity.

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE A.3a: Hypertension MVP MIPS Core Measures

Hypertension MVP MIPS Core Measures
Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
Q236: Controlling High Blood Pressure

TABLE A.3b: Hypertension MVP Clinical Groupings

Hypertension MVP		
Clinical Grouping	**Quality**	**Cost**
Prevention	**(!)(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	Q239: Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents (Collection Type: eCQM)	
	(*) Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q489: Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQM)	
Treatment and Control	**(!)(*) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(*) Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM)	
	(^) Q517: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(!) Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**TPCC_1:** Total Per Capita Cost

Hypertension MVP		
Clinical Grouping	**Quality**	**Cost**
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Hypertension Improvement Activities

- **(!!) IA_AHW_1:** Chronic care and preventative care management for empaneled patients
- **(^)(!!) IA_AHW_5:** Lifestyle Approaches to Diabetes Remediation
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **(!!) IA_BMH_2:** Tobacco use
- **(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(*)(!!) IA_PM_4:** Glycemic management services
- **(!!) IA_PM_5:** Engagement of community for health status improvement
- **(!!) IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk
- **(*) IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools, including AI-enabled predictive decision-support interventions—and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported this new MVP. A couple of commenters supported the inclusion of Q517:Low-Density Lipoprotein (LDL-C) Monitoring and Management in this MVP.

Response: We thank the commenters for their support.

Comment: A couple of commenters requested the addition of Q488: Kidney Health Evaluation to this MVP. A commenter recommended the inclusion of Q493: Adult Immunization Status. A commenter urged that this MVP prioritize outcome measures such as rates of achieved disease control in a clinician's panel, rather than process attestations, noting that documenting counseling without improving control fails to deliver value to the public. One commenter believed further refinements are needed. The commenter stated that the MVP is overly broad and that its groupings are organized by specialty.

Response: Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter requested the inclusion of at least one adult nutrition-focused measure to this MVP so registered dietitians electing to report this MVP can satisfy the four-measure requirement, noting Q239: Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents is specified for patients aged 3 to 17 and is therefore inapplicable to the Medicare population that registered dietitians serve.

Response: The eCQM collection type uses all-payer data and therefore this measure is appropriate for inclusion; however, we acknowledge not all measures included within the MVP will be applicable to all clinicians that elect to report the MVP. The commenter is encouraged to submit recommended changes to an MVP. Guidance on how to submit recommended changes can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter recommended the addition of measures recognizing appropriate diagnostic testing, timely diagnosis, and follow-up based on test results in this MVP. Another commenter recommended anchoring MVP performance metrics in this MVP in objective, laboratory confirmed results, such as glycemic status assessment,

kidney health evaluation, and lipid management. A commenter requested measures and activities be included in this MVP that would allow for pharmacists to participate, including medication-specific quality measures (e.g., medication optimization, adherence, reconciliation, comprehensive medication management) that capture the impact of pharmacist-led services on outcomes and costs, especially for chronic conditions commonly addressed in the Quality Payment Program.

Response: We encourage the commenters to reach out to measure developers to develop new measures applicable and meaningful to the clinical topic of this MVP and submit them to the Call for Measures for possible future implementation. Finalized MVPs are reviewed annually to determine if additional updates are needed to meet the needs of the MVP and program requirements.

Comment: A commenter opposed this MVP, stating it duplicates existing MVPs. They noted that all its quality measures already appear in the Value in Primary Care and Advancing Care for Heart Disease MVPs, making a separate MVP unnecessary and adding avoidable administrative complexity. Another commenter recommended that this MVP either adopt a narrower focus limited to the treatment of hypertension, or that the Advancing Care for Heart Disease MVP be updated to include measures addressing hypertension treatment in addition to the existing measures related to heart failure and other cardiac conditions.

Response: We acknowledge that there may be overlap between MVPs; however, each MVP is designed to target a specific clinical topic or specialty, allowing clinicians to report on the MVP most relevant to their patient population and scope of care. Additionally, each quality measure has unique denominator criteria which may constrain applicability to settings, clinician types, or patient populations. Our goal with offering disease-specific MVPs is to increase flexibility in the MVPs that clinicians can report. Consolidating these measures into existing MVPs would pull in specialties and patients beyond its intended scope.

Comment: A few commenters recommended the Low-Density Lipoprotein (LDL-C) Monitoring and Management measure be identified as a MIPS core measure.

Response: We may consider alternative MIPS core measures for this MVP through future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A couple of commenters expressed concern that Q236: Controlling High Blood Pressure does not reflect current evidence-based clinical guidelines and is identified as a MIPS core measure for this MVP. Q236 uses a less stringent blood pressure control threshold of 140/90 mm Hg than the American Heart Association and American College of Cardiology recommendation of 130/80, as evidence indicates further reduces the risk of heart attack, stroke, heart failure, cardiovascular events, and death.

Response: We thank the commenters for sharing their concern regarding alignment with current evidence-based hypertension guidelines. Q236: Controlling High Blood Pressure is a MIPS core measure for this MVP for several reasons. Q236 is a standardized quality measure with an established 140/90 mm Hg control threshold that supports consistent data collection which allows comparability across practices and enables benchmarking against existing national performance. While its 140/90 mm Hg threshold is less aggressive than the 130/80 mm Hg target recommended by the American Heart Association and American College of Cardiology, it still reflects a clinically meaningful level of control and allows us to assess hypertension management. Including Q236 as a MIPS core measure provides a practical and interpretable outcome measure that supports early learning, comparability, and broad adoption across many practice settings. We will continue to monitor the evidence base and measure landscape and may consider updates in future program years.

Comment: A commenter opposed limiting participation in this MVP. The commenter explained that focusing only on hospital-based physicians fails to reflect how hypertension care is actually delivered, since effective management relies on interdisciplinary teams that include registered nurses, advanced practice registered nurses (APRNs), primary care clinicians, care coordinators, pharmacists, and other professionals involved in patient education, medication management, care coordination, and ongoing monitoring across settings. The commenter recommended revising this MVP to better recognize and incentivize these interdisciplinary care teams, including nurses, that coordinate and deliver high-quality hypertension care.

Response: We appreciate the commenter's feedback. This MVP is not limited to facility-based clinicians. All MIPS-eligible clinicians whose scope of care relates to this MVP and the measures and activities in it may report this MVP.

Comment: A commenter noted that several measures included in this MVP may overlap conceptually or operationally. For example, the Ischemic Vascular Disease All-or-None Outcome Measure includes blood pressure control, smoking cessation, statin therapy, and other components that are also represented elsewhere in the MVP. The commenter questioned whether this overlap creates duplicate accountability, increases reporting burden, or disproportionately influences performance scoring without providing additional clinical value.
The commenter also observed that hypertension management increasingly relies on out-of-office blood pressure assessment and encouraged continued exploration of opportunities to incorporate validated home blood pressure measurements and ambulatory blood pressure monitoring into future quality measurement efforts when appropriate infrastructure exists. The commenter emphasized that current practice increasingly depends on out-of-office monitoring to support accurate diagnosis, treatment adjustment, and long-term management and recommended that future MVP development reflect this growing role while avoiding unnecessary reporting burden.

Response: We thank the commenter for the feedback. The individual measures can assess performance on specific processes or outcomes, which can help clinicians pinpoint where gaps exist and guide quality improvement efforts. The IVD All-or-None Outcome Measure assesses whether patients receive all recommended elements of care, providing a broader view of care coordination and overall quality that is not fully captured by any single component measure.

Please note, in reference to the numerator element for the IVD All-or-None Outcome Measure, only blood pressure readings performed by a clinician or an automated blood pressure monitor or device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by an automated blood pressure monitor or device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the automated blood pressure monitor or device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: If the TPCC cost measure will be included in this MVP, a commenter recommended revising the measure so that it is limited to or focused on cost components physicians can reasonably control and does not disincentivize preventive care, including by excluding preventive services from cost calculations and grouping costs by patient condition categories.

Response: We consider TPCC the most appropriate cost measure available for use in this MVP. There is currently no episode-based measure applicable to hypertension. Clinicians or groups who choose to report the Hypertension MVP will be scored on TPCC if they meet the established case minimum. The costs of the primary care services captured by TPCC may be related to management of hypertension. Assessing the cost of care for this population encourages clinicians to provide effective, well-coordinated care to patients with hypertension in a way that supports both improved outcomes and lower overall cost of care. We appreciate the commenter's recommendation regarding the design of the TPCC measure. The TPCC measure incorporates several features intended to limit costs outside of a clinician's influence, including an updated attribution methodology, specialty exclusion criteria, risk adjustment, and payment standardization. We do not currently exclude preventive services from the measure's cost calculations, as these services are relevant to the cost of primary care and doing so could create adverse incentives. We consider the measure as it is currently specified appropriate for use in the Hypertension MVP. However, we will consider enhancements to the TPCC measure and its actionability for future rulemaking. We may consider the addition or removal of cost measures through the MVP Maintenance Process and future rulemaking, such as the availability of a related hypertension episode-based measure. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Hypertension MVP* as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

Group B: Modifications to Previously Finalized MVPs for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

B.1: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

Table B.1a represents the proposed MIPS core measures for the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP. The B.1b table, followed by a list of improvement activities, represents the measures and activities finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP (90 FR 50406 through 50408) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP focuses on important assessors of the care emergency clinicians provide to patients. By focusing on these specific measures and activities, emergency clinicians can reduce clinical variability, improve the quality of emergency care and potentially lower costs. This MVP would be most applicable to clinicians who treat patients within the practice of emergency medicine, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.1b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[541] we proposed the following measures as MIPS core measures for the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP:

- **Q116:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis
- **Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)
- **Q416:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years

We proposed adding one MIPS quality measure:

- **Q066:** Appropriate Testing for Pharyngitis: This appropriate use MIPS quality measure assesses for completion of a group A streptococcus test for patients diagnosed with pharyngitis or tonsilitis who were prescribed an antibiotic.

For the reasons stated in the introduction of this appendix,[542] we proposed to remove **Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older. We proposed to remove one QCDR measure due to low adoption, no benchmark after 2 consecutive years in MIPS and one high performing QCDR measure:

- **ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Acute Atraumatic Low Back Pain (low adoption, no benchmark after 2 consecutive years in MIPS)
- **ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (high performing)

Modifications were considered for the following QCDR measure:

- **ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Acute Atraumatic Low Back Pain: If the measure is not finalized for removal in the CY 2027 PFS final rule, this QCDR measure would undergo modifications to the denominator to exclude patients aged 65 and older, as they experience higher rates of osteoporosis-related vertebral fractures during routine activities and have higher rates of

[541] See MVP Development: Quality Measure and Improvement Activity Updates
[542] Ibid.

malignancies with spinal metastases compared to patients under 65 years old.

Symbol Key:
Single exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.1a: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP MIPS Core Measures

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP MIPS Core Measures
Q116: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis
Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)
Q416: Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years

TABLE B.1b: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Clinical Groupings

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP		
Clinical Grouping	**Quality**	**Cost**
Infectious Disease/ Antibiotic Stewardship	**Q065:** Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM, MIPS CQM)	**COST_EDV_1:** Emergency Medicine
	(+) Q066: Appropriate Testing for Pharyngitis (Collection Type: eCQM, MIPS CQM)	
	(!) Q116: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQM)	
	(!) Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQM)	
	HCPR24: Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	
Trauma	**(!) Q416:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years (Collection Type: MIPS CQM)	**COST_EDV_1:** Emergency Medicine
Experience of Care	**Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CMS-approved Survey Vendor)	**COST_EDV_1:** Emergency Medicine
	ACEP50: ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR)	

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BMH_12:** Promoting Clinician Wellbeing
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways

- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **(!!) IA_PSPA_15:** Implementation of an ASP

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. Another commenter specifically supported the addition of Q066: Appropriate Testing for Pharyngitis.

Response: We thank the commenters for their support.

Comment: A commenter recommended the addition of Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy and Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis to this MVP. Another commenter recommended the inclusion of the Medicare Spend Per Beneficiary (MSPB) and Total Per Capita Cost (TPCC) cost measures as they are currently available to emergency medicine clinicians.

Response: We may consider the addition of quality and cost measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter was concerned that several of the measures identified as MIPS core measures in this MVP were not universally applicable across emergency medicine practice settings and requested that the MIPS core measures be broadly appliable and reflective of the full spectrum of emergency medicine.

Response: We appreciate the commenter's feedback and may consider alternative MIPS core measures for this MVP through future rulemaking. Understanding that some clinicians may be unable to report the selected MIPS core measures, we do allow attestation for cases in which a MIPS core measure is not available and applicable. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A few commenters opposed removing Q415: Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older, arguing there is no feasible replacement and that the measure provides important clinical stewardship for imaging. The commenter noted Q415 is high-volume and widely reportable, so its removal could leave many clinicians unable to meet case minimums and stressed that topped-out status should be weighed against feasibility and denominator volume. Another commenter believed it is critical that the MVP includes enough measure options for clinicians, especially with the proposed sunsetting of traditional MIPS.

Response: We acknowledge the commenters' concern regarding the removal of measure Q415: Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older. We seek to balance meaningful quality reporting with minimizing strain placed on clinicians. This measure may still represent an important aspect of care, however, it meets criteria for removal from MIPS, finalized in the CY2017 Quality Payment Program final rule (81 FR 77558 through 77675).

Comment: A commenter opposed the removal of ACEP52 and ECPR46, both of which are part of ACEP's Qualified Clinical Data Registry (QCDR), and the Clinical Emergency Data Registry (CEDR). With these removals, only one CEDR measure would remain available within the MVP, significantly limiting emergency physicians' ability to report measures tailored to emergency medicine practice. The commenter believed QCDR measures are essential for capturing specialty specific quality and safety priorities which is not reflected in general MIPS measures. The commenter agreed with the proposed modifications for ACEP52 and believed its removal would be premature, particularly given ongoing efforts to improve adoption and benchmarking.

Response: We appreciate the commenters' feedback on ACEP52 and ECPR46. We agree that ACEP52 may be showing increased adoption; therefore, it will continue to be removed from the MVP based on the reporting requirements. However, we will consider maintaining it in MIPS for an additional year to monitor adoption. While we agree these concepts are important to quality care, the removal of these measures does not preclude clinicians

from continuing these quality actions. Whether the clinician is being assessed for the quality action or not, it should still be completed as part of routine clinical practice. Additionally, QCDR measures must meet established inclusion criteria to be finalized for MIPS and for inclusion within an MVP. Based upon review of ECPR46, it no longer meets MVP inclusion criteria. MIPS performance data shows high performance and presents limited opportunity to further improve clinical outcomes.

After consideration of public comments, we are finalizing the *Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.2: Advancing Cancer Care MVP

Table B.2a represents the proposed MIPS core measures for the Advancing Cancer Care MVP. The B.2b table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Cancer Care MVP (90 FR 50408 through 50411) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Advancing Cancer Care MVP focuses on the clinical specialty of providing fundamental treatment and management of cancer care. This MVP would be most applicable to clinicians who treat patients within the practices of oncology and hematology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.2b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[543] we proposed the following measures as MIPS core measures for the Advancing Cancer Care MVP:

- **Q102:** Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients
- **Q144:** Oncology: Medical and Radiation - Plan of Care for Pain
- **Q451:** RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy
- **Q457:** Percentage of Patients who Died with Cancer Enrolled in Hospice For At Least 3 Days Immediately Before Death
- **Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood
- **Q506:** Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy

We proposed adding two QCDR measures:

- **PIMSH19:** Antiemetic Therapy for Low- and Minimal-Emetic-Risk Antineoplastic Agents - Avoidance of Overuse (Lower Score - Better): This QCDR measure is an inverse measure (lower score is better) that ensures clinicians follow clinical guidelines for patients treated with low- or minimal-emetic-risk antineoplastic agents by assessing for inappropriate pre-treatment antiemetic therapy.
- **PIMSH20:** Appropriate Antiemetic Therapy for High- and Moderate-Emetic-Risk Antineoplastic Agents: This QCDR measure ensures clinicians follow clinical guidelines for patients treated with high- or moderate-emetic-risk antineoplastic agents by ensuring they receive the appropriate pre-treatment antiemetic therapy, which could result in

[543] See MVP Development: Quality Measure and Improvement Activity Updates

improved control of nausea and vomiting in patients.

For the reasons stated in the introduction of this appendix,[544] we proposed to remove **Q143:** Oncology: Medical and Radiation – Pain Intensity Quantified.

Modifications were considered for the following QCDR measure:

- **PIMSH13:** Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy: This QCDR measure is undergoing modifications to provide additional clarification and to emphasize its focus on first-line treatment. Updates are being made to the description, denominator, denominator exclusions, and numerator, along with the addition of a numerator note.

Improvement Activities

We proposed adding one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix,[545] we proposed to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Single exclamation point (!): MIPS core measure within an MVP.

Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.

Single asterisk (*): existing measures and improvement activities with finalized revisions.

Double asterisk (**): measures and improvement activities only available when included in an MVP.

Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.2a: Advancing Cancer Care MVP MIPS Core Measures

Advancing Cancer Care MVP MIPS Core Measures
Q102: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients
Q144: Oncology: Medical and Radiation - Plan of Care for Pain
Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy
Q457: Percentage of Patients who Died with Cancer Enrolled in Hospice For At Least 3 Days Immediately Before Death
Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood
Q506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy

TABLE B.2b: Advancing Cancer Care MVP Clinical Groupings

Advancing Cancer Care MVP		
Clinical Grouping	**Quality**	**Cost**
Medical Oncology	**Q450:** Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost

[544] See MVP Development: Quality Measure and Improvement Activity Updates

[545] Ibid.

Advancing Cancer Care MVP		
Clinical Grouping	**Quality**	**Cost**
	(!) Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy (Collection Type: MIPS CQM)	
	Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM)	**COST_PC_1:** Prostate Cancer **TPCC_1:** Total Per Capita Cost
	Q490: Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors (Collection Type: MIPS CQM)	
	(!) Q506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(*) Q507: Appropriate Germline Testing for Ovarian Cancer Patients (Collection Type: MIPS CQM)	
	(*) PIMSH13: Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy (Collection Type: QCDR)	
	PIMSH17: Oncology: Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure) (Collection Type: QCDR)	**TPCC_1:** Total Per Capita Cost
	(+) PIMSH19: Antiemetic Therapy for Low- and Minimal-Emetic-Risk Antineoplastic Agents - Avoidance of Overuse (Lower Score - Better) (Collection Type: QCDR)	**COST_PC_1:** Prostate Cancer **TPCC_1:** Total Per Capita Cost
	(+) PIMSH20: Appropriate Antiemetic Therapy for High- and Moderate-Emetic-Risk Antineoplastic Agents (Collection Type: QCDR)	
Radiation Oncology	**(!)(*) Q102:** Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (Collection Type: eCQM, MIPS CQM)	**COST_PC_1:** Prostate Cancer **TPCC_1:** Total Per Capita Cost
	(!)(*) Q144: Oncology: Medical and Radiation - Plan of Care for Pain (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_PC_1:** Prostate Cancer **TPCC_1:** Total Per Capita Cost
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_PC_1:** Prostate Cancer **TPCC_1:** Total Per Capita Cost
	Q321: CAHPS for MIPS Clinician/Group Survey (Collection Type: CMS-approved Survey Vendor)	
	(*) Q453: Percentage of Patients who Died with Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQM)	

Advancing Cancer Care MVP		
Clinical Grouping	**Quality**	**Cost**
	(!)(*) Q457: Percentage of Patients who Died with Cancer Enrolled in Hospice For At Least 3 Days Immediately Before Death (Collection Type: MIPS CQM)	
	(!) Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Advancing Cancer Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_24:** Financial Navigation Program
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **(+)(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_CC_17:** Patient Navigator Program
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients
- **IA_PM_15:** Implementation of episodic care management practice improvements
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative
- **(*) IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools, including AI-enabled predictive decision-support interventions—and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported this MVP. A commenter supported Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood as a MIPS core measure in this MVP. Other commenters supported the addition of PIMSH19: Antiemetic Therapy for Low- and Minimal-Emetic Risk Antineoplastic Agents - Avoidance of Overuse, and PIMSH20: Appropriate Antiemetic Therapy for High- and Moderate-Emetic-Risk Antineoplastic Agents.

Response: We thank the commenters for their support.

Comment: A commenter recommended PIMSH19 and PIMSH20 be considered MIPS core measures for this MVP given their broad applicability.

Response: MIPS core measures must be publicly available measures. For details on the finalized MIPS core measure proposal and selection criteria for MVPs refer to section IV.A.4.d.(1)(c) of this final rule. We may consider alternative MIPS core measures for this MVP through future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter recommended broadening this MVP to include additional cancer-related measures from key diagnostic and management specialties—such as Diagnostic Radiology (Q405, Q406), Women's Health (Q112, Q309), and Pathology (Q249, Q250, Q395, Q396, Q397, Q440, Q491). The commenter believed these measures capture critical information on diagnosis and tumor staging that directly informs treatment decisions and affects patient outcomes and, as such, should be recognized as part of comprehensive cancer care. The commenter further

suggested that expanding the MVP to incorporate measures across the cancer care continuum would better support meaningful performance measurement, reduce reporting burden for multispecialty organizations, and advance efforts to improve patient outcomes. Another commenter recommended the addition of the PIMSH4: Patient-Reported Pain Improvement Within 30 Days, a patient-reported outcome measure.

Response: We may consider the addition of quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A few commenters opposed the removal of Q143: Oncology: Medical and Radiation – Pain Intensity Quantified from this MVP, explaining that removing this measure would leave an insufficient number of eCQMs to support an all-eCQM reporting strategy and would force organizations to contract with third-party vendors to report alternative measure types solely to meet the requirement to report four quality measures. Another commenter opposed the removal of Q143: Oncology: Medical and Radiation – Pain Intensity Quantified from this MVP because Q143 and Q144: Plan of Care for Pain function as a paired workflow, requiring pain to be quantified before a plan of care is documented. Removing Q143 would force practices to continue collecting pain intensity data to satisfy Q144 without receiving reporting credit. The commenter also noted that Q143 and Q144 are currently used in the Enhancing Oncology Model (EOM-4), and removing Q143 from this MVP would create administrative disruption and benchmarking misalignment between this MVP and EOM. The commenter is developing a new pain Patient-Reported Outcome Performance Measure (PRO-PM) intended to ultimately replace both Q143 and Q144. They therefore recommended retaining Q143 alongside Q144 in this MVP until the new Pain PRO-PM is fully developed, validated through the MUC process, and ready for implementation, with both Q143 and Q144 serving as MIPS core measures in the meantime.

Response: We acknowledge the commenters' concern regarding the removal of measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified; however, as we refine the MIPS quality measure inventory we seek to remove measures that split apart quality actions, as the resultant data doesn't represent a full assessment of the patient's quality of care. While we endeavor to align across programs as applicable, this measure meets criteria for removal from MIPS, finalized in the CY2017 Quality Payment Program final rule (81 FR 77558 through 77675). Please refer to Appendix 1: MIPS Quality Measures (Table Group C) in this final rule for details on the removal of Q143.

After consideration of public comments, we are finalizing the *Advancing Cancer Care MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.3: Advancing Care for Heart Disease MVP

Table B.3a represents the proposed MIPS core measures for the Advancing Care for Heart Disease MVP. The B.3b table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Care for Heart Disease MVP (90 FR 50411 through 50415) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Advancing Care for Heart Disease MVP focuses on the clinical theme of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, heart disease. This MVP would be most applicable to clinicians who treat patients within the practices of cardiology, internal medicine and family medicine, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.3b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[546] we proposed the following measures as MIPS core measures for the Advancing Care for Heart Disease MVP:

- **Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)
- **Q492:** Risk-standardized Acute Cardiovascular-related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System
- **Q517:** Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management

We proposed adding one MIPS quality measure:

- **Q517:** Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management: This proposed intermediate outcome MIPS quality measure ensures lipid monitoring in patients with atherosclerotic cardiovascular disease (ASCVD) and achieving the target goal of an LDL-C less than 70mg/dL.

For the reasons stated in the introduction of this appendix,[547] we proposed to remove **Q006:** Coronary Artery Disease (CAD): Antiplatelet Therapy, **Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%), and **Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy.

Improvement Activities

For the reasons stated in the introduction of this appendix,[548] we proposed to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): finalized new measure or improvement activity.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.3a: Advancing Care for Heart Disease MVP MIPS Core Measures

Advancing Care for Heart Disease MVP MIPS Core Measures
Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)
Q492: Risk-standardized Acute Cardiovascular-related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System
Q517: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management

TABLE B.3b: Advancing Care for Heart Disease MVP Clinical Groupings

[546] See MVP Development: Quality Measure and Improvement Activity Updates
[547] See MVP Development: Quality Measure and Improvement Activity Updates
[548] See MVP Development: Quality Measure and Improvement Activity Updates

Advancing Care for Heart Disease MVP		
Clinical Grouping	**Quality**	**Cost**
Congestive Heart Failure	**Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM, MIPS CQM)	**COST_HF_1:** Heart Failure **TPCC_1:** Total Per Capita Cost
	Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM, MIPS CQM)	
	Q377: Functional Status Assessments for Heart Failure (Collection Type: eCQM)	
	(!) Q492: Risk-standardized Acute Cardiovascular-related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System (Collection Type: Administrative Claims)	
General Cardiology	**Q118:** Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%) (Collection Type: MIPS CQM)	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **TPCC_1:** Total Per Capita Cost
	Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQM)	
	(!)(*) Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(!)(^)(+) Q517: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management (Collection Type: MIPS CQM)	
Electrophysiology	**(*) Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q393: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQM)	**COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI)

Advancing Care for Heart Disease MVP		
Clinical Grouping	**Quality**	**Cost**
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **TPCC_1:** Total Per Capita Cost **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q238: Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **TPCC_1:** Total Per Capita Cost **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Advancing Care for Heart Disease Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **IA_BE_24:** Financial Navigation Program
- **IA_BE_25:** Drug Cost Transparency
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. Several commenters supported the inclusion of the Low-Density Lipoprotein (LDL-C) Monitoring and Management measure in this MVP. The commenters believed the measure is meaningful, guideline-directed, and outcome-based and therefore critical to influencing clinician and patient behavior to improve chronic disease outcomes in the United States. A couple of commenters supported the measure as a MIPS core measure in this MVP. Another commenter supported the removal of Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy, Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%), and Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy.

Response: We thank the commenters for their support.

Comment: A commenter recommended the inclusion of Q488: Kidney Health Evaluation to this MVP. The commenter believed the measure will help reinforce the importance of identifying and managing kidney disease risk

in patients with cardiovascular conditions and would better reflect the interconnected nature of cardiovascular-kidney-metabolic health.

Response: We may consider the addition of quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter requested Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood be considered a MIPS core measure within this MVP.

Response: We may consider alternative MIPS core measures for this MVP through future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter expressed concern that the three proposed MIPS core measures may not be applicable across the diverse cardiovascular subspecialties expected to participate in this MVP. Some cardiovascular clinicians may have limited opportunity to influence these measures in a way that meaningfully reflects their practice.

Response: We thank the commenter for their feedback and acknowledge limitations to MIPS core measure selection based upon the current MIPS quality measure inventory. Therefore, we had to balance between choosing measures that most closely represent care central to the MVP intent, while also ensuring measure availability for those clinicians who chose to report the MVP. Additionally, the policy includes an option for self-attestation when the MIPS core measures are not appropriate or applicable to their scope of care, allowing clinicians to choose an alternate measure that is more relevant. We encourage interested parties to submit potential new measures that will align with current program goals and priorities and fill these identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS during the annual Call for Measures.

After consideration of public comments, we are finalizing the *Advancing Care for Heart Disease MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.4: Advancing Rheumatology Patient Care MVP

Table B.4a represents the proposed MIPS core measures for the Advancing Rheumatology Patient Care MVP. The B.4b table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Rheumatology Patient Care MVP (90 FR 50415 through 50418) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Advancing Rheumatology Patient Care MVP focuses on the clinical theme of providing fundamental treatment and management of rheumatological conditions. This MVP would be most applicable to clinicians who treat patients within the practice of rheumatology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.4b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[549] we proposed the following measures as MIPS core measures for the Advancing Rheumatology Patient Care MVP:

- **Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age
- **Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment

[549] See MVP Development: Quality Measure and Improvement Activity Updates

- **Q180:** Rheumatoid Arthritis (RA): Glucocorticoid Management

We proposed adding one QCDR measure:

- **UREQA8:** Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved: This QCDR measure ensures that patients diagnosed with osteopenia or osteoporosis maintain a hydroxy-vitamin D level at or above the targeted threshold.

We proposed to remove one process QCDR measure that does not include a quality action:

- **ACR12:** Disease Activity Measurement for Patients with PsA

Modifications were considered for the following QCDR measures:

- **ACR10:** Hepatitis B Safety Screening: This QCDR measure is undergoing modifications to add denominator instructions that provide clearer guidance on what qualifies as a 'newly initiated' biologic.
- **ACR12:** Disease Activity Measurement for Patients with PsA: If the measure is not finalized for removal in the CY 2027 PFS final rule, this QCDR measure would undergo modifications to the denominator to add a specific age-related timeframe and clarify the required timeframe for the additional face-to-face encounter.
- **ACR14:** Gout: Serum Urate Target: This QCDR measure is undergoing modifications to the denominator to include a specific age-related timeframe. There would also be updates to the denominator exceptions to align with the American College of Rheumatology (ACR) clinical guidelines.
- **ACR15:** Safe Hydroxychloroquine Dosing: This QCDR measure is undergoing modifications to the description and numerator to add a second option for meeting numerator compliance. An alternative criterion, allowing completion and documentation of an Hydroxychloroquine (HCQ) whole blood level measurement would satisfy numerator requirements.

Improvement Activities

We proposed adding one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix,[550] we proposed to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.4a: Advancing Rheumatology Patient Care MVP MIPS Core Measures

[550] See MVP Development: Quality Measure and Improvement Activity Updates

Advancing Rheumatology Patient Care MVP MIPS Core Measures
Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age
Q178: Rheumatoid Arthritis (RA): Functional Status Assessment
Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management

TABLE B.4b: Advancing Rheumatology Patient Care MVP Clinical Groupings

Advancing Rheumatology Patient Care MVP		
Clinical Grouping	**Quality**	**Cost**
Rheumatoid Arthritis	**Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQM)	**COST_RA_1:** Rheumatoid Arthritis **TPCC_1:** Total Per Capita Cost
	(!)(*) Q178: Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQM)	
	(!) Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQM)	
Autoimmune/ Inflammatory Diseases	**(*) ACR14:** Gout: Serum Urate Target (Collection Type: QCDR)	**TPCC_1:** Total Per Capita Cost
	(*) ACR15: Safe Hydroxychloroquine Dosing (Collection Type: QCDR)	**COST_RA_1:** Rheumatoid Arthritis **TPCC_1:** Total Per Capita Cost
	UREQA10: Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function (Collection Type: QCDR)	**TPCC_1:** Total Per Capita Cost
Advancing Health and Wellness	**(!) Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_RA_1:** Rheumatoid Arthritis **TPCC_1:** Total Per Capita Cost
	(*) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(*) Q176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQM)	
	(*) ACR10: Hepatitis B Safety Screening (Collection Type: QCDR)	
	(+) UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved (Collection Type: QCDR)	
	UREQA9: Screening for Osteoporosis for Men Aged 70 Years and Older (Collection Type: QCDR)	
	Q493: Adult Immunization Status (Collection Type: MIPS CQM)	
Experience of Care	**Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	**COST_RA_1:** Rheumatoid Arthritis

Advancing Rheumatology Patient Care MVP		
Clinical Grouping	**Quality**	**Cost**
		TPCC_1: Total Per Capita Cost

Advancing Rheumatology Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_24:** Financial Navigation Program
- **IA_BE_25:** Drug Cost Transparency
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!!) IA_BMH_2:** Tobacco use
- **(+)(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. A couple of commenters supported the designation of Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age as a MIPS core measure for this MVP.

Response: We thank the commenters for their support.

Comment: A commenter opposed the removal of ACR12: Disease Activity Measurement for Patients with PsA from this MVP, arguing that it further reduces the already limited number of specialty-relevant measures and eliminated the only psoriatic arthritis measure, thereby disadvantaging rheumatologists. The commenter believed the removal is premature because no concerns had been raised when prior measure changes were communicated and noted that the measure steward could have revised and improved ACR12 if alerted earlier. They requested that ACR12 be retained for the upcoming performance year and refined collaboratively in future rulemaking to maintain meaningful, rheumatology-specific quality assessment.

Response: We thank the commenter for their feedback. We agree that the concept is important to the care of rheumatology patients, specifically those with psoriatic arthritis. However, this process measure only requires the screening of disease activity and does not evaluate whether appropriate follow-up care or interventions occur after the screening. Removing this process measure will support the goal of prioritizing measures that improve patient outcomes and have meaningful impact. We do not want to arbitrarily limit measures within MVPs; however, we do want to have a streamlined set of robust quality measures that drive positive outcomes. We note this MVP still contains over 10 meaningful quality and QCDR measures to ensure applicability and clinician choice for selection. Lastly, we encourage the commenter to reach out to measure developers and stewards to develop new outcome measures for submission to the Call for Measures for possible future implementation.

After consideration of public comments, we are finalizing the *Advancing Rheumatology MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.5 Complete Ophthalmologic Care MVP

Table B.5a represents the proposed MIPS core measures for the Complete Ophthalmologic Care MVP. The B.5b table, followed by a list of improvement activities, represents the measures and activities finalized within the Complete Ophthalmologic Care MVP (90 FR 50418 through 50421) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. This MVP would be most applicable to clinicians who treat patients within the practices of ophthalmology and optometry, including NPPs such as nurse practitioners,

clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.5b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[551] we proposed the following measures as MIPS core measures for the Complete Ophthalmologic Care MVP:

- **Q012:** Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation
- **Q141:** Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care
- **Q304:** Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery
- **Q385:** Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery
- **Q501:** Acute posterior vitreous detachment and acute vitreous hemorrhage appropriate examination and follow-up

Modifications were considered for the following QCDR measure:

- **IRIS2:** Glaucoma – Intraocular Pressure Reduction: This QCDR measure is undergoing modifications to ensure compliance is based upon assessment of intraocular pressure for each eye effected.

For the reasons stated in the introduction of this appendix,[552] we proposed to remove **Q384:** Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery. We proposed to remove two high performing QCDR measures:

- **IRIS13:** Diabetic Macular Edema - Loss of Visual Acuity
- **IRIS54:** Complications After Cataract Surgery

Improvement Activities

We proposed adding one improvement activity relevant to this MVP, which includes elements of an activity that is proposed for removal from MIPS:

- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements.

For the reasons stated in the introduction of this appendix,[553] we proposed to remove **IA_CC_10:** Care transition documentation practice improvements.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.5a: Complete Ophthalmologic Care MVP MIPS Core Measures

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[551] See MVP Development: Quality Measure and Improvement Activity Updates
[552] Ibid.
[553] Ibid.

Complete Ophthalmologic Care MVP MIPS Core Measures
Q012: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation
Q141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care
Q304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery
Q385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery
Q501: Acute posterior vitreous detachment and acute vitreous hemorrhage appropriate examination and follow-up

TABLE B.5b: Complete Ophthalmologic Care MVP Clinical Groupings

Complete Ophthalmologic Care MVP		
Clinical Grouping	**Quality**	**Cost**
Cataract	**(*) Q191:** Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery (Collection Type: eCQM, MIPS CQM)	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	Q303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (Collection Type: MIPS CQM)	
	(!) Q304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery (Collection Type: MIPS CQM)	
	Q389: Cataract Surgery: Difference Between Planned and Final Refraction (Collection Type: MIPS CQM)	
	IRIS61: Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery (Collection Type: QCDR)	
General Ophthalmology	**Q117:** Diabetes: Eye Exam (Collection Type: eCQM, MIPS CQM)	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	
Retinal Disease	**Q019:** Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (Collection Type: eCQM)	**N/A**
	(!) Q385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery (Collection Type: MIPS CQM)	
	Q499: Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy (Collection Type: MIPS CQM)	
	Q500: Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up (Collection Type: MIPS CQM)	
	(!) Q501: Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up (Collection Type: MIPS CQM)	

Complete Ophthalmologic Care MVP		
Clinical Grouping	**Quality**	**Cost**
	IRIS58: Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days (Collection Type: QCDR)	
Glaucoma	**(!) Q012:** Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation (Collection Type: eCQM)	**N/A**
	(!)(*) Q141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care (Collection Type: Medicare Part B Claims, MIPS CQM)	
	(*) IRIS2: Glaucoma – Intraocular Pressure Reduction (Collection Type: QCDR)	
	IRIS39: Intraocular Pressure Reduction Following Trabeculectomy or an Aqueous Shunt Procedure (Collection Type: QCDR)	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
Experience of Care	**Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation

Complete Ophthalmologic Care Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_25:** Drug Cost Transparency
- **(+)(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP.

Response: We thank the commenter for their support.

Comment: A commenter expressed concern with the selection of Q304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery as a MIPS core measure for this MVP.

Response: We thank the commenter for their feedback and acknowledge that not all MIPS core measures will be applicable to all clinicians reporting the MVP. Therefore, in each MVP, we identified multiple MIPS core measures that represent care central to the MVP intent, ensuring measure availability for those clinicians who chose to report the MVP.

Comment: A couple of commenters opposed the removal of IRIS13: Diabetic Macular Edema - Loss of Visual Acuity and IRIS54: Complications After Cataract Surgery, with one commenter also opposing the removal of Q384: Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery. The commenters believed eliminating these measures would further narrow an already limited measure set, reduce the MVP's relevance across the scope of ophthalmic practice, and remove a measure that directly supports our priority of addressing chronic disease.

Response: We appreciate the commenter's feedback on IRIS13: Diabetic Macular Edema - Loss of Visual Acuity and IRIS54: Complications After Cataract Surgery. While we agree the focus of these QCDR measures are important to addressing this highly prevalent chronic disease, the removal of these measures does not preclude clinicians from continuing these quality actions. Whether the clinician or group is being assessed for the quality action or not, it should still be completed as part of routine clinical practice. Additionally, we seek to balance meaningful quality reporting with minimizing burden placed on clinicians. While topped-out measures may still represent an important aspect of care, the associated quality actions are generally considered a standard of practice, presenting limited opportunity to further improve clinical outcomes. Measure Q384 meets criteria for removal from MIPS, finalized in the CY2017 Quality Payment Program final rule (81 FR 77558 through 77675). Please refer to Appendix 1: MIPS Quality Measures (Table Group C) in this final rule for details on the removal of Q384. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter requested additional measures be added to this MVP. The commenter is concerned that the current ophthalmology MVP measure is too limited and does not adequately represent the full breadth of ophthalmic practice, particularly for subspecialties with few or no meaningful reporting options, and that adding registry-based QCDR measures such as IRIS1: Endothelial Keratoplasty – Post-operative improvement in best corrected visual acuity to 20/40 or better; IRIS17: Acute Anterior Uveitis – Post-treatment Grade 0 anterior chamber cells; IRIS23: Refractive Surgery – Patients with a postoperative improvement in uncorrected visual acuity of 20/20 or better within 30 days; IRIS38: Endothelial Keratoplasty – Dislocation Requiring Surgical Intervention; IRIS50: Amblyopia – Interocular visual acuity; IRIS59: Regaining Vision After Cataract Surgery; and IRIS63: Exudative Age-Related Macular Degeneration – Gain of Visual Acuity would provide more meaningful reporting opportunities across cornea, uveitis, pediatric ophthalmology, and other subspecialties.

Response: We appreciate the commenter's feedback. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the QPP website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Complete Ophthalmologic Care MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.6: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

Table B.6a represents the proposed MIPS core measures for the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP. The B.6b table, followed by a list of improvement activities, represents the measures and activities finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP (90 FR 50422 through 50424) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP focuses on the clinical theme of providing fundamental prevention and treatment of those patients at risk for or have had a stroke. This MVP would be most applicable to clinicians who treat patients within the practices of neurology, neurosurgical, and vascular surgery, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received

and our responses to this MVP are included immediately after Table B.6b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[554] we proposed the following measures as MIPS core measures for the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP:

- **Q047:** Advance Care Plan
- **Q236:** Controlling High Blood Pressure
- **Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control).

For the reasons stated in the introduction of this appendix,[555] we proposed to remove **Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy.

Symbol Key:

Exclamation point (!): MIPS core measures within MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.6a: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP MIPS Core Measures

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP MIPS Core Measures
Q047: Advance Care Plan
Q236: Controlling High Blood Pressure
Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

TABLE B.6b: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Clinical Groupings

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP		
Clinical Grouping	**Quality**	**Cost**
Stroke Prevention	**(!)(*) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q344: Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQM)	
	(*) Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	

[554] See MVP Development: Quality Measure and Improvement Activity Updates
[555] Ibid.

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP		
Clinical Grouping	**Quality**	**Cost**
	(!)(*) Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM)	
Stroke Care	**Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQM)	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q413: Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQM)	
Experience of Care	**(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_24:** Financial Navigation Program
- **IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_CC_17:** Patient Navigator Program
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_15:** Implementation of episodic care management practice improvements

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP.

Response: We thank the commenter for their support.

Comment: A few commenters recommended the inclusion of Q517: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management to this MVP.

Response: We may consider the addition of quality measures for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

Comment: A commenter expressed concern that Q236: Controlling High Blood Pressure does not reflect current evidence-based clinical guidelines and is identified as a MIPS core measure for this MVP. Q236 uses a less stringent blood pressure control threshold of 140/90 mm Hg than the American Heart Association and American College of Cardiology recommendation of 130/80, as evidence indicates further reduces the risk of heart attack, stroke, heart failure, cardiovascular events, and death.

Response: We thank the commenter for sharing their concern regarding alignment with current evidence-based hypertension guidelines. Q236: Controlling High Blood Pressure is a MIPS core measure for this MVP for several reasons. Q236 is a standardized quality measure with an established 140/90 mm Hg control threshold that supports consistent data collection which allows comparability across practices and enables benchmarking against existing national performance. While its 140/90 mm Hg threshold is less aggressive than the 130/80 mm Hg target recommended by the American Heart Association and American College of Cardiology, it still reflects a clinically meaningful level of control and allows us to assess hypertension management. Including Q236 as a MIPS core measure provides a practical and interpretable outcome measure that supports early learning, comparability, and

broad adoption across many practice settings. We will continue to monitor the evidence base and measure landscape and may consider updates in future program years.

Comment: A commenter requested Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood be considered a MIPS core measure within this MVP.

Response: We may consider alternative MIPS core measures for this MVP through future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.7: Dermatological Care MVP

Table B.7a represents the proposed MIPS core measures for the Dermatological Care MVP. The B.7b table, followed by a list of improvement activities, represents the measures and activities finalized within the Dermatological Care MVP (90 FR 50424 through 50428) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Dermatological Care MVP focuses on the clinical theme of providing treatment and management of dermatologic care. This MVP would be most applicable to clinicians who treat patients within the practice of dermatology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.7b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[556] we proposed the following measures as MIPS core measures for the Dermatological Care MVP:

- **Q176:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy
- **Q410:** Psoriasis: Clinical Response to Systemic Medications
- **Q486:** Dermatitis – Improvement in Patient-Reported Itch Severity

We proposed to remove one high performing QCDR measure:

- **AAD16:** Avoidance of Post-operative Systemic Antibiotics for Office-based Closures and Reconstruction After Skin Cancer Procedures

Modifications were considered for the following QCDR measures:

- **AAD6:** Skin Cancer: Biopsy Reporting Time - Clinician to Patient: This QCDR measure is undergoing modifications to update the description and numerator to reflect a shortened timeframe for clinician notification of final pathology findings, reducing the requirement from 8 days to 7 days.
- **AAD12:** Melanoma: - Appropriate Surgical Margins: This QCDR measure is undergoing modifications to update the title, description, denominator, and numerator to reflect a broader measure that would include additional skin cancers, specifically squamous cell carcinoma and basal cell carcinoma.

Improvement Activities

[556] See MVP Development: Quality Measure and Improvement Activity Updates

We proposed adding one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix,[557] we proposed to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.7a: Dermatological Care MVP MIPS Core Measures

Dermatological Care MVP MIPS Core Measures
Q176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy
Q410: Psoriasis: Clinical Response to Systemic Medications
Q486: Dermatitis – Improvement in Patient-Reported Itch Severity

TABLE B.7b: Dermatological Care MVP Clinical Groupings

Dermatological Care MVP		
Clinical Grouping	**Quality**	**Cost**
Skin Cancer	**(*) Q397:** Melanoma Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_MR_1:** Melanoma Resection
	(*) Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician (Collection Type: MIPS CQM)	
	(*) Q509: Melanoma: Tracking and Evaluation of Recurrence (Collection Type: MIPS CQM)	
	(*) **AAD12:** Melanoma: - Appropriate Surgical Margins (Collection Type: QCDR)	
	(*) AAD6: Skin Cancer: Biopsy Reporting Time – Clinician to Patient (Collection Type: QCDR)	
Inflammatory Conditions	**(!)(*) Q176:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQM)	**N/A**
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(!) Q410: Psoriasis: Clinical Response to Systemic Medications (Collection Type: MIPS CQM)	

[557] See MVP Development: Quality Measure and Improvement Activity Updates

Dermatological Care MVP		
Clinical Grouping	**Quality**	**Cost**
	Q485: Psoriasis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQM)	
	(!) Q486: Dermatitis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_MR_1:** Melanoma Resection
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	
	AAD8: Chronic Skin Conditions: Patient Reported Quality-of-Life (Collection Type: QCDR)	
Advancing Health and Wellness	**Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	**COST_MR_1:** Melanoma Resection

Dermatological Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(+)(*)(!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(!!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_8:** Use of Patient Safety Tools

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP.

Response: We thank the commenter for their support.

Comment: A couple of commenters expressed concern regarding the removal of AAD16: Avoidance of Post-operative Systemic Antibiotics for Office-based Closures and Reconstruction After Skin Cancer Procedures, believing this measure is crucial for ensuring that clinicians are not unnecessarily prescribing post-operative systemic antibiotics immediately after reconstruction surgery, that its removal would further reduce the pool of available measures in an MVP that already has a limited number of measures and insufficient measures for dermatologic subspecialties, and that retaining it is important to produce a performance benchmark that is more representative of real-world practice. The commenter also requested the inclusion of IA_PSPA_7: Use of QCDR Data for Ongoing Practice Assessment and Improvements to provide dermatology practices with a meaningful improvement activity that is directly relevant to specialty-specific quality improvement.

Response: We acknowledge the commenters' concerns regarding the removal of measure AAD16: Avoidance of Post-operative Systemic Antibiotics for Office-based Closures and Reconstruction After Skin Cancer Procedures; however, we seek to balance meaningful quality reporting with minimizing burden placed on clinicians. While topped-out measures may still represent an important aspect of care, the associated quality actions are generally considered a standard of practice, presenting limited opportunity to further improve clinical outcomes. The removal of this measure does not preclude clinicians from continuing these quality actions. Whether the clinician is being assessed for the quality action or not, it should still be completed as part of routine clinical practice. Additionally, we encourage the commenter to reach out to measure developers and stewards to develop new measures applicable and meaningful to dermatologists for submission to the Call for Measures for possible future implementation. Interested parties are also welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will

evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter was concerned that the three proposed MIPS core measures, which all focus on inflammatory skin disease, did not reflect the full scope of dermatologic care, particularly skin cancer detection, biopsy, pathology, and surgical management. The commenter urged expanding the MIPS core measure options to include measures representing these areas and recommends Q238: Use of High-Risk Medications in Older Adults, Q397: Melanoma Reporting, Q509: Melanoma: Tracking and Evaluation of Recurrence, and as a fourth option, Q486: Dermatitis – Improvement in Patient-Reported Itch Severity as a MIPS core measure set that better reflects general dermatology, dermatopathology, dermatologic surgery, and inflammatory conditions.

Response: We thank the commenter for the suggestions provided to refine the MIPS core measure set for this MVP. We acknowledge that not all MIPS core measures will be applicable to all clinicians reporting an MVP; however, to the extent possible, we considered implementation factors and availability. While broadly applicable measures, such as measure Q238, were included in some MVPs based upon topic alignment and support of clinician's reporting the MVP, we noted that the specialty specific measures were more indicative of dermatological care. Additionally, we accounted for each measure's clinician type applicability; the final selected measures represent that balance between clinical topic alignment, availability, and applicability.

After consideration of public comments, we are finalizing the *Dermatological Care MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.8 Diagnostic Radiology MVP

Table B.8a represents the proposed MIPS core measures for the Diagnostic Radiology MVP. The B.8b table, followed by a list of improvement activities, represents the measures and activities finalized within the Diagnostic Radiology MVP (90 FR 50376 through 50381) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Diagnostic Radiology MVP assesses meaningful outcomes in diagnostic radiology. This MVP would be most applicable to clinicians who treat patients within the practices of diagnostic radiology and nuclear medicine. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.8b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[558] we proposed the following measures as MIPS core measures for the Diagnostic Radiology MVP:

- **Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy
- **Q360:** Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies
- **Q405:** Appropriate Follow-up Imaging for Incidental Abdominal Lesions

We proposed adding four MIPS quality measures to the new Nuclear Medicine clinical grouping:

- **Q282:** Dementia: Functional Status Assessment: This MIPS quality measure focuses on the importance of ensuring that patients diagnosed with dementia receive a comprehensive functional assessment annually.
- **Q286:** Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia: This MIPS quality measure aims to address safety concerns in patients diagnosed with dementia by ensuring that appropriate screening and follow-up actions are conducted.

[558] See MVP Development: Quality Measure and Improvement Activity Updates

- **Q288:** Dementia: Education and Support of Caregivers for Patients with Dementia: This MIPS quality measure focuses on the importance of providing education and support to caregivers of patients with Dementia.
- **Q386:** Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences: This MIPS quality measure focuses on the importance of addressing end-of-life care preferences for patients diagnosed with ALS.

We proposed adding one QCDR measure:

- **ACRAD34:** Multi-strata weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT abdomen-pelvis with contrast/single-phase scan, CT chest without contrast/single-phase scan, and CT head/brain without contrast/single-phase scan): This QCDR measure ensures that all CT scans—abdomen-pelvis with contrast, chest without contrast, and head/brain single-phase—maintain a Dose Length Product at or below the established threshold to help manage patient radiation exposure.

Improvement Activities

For the reasons stated in the introduction of this appendix,[559] we proposed to remove **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings and **IA_PSPA_2:** Participation in MOC Part IV.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.8a: Diagnostic Radiology MVP MIPS Core Measures

Diagnostic Radiology MVP MIPS Core Measures
Q145: Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy
Q360: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies
Q405: Appropriate Follow-up Imaging for Incidental Abdominal Lesions

TABLE B.8b: Diagnostic Radiology MVP Clinical Groupings

Diagnostic Radiology MVP		
Clinical Grouping	**Quality**	**Cost**
General Diagnostic Radiology	**(!) Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q360: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation	

[559] See MVP Development: Quality Measure and Improvement Activity Updates

Diagnostic Radiology MVP		
Clinical Grouping	**Quality**	**Cost**
	Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies (Collection Type: MIPS CQM)	
	Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Clinician Level) (Collection Type: eCQM)	
	(+) ACRAD34: Multi-strata weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT abdomen-pelvis with contrast/single-phase scan, CT chest without contrast/single-phase scan, and CT head/brain without contrast/single-phase scan) (Collection Type: QCDR)	
Body Imaging (Thoracic/Abdominal)	**Q364:** Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines (Collection Type: MIPS CQM)	**N/A**
	(!) Q405: Appropriate Follow-up Imaging for Incidental Abdominal Lesions (Collection Type: Medicare Part B Claims, MIPS CQM)	
	Q406: Appropriate Follow-up Imaging for Incidental Thyroid Nodules (Collection Type: Medicare Part B Claims, MIPS CQM)	
	QMM17: Appropriate Follow-up Recommendations for Ovarian-Adnexal Lesions using the Ovarian-Adnexal Reporting and Data System (O-RADS) (Collection Type: QCDR)	
Nuclear Medicine	**(+) Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQM)	**N/A**
	(+) Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM)	
	(+)(*) Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM)	
	(+) Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**QMM18:** Use of Breast Cancer Risk Score on Mammography (Collection Type: QCDR)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	QMM26: Screening Abdominal Aortic Aneurysm Reporting with Recommendations (Collection Type: QCDR)	

Diagnostic Radiology Improvement Activities

- **IA_BE_6**: Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BMH_12**: Promoting Clinician Well-Being
- **IA_CC_7**: Regular training in care coordination
- **(*) IA_CC_8**: Implementation of documentation improvements for practice/process improvements
- **IA_CC_19**: Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes

- **(**) IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1**: Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_7**: Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_12**: Participation in private payer CPIA

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. Another commenter supported the addition of ACRAD34: Overall Percent of CT Exams for which Dose Length Product is at or below the Size-Specific Dose Reference Level in this MVP.

Response: We thank the commenters for their support.

Comment: One commenter expressed appreciation that the proposed MIPS core measures are widely used and commonly reported by radiologists but noted that all three have been topped out for many years. They recommended working with relevant specialty societies to develop and introduce new, clinically meaningful measures that are not topped out, and to create pathways for newer measures that do not yet have established benchmarks.

Response: We appreciate the commenter's feedback. We encourage the commenter to reach out to measure developers and stewards to develop new measures applicable and meaningful to diagnostic radiology for submission to the Call for Measures for possible future implementation. Finalized MVPs are reviewed annually to determine if additional updates are needed to meet the needs of the MVP and program requirements.

Comment: A commenter recommended considering Q494 as a MIPS core measure in this MVP. CT radiation doses vary widely and are projected to cause substantial numbers of preventable cancers in adults and children, yet the measures identified as MIPS core measures are process-based, largely topped out, and do not directly influence dose or image quality. ACRAD34 only partially addresses dose, omits multiphase scanning (a major source of excess exposure), lacks an image-quality safeguard, and is ineligible for core status. By contrast, Q494 is an automated, low-burden intermediate outcome measure that flags CT exams with excessive size-adjusted dose or inadequate image quality using indication-specific thresholds, while keeping patient data within the institution. The commenter noted that core designation would align clinician and facility accountability for dose-related decisions and is projected to reduce unnecessary multiphase scanning, lower radiation exposure, prevent about 39,600 cancers over a decade, and save approximately $26.7 billion across all payers—benefits that documentation-focused measures cannot achieve.

Response: We thank the commenter for their feedback and acknowledge the importance of minimizing CT radiation doses. However, as currently specified, the measure requires specific software capability for calculating and reporting. As part of identifying MIPS core measures, we want to ensure that we are selecting measures most meaningful to the specific clinician specialty while also ensuring they are widely available and implementable within MIPS. To avoid requiring clinicians to expend resources on reporting this measure, we have not included it as a MIPS core measure at this time.

Comment: A commenter recommended the inclusion of QMM23: Low-Dose Cancer Screening Recommendation for CT and CTA of the Chest with Diagnosis of Emphysema and ACRAD44: Comprehensive Reporting of Coronary Artery Calcification (CAC) on Chest CT as these measures focus on improving preventative care, and chronic disease management. Another commenter recommended the inclusion of the Rate of Timely Follow-up on Abnormal Screening Mammograms for Breast Cancer Detection measure in this MVP. Commenters also recommended the inclusion of the new Clinician Use of Artificial Intelligence (AI) to Improve Patient Care improvement activity.

Response: We may consider the addition of quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter expressed concern that expecting QCDRs to support the measures included in the Nuclear Medicine clinical grouping is inappropriate as they noted the measures are not aligned with radiology workflows or data capture. A few commenters recommended the removal of the Nuclear Medicine clinical grouping measures

(measures Q282, Q286, Q288, and Q386) and replacing them with measures that reflect the real-world clinical work of diagnostic radiologists.

Response: We thank the commenters for their feedback regarding Nuclear Medicine clinical grouping measures. This MVP reflects recommendations received from clinical specialties to support different scopes of care to allow for comprehensive MVP reporting. We acknowledge that not all quality measures will be appropriate or applicable to all clinicians who choose to report the MVP.

After consideration of public comments, we are finalizing the *Diagnostic Radiology MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.9: Focusing on Women's Health MVP

Table B.9a represents the proposed MIPS core measures for the Focusing on Women's Health MVP. The B.9b table, followed by a list of improvement activities, represents the measures and activities finalized within the Women's Health MVP (90 FR 50428 through 50430) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Focusing on Women's Health MVP focuses on the clinical specialty of providing treatment and management of women's health. This MVP would be most applicable to clinicians who treat patients within the practices of gynecology, obstetrics, and urogynecology, including NPPs such as certified nurse-midwives, nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.9b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[560] we proposed the following measures as MIPS core measures for the Focusing on Women's Health MVP:

- **Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age
- **Q112:** Breast Cancer Screening
- **Q432:** Proportion of Patients Sustaining a Bladder or Bowel Injury at the Time of any Pelvic Organ Prolapse Repair

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.9a: Focusing on Women's Health MVP MIPS Core Measures

[560] See MVP Development: Quality Measure and Improvement Activity Updates

Focusing on Women's Health MVP MIPS Core Measures
Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age
Q112: Breast Cancer Screening
Q432: Proportion of Patients Sustaining a Bladder or Bowel Injury at the Time of any Pelvic Organ Prolapse Repair

TABLE B.9b: Focusing on Women's Health MVP Clinical Groupings

Focusing on Women's Health MVP		
Clinical Grouping	**Quality**	**Cost**
Obstetrics	**Q335:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q336: Maternity Care: Postpartum Follow-up and Care Coordination (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **TPCC_1:** Total Per Capita Cost
	Q496: Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
Gynecology	**Q422:** Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q432: Proportion of Patients Sustaining a Bladder or Bowel Injury at the Time of any Pelvic Organ Prolapse Repair (Collection Type: MIPS CQM)	
	Q448: Appropriate Workup Prior to Endometrial Ablation (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(!) Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **TPCC_1:** Total Per Capita Cost
	Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	
	(!)(**) Q112: Breast Cancer Screening (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	

Focusing on Women's Health MVP		
Clinical Grouping	**Quality**	**Cost**
	Q309: Cervical Cancer Screening (Collection Type: eCQM)	
	Q310: Chlamydia Screening in Women (Collection Type: eCQM)	
	Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	
	Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQM)	
	(*) Q475: HIV Screening (Collection Type: eCQM)	
	Q493: Adult Immunization Status (Collection Type: MIPS CQM)	
	UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved (Collection Type: QCDR)	

Focusing on Women's Health Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_BMH_11:** Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice
- **(!!) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(!!) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. A couple of commenters supported the designation of Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age as a MIPS core measure for this MVP. Several commenters supported the MVP's overall direction and recommended adding specific measures to better assess and improve women's health care. Suggestions included adding a menopause-management measure to systematically evaluate care for midlife women, in line with the principle that what is not measured is not managed; expanding maternal health measures beyond a single encounter or hospital stay to include breastfeeding initiation and continuation and the use of longitudinal, patient-generated data after discharge; and creating a measure for management of genitourinary syndrome of menopause and recurrent urinary tract infections, including use of vaginal estrogen. A commenter recommended the inclusion of the Rate of Timely Follow-up on Abnormal Screening Mammograms for Breast Cancer Detection measure in this MVP. A few commenters requested the addition of Q418: Osteoporosis Management in Women Who Had a Fracture. Other commenters recommended the addition of Q517: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management to this MVP.

Response: We appreciate the commenters' feedback and thank them for their support. We encourage interested parties to submit potential new measures that will align with current program goals and priorities and fill these identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS during the annual Call for Measures. We may consider the addition of quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Focusing on Women's Health MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.10: Gastroenterology Care MVP

Table B.10a represents the proposed MIPS core measures for the Gastroenterology Care MVP. The B.10b table, followed by a list of improvement activities, represents the measures and activities finalized within the Gastroenterology Care MVP (90 FR 50430 through 50434) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Gastroenterology Care MVP focuses on the clinical theme of providing treatment and management of the digestive system and the liver. This MVP would be most applicable to clinicians who treat patients within the practice of gastroenterology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality and cost measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.10b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[561] we proposed the following measures as MIPS core measures for the Gastroenterology Care MVP:

- **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
- **Q275:** Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy
- **Q516:** Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

For the reasons stated in the introduction of this appendix,[562] we proposed to remove **Q320:** Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients. We proposed to remove one high performing QCDR measure:

- **NHCR4:** Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation.

Modifications were considered for the following QCDR measures:

- **GIQIC23:** Appropriate follow-up interval based on pathology findings in screening colonoscopy: This QCDR measure is undergoing modifications to ensure patients are receiving appropriate follow up within the recommended timeframe.

Improvement Activities

We proposed adding one improvement activity relevant to this MVP:

- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements.

For the reasons stated in the introduction of this appendix,[563] we proposed to remove **IA_CC_10:** Care transition documentation practice improvements.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.

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[561] See MVP Development: Quality Measure and Improvement Activity Updates

[562] See MVP Development: Quality Measure and Improvement Activity Updates

[563] Ibid.

Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.10a: Gastroenterology Care MVP MIPS Core Measures

Gastroenterology Care MVP MIPS Core Measures
Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
Q275: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy
Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

TABLE B.10b: Gastroenterology Care MVP Clinical Groupings

Gastroenterology Care MVP		
Clinical Grouping	**Quality**	**Cost**
Interventional/ Endoscopy	**GIQIC26:** Screening Colonoscopy Adenoma Detection Rate (Collection Type: QCDR)	**COST_SSC_1:** Screening/Surveillance Colonoscopy
	N/A	**COST_LGH_1:** Lower Gastrointestinal Hemorrhage
Hepatobiliary	**Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQM)	
	(!) Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR) (Collection Type: MIPS CQM)	
Inflammatory	**(!) Q275**: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
General Gastroenterology	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	**COST_SSC_1:** Screening/Surveillance Colonoscopy **TPCC_1:** Total Per Capita Cost **COST_LGH_1:** Lower Gastrointestinal Hemorrhage
Advancing Health and Wellness	**(**) Q113:** Colorectal Cancer Screening (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_SSC_1:** Screening/Surveillance Colonoscopy **TPCC_1:** Total Per Capita Cost
	(*) Q130: Documentation of Current Medications in the Medical Record	

Gastroenterology Care MVP		
Clinical Grouping	**Quality**	**Cost**
	(Collection Type: eCQM, MIPS CQM)	**COST_LGH_1:** Lower Gastrointestinal Hemorrhage
	(!) Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	GIQIC23: Appropriate follow-up interval based on pathology findings in screening colonoscopy (Collection Type: QCDR)	
Experience of Care	**Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	**COST_SSC_1:** Screening/Surveillance Colonoscopy **TPCC_1:** Total Per Capita Cost **COST_LGH_1:** Lower Gastrointestinal Hemorrhage

Gastroenterology Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7:** Regular training in care coordination
- **(+)(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(!!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP.

Response: We thank the commenter for their support.

Comment: A commenter asserted that the proposed MIPS core measures for this MVP do not reflect where most gastroenterology specialists spend their clinical time and effort. They noted that most individual gastroenterologists, and even many groups, are unlikely to meet the 20-case minimum needed to be scored on Q275 or Q516, effectively leaving Q226—which does not represent "the care that is central to the clinical focus" of gastroenterology—as the only reliably scorable MIPS core measure for many GI clinicians. The commenter therefore recommended delaying implementation of the MIPS core measure requirement for this MVP until MIPS core measures can be identified that satisfy the selection criteria for gastroenterology.

Response: We thank the commenter for their feedback and acknowledge that there were limitations to MIPS core measure selection based upon the current MIPS quality measure inventory. Therefore, we had to balance between choosing measures that most closely represent care central to the MVP intent, while also ensuring measure availability for those clinicians who chose to report the MVP. Of note, reversion to the high priority requirement would create a similar situation and may even decrease ability to achieve maximum points. We will continue to review MIPS core measures annually to determine if revisions are appropriate.

Comment: A couple of commenters opposed the removal of NHCR4: Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation and Q320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients from this MVP and requested their retention. One commenter stated that NHCR4 addresses a critical and still-unresolved quality gap: when bowel preparation is inadequate, patients are at substantially higher risk of missed adenomas, yet only about 25% are advised to have the recommended repeat

exam within one year. The commenter asserted that the measure is therefore not topped out and continues to identify important underuse of follow-up care. They further stated that maintaining NHCR4 preserves the integrity of this MVP, maintains economic value for patients who already paid for an incomplete colonoscopy, and keeps attention on payer and prior authorization barriers that limit access to better bowel prep regimens and undermine colorectal cancer prevention. This commenter also requested that Q320 be retained through the CY 2028 performance period. Another commenter asserted that eliminating these measures would leave the MVP with only two colonoscopy-specific QCDR measures (GIQIC26 and GIQIC23), neither of which would be eligible for designation as a MIPS core measure. Given that colonoscopy and upper endoscopy codes (45378, 45385, 45380, G0121/G0105, 43239, 43235) represent some of the highest-volume procedures billed by gastroenterologists, this commenter expressed concern that the resulting colonoscopy-related measure set within the MVP would be unacceptably limited. The commenter also recommended that GIQIC23: Appropriate Follow-Up Interval Based on Pathology Findings in Screening Colonoscopy be maintained as currently specified, emphasizing that it evaluates the clinical decision made and documented by the physician performing the procedure and communicated to the patient and referring clinician, thereby guiding the timing of the patient's next colonoscopy. They added that if a separate retrospective measure of completed follow-up or surveillance is desired, that concept should be independently specified, tested, and validated rather than replacing the existing prospective measure.

Response: While we agree the concepts are important to quality care, the removal of these measures does not preclude the quality action from continuing. Whether the clinician is being assessed for the quality action or not, it should still be completed as a matter of high-quality care. Regarding NHCR4: Repeat Screening or Surveillance Colonoscopy Recommended Within One Year Due to Inadequate Bowel Preparation, QCDR measures must meet established inclusion criteria to be finalized for MIPS and for inclusion within an MVP. Based upon review of NHCR4, the measure no longer meets that MVP inclusion criteria. MIPS performance data indicate that NHCR4 is high-performing and presents limited opportunity to further improve clinical outcomes. For measure Q320, see Table Group C of Appendix 1 in this final rule for any comments and responses pertaining to measures that were proposed for removal from MIPS.

We agree with the commenter and the proposed modification to GIQIC23: Appropriate Follow-Up Interval Based on Pathology Findings in Screening Colonoscopy will not be finalized as the measure steward determined no updates to the measure were necessary for CY 2027.

After consideration of public comments, we are finalizing the *Gastroenterology Care MVP* with modifications in Table B.10b for the CY 2027 performance period/2029 MIPS payment year and future years. We are not finalizing the modifications to GIQIC23: Appropriate follow-up interval based on pathology findings in screening colonoscopy as the measure steward has determined updates to the measure were unnecessary for CY2027.

B.11: Improving Care for Lower Extremity Joint Repair MVP

Table B.11a represents the proposed MIPS core measures for the Improving Care for Lower Extremity Joint Repair MVP. The B.11b table, followed by a list of improvement activities, represents the measures and activities finalized within the Improving Care for Lower Extremity Joint Repair MVP (90 FR 50434 through 50435) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Improving Care for Lower Extremity Joint Repair MVP focuses on the clinical theme of providing fundamental treatment and management of patients with osteoarthritis and lower extremity surgical repair, such as fracture and total joint replacement, to ensure appropriate care and reduce costs. This MVP would be most applicable to clinicians who treat patients within the practice of orthopedic surgery, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.11b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[564] we proposed the following measures as MIPS core measures for the Improving Care for Lower Extremity Joint Repair MVP:

- **Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation
- **Q470:** Functional Status After Primary Total Knee Replacement
- **Q480:** Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

For the reasons stated in the introduction of this appendix,[565] we proposed to remove **Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy.

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.11a: Improving Care for Lower Extremity Joint Repair MVP MIPS Core Measures

Improving Care for Lower Extremity Joint Repair MVP MIPS Core Measures
Q351: Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation
Q470: Functional Status After Primary Total Knee Replacement
Q480: Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

TABLE B.11b: Improving Care for Lower Extremity Joint Repair MVP Clinical Groupings

Improving Care for Lower Extremity Joint Repair MVP		
Clinical Grouping	**Quality**	**Cost**
Non-Surgical	**Q024:** Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims, MIPS CQM)	**N/A**
Surgical	**(!) Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQM)	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty
	Q376: Functional Status Assessments for Total Hip Replacement (Collection Type: eCQM)	**COST_PHA_1:** Elective Primary Hip Arthroplasty

[564] See MVP Development: Quality Measure and Improvement Activity Updates
[565] Ibid.

Improving Care for Lower Extremity Joint Repair MVP		
Clinical Grouping	**Quality**	**Cost**
	(!) Q470: Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQM)	**COST_KA_1:** Knee Arthroplasty
	(!) Q480: Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims)	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty

Improving Care for Lower Extremity Joint Repair Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7:** Regular training in care coordination
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_CC_15:** PSH Care Coordination
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP.

Response: We thank the commenter for their support.

Comment: A commenter requested the addition of the following measures: Q155: Falls: Plan of Care, Q318: Falls: Screening for Future Fall Risk, Q355: Unplanned Reoperation Within the 30-Day Postoperative Period, Q357: Surgical Site Infection, Q461: Leg Pain After Lumbar Surgery.

Response: Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: One commenter expressed concern regarding the removal of Q350: Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy from this MVP, and noted the measure promotes meaningful shared decision-making between clinicians and patients that is critically important to high-quality care and that removing will reduce the number of MIPS CQMs to four, effectively eliminating meaningful measure choice for clinicians reporting MIPS CQMs within this MVP.

Response: We acknowledge the commenter's concern regarding the removal of measure Q350: Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy. While process measures may still represent an important aspect of care, this measure's associated quality action essentially assesses for informed consent, a standard of care. Please refer to Appendix 1: MIPS Quality Measures (Table Group C) in this final rule for details on the removal of measure Q350.

After consideration of public comments, we are finalizing the *Improving Care for Lower Extremity Joint Repair MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.12 Interventional Radiology MVP

Table B.12a represents the proposed MIPS core measures for the Interventional Radiology MVP. The B.12b table, followed by a list of improvement activities, represents the measures and activities finalized within the Interventional Radiology MVP (90 FR 50381 through 50386) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Interventional Radiology MVP assesses meaningful outcomes in interventional radiology. This MVP would be most applicable to clinicians who treat patients within the practice of interventional radiology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.12b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[566] we proposed the following measures as MIPS core measures for the Interventional Radiology MVP:

- **Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy
- **Q413:** Door to Puncture Time for Endovascular Stroke Treatment
- **Q420:** Varicose Vein Treatment with Saphenous Ablation: Outcome Survey

Improvement Activities

We proposed to remove one improvement activity as the activity is more relevant to general surgery and surgical subspecialties:

- **IA_CC_15:** PSH Care Coordination

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.12a: Interventional Radiology MVP MIPS Core Measures

Interventional Radiology MVP MIPS Core Measures
Q145: Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy
Q413: Door to Puncture Time for Endovascular Stroke Treatment
Q420: Varicose Vein Treatment with Saphenous Ablation: Outcome Survey

TABLE B.12b: Interventional Radiology MVP Clinical Groupings

[566] See MVP Development: Quality Measure and Improvement Activity Updates

Interventional Radiology MVP		
Clinical Grouping	**Quality**	**Cost**
Vascular	**(!) Q420:** Varicose Vein Treatment with Saphenous Ablation: Outcome Survey (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q421: Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal (Collection Type: MIPS CQM)	
	Q465: Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries (Collection Type: MIPS CQM)	
Dialysis-Related	**RCOIR12:** Tunneled Hemodialysis Catheter Clinical Success Rate (Collection Type: QCDR)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	RCOIR13: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate (Collection Type: QCDR)	
	RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate (Collection Type: QCDR)	
	RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate (Collection Type: QCDR)	
Neurological Intervention	**(!) Q413:** Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
General Interventional Radiology	**(!) Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	

Interventional Radiology Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!!) IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_7:** Regular training in care coordination
- **(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_CC_17:** Patient Navigator Program
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **(!!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_17:** Participation in Population Health Research
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization.
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level

- **IA_PSPA_25:** Cost Display for Laboratory and Radiographic Orders

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. Another commenter requested the addition of quality measures and improvement activities that are broadly applicable to interventional radiology practice, including measures addressing care coordination, patient safety, shared decision-making, patient-reported outcomes, access, and practice-based quality improvement.

Response: We thank the commenters for their support and feedback. We may consider the addition of quality measures and improvement activities through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Interventional Radiology MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.13 Neuropsychology MVP

Table B.13a represents the proposed MIPS core measures for the Neuropsychology MVP. The B.13b table, followed by a list of improvement activities, represents the measures and activities finalized within the Neuropsychology MVP (90 FR 50386 through 50390) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Neuropsychology MVP focuses on the clinical specialty of providing treatment and management of neuropsychological care. This MVP would be most applicable to clinicians who treat patients within the practice of neuropsychology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.13b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[567] we proposed the following measures as MIPS core measures for the Neuropsychology MVP:

- **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan
- **Q181:** Elder Maltreatment Screen and Follow-up Plan
- **Q282:** Dementia: Functional Status Assessment

Improvement Activities

For the reasons stated in the introduction of this appendix,[568] we proposed to remove **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.

[567] See MVP Development: Quality Measure and Improvement Activity Updates
[568] Ibid.

Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.13a: Neuropsychology MVP MIPS Core Measures

Neuropsychology MVP MIPS Core Measures
Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan
Q181: Elder Maltreatment Screen and Follow-up Plan
Q282: Dementia: Functional Status Assessment

TABLE B.13b: Neuropsychology MVP Clinical Groupings

Neuropsychology MVP		
Clinical Grouping	**Quality**	**Cost**
Neurodegenerative Disorders	**(!) Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **TPCC_1:** Total Per Capita Cost
	Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM)	
	(*) Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **TPCC_1:** Total Per Capita Cost
	(!)(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(!) Q181: Elder Maltreatment Screen and Follow-up Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	

Neuropsychology Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(!!) IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_22:** Improved Practices that Engage Patients Pre-Visit
- **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **(*) IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_21:** Advance Care Planning

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. Another commenter recommended Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood be added to this MVP. Another commenter requested the addition of IA_BMH_1: Antipsychotic-Medication-Associated Physical Health Condition Assessment and Monitoring to this MVP.

Response: We thank the commenter for their support. We may consider the addition of quality measures for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

After consideration of public comments, we are finalizing the *Neuropsychology MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.14: Optimal Care for Kidney Health MVP

Table B.14a represents the proposed MIPS core measures for the Optimal Care for Kidney Health MVP. The B.14b table, followed by a list of improvement activities, represents the measures and activities finalized within the Optimal Care for Kidney Health MVP (90 FR 50435 through 50438) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Optimal Care for Kidney Health MVP focuses on the clinical specialty of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, kidney disease. This MVP would be most applicable to clinicians who treat patients within the practice of nephrology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.14b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[569] we proposed the following measures as MIPS core measures for the Optimal Care for Kidney Health MVP:

- **Q236:** Controlling High Blood Pressure
- **Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate
- **Q489:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Improvement Activities

We proposed adding one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix,[570] we proposed to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.14a: Optimal Care for Kidney Health MVP MIPS Core Measures

[569] See MVP Development: Quality Measure and Improvement Activity Updates
[570] Ibid.

Optimal Care for Kidney Health MVP MIPS Core Measures
Q236: Controlling High Blood Pressure
Q482: Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate
Q489: Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

TABLE B.14b: Optimal Care for Kidney Health MVP Clinical Groupings

Optimal Care for Kidney Health MVP		
Clinical Grouping	**Quality**	**Cost**
General Nephrology	**(*) Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management **TPCC_1:** Total Per Capita Cost
	(!)(*) Q236: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q488: Kidney Health Evaluation (Collection Type: eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(!) Q489: Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQM)	**COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **TPCC_1:** Total Per Capita Cost
Dialysis/Transplant	**(!) Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQM)	**COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **TPCC_1:** Total Per Capita Cost
	Q510: First Year Standardized Kidney Transplant Waitlist Ratio (FYSWR) (Collection Type: MIPS CQM)	**COST_ESRD_1:** End-Stage Renal Disease **TPCC_1:** Total Per Capita Cost
	Q511: Percentage of Prevalent Patients Waitlisted for Kidney Transplant (PPPW) and Percentage of Prevalent Patients Waitlisted for Kidney Transplant in Active Status (aPPPW) (Collection Type: MIPS CQM)	
	Q512: Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR)	

Optimal Care for Kidney Health MVP		
Clinical Grouping	**Quality**	**Cost**
	(Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management **TPCC_1:** Total Per Capita Cost
	Q493: Adult Immunization Status (Collection Type: MIPS CQM)	
Experience of care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management **TPCC_1:** Total Per Capita Cost
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Optimal Care for Kidney Health Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care
- **(!!) IA_BE_16**: Promote Self-management in Usual Care
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(+)(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_CC_13**: Practice improvements to align with OpenNotes principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular Review Practices in Place on Targeted Patient Population Needs
- **IA_PM_16:** Implementation of medication management practice improvements
- **(*) IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools, including AI-enabled predictive decision-support interventions—and standardized treatment protocols to manage workflow on the care team to meet patient needs

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. A few commenters recommended the inclusion of the Low-Density Lipoprotein (LDL-C) Monitoring and Management measure in this MVP. One commenter supported

the updates to this MVP and recommend adding new early-stage measures to not only advance the important goals of prevention, earlier intervention, and chronic disease management, but also make the make the MVP most useful for clinicians who are interested in focusing on prevention and early intervention.

Response: We appreciate the commenters' support. We may consider the addition of quality measures for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

Comment: A commenter expressed concern that Q236: Controlling High Blood Pressure does not reflect current evidence-based clinical guidelines and is identified as a MIPS core measure for this MVP. Q236 uses a less stringent blood pressure control threshold of 140/90 mm Hg than the American Heart Association and American College of Cardiology recommendation of 130/80, as evidence indicates further reduces the risk of heart attack, stroke, heart failure, cardiovascular events, and death.

Response: We appreciate the commenters' concern regarding alignment with current evidence-based hypertension guidelines. Q236: Controlling High Blood Pressure is a MIPS core measure for this MVP for several reasons. Q236 is a standardized quality measure with an established 140/90 mm Hg control threshold that supports consistent data collection which allows comparability across practices and enables benchmarking against existing national performance. While its 140/90 mm Hg threshold is less aggressive than the 130/80 mm Hg target recommended by the American Heart Association and American College of Cardiology, it still reflects a clinically meaningful level of control and allows us to assess hypertension management. Including Q236 as a MIPS core measure provides a practical and interpretable outcome measure that supports early learning, comparability, and broad adoption across many practice settings. We will continue to monitor the evidence base and measure landscape and may consider updates in future program years.

Comment: A commenter requested Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood be considered a MIPS core measure within this MVP.

Response: We may consider alternative MIPS core measures for this MVP through future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Optimal Care for Kidney Health MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.15: Optimal Care for Patients with Urologic Conditions MVP

Table B.15a represents the proposed MIPS core measures for the Optimal Care for Patients with Urologic Conditions MVP. The B.15b table, followed by a list of improvement activities, represents the measures and activities finalized within the Optimal Care for Patients with Urologic Conditions MVP (90 FR 50438 through 50441) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Optimal Care for Patients with Urologic Conditions MVP focuses on assessing optimal care for patients treated for a broad range of urologic conditions, including kidney stones, urinary incontinence, bladder cancer, and prostate cancer. This MVP would be most applicable to clinicians who treat patients within the practices of urology, general urologists, urology oncologists, and urogynecology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.15b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[571] we proposed the following measures as MIPS core measures for the Optimal Care for Patients with Urologic Conditions MVP:

- **Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older
- **Q358:** Patient-Centered Surgical Risk Assessment and Communication
- **Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

We proposed to remove two high performance QCDR measures, one process QCDR measure, and one QCDR measure due to low adoption, no benchmark after 2 consecutive years in MIPS:

- **AQUA8:** Hospital Admissions or Infectious Complications Within 30 days of Prostate Biopsy (high performing)
- **AQUA14:** Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment (high performing)
- **AQUA15:** Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures (process measure)
- **AQUA16:** Non-Muscle Invasive Bladder Cancer: Repeat Transurethral Resection of Bladder Tumor (TURBT) for T1 Disease (low adoption, no benchmark after 2 consecutive years in MIPS)

Modifications were considered for the following QCDR measures:

- **AQUA14:** Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment: If the measure is not finalized for removal in the CY 2027 PFS final rule, this QCDR measure would undergo modifications to the title, description, and numerator to align with the American Urological Association (AUA) updated clinical guidelines, which recommend a second SWL or ureteroscopy (URS) when the initial SWL does not achieve complete clearance.
- **AQUA15:** Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures: If the measure is not finalized for removal in the CY 2027 PFS final rule, this QCDR measure would undergo modifications to add a quality action to the numerator to ensure abnormal results are appropriately addressed.
- **MUSIC4:** Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low Risk Prostate Cancer Patients: This QCDR measure is undergoing modifications to ensure patients newly diagnosed with low-risk prostate cancer on active surveillance undergo a confirmation biopsy within 24 months of their diagnosis.

Improvement Activities

We proposed adding two improvement activities relevant to this MVP, both of which include an advancing health and wellness component:

- **IA_BE_16:** Promote Self-management in Usual Care
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix,[572] we proposed to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.

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[571] See MVP Development: Quality Measure and Improvement Activity Updates

[572] See MVP Development: Quality Measure and Improvement Activity Updates

Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.15a: Optimal Care for Patients with Urologic Conditions MVP MIPS Core Measures

Optimal Care for Patients with Urologic Conditions MVP MIPS Core Measures
Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older
Q358: Patient-Centered Surgical Risk Assessment and Communication
Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

TABLE B.15b: Optimal Care for Patients with Urologic Conditions MVP Clinical Groupings

Optimal Care for Patients with Urologic Conditions MVP		
Clinical Grouping	**Quality**	**Cost**
Urological Cancer	**(!) Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM)	**COST_PC_1:** Prostate Cancer **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q476: Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia (Collection Type: eCQM)	
	(*) Q481: Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer (Collection Type: eCQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low Risk Prostate Cancer Patients (Collection Type: QCDR)	**COST_PC_1:** Prostate Cancer **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
General Urology	**(!) Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	**COST_RUSST_1:** Renal or Ureteral Stone Surgical Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**Q318:** Falls: Screening for Future Fall Risk (Collection Type: eCQM)	**COST_PC_1:** Prostate Cancer **COST_RUSST_1:** Renal or Ureteral Stone Surgical Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CMS-approved Survey Vendor)	**COST_PC_1:** Prostate Cancer **COST_RUSST_1:** Renal or Ureteral Stone Surgical
	(!) Q358: Patient-Centered Surgical Risk Assessment and Communication	

Optimal Care for Patients with Urologic Conditions MVP		
Clinical Grouping	**Quality**	**Cost**
	(Collection Type: MIPS CQM)	Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Optimal Care for Patients with Urologic Conditions Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(+)(!!) IA_BE_16:** Promote Self-management in Usual Care
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7**: Regular training in care coordination
- **(+)(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_CC_17:** Patient Navigator Program
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_17:** Participation in Population Health Research
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_12:** Participation in private payer CPIA
- **IA_PSPA_21:** Implementation of fall screening and assessment programs

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. A commenter supported the removal of AQUA14 and the improvement activity modifications.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that clinically meaningful urology quality measures should not be removed without replacements. The proposed removal of AQUA8, AQUA14, AQUA15, and AQUA16 would eliminate measures addressing prostate biopsy complications, repeat shock wave lithotripsy, urine testing before stone procedures, and repeat TURBT for T1 bladder cancer. A commenter urged AQUA8 be maintained as they believed as more clinicians report the measure, performance will look different. This commenter believed AQUA15 should be maintained because it addresses an important clinical area. In addition, the commenter opposed any modifications to the measure outside of the measure development and update process established by the measure developer or intellectual property holder. Also, the commenter requested AQUA16 be retained due to its clinical importance and the likelihood of increased adoption as more urologists elect MVP reporting. The commenters believed these measures are relevant patient safety and quality measures and noted high performance or limited adoption should prompt improvement of the measures and reporting process, not automatic removal.

Response: We appreciate the commenter's feedback on AQUA8, AQUA14, AQUA15, and AQUA16. While we agree the concepts addressed by these measures are important to delivering high-quality care, the removal of these measures does not preclude clinicians from continuing these quality actions. Whether the clinician or group is being assessed for the quality action or not, it should still be completed as part of routine clinical practice. Additionally, QCDR measures must meet established inclusion criteria to be finalized for MIPS and for inclusion within an MVP. Based upon review of AQUA8, AQUA14, AQUA15, and AQUA16, they no longer meet the MVP inclusion criteria. MIPS performance data indicates that AQUA14 is high performing and AQUA8 has had minimal variation in its historical benchmark. AQUA16 has not met the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years. In addition, AQUA15 only assesses for documentation of a urinalysis or urine culture and does not require a quality action or plan of care to account for abnormal results; therefore, missing a workflow step necessary to driving positive health outcomes.

Comment: A commenter requested that more generally applicable measures and a broader range of measures be added to this MVP so that urology clinicians can more easily meet minimum reporting thresholds.

Response: We may consider the addition of quality measures for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

Comment: A commenter opposed the MIPS core measures in this MVP as they noted the measures identified as MIPS core measures do not provide meaningful options across urology subspecialties and were selected without sufficient specialty input.

Response: We thank the commenter for their feedback and acknowledge that there were limitations to MIPS core measure selection based upon the current inventory of quality measures. Therefore, we had to balance between choosing measures that most closely represent care central to the MVP intent, while also ensuring measure availability for those clinicians who chose to report the MVP. We will continue to review MIPS core measures annually to determine if revisions are appropriate.

Comment: A commenter opposed the proposed modification to MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low Risk Prostate Cancer Patients as it is outside of the measure development and update process established by the measure developer or intellectual property holder.

Response: Proposed modifications to MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low Risk Prostate Cancer Patients will not be finalized as the measure steward determined no updates to the measure were necessary for CY 2027.

After consideration of public comments, we are finalizing the *Optimal Care for Patients with Urologic Conditions MVP* with modifications in Table B.15b for the CY 2027 performance period/2029 MIPS payment year and future years. We are not finalizing the modifications to MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low Risk Prostate Cancer Patients as the measure steward has determined updates to the measure were unnecessary for CY2027.

B.16 Pathology MVP

Table B.16a represents the proposed MIPS core measures for the Pathology MVP. The B.16b table, followed by a list of improvement activities, represents the measures and activities finalized within the Pathology MVP (90 FR 50390 through 50395) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Pathology MVP focuses on assessing meaningful outcomes in pathology. This MVP would be most applicable to pathology clinicians. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.16b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[573] we proposed the following measures as MIPS core measures for the Pathology MVP:

- **Q396:** Lung Cancer Reporting (Resection Specimens)
- **Q440:** Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician
- **Q491:** Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status

We proposed adding one QCDR measure that is relevant to this MVP:

- **QMM33:** Immunohistochemistry (IHC) and/or Molecular BRAF Testing Status in Metastatic Melanoma: This QCDR measure ensures that pathologists include a recommendation for BRAF testing, documentation of current or prior BRAF test results,

[573] See MVP Development: Quality Measure and Improvement Activity Updates

or confirmation that BRAF testing is pending in all final immunohistochemical staining reports for patients with an initial diagnosis of metastatic melanoma.

We proposed to remove one QCDR measure due to low adoption, no benchmark after 2 consecutive years in MIPS:

- **QMM25:** Use of Structured Reporting for Urine Cytology Specimens

Modifications were considered for the following QCDR measures:

- **CAP30:** Urinary Bladder Cancer: Complete Analysis and Timely Reporting: This QCDR measure is undergoing modifications to the title and description to clarify the quality action in relation to patient outcomes and the overarching goal of supporting informed treatment decisions.

Improvement Activities

We proposed adding four additional improvement activities relevant to this MVP, all of which include an advancing health and wellness component:

- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **IA_CC_20:** Use of Data to Improve Practice Workflows
- **IA_CC_21:** Understand and Improve Diagnostic Performance
- **IA_EPA_8:** Provide Education Opportunities for New Clinicians

For the reasons stated in the introduction of this appendix,[574] we proposed to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care, **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings and **IA_PSPA_2:** Participation in MOC Part IV.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): finalized new measure or improvement activity.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.16a: Pathology MVP MIPS Core Measures

Pathology MVP MIPS Core Measures
Q396: Lung Cancer Reporting (Resection Specimens)
Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician
Q491: Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status

TABLE B.16b: Pathology MVP Clinical Groupings

[574] See MVP Development: Quality Measure and Improvement Activity Updates

Pathology MVP		
Clinical Grouping	**Quality**	**Cost**
Pathology	**Q249:** Barrett's Esophagus (Collection Type: Medicare Part B Claims, MIPS CQM)	**N/A**
	(*) Q250: Radical Prostatectomy Pathology Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q395: Lung Cancer Reporting (Biopsy/Cytology Specimens) (Collection Type: Medicare Part B Claims, MIPS CQM)	**N/A**
	(!)(*) Q396: Lung Cancer Reporting (Resection Specimens) (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q397: Melanoma Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	**N/A**
	(!)(*) Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician (Collection Type: MIPS CQM)	
	(!)(*) Q491: Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status (Collection Type: MIPS CQM)	
	(*) CAP30: Urinary Bladder Cancer: Complete Analysis and Timely Reporting (Collection Type: QCDR)	
	CAP34: Molecular Assessment: Biomarkers in Non-Small Cell Lung Cancer (Collection Type: QCDR)	
	CAP40: Squamous Cell Skin Cancer: Complete Reporting (Collection Type: QCDR)	
	QMM21: Incorporating results of concurrent studies into Final Reports for Bone Marrow Aspirate of patients with Leukemia, Myelodysplastic syndrome, or Chronic Anemia (Collection Type: QCDR)	
	QMM29: Use of Appropriate Classification System for Lymphoma Specimen (Collection Type: QCDR)	
	QMM30: Appropriate Use of Bethesda System for Reporting Thyroid Cytopathology on Fine Needle Aspirations (FNA) of Thyroid Nodule(s) (Collection Type: QCDR)	
	(+) QMM33: Immunohistochemistry (IHC) and/or Molecular BRAF Testing Status in Metastatic Melanoma (Collection Type: QCDR)	

Pathology Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!!) IA_BMH_12:** Promoting Clinician Well-Being
- **(+)(*)(!!) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(^)(+) IA_CC_20:** Use of Data to Improve Practice Workflows
- **(^)(+) IA_CC_21:** Understand and Improve Diagnostic Performance

- **(+) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_12:** Participation in private payer CPIA
- **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative
- **IA_PSPA_35:** Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP.

Response: We thank the commenter for their support.

Comment: One commenter requested the addition of CAP43: Complete Reporting of Gastrointestinal Metaplasia, and CAP44: Molecular Assessment for Endometrial Carcinoma to this MVP. The commenter believed these new measures would expand the diseases addressed and represent opportunities for improvement for pathologists.

Response: We may consider the addition of quality measures for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

After consideration of public comments, we are finalizing the *Pathology MVP* with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. We are not finalizing the modifications to the title for CAP30: Urinary Bladder Cancer: Complete Analysis and Timely Reporting as the measure steward has determined updates to the measure title were unnecessary for CY2027. Additionally, the measure steward updated the numerator to align with the clarification added in the description.

B.17: Patient Safety and Support of Positive Experiences with Anesthesia MVP

Table B.17a represents the proposed MIPS core measures for the Patient Safety and Support of Positive Experiences with Anesthesia MVP. The B.17b table, followed by a list of improvement activities, represents the measures and activities finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP (90 FR 50441 through 50444) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Patient Safety and Support of Positive Experiences with Anesthesia MVP focuses on increasing the quality of anesthesia care, improving postoperative outcomes, promoting patient safety, and enhancing satisfaction for patients receiving anesthesia. This MVP would be most applicable to anesthesiologists practicing within ambulatory, outpatient, and inpatient hospital settings, including NPPs such as certified registered nurse anesthetists (CRNAs), nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.17b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[575] we proposed the following measures as MIPS core measures for the Patient Safety and Support of Positive Experiences with Anesthesia MVP:

[575] See MVP Development: Quality Measure and Improvement Activity Updates

- **Q404:** Anesthesiology Smoking Abstinence
- **Q477:** Multimodal Pain Management
- **Q525:** Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases

We proposed adding two new MIPS quality measures and two QCDR measures:

- **Q525:** Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases: This proposed MIPS quality measure assesses the mean arterial pressure (MAP) of patients undergoing noncardiac, non-emergency surgery that requires general anesthesia or monitored anesthesia.
- **Q524:** Patient-Reported Experience with Anesthesia: This proposed MIPS quality measure assesses patient experience and satisfaction with anesthesia care.
- **AQI65:** Avoidance of Cerebral Hyperthermia for Procedures Involving Cardiopulmonary Bypass: This QCDR measure ensures patients receive appropriate intraoperative temperature monitoring during cardiopulmonary bypass, with documentation that pulmonary artery, oropharyngeal, or nasopharyngeal temperatures are maintained at or above 37.0 degrees Celsius.
- **AQI71:** Ambulatory Glucose Management: This QCDR measure ensures patients with diabetes undergoing office-based or ambulatory surgery receive appropriate blood glucose monitoring and intervention throughout the entire anesthesia care episode.

For the reasons stated in the introduction of this appendix,[576] we proposed to remove **Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy and **Q463:** Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics). We proposed to remove one high performing QCDR measures and two QCDR measures proposed to transition to MIPS measures:

- **ABG44:** Low Flow Inhalational General Anesthesia (high performing)
- **AQI48:** Patient-Reported Experience with Anesthesia (proposed as a MIPS measure)
- **EPREOP31:** Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases (proposed as a MIPS measure)

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): finalized new measure or improvement activity.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.17a: Patient Safety and Support of Positive Experiences with Anesthesia MVP MIPS Core Measures

Patient Safety and Support of Positive Experiences with Anesthesia MVP MIPS Core Measures
Q404: Anesthesiology Smoking Abstinence
Q477: Multimodal Pain Management
Q525: Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases

[576] Ibid.

TABLE B.17b: Patient Safety and Support of Positive Experiences with Anesthesia MVP Clinical Groupings

Patient Safety and Support of Positive Experiences with Anesthesia MVP		
Clinical Grouping	**Quality**	**Cost**
Sedation/General Anesthesia	**(!) Q404:** Anesthesiology Smoking Abstinence (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!)(^)(+) Q525: Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases (Collection Type: MIPS CQM)	
	(+) AQI65: Avoidance of Cerebral Hyperthermia for Procedures Involving Cardiopulmonary Bypass (Collection Type: QCDR)	
	(+) AQI71: Ambulatory Glucose Management (Collection Type: QCDR)	
Pain Management	**(!) Q477**: Multimodal Pain Management (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**(^)(+) Q524:** Patient-Reported Experience with Anesthesia (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Patient Safety and Support of Positive Experiences with Anesthesia Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_22:** Improved practices that engage patients pre-visit
- **(!!) IA_BMH_2:** Tobacco use
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **(*) IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools, including AI-enabled predictive decision-support interventions—and standardized treatment protocols to manage workflow on the care team to meet patient needs

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. Another commenter supported the inclusion of Q525: Interoperative Hypotension Among Non-Emergent Noncardiac Surgical Cases as well as the addition of addition of AQI65 and AQI71 to this MVP.

Response: We thank the commenters for their support.

Comment: A commenter supported the concepts for the Interoperative Hypotension Among Non-Emergent Noncardiac Surgical Cases and Patient-Reported Experience with Anesthesia measures but had significant concerns about immediate feasibility. The commenter explained that the intraoperative hypotension measure depends on electronic intraoperative blood pressure data from anesthesia information management systems (AIMS) or automated monitor integrations that many anesthesia practices cannot access or control, particularly when clinicians work across multiple facilities with different platforms and limited authority to modify interfaces, standardize workflows, or implement upgrades. The commenter also noted that the patient experience measure relies on post-discharge surveys and robust patient engagement and communication capabilities that are often managed by facilities or vendors rather than anesthesia organizations and would require substantial new infrastructure and resources. The commenter recommended a transition period of at least 12–24 months, with optional reporting for the patient experience measure, so practices could work with facilities to upgrade systems and develop the technical and patient engagement infrastructure needed before these measures become mandatory. Another commenter expressed concern that many anesthesia groups do not own or control the electronic medical record (EMR), making extraction

of the detailed data required for certain measures in this MVP—such as Intraoperative Hypotension/EPREOP 31 and similar measures—nearly impossible. The commenter further noted that AQI65 has a very limited denominator, making it difficult for clinicians outside cardiac anesthesia to have enough eligible cases, and that the ongoing removal of measures like Q430 and Q463 leaves the anesthesia specialty with few achievable options unless groups own the EMR and practice in high-volume academic settings.

Response: We appreciate the commenters' feedback and their support for the concepts underlying the intraoperative hypotension and anesthesia patient experience measures, as well as their detailed explanations of feasibility concerns. We acknowledge that not all quality measures will be applicable or available to all clinicians reporting an MVP, and these measures remain optional for reporting as we continue working towards the sunsetting of traditional MIPS, providing transition time for practices. We recognize that many anesthesia groups do not own or control the electronic medical record (EMR) or AIMS and may face challenges accessing the data required for measures such as Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases and related measures. We also acknowledge concerns about limited denominators for certain measures and the impact of measure removals on the availability of achievable options for anesthesia clinicians. We will continue to encourage collaboration among clinicians, facilities, and vendors to support data access and interoperable workflows that enable more consistent and reliable reporting. We encourage interested parties to reach out to the relevant measure stewards to discuss potential revisions and implementation considerations for future years, including feasibility, denominator size, and data access issues. Finalized MVPs are reviewed annually to determine whether additional updates are needed to meet the needs of the MVP and program requirements, and we will take these comments into account as part of that ongoing review.

Comment: A few commenters opposed the removal of measures Q430 and Q463 as they believed this leaves the MVP with only three MIPS measures to report and therefore forces anesthesia practices to use a QCDR to satisfy MIPS reporting requirements. One commenter recommended maintaining these two measures for a transition period while practices, facilities, vendors, and registries develop the capabilities necessary to support the new measures.

Response: We acknowledge the commenters' concern regarding the removal of measures Q430: Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy, and Q463: Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics); however, we seek to balance meaningful quality reporting with minimizing burden placed on clinicians. While topped-out measures may still represent an important aspect of care, the associated quality actions are generally considered a standard of practice, presenting limited opportunity to further improve clinical outcomes. We have proposed two new MIPS CQM measures, which will result in a total of four MIPS CQM measures available for reporting as well as two QCDR measures. These measures have been finalized for removal from the program and, consequently, will be removed from this MVP. For the full rationale supporting the removal of Q430 and Q463, please refer to Appendix 1: MIPS Quality Measures of this final rule, Table Group C.

Comment: A commenter supported updating and refining this MVP but highlighted the operational complexity for large multispecialty organizations that must evaluate multiple pathways, determine clinician applicability, and set up reporting structures across specialties. The commenter requested that future modifications to existing MVPs continue to account for clinical relevance and operational feasibility across different specialties and practice settings.

A couple of commenters supported the addition of four new quality measures. A commenter supported the creation of a MIPS core measure set for this MVP, stating these changes would improve measurement stability, reduce reporting burden, enhance comparability, and better reflect CRNA services. They agreed with requiring CRNAs to report a MIPS core measure (or attest that none applies) and exempting small practices, but urged that CRNAs have multiple, clinically relevant MIPS core measure options feasible across diverse settings. A commenter recommended ongoing evaluation and expansion of anesthesia-specific MIPS core measures, clarification that newly developed anesthesia measures can be designated as core in future rulemaking, and removal of technical, administrative, and attribution barriers so CRNAs can fully participate and be appropriately attributed in the MVP.

Response: We appreciate the commenters' feedback and thank them for their support. We may consider the addition of quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter opposed the removal of ABG44: Low Flow Inhalational General Anesthesia.

Response: QCDR measures must meet established inclusion criteria to be finalized for MIPS and for inclusion within an MVP. Based upon review of ABG44, the measure no longer meets that MVP inclusion criteria. MIPS performance data indicate that ABG44 is high performing and presents limited opportunity to further improve clinical outcomes.

After consideration of public comments, we are finalizing the *Patient Safety and Support of Positive Experiences with Anesthesia MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.18 Podiatry MVP

Table B.18a represents the proposed MIPS core measures for the Podiatry MVP. The B.18b table, followed by a list of improvement activities, represents the measures and activities finalized within the Podiatry MVP (90 FR 50395 through 50400) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Podiatry MVP focuses on assessing meaningful outcomes in foot and ankle care for patients with chronic conditions, wound/ulcers, and general care for the podiatry patient. This MVP would be most applicable to podiatry clinicians, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.18b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[577] we proposed the following measures as MIPS core measures for the Podiatry MVP:

- **Q126:** Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation
- **Q155:** Falls: Plan of Care
- **Q358:** Patient-Centered Surgical Risk Assessment and Communication

We proposed to remove two QCDR measures due to low adoption, no benchmark after 2 consecutive years in MIPS:

- **REGCLR5:** Offloading with Remote Monitoring
- **REGCLR8:** Monitor and Improve Treatment Outcomes in Chronic Wound Healing

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.18a: Podiatry MVP MIPS Core Measures

[577] See MVP Development: Quality Measure and Improvement Activity Updates

Podiatry MVP MIPS Core Measures
Q126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation
Q155: Falls: Plan of Care
Q358: Patient-Centered Surgical Risk Assessment and Communication

TABLE B.18b: Podiatry MVP Clinical Groupings

Podiatry MVP		
Clinical Grouping	**Quality**	**Cost**
Chronic Conditions	**(!) Q126:** Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q127: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear (Collection Type: MIPS CQM)	
Wound/Ulcer	**USWR32:** Adequate Compression at each visit for Patients with Venous Leg Ulcers (VLUs) appropriate to arterial supply (Collection Type: QCDR)	**N/A**
	USWR33: Diabetic Foot Ulcer (DFU) Healing or Closure (Collection Type: QCDR)	
	USWR34: Venous Leg Ulcer (VLU) Healing or Closure (Collection Type: QCDR)	
	USWR35: Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer (Collection Type: QCDR)	
General Podiatry	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM,)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(!) Q155:** Falls: Plan of Care (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(*) Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(!) Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	
	MEX5: Hammer Toe Outcome (Collection Type: QCDR)	**N/A**
	REGCLR1: Heel Pain Treatment Outcomes for Adults (Collection Type: QCDR)	
	REGCLR3: Bunion Outcome - Adult and Adolescent (Collection Type: QCDR)	

Podiatry Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations

- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_22:** CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain
- **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP.

Response: We thank the commenter for their support.

Comment: A commenter expressed support for the MIPS core measures identified in this MVP and recommended identifying both Q226: Tobacco Use: Screening and Cessation Intervention and Q317: Screening for High Blood Pressure and Follow-Up Documented as MIPS core measure options.

Response: We thank the commenters for their support. We may consider alternative MIPS core measures for this MVP through future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter requested USWR33 and USWR34 be considered MIPS core measures for this MVP. As outcome measures the commenter believed they would be more applicable than the three proposed MIPS core measures which are all process measures. The commenter also requested the inclusion of two additional QCDR measures relevant to this MVP; USWR30: Non-invasive arterial assessment of patients with leg ulcers and USWR22: Nutritional Assessment and Intervention Plan in Patients with Wounds and Ulcers.

Response: We appreciate the commenter's feedback. MIPS core measures must be publicly available measures. For details on the finalized MIPS core measure proposal and selection criteria for MVPs refer to section IV.A.4.d.(1)(c) of this final rule. We may consider the addition of quality measures to this MVP through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A few commenters opposed the removal of REGCLR5: Offloading with Remote Monitoring and REGCLR8: Monitor and Improve Treatment Outcomes in Chronic Wound Healing from this MVP and urged that both measures be retained for CY 2027 and subsequent years to allow time to assess participation, reporting, and benchmarking. One commenter emphasized that these measures should be evaluated for their clinical relevance to podiatry and their importance in keeping this MVP a meaningful reporting pathway for podiatrists who provide chronic wound care. A second commenter argued that these QCDR measures capture important aspects of podiatry care and should be retained despite currently low adoption. This commenter stated that keeping the measures in the MVP would incentivize reporting as clinicians face a more limited, focused set of choices, potentially generating sufficient data to establish benchmarks and offering podiatrists a broader set of measures that better match their patient population. The second commenter also noted that retention would allow Registry Clearinghouse QCDR users to report a full set of four QCDR measures and requested that these measures be maintained for at least a few more years to see whether increased MVP participation improves reporting rates for historically un-benchmarked measures.

Response: We appreciate the commenter's feedback on REGCLR5 and REGCLR8. While we agree these concepts are important to quality care, the removal of these measures does not preclude clinicians from continuing these quality actions. Whether the clinician is being assessed for the quality action or not, it should still be completed as part of routine clinical practice. Additionally, QCDR measures must meet established inclusion criteria to be finalized for MIPS and for inclusion within an MVP. Based upon review of REGCLR5 and REGCLR8, they no longer meet that MVP inclusion criteria. MIPS performance data indicate that both measures have not met reporting requirements and have not established a benchmark after being in the program for 2 consecutive years.

Comment: A commenter requested the addition of Q318: Falls: Screening for Future Fall Risk in this MVP as this measure is included in the Podiatry Specialty Set and therefore recognized as relevant to podiatry, reflects podiatrists' role in fall prevention through pain treatment, balance improvement, and stabilizing devices. The commenter requested the addition of two new improvement activities to this MVP for 2027—one on advance care planning conversations that reflects podiatrists' role in managing chronic conditions and goals of care, and one on responsible clinician use of AI given its rapidly expanding role in clinical care. The commenter acknowledged the existing MVP Maintenance Process, which normally delays changes to finalized MVPs by a year, but argues that this creates unnecessary lag for newly proposed activities and asks that these activities be incorporated into relevant MVPs as soon as they are finalized, noting that the rulemaking process already provides sufficient opportunity for public feedback.

Response: We may consider the addition of quality measures and improvement activities for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

After consideration of public comments, we are finalizing the *Podiatry MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.19: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

Table B.19a represents the proposed MIPS core measures for the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP. The B.19b table, followed by a list of improvement activities, represents the measures and activities finalized within the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP (90 FR 50444 through 50447) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP focuses on promoting quality care for patients suffering from infectious disorders. This MVP would be most applicable to clinicians who treat patients within the practices of infectious disease and immunology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality and cost measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.19b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[578] we proposed the following measures as MIPS core measures for the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP:

- **Q205:** Sexually Transmitted Infection (STI) Testing for People with HIV
- **Q338:** HIV Viral Suppression
- **Q516:** Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

Improvement Activities

We proposed adding one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

[578] See MVP Development: Quality Measure and Improvement Activity Updates

For the reasons stated in the introduction of this appendix,[579] we proposed to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.19a: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP MIPS Core Measures

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP MIPS Core Measures
Q205: Sexually Transmitted Infection (STI) Testing for People with HIV
Q338: HIV Viral Suppression
Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

TABLE B.19b: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP Clinical Groupings

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP		
Clinical Grouping	**Quality**	**Cost**
Chronic: Hep C, HIV/AIDS	**(!) Q205:** Sexually Transmitted Infection (STI) Testing for People with HIV (Collection Type: eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(!) Q338: HIV Viral Suppression (Collection Type: eCQM, MIPS CQM)	
	Q340: HIV Annual Retention in Care (Collection Type: eCQM, MIPS CQM)	
	Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Collection Type: MIPS CQM)	
	Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQM)	
	(!) Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR) (Collection Type: MIPS CQM)	
Acute Infection	**Q065:** Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM, MIPS CQM)	**N/A**
	N/A	**COST_RIH_1:** Respiratory Infection Hospitalization

[579] Ibid.

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP		
Clinical Grouping	**Quality**	**Cost**
		COST_S_1: Sepsis **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**COST_RIH_1:** Respiratory Infection Hospitalization **COST_S_1:** Sepsis **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **TPCC_1:** Total Per Capita Cost
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q240: Childhood Immunization Status (Collection Type: eCQM)	
	Q310: Chlamydia Screening in Women (Collection Type: eCQM)	
	Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	
	(*) Q475: HIV Screening (Collection Type: eCQM)	
	Q493: Adult Immunization Status (Collection Type: MIPS CQM)	

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(+)(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **(!!) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship
- **(!!) IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. A few commenters supported Q205 and Q338 as core MIPS measures in the MVP. One commenter also supported Q516 as a MIPS core measure in this MVP.

Response: We thank the commenters for their support.

Comment: A commenter requested that Q065: Appropriate Treatment for Upper Respiratory Infection, Q130: Documentation of Current Medications in the Medical Record, and Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan be designated as MIPS core measures within the infectious diseases MVP. The commenter stated that this would provide additional viable reporting options and help ensure that, even when clinicians must rely on a topped-out measure, they can still earn meaningful points reflective of their performance.

Response: We welcome feedback on all MIPS core measures and encourage commenters to submit this during the annual MVP maintenance review process. Understanding that some clinicians may be unable to report the selected MIPS core measures, we do allow attestation for cases in which a MIPS core measure is not available and applicable. When identifying MIPS core measures within this MVP, the focus was on HIV and Hepatitis, as they are associated with high healthcare costs and poor patient outcomes.

After consideration of public comments, we are finalizing the *Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.20: Pulmonology Care MVP

Table B.20a represents the proposed MIPS core measures for the Pulmonology Care MVP. The B.20b table, followed by a list of improvement activities, represents the measures and activities finalized within the Pulmonology Care MVP (90 FR 50447 through 50449) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Pulmonology Care MVP focuses on assessing optimal care for patients treated for a broad range of pulmonology conditions including COPD, asthma, sleep apnea, and general pulmonology. This MVP would be most applicable to clinicians who specialize in pulmonology and sleep medicine, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.20b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[580] we proposed the following measures as MIPS core measures for the Pulmonology Care MVP:

- **Q052:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy
- **Q279:** Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy
- **Q398:** Optimal Asthma Control

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.20a: Pulmonology Care MVP MIPS Core Measures

Pulmonology Care MVP MIPS Core Measures
Q052: Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy
Q279: Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy
Q398: Optimal Asthma Control

TABLE B.20b: Pulmonology Care MVP Clinical Groupings

[580] See MVP Development: Quality Measure and Improvement Activity Updates

Pulmonology Care MVP		
Clinical Grouping	**Quality**	**Cost**
Asthma	**(!)(*) Q398:** Optimal Asthma Control (Collection Type: MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD)
COPD	**(!) Q052:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy (Collection Type: MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	ACEP25: Tobacco Use: Screening and Cessation Intervention for Patients with Asthma and COPD (Collection Type: QCDR)	
Sleep Medicine	**Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQM)	**N/A**
	(!) Q279: Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Pulmonology Care Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **(!!) IA_BE_23:** Integration of patient coaching practices between visits
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP.

Response: We thank the commenter for their support.

Comment: A commenter recommended adding Q317: Screening for High Blood Pressure and Follow-Up to this MVP. Another commenter requested adding Q240: Childhood Immunization Status, Q394: Immunizations for Adolescents, and Q493: Adult Immunization Status, while separate commenters recommended adding Q322: Adult Sinusitis: Appropriate Antibiotic Choice and Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood. In addition, a commenter requested that CMS support development of new measures that promote earlier identification of ILD and bronchiectasis in higher-risk pulmonary patients.

Response: We may consider the addition of quality measures for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We also encourage commenters to work with measure developers and stewards to develop and submit measures that address these aspects of care through the Call for Measures process.

After consideration of public comments, we are finalizing the *Pulmonology MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.21: Quality Care for Patients with Neurological Conditions MVP

Table B.21a represents the proposed MIPS core measures for the Quality Care for Patients with Neurological Conditions MVP. The B.21b table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care for Patients with Neurological Conditions MVP (90 FR 50449 through 50451) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Quality Care for Patients with Neurological Conditions MVP focuses on the clinical theme of promoting quality care for patients suffering from neurological conditions. This MVP would be most applicable to clinicians who specialize in neurology care, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.21b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[581] we proposed the following measures as MIPS core measures for the Quality Care for Patients with Neurological Conditions MVP:

- **Q238:** Use of High-Risk Medications in Older Adults
- **Q282:** Dementia: Functional Status Assessment
- **Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.21a: Quality Care for Patients with Neurological Conditions MVP MIPS Core Measures

[581] See MVP Development: Quality Measure and Improvement Activity Updates

Quality Care for Patients with Neurological Conditions MVP MIPS Core Measures
Q238: Use of High-Risk Medications in Older Adults
Q282: Dementia: Functional Status Assessment
Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood

TABLE B.21b: Quality Care for Patients with Neurological Conditions MVP Clinical Groupings

Quality Care for Patients with Neurological Conditions MVP		
Clinical Grouping	**Quality**	**Cost**
Brain Conditions	**Q268:** Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Dementia	**Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q282: Dementia: Functional Status Assessment (Collection Type: MIPS CQM)	
	Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM)	
	(*) Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM)	
Neurodegenerative Disorders	**(*) Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQM)	**MSPB_1**: Medicare Spending Per Beneficiary (MSPB) Clinician
	Q293: Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQM)	
	Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q238: Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	
	(*) Q513: Patient reported falls and plan of care (Collection Type: MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Quality Care for Patients with Neurological Conditions Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings

- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_24:** Financial Navigation Program
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(*)(!!) IA_BMH_4:** Depression Screening, Treatment, and Prevention
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **(!!) IA_PSPA_21:** Implementation of fall screening and assessment programs

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. Another commenter supported Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood as a MIPS core measure in this MVP.

Response: We thank the commenters for their support.

Comment: A commenter requested the addition of IA_BMH_1: Antipsychotic-Medication-Associated Physical Health Condition Assessment and Monitoring to this MVP. Another commenter requested the addition of Q182: Functional Outcome and Q283: Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management to this MVP.

Response: We may consider the addition of quality measures and improvement activities for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

After consideration of public comments, we are finalizing the *Quality Care for Patients with Neurological Conditions MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.22: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

Table B.22a represents the proposed MIPS core measures for the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP. The B.22b table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP (90 FR 50451 through 50453) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP focuses on providing care for patients experiencing some of the most common otolaryngology conditions such as, but not limited to: otologic conditions, chronic rhinosinusitis (CRS), age-related hearing loss (ARHL), and otitis media. This MVP would be most applicable to clinicians who treat patients within the practice of otolaryngology, including NPPs such as audiologists, nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.22b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[582] we proposed the following

[582] See MVP Development: Quality Measure and Improvement Activity Updates

measures as MIPS core measures for the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP:

- **Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)
- **Q357:** Surgical Site Infection (SSI)
- **Q523:** Age-Related Hearing Loss: Comprehensive Audiometric Evaluation

We proposed adding one new MIPS quality measure that is relevant to this MVP:

- **Q523:** Age-Related Hearing Loss: Comprehensive Audiometric Evaluation: This proposed MIPS quality measure assesses patients with hearing loss or tinnitus for completion of a comprehensive audiometric evaluation.

For the reasons stated in the introduction of this appendix,[583] we proposed to remove **Q332:** Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use). We proposed to remove one duplicative QCDR measure and one QCDR measure proposed to transition to a MIPS measure:

- **AAO16:** Age-Related Hearing Loss: Audiometric Evaluation (proposed as a MIPS measure)
- **AAO21:** Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months (duplicative measure)

Modifications were considered for the following QCDR measures:

- **AAO16:** Age-Related Hearing Loss: Audiometric Evaluation: If the measure is not finalized for removal in the CY 2027 PFS final rule, this QCDR measure would undergo modifications to update the description, denominator, and numerator to reflect the addition of a tinnitus diagnosis and clarifying that a hearing screening does not meet the measure's intent. Expanding the measure to include patients diagnosed with tinnitus will help capture a broader group of individuals who may have underlying or undiagnosed hearing loss.
- **AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation: This QCDR measure is undergoing modifications to update the description, denominator, and instructions to remove the otitis media with effusion (OME) diagnosis and expand the eligible population to include all patients undergoing tympanostomy tube insertion. This would increase the measure's applicability and case volume. This change reflects that preoperative hearing evaluation is an important component of care for any patient receiving tubes, not just those with OME.

Improvement Activities

We proposed adding eight improvement activities relevant to this MVP, several of which include an advancing health and wellness component:

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_CC_7:** Regular training in care coordination
- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_17:** Patient Navigator Program
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PM_17:** Participation in Population Health Research

[583] Ibid.

- **IA_PSPA_12:** Participation in private payer CPIA

For the reasons stated in the introduction of this appendix,[584] we proposed to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): finalized new measure or improvement activity.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.22a: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP MIPS Core Measures

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP MIPS Core Measures
Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)
Q357: Surgical Site Infection (SSI)
Q523: Age-Related Hearing Loss: Comprehensive Audiometric Evaluation

TABLE B.22b: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP Clinical Groupings

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP		
Clinical Grouping	**Quality**	**Cost**
Otology	**(*) AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation (Collection Type: QCDR)	**N/A**
Sleep Disorders	**Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQM)	**N/A**
General Otolaryngology	**(!) Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQM)	**N/A**
	(!)(^)(+) Q523: Age-Related Hearing Loss: Comprehensive Audiometric Evaluation (Collection Type: MIPS CQM)	
Surgical	**Q355:** Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	

[584] See MVP Development: Quality Measure and Improvement Activity Updates

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP		
Clinical Grouping	**Quality**	**Cost**
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	

Quality Care for the Treatment of Ear, Nose, and Throat Disorders Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(+) IA_CC_7:** Regular training in care coordination
- **(+)(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(+)(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(+) IA_CC_17:** Patient Navigator Program
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(+) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PM_16:** Implementation of medication management practice improvements
- **(+) IA_PM_17:** Participation in Population Health Research
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **(+) IA_PSPA_12:** Participation in private payer CPIA

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. Another commenter supported the adoption of the new measure for Age-Related Hearing Loss: Comprehensive Audiometric Evaluation measure and addressing a gap in this MVP.

Response: We thank the commenters for their support.

Comment: A couple of commenters recommended the addition of Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented, Q374: Closing the Referral Loop: Receipt of Specialist Report, and Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months to this MVP. The commenter also recommended the addition of IA_AHW_1: Chronic Care and Preventative Care Management for Empaneled Patients, IA_EPA_2: Use of telehealth services that expand practice access, and IA_BE_23: Integration of patient coaching practices between visits.

Response: We may consider the addition of quality measures and improvement activities for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

Comment: A couple of commenters opposed the removal of Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) as this would leave allergy and immunology specialists with three potentially relevant measures to report through this MVP, making it impossible for those clinicians to meet the requirement to report four measures.

Response: We acknowledge the commenters' concern regarding the removal of measure Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use). Please refer to Appendix 1: MIPS Quality Measures (Table Group C) in this final rule for details on the removal of Q332. While this MVP may not contain sufficient quality measures

appropriate to some clinician's scope of care, we encourage you to review other MVPs for potential applicability. In addition, we encourage the commenter to reach out to measure developers and stewards to develop new measures applicable and meaningful to allergists and immunologists for submission to the Call for Measures for possible future implementation. Finalized MVPs are reviewed annually to determine if additional updates are needed to meet the needs of the MVP and program requirements.

Comment: A commenter opposed the removal of AAO21 and consolidating it with AAO20, explaining that although they appear related, they address different patient cohorts and care pathways, and combining them would obscure clinically meaningful differences and affect scoring. The commenter added that eliminating AAO21 would further narrow already limited, specialty-specific quality options in this MVP, making it harder for some otolaryngologists to find four applicable measures, especially since prior recommendations to add ENT-relevant measures were not adopted, and urges retaining AAO21 as a separate measure with decisions based on patient populations, clinical pathways, performance distributions, and impacts on specialty participation.

Response: We thank the commenter for their feedback. Measure AA021: Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months is duplicative of AAO20: Tympanostomy Tubes: Comprehensive Audiometric Evaluation in clinical topic, as both assess receipt of a comprehensive audiometric evaluation when clinically indicated. We therefore proposed its removal, while encouraging the measure steward to incorporate the patient population into measure AAO20 for a more comprehensive assessment of appropriate audiologic care. We do not want to arbitrarily limit measures within MVP; however, we do want to have a streamlined set of robust quality measures that drive positive outcomes.

After consideration of public comments, we are finalizing the *Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.23: Quality Care in Mental Health and Substance Use Disorders MVP

Table B.23a represents the proposed MIPS core measures for the Quality Care in Mental Health and Substance Use Disorders MVP. The B.23b table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care in Mental Health and Substance Use Disorders MVP (90 FR 50453 through 50456) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Quality Care in Mental Health and Substance Use Disorders MVP focuses on clinical actions promoting prevention of and quality care in behavioral health, including mental health and substance use disorders (SUD). This MVP would be most applicable to clinicians who treat patients with mental health and substance use disorders within the practices of mental/behavioral health and psychiatry, including NPPs such as clinical social workers, nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.23b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[585] we proposed the following measures as MIPS core measures for the Quality Care in Mental Health and Substance Use Disorders MVP:

- **Q305:** Initiation and Engagement of Substance Use Disorder Treatment
- **Q370:** Depression Remission at Twelve Months
- **Q383:** Adherence to Antipsychotic Medications For Individuals with Schizophrenia

[585] See MVP Development: Quality Measure and Improvement Activity Updates

Improvement Activities

We proposed adding one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_BMH_4:** Depression Screening, Treatment, and Prevention.

For the reasons stated in the introduction of this appendix,[586] we proposed to remove **IA_BMH_5:** MDD prevention and treatment interventions.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.23a: Quality Care in Mental Health and Substance Use Disorders MVP MIPS Core Measures

Quality Care in Mental Health and Substance Use Disorders MVP MIPS Core Measures
Q305: Initiation and Engagement of Substance Use Disorder Treatment
Q370: Depression Remission at Twelve Months
Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia

TABLE B.23b: Quality Care in Mental Health and Substance Use Disorders MVP Clinical Groupings

Quality Care in Mental Health and Substance Use Disorders MVP		
Clinical Grouping	**Quality**	**Cost**
Mental Health—General	**Q009:** Anti-Depressant Medication Management (Collection Type: eCQM)	**COST_DEP_1**: Depression
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q366: Follow-Up Care for Children Prescribed ADHD Medication (Collection Type: eCQM)	**N/A**
	(!) Q370: Depression Remission at Twelve Months (Collection Type: eCQM, MIPS CQM)	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	(!)(*) Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia	**COST_PRC_1:** Psychoses/Related Conditions

[586] Ibid.

Quality Care in Mental Health and Substance Use Disorders MVP		
Clinical Grouping	**Quality**	**Cost**
	(Collection Type: MIPS CQM)	
	MBHR2: Anxiety Response at 6-months (Collection Type: QCDR)	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	MBHR7: Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children (Collection Type: QCDR)	**N/A**
Mental Health—Suicide	**Q382:** Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM)	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	Q504: Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk (Collection Type: MIPS CQM)	
	(*) Q505: Reduction in Suicidal Ideation or Behavior Symptoms (Collection Type: MIPS CQM)	
Substance Use Disorder	**(!) Q305:** Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM)	**N/A**
	Q468: Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) (Collection Type: MIPS CQM)	
Experience of Care	**Q502:** Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder (Collection Type: MIPS CQM)	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Mental Health and Substance Use Disorders Improvement Activities

- **(!!) IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **(!!) IA_BE_23:** Integration of patient coaching practices between visits
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!!) IA_BMH_2:** Tobacco use
- **(+)(*)(!!) IA_BMH_4:** Depression Screening, Treatment, and Prevention
- **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model
- **(!!) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women
- **(!!) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(!!) IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. Another commenter supported the addition of IA_BMH_4: Depression Screening, Treatment, and Prevention and the removal of IA_BMH_5: MDD prevention and treatment interventions from this MVP.

Response: We thank the commenters for their support.

Comment: A couple of commenters requested the addition of IA_BMH_1: Antipsychotic-Medication-Associated Physical Health Condition Assessment and Monitoring to this MVP.

Another commenter requested the addition of the tobacco use and unhealthy alcohol use preventive screening and counseling measures to this MVP, arguing that excluding measures addressing two of the most commonly abused substances makes the MVP incomplete and that including them would reduce reporting burden for psychiatrists, who have historically reported these measures frequently.

Response: We may consider the addition of quality measures and improvement activities for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

After consideration of public comments, we are finalizing the *Mental Health and Substance Use Disorders MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.24: Rehabilitative Support MVP

Table B.24a represents the proposed MIPS core measures for the Rehabilitative Support MVP. The B.24b table, followed by a list of improvement activities, represents the measures and activities finalized within the Rehabilitative Support for Musculoskeletal Care MVP (90 FR 50457 through 50461) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years, including an MVP title update to Rehabilitative Support MVP to more closely reflect the measures and activities included in the MVP. The Rehabilitative Support MVP focuses on clinical actions promoting quality rehabilitative care for patients. This MVP would be most applicable to clinicians who specialize in providing rehabilitative support such as chiropractic, physiatry, physical therapy and occupational therapy, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.24b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[587] we proposed the following measures as MIPS core measures for the Rehabilitative Support MVP:

- **Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older
- **Q155:** Falls: Plan of Care
- **Q520:** Functional Improvement for Patients with Back Impairments

We proposed adding five new MIPS quality measures relevant to this MVP:

- **Q518:** Functional Improvement for Patients with Neck Impairments: This proposed MIPS quality measure assesses functional improvement for patients with neck impairments after completing an episode of care, excluding surgical interventions. This measure is proposed to replace Q478: Functional Status Change for Patients with Neck

[587] See MVP Development: Quality Measure and Improvement Activity Updates

Impairments.

- **Q519:** Functional Improvement for Patients with Upper Extremity Impairments: This proposed MIPS quality measure assesses functional improvement for patients with upper extremity impairments after completing an episode of care, excluding surgical interventions. This measure is proposed to replace Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments.
- **Q521:** Functional Improvement for Patients with Lower Extremity Impairments: This MIPS quality measure assesses functional improvement for patients with lower extremity impairments after completing an episode of care, excluding surgical interventions. This measure is proposed to replace Q218 Functional Status Change for Patients with Hip Impairments and Q219: Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments.
- **Q522:** Functional Improvement for Patients with Knee Impairments: This proposed MIPS quality measure assesses functional improvement for patients with knee impairments after completing an episode of care, excluding surgical interventions. This measure is proposed to replace Q217: Functional Status Change for Patients with Knee Impairments.
- **Q520:** Functional Improvement for Patients with Back Impairments: This proposed MIPS quality measure assesses functional improvement for patients with back impairments after completing an episode of care, excluding surgical interventions. This measure is proposed to replace Q220: Functional Status Change for Patients with Low Back Impairments.

For the reasons stated in the introduction of this appendix,[588] we proposed to remove **Q217:** Functional Status Change for Patients with Knee Impairments, **Q218:** Functional Status Change for Patients with Hip Impairments, **Q219:** Functional Status Change with Lower Leg, Foot or Ankle Impairments, **Q220:** Functional Status Change for Patients with Low Back Impairments, **Q221:** Functional Status Change for Patients with Shoulder Impairments, **Q222:** Functional Status Change for Patients with Elbow, Wrist or Hand Impairments, and **Q478:** Functional Status Change for Patients with Neck Impairments.

Improvement Activities

We proposed adding one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix,[589] we proposed to remove **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care and **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): finalized new measure or improvement activity.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.

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[588] See MVP Development: Quality Measure and Improvement Activity Updates
[589] Ibid.

Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.24a: Rehabilitative Support MVP MIPS Core Measures

Rehabilitative Support MVP MIPS Core Measures
Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older
Q155: Falls: Plan of Care
Q520: Functional Improvement for Patients with Back Impairments

TABLE B.24b: Rehabilitative Support MVP Clinical Groupings

Rehabilitative Support MVP		
Clinical Grouping	**Quality**	**Cost**
Orthopedic	**Q182:** Functional Outcome Assessment (Collection Type: MIPS CQM)	**COST_LBP_1:** Low Back Pain
	(^)(+) Q518: Functional Improvement for Patients with Neck Impairments (Collection Type: MIPS CQM)	**N/A**
	(^)(+) Q519: Functional Improvement for Patients with Upper Extremity Impairments (Collection Type: MIPS CQM)	
	(^)(+) Q521: Functional Improvement for Patients with Lower Extremity Impairments (Collection Type: MIPS CQM)	
	(^)(+) Q522: Functional Improvement for Patients with Knee Impairments (Collection Type: MIPS CQM)	
	(!)(^)(+) Q520: Functional Improvement for Patients with Back Impairments (Collection Type: MIPS CQM)	**COST_LBP_1:** Low Back Pain
	MSK6: Patients Suffering From a Neck Injury who Improve Pain (Collection Type: QCDR)	**N/A**
	MSK7: Patients Suffering From an Upper Extremity Injury who Improve Pain (Collection Type: QCDR)	
	MSK8: Patients Suffering From a Back Injury who Improve Pain (Collection Type: QCDR)	**COST_LBP_1:** Low Back Pain
	MSK9: Patients Suffering From a Lower Extremity Injury who Improve Pain (Collection Type: QCDR)	**N/A**
Geriatric	**(!) Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	**N/A**
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_LBP_1:** Low Back Pain
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	

Rehabilitative Support MVP		
Clinical Grouping	**Quality**	**Cost**
	(!) Q155: Falls: Plan of Care (Collection Type: MIPS CQM)	

Rehabilitative Support Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!!) IA_BMH_12:** Promoting Clinician Well-Being
- **(!!) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **(*) IA_CC_8**: Implementation of documentation improvements for practice/process improvements
- **(+)(*)(!!) IA_CC_9:** Implementation of Practices/Processes for Developing Regular Individual Care Plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **(!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(*) IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools, including AI-enabled predictive decision-support interventions—and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **(!!) IA_PSPA_21:** Implementation of fall screening and assessment programs

The following is a summary of the comments we received and our responses.

Comment: A couple of commenters supported the updates to this MVP. A few commenters supported the proposed renaming of this MVP. One commenter believed the broader designation better encompasses the holistic, multi-system interventions that occupational therapists provide. A couple of commenters appreciated the inclusion of Q155: Falls: Plan of Care as one of the MIPS core measures and one commenter supported all of the measures identified as MIPS core measures. A few commenters supported the replacement of the FOTO "functional status" measures with the PROMIS PRO-PM measures. While a commenter believed PROMIS could enhance measure relevance and feasibility for physiatrists they noted that key technical details are missing, preventing assessment of how the measures will work or whether they are meaningful. The commenter requested complete specifications to be released early and designed to enable participation by physiatrists across diverse rehabilitation conditions and settings. One commenter supported the core-measure designation for functional improvement in patients with back impairments, given how common and costly low back conditions are in outpatient rehabilitation. And one commenter supported the addition of IA_CC_9.

Response: We thank the commenters for their support. The complete measure specifications will be publicly posted after publication of the final rule.

Comment: A commenter recommended the addition of Q318: Falls: Screening for Future Fall Risk as fall risk is clinically relevant to musculoskeletal and orthopedic rehabilitation patients. In addition, the commenter recommended the addition of Q513: Patient Reported Falls and Plan of Care as an additional applicable measure. Another commenter recommended the addition of Q281: Dementia; cognitive assessment, Q286: Dementia safety concern screening and follow-up for patients with dementia, Q288: Dementia: education and support of caregivers for patients with dementia, Q502: Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder, and Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months to this MVP.

Response: We may consider the addition of quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter requested that a cross-cutting functional outcome MIPS core measure option be added to this MVP. Another commenter recommended the MIPS core measures for this MVP include at least one cross-cutting, patient-reported functional outcome that can apply across body regions and diagnoses, such as PROMIS

Physical Function, and recommended PROMIS Pain Interference or an appropriate Global Health measure stating these measures could offer an additional cross condition option. The commenter also urged CMS to consider using the Patient-Specific Functional Scale (PSFS). Another commenter recommended at least one additional MIPS core measure from the existing PT/OT specialty measure set that captures outcomes beyond physical impairments be included.

Response: We encourage the commenters to suggest changes to the MIPS core measures through the MVP Maintenance Process and we may consider alternative MIPS core measures for this MVP through future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter recommended that, prior to removing IA_BE_15: Engagement of Patients, Family and Caregivers in Developing a Plan of Care and IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings, there should be confirmation that the remaining or replacement activities fully recognize those functions, and, if they do not, IA_BE_15 and IA_CC_12 should be retained. Another commenter wanted to understand how beneficiary-engagement activities previously recognized under IA_BE_15 will be appropriately included under the modified language. Care planning and beneficiary engagement are complementary but distinct activities and eliminating a standalone beneficiary engagement activity may reduce the visibility of patient-centered engagement efforts within the improvement activities performance category.

Response: We acknowledge the commenter's concern regarding the removal of IA_BE_15: Engagement of Patients, Family and Caregivers in Developing a Plan of Care and IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings. These improvement activities have been finalized for removal from the program and, consequently, will be removed from this MVP. Please refer to Appendix 2: Improvement Activities (Table Group C) in this final rule for details on the removal of IA_BE_15 and IA_CC_12. We are seeking to ensure that elements of removed activities such as these two are retained in the Inventory, either in combined activities or other existing activities. We are continuing to prioritize patient-centered engagement efforts in improvement activities. IA_CC_9: Implementation of Practices/Processes for Developing Regular Individual Care Plans has been proposed for addition to this MVP, as part of our preserving elements of removed or combined activities.

Comment: A commenter recommended that quality measures for rehabilitation clinicians focus on patient-centered functional outcomes aligned with rehabilitative goals, rather than process metrics used for physician specialties. The commenter emphasized assessing outpatient rehabilitation by functional improvement, safety, independence, and patient-reported outcomes (including PROMs and PROMIS), arguing this better reflects rehabilitation's value in promoting healthy aging, independence, and reduced healthcare utilization. The commenter suggested expanding the MVP to ensure it adequately reflects the breadth of contemporary rehabilitation practice. Another commenter recommended the incorporation of measures that assess functional cognitive, psychosocial, and participation-based outcomes, and successful engagement in everyday activities.

Response: We thank the commenter for the feedback. We may consider the addition of quality measures for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

Comment: A commenter expressed support for meaningful, functional measures of therapy outcomes and opposed tying accurate valuation and payment to new or untested reporting requirements. The commenter urged closing measurement gaps for occupational therapy, avoiding instruments that simply reflect treatment volume, and ensuring small practices can participate without costly infrastructure. They further recommended that voluntary, CMS-funded testing be used to evaluate whether condition-agnostic patient-reported outcome tools (such as PROMIS Global Health) add value alongside discipline-specific functional measures, with data collected at clinically meaningful intervals rather than every visit and post-treatment follow-up included only when feasible.

Response: We thank the commenter for the support. We encourage interested parties to submit potential new measures that will align with current program goals and priorities and fill these identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS during the annual Call for Measures. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

After consideration of public comments, we are finalizing the *Rehabilitative Support MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years

B.25: Surgical Care MVP

Table B.25a represents the proposed MIPS core measures for the Surgical Care MVP. The B.25b table, followed by a list of improvement activities, represents the measures and activities finalized within the Surgical Care MVP (90 FR 50461 through 50464) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Surgical Care MVP focuses on the clinical theme of surgery. This MVP would be most applicable to clinicians who specialize in general surgery, neurosurgery, and cardiothoracic surgery, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.25b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[590] we proposed the following measures as MIPS core measures for the Surgical Care MVP:

- **Q047:** Advance Care Plan
- **Q164:** Coronary Artery Bypass Graft (CABG): Prolonged Intubation
- **Q354:** Anastomotic Leak Intervention
- **Q357:** Surgical Site Infection (SSI)
- **Q358:** Patient-Centered Surgical Risk Assessment and Communication
- **Q459:** Back Pain After Lumbar Surgery

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.25a: Surgical Care MVP MIPS Core Measures

Surgical Care MVP MIPS Core Measures
Q047: Advance Care Plan
Q164: Coronary Artery Bypass Graft (CABG): Prolonged Intubation
Q354: Anastomotic Leak Intervention
Q357: Surgical Site Infection (SSI)
Q358: Patient-Centered Surgical Risk Assessment and Communication
Q459: Back Pain After Lumbar Surgery

TABLE B.25b: Surgical Care MVP Clinical Groupings

[590] See MVP Development: Quality Measure and Improvement Activity Updates

Surgical Care MVP		
Clinical Grouping	**Quality**	**Cost**
Cardiothoracic Surgery	**(!) Q164:** Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Collection Type: MIPS CQM)	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q167: Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure (Collection Type: MIPS CQM)	
	(*) Q168: Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration (Collection Type: MIPS CQM)	
	Q445: Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG) (Collection Type: MIPS CQM)	
General Surgery	**(!) Q354:** Anastomotic Leak Intervention (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q355: Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQM)	**COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	**COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1**: Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Neurosurgical	**(!) Q459:** Back Pain After Lumbar Surgery (Collection Type: MIPS CQM)	**COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q461: Leg Pain After Lumbar Surgery (Collection Type: MIPS CQM)	
	Q471: Functional Status After Lumbar Surgery (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels

Surgical Care MVP		
Clinical Grouping	**Quality**	**Cost**
		COST_LPMSM_1: Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	

Surgical Care Improvement Activities

- **(!!) IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_17:** Patient Navigator Program
- **(!!) IA_CC_18:** Relationship-Centered Communication
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_8:** Use of Patient Safety Tools

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP.

Response: We thank the commenter for their support.

Comment: A commenter requested expanding this MVP to provide additional clinically meaningful quality measures applicable to spine surgery. The commenter specifically requested the expansion of eligible procedure populations for Q355: Unplanned Reoperation within the 30 Day Postoperative Period, and Q356: Unplanned Hospital Readmission within 30 Days of Principal Procedure, to include appropriate cervical and lumbar spine surgical procedures. Another commenter requested the addition of the following improvement activities: IA_BE_6:

Regularly Assess Patient Experience of Care and Follow Up on Findings and IA_EPA_6: Create and Implement a Language Access Plan.

Response: We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years as well as submission of potential new measures that will align with current program goals and priorities and fill these identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS during the annual Call for Measures. We may consider the inclusion of additional quality measures through the MVP Maintenance Process and future rulemaking. Interested parties are welcome to submit recommended changes to an MVP on an ongoing basis. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: A commenter believed the MIPS core measures identified for this MVP is fundamentally flawed because it applies the same MIPS core measures to very different types of clinicians and procedures, creating misleading comparisons. Measures broad enough to apply across all included clinicians (like Advance Care Plan) do not reflect surgical quality, while measures that truly capture surgical performance (like CABG: Prolonged Intubation) apply only to narrow subsets and are not reportable by most clinicians in the MVP. Requiring three or more MIPS core measures but allowing clinicians to report only one worsens this issue, since two surgeons in the same MVP could report entirely different measures, giving a false impression of comparability. The commenter opposed the MIPS core measure concept as designed and recommended that it should instead focus MIPS core measures on patient-reported outcome–based performance measures (PRO-PMs), which can apply to all patients and better capture outcomes that matter to them, such as function, recovery, quality of life, and goal attainment.

Response: We thank the commenter for their feedback and acknowledge limitations to MIPS core measure selection based upon the current MIPS quality measure inventory. Therefore, we had to balance between choosing measures that most closely represent care central to the MVP intent, while also ensuring measure availability for those clinicians who chose to report the MVP. For some MVPs, such as the Surgical Care MVP, we determined more than three measures must be selected to reflect the care central to the subspecialties able to report MVP. The intent of the selected measures is to provide a comparable data point for each of the represented specialties, while also including a more broadly applicable measure to ensure coverage for those without a specialty-specific surgical quality measure. It would be expected that like clinicians able to report the specialty-specific MIPS core measures would do so, allowing for comparison across that measure's performance. We encourage interested parties to submit potential new measures that will align with current program goals and priorities and fill these identified gaps allowing meaningful and complete assessment of MIPS eligible clinician's performance within MIPS during the annual Call for Measures.

Comment: A commenter expressed concern with the proposed MIPS core measures in this MVP as several are tied to specific procedures—such as CABG, anastomotic leak intervention, and lumbar surgery—and therefore have little or no applicability to neurosurgeons who do not perform them. The commenter added that while broader surgical measures like surgical site infection and patient-centered surgical risk assessment may apply to neurosurgeons, they still do not directly evaluate the specialized clinical care provided by many neurosurgical subspecialists.

Response: We acknowledge that not all MIPS core measures will be applicable to all clinicians reporting an MVP; however, to the extent possible, we took into account implementation factors and availability. Therefore, we identified a small subset of measures within each MVP that represents care central to the MVP intent. For MVPs that represent multiple clinician types, settings, or care scopes, we identified additional MIPS core measures ensuring measure availability for those clinicians who chose to report the MVP. Additionally, the policy includes an option for self-attestation when the MIPS core measures are not appropriate or applicable to their scope of care, allowing clinicians to choose an alternate measure that is more relevant.

After consideration of public comments, we are finalizing the *Surgical Care MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.26: Value in Primary Care MVP

Table B.26a represents the proposed MIPS core measures for the Value in Primary Care MVP. The B.26b table, followed by a list of improvement activities, represents the measures and activities finalized within the Value in Primary Care MVP (90 FR 50465 through 50467) with

modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Value in Primary Care MVP focuses on the clinical theme of promoting quality care for patients to reduce the risk of diseases, disabilities, and death. This MVP would be most applicable to clinicians who specialize in preventive medicine, internal medicine, family medicine, and geriatrics, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.26b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[591] we proposed the following measures as MIPS core measures for the Value in Primary Care MVP:

- **Q001:** Diabetes: Glycemic Status Assessment Greater Than 9%
- **Q134:** Preventive Care and Screening: Screening for Depression and Follow-up Plan
- **Q236:** Controlling High Blood Pressure

We proposed adding one new MIPS quality measure:

- **Q517:** Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management: This proposed intermediate outcome MIPS quality measure ensures lipid monitoring in patients with atherosclerotic cardiovascular disease (ASCVD) and assesses target goal achievement of an LDL-C less than 70mg/dl.

For the reasons stated in the introduction of this appendix,[592] we proposed to remove **Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM).

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): finalized new measure or improvement activity.
Plus sign (+): measures and improvement activities finalized for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.26a: Value in Primary Care MVP MIPS Core Measures

Value in Primary Care MVP MIPS Core Measures
Q001: Diabetes: Glycemic Status Assessment Greater Than 9%
Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan
Q236: Controlling High Blood Pressure

TABLE B.26b: Value in Primary Care MVP Clinical Groupings

[591] See MVP Development: Quality Measure and Improvement Activity Updates
[592] See MVP Development: Quality Measure and Improvement Activity Updates

Value in Primary Care MVP		
Clinical Grouping	**Quality**	**Cost**
Chronic Conditions	**(!)(*) Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_D_1:** Diabetes **TPCC_1:** Total Per Capita Cost
	(!)(*) Q236: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1:** Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **TPCC_1:** Total Per Capita Cost
	Q305: Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM)	**N/A**
	(*) Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	Q504: Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk (Collection Type: MIPS CQM)	**COST_DEP_1:** Depression **TPCC_1:** Total Per Capita Cost
	(^)(+) Q517: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
Advancing Health and Wellness	**(!)(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1:** Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **TPCC_1:** Total Per Capita Cost
	(*) Q475: HIV Screening (Collection Type: eCQM)	
	Q493: Adult Immunization Status (Collection Type: MIPS CQM)	
	(*) Q497: Preventive Care and Wellness (composite) (Collection Type: MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1:** Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **TPCC_1:** Total Per Capita Cost
	Q321: CAHPS for MIPS Clinician/Group Survey (Collection Type: CMS-approved Survey Vendor)	

Value in Primary Care Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making

- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PM_16:** Implementation of medication management practice improvements
- **(!!) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- **(!!) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines
- **(!!) IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. A couple of commenters supported the inclusion of the Low-Density Lipoprotein (LDL-C) Monitoring and Management measure in this MVP.

Response: We thank the commenters for their support.

Comment: A couple of commenters requested the addition of IA_BMH_1: Antipsychotic-Medication-Associated Physical Health Condition Assessment and Monitoring to this MVP. A couple of commenters requested the addition of Q488: Kidney Health Evaluation be added. Other commenters recommended Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood and Q117: Diabetes Eye Exam. Another commenter requested the addition of Q281: Dementia: Cognitive Assessment and Q282: Dementia: Functional Status Assessment. A commenter recommended the addition of measures to this MVP that better capture advanced primary care management and longitudinal, team-based care. The commenter emphasized that these measures should recognize the roles of nurses, advanced practice registered nurses (APRNs), and other interdisciplinary team members in coordinating care, managing complex conditions, improving outcomes, and supporting chronic disease prevention and management.

Response: We may consider the addition of quality measures and improvement activities for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

Comment: A few commenters recommended designating HIV screening as a MIPS core measure in this MVP, emphasizing that screening is the gateway to the full continuum of HIV services. A negative result can prompt prevention discussions and offer pre-exposure prophylaxis (PrEP), while a positive result should lead quickly to confirmatory testing, linkage to care, and treatment. The commenter cautioned that treating HIV screening as optional in primary care contributes to missed and delayed diagnoses, especially when providers make assumptions based on age, gender, sexual orientation, or relationship status. Another commenter requested Q515: Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes be considered a MIPS core measure within this MVP. A few commenters requested the Low-Density Lipoprotein (LDL-C) Monitoring and Management measure be identified as a MIPS core measure.

Response: We thank the commenters for their feedback and agree that screening for HIV is a critically important step in prompting either prevention discussions or treatment options. The intent of the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP is to focus on driving quality care for patients suffering from an infectious disorder, such as HIV, and those clinicians within the practices of infectious disease and immunology, including NPPs. When determining which quality measures to include as MIPS core measures, we sought to include measures that assess quality actions and outcomes for patients that are being actively treated by the clinician. We may consider alternative MIPS core measures for this MVP through future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP.

Comment: Many commenters opposed the removal of Q483: Person-Centered Primary Care Measure Patient-Reported Outcome Performance Measure (PCPCM PRO-PM) from MIPS and from this MVP. They expressed concern that eliminating this measure would leave the MVP without a patient-reported outcome (PRO) performance measure that reflects the core functions of primary care—accessibility, continuity, comprehensiveness, coordination, and person-centeredness—from the patient's perspective.

Response: We acknowledge the commenters' concern regarding the removal of measure Q483: Person-Centered Primary Care Measure Patient-Reported Outcome Performance Measure (PCPCM PRO-PM). This measure has been finalized for removal from the program and, consequently, will be removed from this MVP. Please refer to Appendix 1: MIPS Quality Measures (Table Group C) in this final rule for details on the removal of Q483.

After consideration of public comments, we are finalizing the *Value in Primary Care MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

B.27 Vascular Surgery MVP

Table B.27a represents the proposed MIPS core measures for the Vascular Surgery MVP. The B.27b table, followed by a list of improvement activities, represents the measures and activities finalized within the Vascular Surgery MVP (90 FR 50400 through 50405) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Vascular Surgery MVP focuses on the clinical theme of providing high quality care for patients treated under vascular surgery. This MVP would be most applicable to clinicians who treat patients within the surgical setting of vascular surgery, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. The summary of the public comments received and our responses to this MVP are included immediately after Table B.27b and the list of improvement activities.

Quality Measures

For the reasons stated in the introduction of this appendix,[593] we proposed the following measures as MIPS core measures for the Vascular Surgery MVP:

- **Q344:** Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)
- **Q356:** Unplanned Hospital Readmission within 30 Days of Principal Procedure
- **Q358:** Patient-Centered Surgical Risk Assessment and Communication

Improvement Activities

For the reasons stated in the introduction of this appendix,[594] we proposed to remove **IA_PM_2:** Anticoagulant Management Improvements.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with finalized revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.27a: Vascular Surgery MVP MIPS Core Measures

[593] See MVP Development: Quality Measure and Improvement Activity Updates
[594] See MVP Development: Quality Measure and Improvement Activity Updates

Vascular Surgery MVP MIPS Core Measures
Q344: Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)
Q356: Unplanned Hospital Readmission within 30 Days of Principal Procedure
Q358: Patient-Centered Surgical Risk Assessment and Communication

TABLE B.27b: Vascular Surgery MVP Clinical Groupings

Vascular Surgery MVP		
Clinical Grouping	**Quality**	**Cost**
Interventional	**Q259:** Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q344: Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQM)	
Surgical	**Q355:** Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQM)	**COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q356: Unplanned Hospital Readmission within 30 Days of Principal Procedure (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	**COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Dialysis-Related	**RCOIR12:** Tunneled Hemodialysis Catheter Clinical Success Rate (Collection Type: QCDR)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	RCOIR13: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate (Collection Type: QCDR)	
	RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate (Collection Type: QCDR)	
	RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate (Collection Type: QCDR)	
General Vascular Surgery	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia

Vascular Surgery MVP		
Clinical Grouping	**Quality**	**Cost**
		COST_HAC_1: Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(*) Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia **COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(*) Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia **COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q321: CAHPS for MIPS Clinician/Group Survey (Collection Type: CMS-approved Survey Vendor)	
	(!) Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	

Vascular Surgery Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(!!) IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_15:** PSH Care Coordination
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(!!) IA_PM_5:** Engagement of community for health status improvement
- **IA_PM_11:** Regular Review Practices in Place on Targeted Patient Population Needs
- **IA_PM_15:** Implementation of episodic care management practice improvements
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization

The following is a summary of the comments we received and our responses.

Comment: A commenter supported the updates to this MVP. Another commenter supported the designation of Q344: Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients,

Without Major Complications (Discharged to Home by Post-Operative Day #2) as a MIPS core measure for this MVP.

Response: We thank the commenters for their support.

Comment: A few commenters recommended the inclusion of the Low-Density Lipoprotein (LDL-C) Monitoring and Management measure in this MVP. A commenter recommended the addition of Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood. Another commenter recommended the addition of all of the newly proposed improvement activities.

Response: We may consider the addition of quality measures for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

Comment: A commenter suggested alternative MIPS core measures for this MVP, including Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention; Q259: Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2); Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease; and the new Low-Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management measure.

Response: We may consider alternative MIPS core measures and the addition of quality measures and improvement activities for this MVP through the MVP Maintenance Process and future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Guidance on how to submit recommended changes to an MVP can be found on the Quality Payment Program website.

Comment: A commenter requested this MVP include at least one eCQM, CAHPS Survey Vendor, or Administrative Claims measure as a MIPS core measure option. As proposed, participants may be required to engage a third-party reporting vendor solely to satisfy the MIPS core measure requirements, increasing reporting complexity and expense. Providing a reporting pathway that leverages existing eCQM, CAHPS, or claims-based infrastructure would better support participation while reducing administrative burden.

Response: We thank the commenter for their suggestions. The commenter may suggest changes to the MIPS core measures through the MVP Maintenance Process and we may consider alternative MIPS core measures for this MVP through future rulemaking. We will evaluate the recommendations received and determine if they are appropriate and align with the broader vision for the MVP. Currently, the policy includes an option for self-attestation when the MIPS core measures are not appropriate or applicable to their scope of care, allowing clinicians to choose an alternate measure within the MVP that is more relevant.

After consideration of public comments, we are finalizing the *Vascular Surgery MVP* with modifications as proposed for the CY 2027 performance period/2029 MIPS payment year and future years.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, et al.
Calendar Year 2027 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the Expanded HH Value-Based Purchasing Model; Medicare Provider Enrollment, Durable Medical Equipment (DME), and DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Policies; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 414, 422, 423, 424, 484, and 498

[CMS–1844–F]

RIN 0938–AV80

Calendar Year 2027 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the Expanded HH Value-Based Purchasing Model; Medicare Provider Enrollment, Durable Medical Equipment (DME), and DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Policies

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule sets forth routine updates to the Medicare home health payment rates in accordance with existing statutory and regulatory requirements. In addition, this final rule discusses the behavior adjustments and finalizes a temporary behavior adjustment. It also finalizes the recalibrated case-mix weights and updated functional impairment levels; comorbidity subgroups; and low-utilization payment adjustment (LUPA) thresholds for CY 2027. Additionally, this final rule discusses and responds to comments on the provision of home health palliative care services and includes a summary of comments received on the request for information (RFI) on a home health specific wage index included in the proposed rule.

This rule also finalizes changes to the Home Health Quality Reporting Program (HH QRP) and summarizes potential initiatives to improve alignment between the HH QRP and expanded Home Health Value-Based Purchasing (HHVBP) Model.

Lastly, the rule clarifies the application of the DMEPOS face-to-face encounter requirements for the replacement of DMEPOS items; makes changes to the provider and supplier enrollment requirements; makes changes to implement a DME benefit expansion for infusion pumps and drugs; and discusses collection of information requirement changes regarding the DMEPOS Competitive Bidding Program (CBP) country of origin.

DATES: With the exception of the HH PPS and HH QRP provisions specified in sections II. and III. of this final rule and the regulatory changes at 42 CFR 484.245, these regulations are effective on January 4, 2026. The HH PPS and HH QRP provisions specified in sections II. and III. of this final rule and the regulatory changes at 42 CFR 484.245 are effective January 1, 2027.

FOR FURTHER INFORMATION CONTACT:

For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to *HomeHealthPolicy@cms.hhs.gov.*

For information about the Home Health Quality Reporting Program (HH QRP), send your inquiry via email to *homehealthqualityquestions@cms.hhs.gov.*

For more information about the expanded Home Health Value-Based Purchasing (HHVBP) Model, please visit the Expanded HHVBP Model web page at *https://www.cms.gov/priorities/innovation/innovation-models/expanded-home-health-value-based-purchasing-model* or send your inquiry via email to *HHVBPquestions@cms.hhs.gov.* Nancy Allert (410) 786–4317, Jennifer Phillips (410) 786–1023, Olufemi Shodeke (410) 786–1649, Misty Whitaker (410) 786–4975, for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Encounter Requirements for Identical Replacement Items. Frank Whelan (410) 786–1302, for Medicare provider and supplier enrollment and DMEPOS accreditation.

For more information about the DME Benefit Expansion for Infusion Pumps and Drugs, send your inquiry via email to *DMEPOS@cms.hhs.gov.* Austin Gutowski, (410) 786–1643, for DME Competitive Bidding Program—Country of Origin and Technical Corrections.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose and Legal Authority

1. Home Health Prospective Payment System (HH PPS)

As required under section 1895(b) of the Social Security Act (the Act), this final rule updates the CY 2027 Medicare payment rates for home health agencies (HHAs). In this final rule, we include an analysis of home health utilization, as well as analysis of the difference between assumed versus actual behavior change on estimated aggregate expenditures for home health payments as a result of the change in the unit of payment to 30 days and the implementation of the Patient Driven Groupings Model (PDGM) case-mix adjustment methodology. This final rule also discusses the permanent adjustments applied in previous years and finalizes a temporary adjustment to the CY 2027 home health base payment rate. In addition, this rule recalibrates the PDGM case-mix weights and updates the low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups under sections 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for 30-day periods of care in CY 2027. This final rule updates the CY 2027 fixed-dollar loss (FDL) ratio for outlier payments (so that outlier payments as a percentage of estimated total payments are projected not to exceed 2.5 percent, as required by section 1895(b)(5)(A) of the Act).

Additionally, this rule responds to comments received on the discussion of the provision of palliative care services under the Medicare home health benefit and summarizes public comments received on the request for information (RFI) regarding the construction of a home health specific wage index.

2. Home Health (HH) Quality Reporting Program (QRP)

In accordance with the statutory authority at section 1895(b)(3)(B)(v) of the Act, we are finalizing updated quality reporting policies. First, we summarize potential initiatives to improve alignment between the HH QRP and expanded HHVBP Model. We also finalize revisions to the HH QRP data submission deadlines beginning with the CY 2027 HH QRP. We also revise the HH QRP OASIS and HHCAHPS Annual Payment Update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). We also finalize revisions to the HH QRP OASIS and HHCAHPS Annual Payment Update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). We finalize some revisions to regulatory text in support of rule proposals and to improve digital transfer of information during the reconsiderations process. Finally, we summarize the public comments received in response to a Request for Information (RFI) on future measure concepts for the HH QRP.

3. Expanded Home Health Value-Based Purchasing (HHVBP) Model

We did not propose any expanded HHVBP Model-specific policy changes in the CY 2027 HH PPS proposed rule. However, we have included a brief summary of the Model with context relevant to a potential alignment between the HH QRP and the expanded HHVBP Model.

4. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Encounter Requirements for Identical Replacement Items

We are finalizing clarifications regarding the application of the DMEPOS face-to-face encounter requirements, as outlined in 42 CFR 410.38, and the related documentation necessary to support the replacement of DMEPOS items. We do not believe it necessary to require an additional in-depth beneficiary examination to ''gather[ ] subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered'' for replacement items. Such information should be recorded when the beneficiary is initially assessed and receives the item, and the practitioner should only write replacement orders for beneficiaries with an ongoing medical need for the item(s). Therefore, we are finalizing our proposal that an additional face-to-face encounter within the 6 months preceding an order/prescription for replacement of a DMEPOS item will not be required per 42 CFR 410.38. We clarify that for purposes of 42 CFR 410.38(d)(2), a ''replacement'' refers to the provision of an item that replaces an item falling under the same Healthcare Common Procedure Coding System (HCPCS) code; it does not include those situations involving the provision of a different item, for example, because of a change in medical condition.

5. Provider Enrollment and DMEPOS Accreditation

Consistent with section 1866(j) of the Act, we are finalizing a number of Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include but are not limited to: (1) adding grounds for denying or revoking a provider's or supplier's Medicare enrollment; and (2) expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers, which we believe will assist in protecting the Trust Funds and Medicare beneficiaries.

We also are finalizing several minor changes to our DMEPOS accreditation provisions in § 424.58, such as a timeframe by which an accrediting organization must report suspected fraud, waste, and abuse to CMS. We believe these changes will help improve the DMEPOS accreditation program's efficiency.

6. Durable Medical Equipment (DME) Benefit Expansion for Infusion Pumps and Drugs

We are finalizing changes to the Medicare Part B definition of DME at 42 CFR 414.202 to implement amendments made to the definition of DME at section 1861(n) of the Act by section 6222(a) of the Consolidated Appropriations Act, 2026 (CAA, 2026), expanding the scope of the benefit for DME to include certain external infusion pumps and associated home infusion drugs or other associated supplies. The legal authority for this final rule is provided by section 1861(n) of the Act, as amended by section 6222(a) of the CAA, 2026, and section 1871 of the Act.

7. DMEPOS Competitive Bidding Program—Country of Origin

We discuss requesting to revise the DMEPOS Competitive Bidding Program (CBP) information collection under Office of Management and Budget (OMB) Control Number 0938–1408 (CMS–10744) to require DMEPOS CBP contract suppliers to report the country of origin for the lead items furnished during the contract's period of performance. This information will allow beneficiaries and interested parties to learn where the DMEPOS item originated, if interested.

8. DMEPOS Competitive Bidding Program—Technical Corrections

We discuss technical corrections that need to be made to § 414.414(d) based on a regulations text error in the CY 2026 HH PPS final rule.

B. Summary of the Provisions of the Final Rule

1. Home Health Prospective Payment System (HH PPS)

In section II.B.1. of this final rule, we discuss the permanent behavior adjustment and finalize a temporary adjustment to the base payment rate under the HH PPS.

In section II.C. of this final rule, we finalize the recalibrated CY 2027 PDGM case-mix weights and updated low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups.

In section II.D. of this final rule, we finalize updates to the home health wage index. We also finalize updates to the CY 2027 national, standardized 30-day period payment rates and the CY 2027 national per-visit payment amounts by the home health payment update percentage. Additionally, this rule finalizes the CY 2027 fixed dollar loss (FDL) ratio to ensure that aggregate outlier payments are projected not to exceed 2.5 percent of the total aggregate payments, as required by section 1895(b)(5)(A) of the Act.

In section II.E. of this final rule, we discuss and respond to comments on the provision of palliative care services under the Medicare home health benefit.

In section II.F. of this final rule, we summarize comments received on the request for information (RFI) on the construction of a home health specific wage index.

2. Home Health Quality Reporting Program (HH QRP)

In section III.D. of this final rule, we summarize potential initiatives to improve alignment between the HH QRP and expanded HHVBP Model.

In section III.E. of this final rule, we are finalizing as proposed to revise the HH QRP data submission deadlines beginning with the CY 2027 HH QRP.

We also are finalizing our proposed revisions to the HH QRP OASIS and HHCAHPS Annual Payment Update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). Additionally, we are finalizing as proposed some revisions to regulatory text in support of rule proposals or to improve digital transfer of information during the reconsiderations process.

In section III.F. of this final rule, we discuss the public comments received in response to our request for information (RFI) on future measure concepts for the HH QRP.

3. Expanded Home Health Value Based Purchasing (HHVBP) Model

In section IV. of this final rule, we summarize the expanded HHVBP Model with context relevant to a potential alignment between the HH QRP and expanded HHVBP Model. We did not propose any expanded HHVBP Model-specific changes in the CY 2027 HH PPS proposed rule.

4. DMEPOS Encounter Requirements for Identical Replacement Items

In section V.B. of this final rule, we are finalizing a clarification that while an order would continue to be required for replacement of DMEPOS items, a new face-to-face encounter would not need to occur to support payment for these DMEPOS items.

5. Provider Enrollment and DMEPOS Accreditation

In section V.C. of this final rule, we discuss a number of finalized Medicare

provider enrollment provisions designed to strengthen and clarify certain aspects of the provider enrollment process. These include, but are not limited to, the following:

- Adding grounds for denying or revoking a provider's or supplier's Medicare enrollment.
- Expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations.
- CMS can currently impose a reapplication bar of up to 10 years if the provider or supplier is denied enrollment for submitting false or misleading information on or with their enrollment application. (This means they cannot reapply to Medicare for up to 10 years.) We are expanding this to permit a reapplication bar regardless of the denial reason.

We believe these revisions will help keep unqualified providers and suppliers out of the Medicare program, which, in turn will prevent improper Medicare payments to such parties.

We also are finalizing several minor changes to our DMEPOS accreditation provisions in § 424.58, such as a timeframe by which an accrediting organization must report suspected fraud, waste, or abuse to CMS. We believe these changes will help improve the DMEPOS accreditation program's efficiency.

6. DME Benefit Expansion for Infusion Pumps and Drugs

In section V.D. of this final rule, we finalize a modification to the definition of ''durable medical equipment'' at 42 CFR 414.202 to implement section 6222(a) of the CAA, 2026 by providing that certain external infusion pumps, associated home infusion drugs, or other associated supplies are treated as meeting the ''appropriate for use in the home'' requirement when specified statutory criteria are satisfied.

7. DMEPOS Competitive Bidding Program—Country of Origin

In sections V.E. and VI.B.5. of this final rule, we plan to request a revision to the collection currently approved under OMB Control Number 0938–1408 (CMS–10744) to collect from DMEPOS CBP contract suppliers the country of origin for the lead items furnished during the DMEPOS CBP contract's period of performance.

As done historically with the product information reported on Form C by a DMEPOS CBP contract supplier, the reported country of origin information would be populated in the Medicare Supplier Directory for the contract supplier during the contract period of performance.

8. DMEPOS Competitive Bidding Program—Technical Corrections

In section V.F. of this final rule, we discuss the technical corrections to the provisions at § 414.414(d) regarding the covered document review date that were finalized in the CY 2026 HH PPS final rule.

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TABLE 1: SUMMARY OF ECONOMIC COSTS AND TRANSFERS, BY FINAL PROVISION

Provision Description	Costs and Cost Savings	Transfers	Other Notes
CY 2027 HH PPS Payment Rate Update		The overall economic impact related to the finalized changes in payments under the HH PPS for CY 2027 is estimated to be $415 million (2.4 percent). The $415 million increase in estimated payments for CY 2027 reflects the effects of the CY 2027 final home health payment update percentage of 2.1. percent ($365 million increase), and an estimated 0.3 percent increase that reflects the effects of an updated FDL ($50 million increase).	To ensure that home health payments are consistent with statutory payment authority for CY 2027.
HH QRP	There are no anticipated changes to burden related to the HH QRP proposals.		
Expanded HHVBP Model		The overall economic impact of the expanded HHVBP Model for CYs 2023 through 2027 is an estimated $3.376 billion in total savings to fee-for-service (FFS) Medicare from a reduction in unnecessary hospitalizations and skilled nursing facility (SNF) usage as a result of greater quality improvements in the home health industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to HHAs competing in the expanded HHVBP Model.	
DMEPOS Encounter Requirements for Identical Replacement Items			The fiscal impact of this proposed clarification cannot be estimated as it only identifies whether a face-to-face encounter is required for payment for replacement of DMEPOS items.
Provider Enrollment and DMEPOS Accreditation	We project an annual cost of approximately $1.4 million to conduct the State surveys or accreditations for reactivating hospices. We project a total cost of $46.8 million over the first three years of this rule (or $15.6 million per year) for providers and suppliers to comply with the signage requirement in § 424.510(f).	We estimate an annual transfer from Medicare providers and suppliers to the federal government of approximately $82 million. This will stem from our expansion of the grounds for which we can retroactively revoke providers and suppliers.	
DME Benefit Expansion for Infusion Pumps and Drugs		The expansion is estimated to result in net savings to Medicare of approximately $800,000 per year.	Beneficiaries may be able to choose to receive additional drugs via home infusion that are currently only available in an outpatient healthcare setting.
DMEPOS Competitive Bidding Program--Country of Origin	We anticipate a minimal financial impact for DMEPOS contract suppliers as we believe they will be familiar with the DMEPOS they provide and should be able to identify the country of origin based on the markings on the product or by obtaining documentation from the manufacturer. The estimated burden estimates for DMEPOS contract suppliers are included in the COI section.		
DMEPOS Competitive Bidding Program—Technical Corrections	There are no costs or savings associated with these technical corrections.		

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II. Home Health Prospective Payment System

A. Overview of the Home Health Prospective Payment System

1. Statutory Background

Section 1895(b)(1) of the Act requires the Secretary to establish a Home Health Prospective Payment System (HH PPS) for all costs of home health services paid under Medicare. Section 1895(b)(2)(A) of the Act requires that, in defining a prospective payment amount, the Secretary shall consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services. In accordance with the statute, as amended by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), we issued a final rule which appeared in the July 3, 2000, **Federal Register** (65 FR 41128) to implement the HH PPS legislation.

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring home health agencies (HHAs) to submit data for purposes of measuring health care quality, and linking the quality data submission to the annual applicable home health payment update percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. Pursuant to section 1895(b)(3)(B)(v)(I) of the Act, if an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006, **Federal Register** (71 FR 65935), we issued a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

Section 51001(a)(1)(B) of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) amended section 1895(b) of the Act to require a change to the home health unit of payment to 30-day periods beginning January 1, 2020. Section 51001(a)(2)(A) of the BBA of 2018 added a new subclause (iv) under section 1895(b)(3)(A) of the Act, requiring the Secretary to calculate a standard prospective payment amount (or amounts) for 30-day units of service furnished that end during the 12-month period beginning January 1, 2020, in a budget neutral manner, such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of service. Section 1895(b)(3)(A)(iv) of the Act requires that the calculation of the standard prospective payment amount (or amounts) for CY 2020 be made before the application of the annual update to the standard prospective payment amount as required by section 1895(b)(3)(B) of the Act.

Additionally, section 1895(b)(3)(A)(iv) of the Act requires that in calculating the standard prospective payment amount (or amounts), the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of service under section 1895(b)(2)(B) of the Act and case-mix adjustment factors established under section 1895(b)(4)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act further requires the Secretary to provide a description of the behavior assumptions made in notice and comment rulemaking. CMS finalized these behavior assumptions in the CY 2019 HH PPS final rule with comment period (83 FR 56461).

Section 51001(a)(2)(B) of the BBA of 2018 also added a new subparagraph (D) to section 1895(b)(3) of the Act. Section 1895(b)(3)(D)(i) of the Act requires the Secretary annually to determine the impact of differences between assumed behavior changes, as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, section 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing the payment amount for a unit of home health services for a subsequent year. Finally, section 51001(a)(3) of the BBA of 2018 amends section 1895(b)(4)(B) of the Act by adding a new clause (ii) to require the Secretary to eliminate the use of therapy thresholds in the case-mix system for CY 2020 and subsequent years.

Division FF, section 4136 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328) amended section 1834(s)(3)(A) of the Act to require that, beginning with 2024, the separate payment for furnishing negative pressure wound therapy (NPWT) be for just the device and not for nursing and therapy services. Payments for nursing and therapy services are to be included as part of payments under the HH PPS. The separate payment for 2024 was required to be equal to the supply price used to determine the relative value for the service under the Medicare Physician Fee Schedule (as of January 1, 2022) for the applicable disposable device updated by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI–U). The separate payment for 2025 and each subsequent year is to be the payment amount for the previous year updated by the percentage increase in the CPI–U (United States city average) for the 12-month period ending in June of the previous year reduced by the productivity adjustment as described in section 1886(b)(3)(B)(xi)(II) of the Act for such year. The CAA, 2023 also added section 1834(s)(4) of the Act to require that beginning with 2024, as part of submitting claims for the separate payment, the Secretary shall accept, and process claims submitted using the type of bill that is most commonly used by HHAs to bill services under a home health plan of care.

2. Current System for Payment of Home Health Services

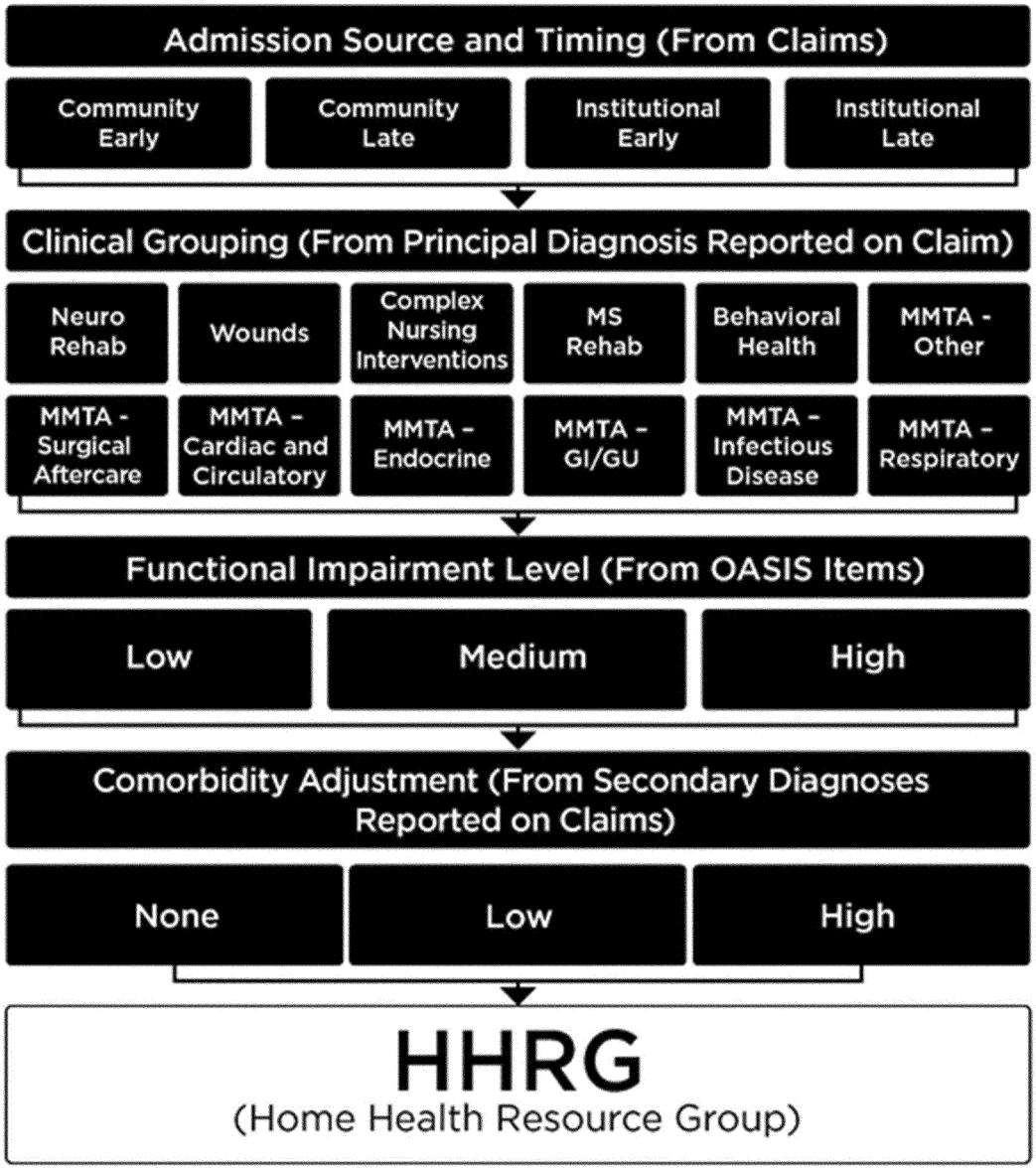
For home health periods of care beginning on or after January 1, 2020, Medicare makes payment under the HH PPS on the basis of a national, standardized 30-day period payment rate that is adjusted for case-mix and area wage differences in accordance with section 51001(a)(1)(B) of the BBA of 2018. The national, standardized 30-day period payment rate includes

payment for the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is also part of the national, standardized 30-day period rate. Durable medical equipment (DME) provided as a home health service, as defined in section 1861(m)(5) of the Act, is paid the fee schedule amount or is paid through the competitive bidding program and such payment is not included in the national, standardized 30-day period payment amount. Additionally, the 30-day period payment rate does not include payment for certain injectable osteoporosis drugs and disposable negative pressure wound therapy (dNPWT) devices, but such drugs and devices must be billed by the HHA while a patient is under a home health plan of care, as the law requires separate consolidated billing of certain osteoporosis drugs and dNPWT devices.

To better align payment with patient care needs and to better ensure that clinically complex and ill beneficiaries have adequate access to home health care, in the CY 2019 HH PPS final rule with comment period (83 FR 56406), we finalized case-mix methodology refinements, including the removal of therapy thresholds, through the Patient-Driven Groupings Model (PDGM) for home health periods of care beginning on or after January 1, 2020. The PDGM did not change eligibility or coverage criteria for Medicare home health services, and if the individual meets the criteria for home health services as described at 42 CFR 409.42, the individual can receive Medicare home health services, including therapy services. For more information about the role of therapy services under the PDGM, we refer readers to the Medicare Learning Network (MLN) Matters article SE20005 available at *https://www.cms.gov/regulations-and-guidance guidancetransmittals2020-transmittals/se20005*. To adjust for case-mix for 30-day periods of care beginning on and after January 1, 2020, the HH PPS uses a 432-category case-mix classification system to assign patients to a home health resource group (HHRG) using patient characteristics and other clinical information from Medicare claims and the Outcome and Assessment Information Set (OASIS) instrument. These 432 HHRGs represent the different payment groups based on five main case-mix categories under the PDGM, as shown in figure 1. Each HHRG has an associated case-mix weight that is used in calculating the payment for a 30-day period of care. For periods of care with visits less than the low-utilization payment adjustment (LUPA) threshold for the HHRG, Medicare pays national per-visit rates based on the discipline(s) providing the services. Medicare also adjusts the national standardized 30-day period payment rate for certain intervening events that are subject to a partial payment adjustment. For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

Under this case-mix methodology, case-mix weights are generated for each of the different PDGM payment groups by regressing resource use for each of the five categories (admission source, timing, clinical grouping, functional impairment level, and comorbidity adjustment) using a fixed effects model. A detailed description of each of the case-mix variables under the PDGM have been described previously, and we refer readers to the CY 2021 HH PPS final rule (85 FR 70303 through 70305) for further information.

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



Notes: MMTA (Medication Management, Teaching and Assessment), MS (Musculoskeletal), GI (Gastrointestinal tract), GU (Genitourinary system)

B. CY 2027 Payment Adjustments Under the HH PPS

1. Behavior Adjustments Under the HH PPS

a. Background

As discussed in section II.A.1. of this final rule, starting in CY 2020, the Secretary was required by section 1895(b)(2)(B) of the Act to change the unit of payment under the HH PPS from a 60-day episode of care to a 30-day period of care. CMS was also required to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and the case-mix adjustment factors that eliminated the use of therapy thresholds. In the CY 2019 HH PPS final rule with comment period (83 FR 56455), we finalized three behavior change assumptions which were also described in the CY 2022 and 2023 HH PPS rules (86 FR 35890, 87 FR 37614, and 87 FR 66795 through 66796). In the CY 2020 HH PPS final rule with comment period (84 FR 60519), we included these behavior change assumptions in the calculation of the 30-day budget neutral payment amount for CY 2020, finalizing a negative 4.36 percent behavior change assumption adjustment (''assumed behaviors''). We did not propose any changes for CYs 2021 and 2022 related to the behavior change assumptions finalized in the CY 2019 HH PPS final rule with comment period, or to the negative 4.36 percent behavior change assumption adjustment, finalized in the CY 2020 HH PPS final rule with comment period.

In the CY 2023 HH PPS final rule (87 FR 66796), we stated that we had concluded, based on our annual monitoring at that time, that the three expected behavior changes did in fact occur as a result of the implementation of the PDGM and that other behaviors,

such as changes in the provision of therapy and changes in functional impairment levels, had also occurred. We also reminded readers that in the CY 2020 HH PPS final rule with comment period (84 FR 60513), we stated that we interpret actual behavior changes to encompass behavior changes that were previously outlined as assumed by CMS, and other behavior changes not identified at the time we established the budget-neutral 30-day payment rate for CY 2020. In the CY 2023 HH PPS final rule (87 FR 66796), we provided supporting evidence that indicated the number of therapy visits declined in CYs 2020 and 2021, as well as a slight decline in therapy visits beginning in CY 2019 after the finalization of the removal of therapy thresholds, but prior to implementation of the PDGM. In section II.B.1. of the CY 2025 HH PPS proposed rule (89 FR 55318), our analysis continued to show the actual 30-day periods are similar overall to the simulated 30-day periods as well as a continued decline in therapy visits, indicating that HHAs changed their behavior to reduce therapy visits. Although the analysis demonstrates evidence of individual behavior changes (for example, in the volume of visits for LUPAs, therapy sessions, etc.), we use the entirety of the behaviors to calculate estimated aggregate expenditures. The law instructs us to ensure that estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that otherwise would have been made under the prior system.

Section 4142(a) of the CAA, 2023 required CMS to present, to the extent practicable, a description of the actual behavior changes occurring under the HH PPS from CYs 2020 through 2026. This subsection of the CAA, 2023 also required CMS to provide datasets underlying the simulated 60-day episodes and discuss and provide time for stakeholders to provide input on and ask questions about the payment rate development for CY 2023. CMS complied with these requirements by posting online both the supplemental limited data set (LDS) and descriptive files and the description of actual behavior changes that affected CY 2023 payment rate development. Additionally, on March 29, 2023, CMS conducted a webinar entitled ''Medicare Home Health Prospective Payment System (HH PPS) Calendar Year (CY) 2023 Behavior Change Recap, 60-Day Episode Construction Overview, and Payment Rate Development.'' The webinar was open to the public and discussed the actual behavior changes that occurred upon implementation of the PDGM; our approach used to construct simulated 60-day episodes using 30-day periods; payment rate development for CY 2023; and information on the supplemental data files containing information on the simulated 60-day episodes and actual 30-day periods used in calculating the permanent adjustment to the payment rate. Materials from the webinar, including the presentation and the CY 2023 descriptive statistics from the supplemental LDS files containing information on the number of simulated 60-day episodes and actual 30-day periods in CY 2021 that were used to construct the permanent adjustment to the payment rate, as well as information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments, can be found on the Home Health Patient-Driven Groupings Model web page at *https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health/home-health-patient-driven-groupings-model.*

b. Method To Annually Determine the Impact of Differences Between Assumed Behavior Changes and Actual Behavior Changes on Estimated Aggregate Expenditures

In the CY 2023 HH PPS final rule (87 FR 66804), we finalized the methodology to evaluate the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures. In the CY 2024 HH PPS final rule (88 FR 77687 through 77688), we provided an overview of the methodology with detailed instructions for each step of the calculation.

Under the prior 153-group system (and the first 3 years for assessments associated with the PDGM completed prior to CY 2023), HHAs submitted the Outcome and Assessment Information Set (OASIS) instrument version D. However, OMB approved an updated version of the OASIS instrument, OASIS–E, under OMB control number 0938–1279,[1] on November 30, 2022, effective January 1, 2023. Therefore, in the CY 2025 HH PPS final rule (89 FR 88364), we finalized two additional methodological assumptions related to mapping and imputation of OASIS–D responses from OASIS–E. We refer readers to the CY 2024 and CY 2025 HH PPS final rules for further information about the methodology.

[1] The current expiration date for this information collection request is December 31, 2027.

c. Calculating Permanent and Temporary Payment Adjustments

To adjust the base payment rate based on increases or decreases in estimated aggregate expenditures that result from differences between assumed behavior changes and actual behavior changes for 2020 through 2026, we calculate one or more permanent prospective adjustments by calculating the percent change between the actual 30-day base payment rate and the recalculated 30-day base payment rate. This percent change is converted into an adjustment factor and applied in the annual rate update process.

To account for increases or decreases in estimated aggregate expenditures that result from differences between assumed behavior changes and actual behavior changes from 2020 through 2026, we calculate one or more temporary prospective adjustments by calculating the dollar amount difference between the estimated aggregate expenditures from all 30-day periods using the recalculated 30-day base payment rate, and the aggregate expenditures for all 30-day periods using the actual 30-day base payment rate for each of those years once data is available (87 FR 66804). In other words, when determining the dollar amount of aggregate expenditures in prior years that we must offset in future years, we use the full dataset of actual 30-day periods using both the actual and recalculated 30-day base payment rates to ensure that the utilization and distribution of claims are the same. In accordance with section 1895(b)(3)(D)(iii) of the Act, each temporary adjustment is applied prospectively but, as its name suggests, only with respect to the year for which such temporary increase or decrease is made.

Therefore, after we determine the dollar amount we plan to reconcile in a given year, we calculate a temporary adjustment factor to be applied to the base payment rate for that year. The temporary adjustment factor is based on an estimated number of 30-day periods in the next year using historical data trends, and as applicable, controls for any permanent adjustment factor, case-mix weight recalibration neutrality factor, wage index budget neutrality factor, and the home health payment update. The temporary adjustment factor is applied last since the adjustment applies only to the respective year. That is, the temporary adjustment is not permanently fixed into future base payment rates. We refer readers to the CY 2024 HH PPS final rule (88 FR 77689 through 77694) for

analysis of CYs 2020 through 2022 claims, the CY 2025 HH PPS final rule (89 FR 88366 through 88369) for analysis of CY 2023 claims, and the CY 2026 HH PPS final rule (90 FR 55365 through 55367) for analysis of CY 2024 claims.

d. CY 2025 Final Claims Results

We stated in the CY 2026 HH PPS final rule (90 FR 55365) that we were exercising our authority expressly delegated under the statute to apply permanent adjustments ''at a time and in a manner appropriate'' not to apply any permanent adjustment for CY 2026 based on CY 2023 or 2024 data, as these years may contain data with behaviors attributable to factors beyond the implementation of the PDGM and a 30-day unit of payment. However, we also noted we will continue to annually analyze the data through CY 2026 claims, as required by law, to determine if any additional permanent adjustments would need to be made based on the impact of assumed versus actual behavior change on estimated aggregate expenditures resulting from the implementation of the PDGM and the 30-day unit of payment. While the law requires us to continue to evaluate the need for any additional permanent adjustments in future rulemaking, we reiterate that any additional permanent adjustment(s) would need to be related to actual behavior change resulting only from the implementation of the PDGM and the change in the unit of payment as required by law. Therefore, we will continue to compare estimated aggregate expenditures under the PDGM and the 153-group payment system, using the most recent complete home health claims data available at the time of rulemaking, as required by section 1895(b)(3)(D)(i) of the Act. The CY 2027 HH PPS final rule uses the complete CY 2025 data to determine any permanent and temporary adjustments needed to the CY 2027 payment rate. However, while the claims data and the permanent and temporary adjustments results are considered complete for CY 2027, any adjustments to future payment rates may be subject to additional considerations such as permanent adjustments taken in previous years.

The claims data used in rulemaking is released in the HH PPS LDS file twice each year, one with the proposed and one with the final rule. Accordingly, the HH PPS LDS file released with this final rule includes two files: the actual CY 2025 30-day periods and the CY 2025 simulated 60-day episodes.

We remind readers that a data use agreement (DUA) is required to purchase the CY 2027 final HH PPS LDS file using the CMS–R–0235A form under OMB control number 0938–0734. Access would be granted for both the 30-day periods and the simulated 60-day episodes under one DUA. Visit the HH PPS LDS web page for more information.[2] In addition, the final CY 2027 Home Health Descriptive Statistics from the LDS Files spreadsheet is available on the HH PPS Regulations and Notices web page,[3] does not require a DUA and is available at no cost to interested parties. The spreadsheet contains information on the number of simulated 60-day episodes and actual 30-day periods in CY 2025 that were used to determine the adjustments. The spreadsheet also provides information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments.

e. Applying the Methodology to CY 2025 Data To Determine the CY 2027 Permanent and Temporary Adjustments

To comply with Section 1895(b)(3)(D)(ii) of the Act, we are required to annually analyze data from CY 2020 through CY 2026 and show the calculations to illustrate how the aggregate expenditures differ from actual and assumed behavior changes. We also continue to analyze differences in aggregate expenditures and calculate what the budget neutral rate would be to understand how the budget neutral rate differs from the actual finalized payment rate for CY 2025. We then determine whether the difference between the budget neutral rate and actual finalized payment rate can be directly attributed to behavior from PDGM implementation as discussed in CY 2026 HH PPS final rule.

Using the methodology finalized in the CY 2023 HH PPS final rule to apply for all the years in which an adjustment is appropriate, we continue to use actual CY 2025 30-day periods to determine what the final permanent and temporary payment adjustments should be to offset for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes. We provide tables 2 and 3 to illustrate the same information displayed in prior rules to show the permanent adjustment that would need to be applied if the comparison of the aggregate expenditures was a result of behavior change due to the implementation of the PDGM. However, similar to what was finalized in the CY 2026 HH PPS final rule (90 FR 55364 through 55365), we believe any behavior changes reflected in the final CY 2025 claims for this CY 2027 final rule are not directly attributable to the PDGM but other confounding factors related to policy changes that began in CY 2023 (that is, continued recalibration of case-mix weights, a change to the OASIS–E, and previous reductions to the home health payment rate). The permanent adjustment calculated will be illustrative as part of our analysis of CY 2025 claims; however, we did not propose to apply a permanent adjustment to the CY 2027 payment rate, as discussed previously. We provide table 4 as another illustrative example showing a calculated permanent adjustment, using CY 2025 aggregate expenditures if we were to determine that the behavior changes that occurred could be directly attributed to the implementation of the PDGM.

Using the final CY 2025 dataset, we began with 8,382,176 30-day periods of care and dropped 491,954 30-day periods of care that had a claim occurrence code 50 date after October 31, 2025. We also excluded 847,742 30-day periods of care that had a claim occurrence code 50 date before January 1, 2025, to ensure the 30-day period will not be part of a simulated 60-day episode that began in CY 2024. Applying the additional exclusions and assumptions as described in the finalized methodology (87 FR 66804), an additional 61,147 30-day periods were excluded. Additionally, we excluded 319,999 simulated 60-day episodes of care where no OASIS information was available in the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC), a recent start of care/resumption of care (SOC/ROC) OASIS was not available, a wage index was not available, or the episode could not be grouped to a Health Insurance Prospective Payment System (HIPPS) code due to a missing primary diagnosis or other reason.

Using the final dataset for CY 2025 (6,661,334 actual 30-day periods which made up the 3,917,201 simulated 60-day episodes) we determined the estimated aggregate expenditures using the finalized CY 2025 HH PPS payment rate were lower than the actual estimated aggregate expenditures under the PDGM HH PPS. As shown in table 2, aggregate expenditures under the PDGM were higher than if the 153-group payment system were still in place in CY 2025

[2] *https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/home_health_pps_lds.*

[3] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.*

and therefore, we determined the CY 2025 30-day base payment rate should have been $1,959.08 based on actual behavior changes.

We determined that for CYs 2020 through CY 2022 a total of −9.480 percent permanent adjustment was needed (after accounting for the −3.925 percent applied to the CY 2023 payment rate, the −2.890 percent applied to the CY 2024 payment rate, and the −1.975 percent applied to the CY 2025 payment rate). The CY 2026 permanent adjustment was calculated using the permanent adjustments already applied to CYs 2023, 2024, and 2025 finalized payment rates and to reach the payment rate reduction needed for CYs 2020 through 2022.

In order to determine behavior changes only applicable to CY 2025, we simulated what the CY 2025 base payment rate would have been if the −1.023 percent adjustment that we determined using CY 2024 claims had been implemented and to compare PDGM claims with 153-group priced claims using 60-day simulated episodes.

To do so, we started with the budget neutral CY 2024 base payment of $1,914.73 generated by CY 2024 simulated 60-day episodes (as published in the CY 2026 HH PPS final rule (90 FR 55366)) and applied the CY 2025 case-mix weights recalibration neutrality factor (1.0039), the CY 2025 wage index budget neutrality factor (0.9988), the CY 2024 labor-related share budget neutrality factor (1.0), and the CY 2025 home health payment update factor (1.027). We determined the CY 2025 base payment rate for assumed behavior would have been $1,971.73.

For the CY 2025 annual permanent adjustment, we calculated the percent change between the two payment rates for only CY 2025. For the CY 2025 annual temporary adjustment we calculated the difference in aggregate expenditures in dollars for all CY 2025 PDGM 30-day claims using the two payment rates. This difference is shown as the retrospective dollar amount we would need to offset payment using one or more temporary adjustments in future years. Our results for the CY 2025 annual (single year) permanent and temporary adjustment calculations using CY 2025 final claims data are shown in table 2.

TABLE 2: ILLUSTRATIVE CY 2025 PERMANENT AND TEMPORARY ADJUSTMENT CALCULATIONS WHEN COMPARING PDGM CLAIMS USING SIMULATED 60-DAY EPISODES

	Budget-neutral 30-day Payment Rate with Assumed Behavior Changes	Budget-neutral 30-day Payment Rate with Actual Behavior Changes	CY 2025 Only Adjustment
Base Payment Rate	$1,971.73*	$1,959.08	**Permanent** -0.642%
Aggregate Expenditures	$ 16,957,268,010.43**	$ 16,237,591,241.69	**Temporary** -$ 719,676,768.74

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

*The $1,971.73 (shown in table 2) is equal to the recalculated budget neutral 30-day base payment rate of $1,914.73 for CY 2024 multiplied by the CY 2025 recalibration factor (1.0039), CY 2025 wage index budget neutrality factor (0.9988), CY 2025 labor-related share budget neutrality factor (1.0), and the CY 2025 home health payment update factor (1.027).

** The estimated aggregate expenditures for assumed behavior ($16.6 billion), uses the actual CY 2025 payment rate of $2,057.35 as finalized in the CY 2025 HH PPS final rule (89 FR 88424).

Table 2 illustrates that a permanent prospective adjustment of −0.642 percent to the CY 2027 30-day payment rate (assuming all adjustments from prior years were applied) for CY 2025 would be required to offset for such increases in estimated aggregate expenditures. Again, table 2 is illustrative because we are continuing to limit the calculation of the permanent adjustments to only include data from CYs 2020 through 2022 as finalized in the CY 2026 HH PPS final rule (90 FR 55365 through 55367) and the calculated permanent adjustment does not include implemented permanent adjustments from prior years. We reiterate that any additional permanent adjustment(s) must be determined to be related to actual behavior change resulting only from the implementation of the PDGM and the change in the unit of payment as required by law.

f. CY 2027 Permanent Adjustment and Temporary Adjustment Calculations

In the preceding section we describe how we analyzed CY 2025 final claims data to determine the effects of actual behavior change on estimated aggregate expenditures. Again, that illustrative analysis included simulations that assumed the full permanent adjustments were already taken. We note that CMS implemented a payment adjustment of −1.975 percent for the CY 2025 payment rate, rather than the −3.95 percent we calculated (89 FR 88373), so the calculations set forth later in this section reflect the remaining adjustments that still needed to be recognized.

Therefore, the calculation in this section includes any of the remaining adjustments not applied in previous years (that is, CYs 2020 through 2024 claims data), as well as the adjustment needed to account for CY 2025 claims. In calculating the full permanent adjustment needed to the CY 2027 30-day payment rate, we compare estimated aggregate expenditures under the PDGM and the prior system. Unlike the annual adjustments described in

table 2, we do not assume we made the full adjustment from prior years. This section also includes calculation of a permanent adjustment using the actual CY 2025 payment rate and the budget neutral rate for CY 2025 using the method discussed in the CY 2026 HH PPS final rule.

As discussed in section II.B.1.e. of this final rule, using the final dataset for CY 2025 (6,661,334 actual 30-day periods which made up the 3,917,201 simulated 60-day episodes) we determined the CY 2025 30-day base payment rate should have been $1,959.08 based on actual behavior. We then compared the repriced 30-day base payment rate based on actual behavior to the CY 2025 30-day base payment rate of $2,057.35 we paid based on assumed behaviors. The percent change, as summarized in table 3, between the actual CY 2025 base payment rate of $2,057.35 (based on assumed behaviors) and the CY 2025 recalculated base payment rate of $1,959.08 (based on actual behaviors) illustrates the total permanent adjustment that would reflect CY 2020 through CY 2025 claims. We conduct this calculation to satisfy the requirements described in section 1895(b)(3)(D)(ii) of the Act to illustrate what the permanent adjustment would be. We consider table 3 illustrative because we are limiting the calculation of the permanent adjustments to only include data from CYs 2020 through 2022 as finalized in the CY 2026 HH PPS final rule (90 FR 55365 through 55367).

TABLE 3: ILLUSTRATIVE TOTAL PERMANENT ADJUSTMENT FOR CYs 2020 THROUGH 2025 CLAIMS

Actual CY 2025 Base Payment Rate (Assumed Behavior)	Recalculated CY 2025 Base Payment Rate (Actual Behavior)	Total Permanent Prospective Adjustment
$2,057.35	$1,959.08	-4.777%*

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

* This is the total permanent adjustment based on CY 2025 data which includes the previous permanent adjustment of -1.975% applied. However, as described later, we recognized that for CY 2027 we must also account for adjustment made in CY 2026.

As shown in table 3, a permanent prospective adjustment of −4.777 percent to the CY 2027 30-day payment rate would be required to offset for such increases in estimated aggregate expenditures. To illustrate this calculation:

$$\frac{(\$1{,}959.08 - \$2{,}057.35)}{\$2{,}057.35} = -4.777\ \%$$

As we stated in the CY 2026 HH PPS final rule (90 FR 55357), applying a −1.975 percent (half of the proposed −3.95 percent) permanent adjustment to the CY 2025 30-day payment rate would not adjust the rate fully to account for differences in behavior changes on estimated aggregate expenditures in CYs 2020, 2021, 2022, and 2023. Using CY 2025 claims data, as shown in table 3, a permanent prospective adjustment of −4.777 percent to the CY 2027 30-day payment rate would offset for increases in estimated aggregate expenditures for CYs 2020 through 2025. We note that adjustment factors are multiplied in this payment system, and individual numbers (that is, percentages) cannot be added or subtracted together to determine the final adjustment. Therefore, we cannot determine the illustrative CY 2027 permanent adjustment, which would include estimated aggregate expenditures in CY 2025, by simply subtracting the −1.975 percent applied in CY 2025 and the −1.023 percent applied in CY 2026 from the total permanent adjustment of −4.777 percent as shown in table 3.

Instead, we account for the permanent adjustment applied in prior years when we calculate the CY 2027 permanent adjustment by solving the following equation

$(1 - 0.01023) \times (1 - x) = (1 - 0.04777)$

To illustrate this calculation we used the following approach.

$$x = 1 - \left(\frac{1-0.04777}{1-0.01023}\right)$$

$x = 1 - 0.96207$

$x = 0.03793$ (that is, 3.793 percent)

We note that the −3.793 percent is calculated as a permanent adjustment for CY 2027 illustrating what we would need if we were to offset the difference in aggregate expenditures between CY 2025 claims priced under the PDGM and the 153-group system and adjusting for the permanent adjustments applied in prior years.

We continue to apply the methodology finalized in the CY 2026 HH PPS final rule to determine what the permanent adjustment for CY 2025 claims would be even though we stopped comparing claims priced under the PDGM and the 153-group after CY 2022 claims for the purposes of applying a permanent adjustment in this final rule. As displayed in table 4, we

calculate the permanent adjustment for CY 2025 by determining the percent change between the actual CY 2025 30-day payment rate ($2,057.35) and the budget neutral rate for CY 2025 ($2,036.29). The budget neutral rate for CY 2025 is the finalized CY 2024 budget neutral rate discussed in CY 2026 final rule ($1,977.43) multiplied by the CY 2025 case-mix weights recalibration neutrality factor (1.0039), the CY 2025 wage index budget neutrality factor (0.9988), and the CY 2025 home health payment update factor (1.027).

TABLE B4: ILLUSTRATIVE CY 2025 PERMANENT AND FINAL TEMPORARY ADJUSTMENT CALCULATIONS

	CY 2025 Nationalized Standardized 30-day Period Payment	CY 2025 Budget Neutral Payment Rate	CY 2025 Only Adjustment
Base Payment Rate	$2,057.35*	$2,036.29	**Permanent** -1.024%
Aggregate Expenditures	$ 16,957,268,010.43**	$ 16,802,166,149.24	**Temporary** -$ 155,101,861.19

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

* The $2,057.35 corresponds to the actual CY2025 payment rate. ** The estimated aggregate expenditures for assumed behavior ($16.6 billion), uses the actual CY 2025 payment rate of $2,057.35 as finalized in the CY 2025 HH PPS final rule.

In section II.C.1.d of CY 2027 HH PPS proposed rule, we discuss various trends that are part of monitoring changes related to the PDGM using analysis of CY 2025 claims. The data continues to show minimal changes that could be attributed to the PDGM implementation after CY 2022 by a large proportion of home health providers. We also continue to acknowledge the difficulty in attributing any behavior change occurring from CYs 2023 through 2025 directly to the PDGM implementation and its effects on expenditures from the other policy changes occurring in those years. As discussed in the CY 2026 HH PPS final rule, CMS introduced several policy changes that make isolating the effect of implementing a permanent adjustment, with claims data from CYs 2023 through 2025, for the PDGM difficult. These changes include recalibration of case-mix weights and LUPA visit thresholds finalized in the CY 2023, 2024, 2025, and 2026 final rules; reassignment of certain ICD–10–CM codes related to the PDGM clinical groups and comorbidity groups in the CY 2023 HH PPS final rule; finalized permanent adjustments in the CY 2023, 2024, and 2025 HH PPS final rules; the introduction of OASIS–E in 2023 and finalized mapping of OASIS–E to OASIS–D in the CY 2025 HH PPS final rule for calculating functional points for functional impairment levels during repricing; and the expanded HHVBP Model. For these reasons, we maintain that limiting the application of the permanent adjustment to analysis of data from CYs 2020 through 2022 continues to be the most accurate application of the law. However, as required by law, we will continue to analyze data through CY 2026 claims to determine if any additional permanent adjustments are needed to account for the impact of assumed versus actual behavior change related to the implementation of the PDGM and the change to a 30-day unit of payment on estimated aggregate expenditures.

The dollar amount that needs to be collected through the temporary adjustment increased when examining home health claims from CY 2025 because those claims were paid using the actual 30-day payment rate ($2,057.35) instead of the calculated budget neutral payment rate for CY 2025 ($2,036.29). That is, had the payment rate in CY 2025 been $2,036.29, there would not be an increase in what needs to be collected through the temporary adjustment when examining home health claims from CY 2025. Because the 30-day payment rate was not budget neutral until the CY 2026 payment rate with the application of the −1.023 percent permanent adjustment, the temporary adjustment continued to accrue.

As described previously in this final rule, to account for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes in any given year from CY 2020 to CY 2026, we calculate the temporary prospective adjustment by calculating the dollar amount difference between the estimated aggregate expenditures from all 30-day periods using the recalculated 30-day base payment rate, and the aggregate expenditures for all 30-day periods using the actual 30-day base payment rate for that year. In other words, when determining the temporary retrospective dollar amount, we used the full dataset of actual 30-day periods using both the actual and recalculated 30-day base payment rates to ensure that the utilization and distribution of claims are the same. We refer readers to the CY 2024 HH PPS final rule (88 FR 77689 through 77694) for analysis of CYs 2020 through 2022 claims, the CY 2026 HH PPS final rule (90 FR 55366 through 55367) for analysis of CY 2023 and CY 2024 claims, and section II.C.1.d. of this final rule for the analysis of CY 2025 claims. Table 5 provides a summary of the temporary adjustment dollar amount for CYs 2020 through 2026.

TABLE 5: SUMMARY OF TEMPORARY ADJUSTMENTS DOLLAR AMOUNTS FOR CYs 2020 – 2026

Claims Analysis Year	Dollar Amount
CY 2020	-$873,073,121
CY 2021	-$1,211,002,953
CY 2022	-$1,405,447,290
CY 2023	- $836,208,180
CY 2024	- $430,435,218
CY 2025 – This final rule	-$155,101,861
CY 2026	TBD
Total (through CY 2025)	-$4,911,268,623

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed from the CCW on July 12, 2021. CY 2021 Home Health Claims Data, Periods that end in CY 2021 accessed from the CCW on July 15, 2022. CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed from the CCW on July 15, 2023. CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed from the CCW on July 11, 2024. CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed from the CCW on July 11, 2025. CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.
Note: The anticipated temporary adjustments of approximately $4.9 billion (through CY 2025) will require temporary adjustment(s) to the base payment rate to offset for such increases in estimated aggregate expenditures. The dollar amount will be converted to a factor when implemented in future rulemaking.

Therefore, we exercise our authority under section 1895(b)(3)(D)(iii) of the Act to apply ''one or more'' temporary adjustments to continue recoupment of the retrospective overpayments for CYs 2020 through 2025. Specifically, we proposed implementing a 3.0 percent reduction in CY 2027, that is equivalent to a 0.9700 temporary adjustment factor, to the CY 2027 national, standardized payment rate. Using historical trends, we estimated 7,680,775 30-day periods would occur in CY 2027. Using this estimated utilization, a 3.0 percent reduction to the CY 2027 30-day payment rate would begin to collect approximately $500 million of the total temporary adjustment dollar amount, equating to about 10 percent of the total $4.9 billion shown in table 6. In doing so; however, we noted we would need to account for the remaining temporary adjustment dollar amount for CYs 2020 through 2026, plus any possible adjustments for CY 2027 and 2028, in future years. It is important to note that the estimated $500 million dollar amount anticipated to be collected by the implementation of the temporary adjustment factor is based on an estimate of the number of 30-day periods that would occur in CY 2027. It may not reflect the actual dollar amount to be collected if the actual number of 30-day periods and other utilization trends in CY 2027 differ from what was estimated. In other words, as noted in the proposed rule, CMS will calculate the actual amount collected from the temporary adjustment in CY 2027 and credit it to the overall cumulative temporary dollar amount.

In accordance with section 1895(b)(3)(D)(iii) of the Act, the temporary adjustment is to be applied on a prospective basis and shall apply only with respect to the year for which such temporary increase or decrease is made. This means we would not include the −3.0 percent temporary adjustment applied for CY 2027 when calculating the CY 2028 base payment rates. However, to continue recoupment of the retrospective overpayments, we may propose additional temporary adjustments in future rulemaking and did not propose that the −3.0 percent temporary adjustment would be applied each year after CY 2027. Rather, as noted in the proposed rule, we will continue to analyze the data each year through CY 2026 claims as required by law, and in a time and manner deemed appropriate, we will propose one or more temporary adjustments to account for retrospective overpayments. We also note the $4.9 billion does not account for any monies recouped in CY 2026, as we do not have this dollar amount at the time of this CY 2027 rulemaking. In future rulemaking, we will show the remaining balance, accounting for the previous recoupment amount; however, there will be a lag. We refer readers to section II.E.3.b. for the CY 2027 base payment rates with and without the temporary adjustment.

We solicited comments on the proposals to not apply a permanent adjustment and to apply the −3.0 percent temporary adjustment to the CY 2027 home health base payment rate. The following is a summary of the comments we received and our responses.

Comment: One commenter, the Medicare Payment Advisory Commission (MedPAC), supported the proposed temporary payment adjustment for CY 2027. MedPAC stated that although the proposed payment update is larger than the Commission's recommendation for CY 2027, the proposed temporary behavioral adjustment would further align Medicare payments with providers' costs. They also stated that the home health base payment rate currently exceeds the estimated cost of a typical 30-day payment period by 34 percent.

Response: We thank MedPAC for their comment.

Comment: Several commenters recommended that CMS eliminate all permanent and temporary adjustments due to methodological flaws and data concerns, such as the inability to discern behavior related and unrelated to the PDGM. These commenters also recommended excluding anomalous data from areas with suspect billing patterns, similar to the policy finalized in The Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program (MSSP) Financial Calculations in Calendar Year 2023 final rule. Commenters also raised concerns about the anomalous data having effects on

varying case-mix weights, outlier calculations, PEPs changes in LUPAs and number of episodes.

Response: The methodological and data concerns raised by commenters were addressed in the CY 2026 HH PPS final rule (90 FR 55360 through 55365). As required by law, our methodology (that is, the repricing methodology) compares aggregate expenditures between the actual 30-day periods and simulated 60-day episodes paid under the prior payment system within a single claims' year to determine what the payment rate should be to ensure that payments under the two systems would be equal. When using the repricing methodology, we create simulated 60-day episodes to reprice the claims for CYs 2020 through 2022 and use the same claims data sets to calculate both pre-PDGM and PDGM payments. Regardless of the magnitude and frequency of individual behavior changes (for example, number of episodes, changes in LUPAs, therapy, PEPs, visits, etc.), the occurrence of any behavior change is captured by the methodology to determine the impact on aggregate expenditures.

Furthermore, not all anomalous billing patterns indicate fraudulent practices, and we would need further evidence to determine which providers with anomalous billing patterns could be connected to fraud and abuse. Excluding data some commenters view as ''anomalous'' from the calculation of the national 30-day base payment rate would require CMS to develop a new policy, including developing thresholds for determining deviations excluded from the analytical sample. Regarding the suggestion from commenters on the policy under which CMS made adjustments to Medicare Shared Savings Program (MSSP) financial benchmark calculations to account for significant, anomalous, and highly suspect billing activity in CY 2023 (89 FR 79156 through 79165), we lack the same statutory authority to apply a similar policy for setting the national standardized 30-day payment rate for HHAs as required by section 1895(b)(3) of the Act. In finalizing this policy, MSSP relied on statutory authority undersection 1899(d)(1)(B)(ii) of the Act, which permits the Secretary to adjust benchmark expenditures for beneficiary characteristics and such other factors as the Secretary determines appropriate. MSSP relied on this authority to remove payments for the specified catheter codes from the determination of benchmark expenditures where CY 2023 serves as a benchmark year when establishing benchmarks for ACOs in agreement periods beginning in January 2024, January 2025, or January 2026. While we do not have similar statutory authority for the HH PPS, CMS continues to investigate anomalous providers and has made referrals to law enforcement and terminated certain suppliers and providers from the Medicare program. CMS also continues to work closely with the HHS–OIG and Department of Justice, as well as our Unified Program Integrity Contractors (UPIC), to investigate health care fraud activities.

Comment: Some commenters raised concerns regarding the way in which CMS was meeting the statutory requirements of section 1895(b)(3)(D) of the Act through the budget neutrality calculation methodology finalized in CY 2023 HH PPS final rule. Specifically, commenters raised concerns about repricing claims using simulated 60-day episodes stating that the methodology does not meet the statutory requirement, including how claims are excluded, structural LUPA differences between the pre-PDGM system and the PDGM, outlier assumptions for simulated 60-day episodes, and recalibrating pre-PDGM case-mix update factors. Commenters also raised concerns that recalibration did not control for the impact of COVID–19 and suggested these claims be excluded.

Response: The concerns raised by commenters were previously discussed in the CY 2023 HH PPS final rule (87 FR 66797 through 66804) and in the CY 2026 HH PPS final rule (90 FR 55362 through 55364). CMS continues to reiterate that the methodology is technically accurate in that it captures actual changes in behavior that have been explained in previous rulemaking, as well as this final rule. As required by law, our methodology compares aggregate expenditures between the actual 30-day periods and simulated 60-day episodes paid under the prior payment system within a single claims' year to determine what the payment rate should be to ensure that payments under the two systems would be equal. Regardless of the magnitude and frequency of individual behavior change (for example, changes in LUPAs, therapy, etc.), the occurrence of any behavior change is captured by the methodology to determine the impact on aggregate expenditures.

We previously explained that the exclusion criteria in the finalized methodology dropped 30-day periods of care that had a claim occurrence code 50 after October 31, and before January 1 of the claims year we are analyzing, to ensure the 30-day period will not be part of a simulated 60-day period that began in the prior year and to ensure a simulated 60-day episode (simulated from two 30-day periods) does not overlap years (90 FR 29129). Additional exclusions include 60-day periods where no OASIS information was available, a recent SOC/ROC OASIS was not available, a wage index was not available, or the episode cannot be grouped to a HIPPS code due to a missing primary diagnosis or other reason. All the exclusion criteria are applied because the criteria are needed to appropriately price the simulated 60-day episodes for within the year the claims would have been paid. It is immaterial whether the 30-day periods that are excluded have different case-mix characteristics or higher visits if the 30-day periods are not able to be repriced accordingly as a simulated 60-day period. As stated in previous rulemaking (87 FR 66804), without these exclusions, we would not be confident we were appropriately grouping 30-day periods into simulated 60-day episodes. The permanent adjustment is based on the percentage change between the payment rates (which utilizes the same claims), and the temporary adjustment is based on the aggregate expenditures of all claims (that is, no exclusions) using the two payment rates (that is, the actual payment rate and the budget neutral payment rate with the permanent adjustment applied). Therefore, we do not believe that the small portion of excluded claims significantly biased our results.

Excluding claims with COVID–19 as a diagnosis lacks a clear rationale. Simulated 60-day episodes with a primary diagnosis of COVID–19 would still be assigned a HIPPS under the V8219 Home Health Grouper and would not have been excluded from the repricing analysis unless there was another unrelated issue with the claim that prevented grouping. As described in the CY 2023 HH PPS final rule (87 FR 66800), our methodology includes the effect of the COVID–19 public health emergency (PHE) and ensures that any difference between the two calculated spending amounts for estimated budget-neutral amount and actual home health expenditures is not attributable to the PHE.

Recalibrating the pre-PDGM case-mix weights to reflect changes due to the COVID–19 PHE would not increase the aggregate payments estimated for simulated 60-day periods paid under the pre-PDGM case-mix system. Because we are comparing a single year of data priced under the PDGM and the 153-group case-mix system, the COVID–19 PHE would not bias the PDGM

payments differently than the 153-group or vice-versa. Our methodology ensured that we used actual claims with the same episodes, same diagnoses, same therapy and non-therapy visit counts, same clinical documentation, same LUPA patterns, all shaped by the COVID–19 PHE—and ran them through two different payment calculations: (1) actual payment under PDGM's case-mix methodology, and (2) a hypothetical repricing under the prior 153-group system's case-mix methodology. Because both calculations draw on the identical underlying utilization data, any COVID–19 PHE-driven change in the volume or intensity of care (fewer visits, shorter episodes, telehealth substitution, deferred admissions) shows up in both the actual and the counterfactual payment amount. If we were to implement recalibration of case-mix weights (including early vs. late visits or admission source) when determining aggregate payments under the 60-day payment system, the aggregate expenditures would not change because we would implement the recalibration of case-mix weights in a budget neutral manner.

There are several factors that contribute to how the case-mix weight is set for a particular case-mix group (such as the number of visits, length of visits, types of disciplines providing visits, and non-routine supplies) and the case-mix weight is derived by comparing the average resource use for the case-mix group relative to the average resource use across all groups. We continue to believe that the COVID–19 PHE would have impacted utilization within all case-mix groups similarly. We acknowledge that the COVID–19 PHE changed the underlying clinical picture in 2020 (more respiratory diagnoses, fewer therapy visits, more skilled nursing visits, altered LUPA thresholds, telehealth-driven changes in visit patterns, etc.). However the PHE would have affected care patterns regardless of whether payment was made under the 153-group system or the PDGM. However, the impact of the COVID–19 PHE contributes to case-mix changes and changes in utilization that will be reflected in the single year of claims that is priced as the simulated 60-day episodes in our repricing methodology. When we compare the aggregate expenditures between the two payment systems that are similarly affected by the COVID–19 PHE, we determine the difference in aggregate expenditures that can be attributed to the PDGM. In addition, when we create the case-mix weight for each 30-day period under PDGM, the predicted resource use is divided by the overall resource use of the 30-day periods used to estimate the regression model for recalibration. Therefore, the impact of any reduction in resource use caused by the COVID–19 PHE on the calculation of the case-mix weight would be minimal since the impact would be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight.

We previously explained the outlier assumptions for simulated 60-day episodes in the CY 2026 HH PPS final rule (90 FR 55363). If we were to implement an updated FDL instead of using the finalized CY 2020 FDL to determine outlier payments under the simulated episodes, it is unclear whether retrospectively assigning the necessary FDL to hit a 2.5 percent target for the years after CY 2020 would be an accurate representation of what would happen under the previous payment system as discussed previously in the CY 2026 HH PPS final rule (90 FR 55363). In addition, updating the FDL for the 153-group payment system would require an iterative process to adjust the PDGM FDL used in repricing to also hit the 2.5 percent target of total PDGM expenditures. We note that the 2.5 percent is only a target amount that is set prospectively and is never reconciled and adjusted for.

Comment: Some commenters reminded CMS of its legal responsibilities under the Administrative Procedure Act to exercise informed decision-making that includes public input and for the Agency to ensure that consideration is given to data and perspectives that the Agency may not have considered or overlooked. These same commenters referenced *Loper Bright Enterprises* v. *Raimondo,* 603 U.S. 369 (2024), which reinforced the principle that courts must exercise independent judgment to ensure Agency actions are lawful and within their statutory authority. These commenters noted that *Loper Bright* shifted the focus away from deference to Agency interpretations of statutes, and gaps in them, and solidified the requirement for agencies to engage in reasoned decision making, including considering and responding to public comments, as a foundational aspect of the regulatory process. Using these legal foundational principles, the commenters stated that their recommendations regarding flaws in CMS's approach related to the calculation of the permanent and temporary adjustments must be addressed.

Response: CMS has responded, in this and prior HH PPS final rules (for example, 90 FR 55342), to the substance of the commenters' recurring methodological objections, including through the previous detailed responses. The APA requires reasoned engagement with significant comments, not acceptance of a commenter's preferred outcome, and CMS's obligation to explain its reasoning is unchanged by *Loper Bright. Loper Bright* addresses the standard courts apply when reviewing an agency's interpretation of statutory text; it does not impose a new or heightened comment-response obligation beyond existing APA requirements. CMS maintains that its interpretation of section 1895(b)(3)(A)(iv) of the Act—which requires that the estimated aggregate amount of expenditures under the PDGM be equal to the estimated aggregate amount of expenditures under the previous 153-group payment system—reflects the best reading of the statutory text, which is the standard *Loper Bright* directs courts to apply independently.

Comment: Some commenters stated that simulating 60-day episodes may understate differences, including differences in clinical group assignments between the pre-PDGM and the PDGM systems. They stated that because CMS assigns the first period's diagnosis and clinical group to the entire episode, it may understate counterfactual case mix when the second period reflects greater acuity and does not capture mid-episode case-mix changes permitted under the former system.

Response: Any change in the average case-mix weight is counteracted through a corresponding change in the payment rate so that aggregate expenditures are budget neutral regardless of whether there are clinical group differences. Recalibration ensures that payment incentives for future utilization are aligned with the design of the payment system (for example, recalibration ensures roughly a third of periods and episodes are in a particular functional level grouping). Any differences, such as clinical group assignments, that are part of the changes attributed to the PDGM are accounted for when we compare the aggregate expenditures from pre-PDGM and PDGM claims.

Comment: Some commenters raised concerns about the assumptions CMS used to crosswalk the Outcome and Assessment Information (OASIS)-E to OASIS–D during repricing. They believe that mapping OASIS–E responses back to earlier OASIS–E specifications could understate severity or misclassify counterfactual case-mix groups.

Response: As discussed in the CY 2025 HH PPS final rule (89 FR 88361), in response to an update of the OASIS instrument, we updated two minor technical parts and added new assumptions in the first repricing step (creating simulated 60-day episodes from 30-day periods). However, in the CY 2026 HH PPS final rule (90 FR 55364), we acknowledged that because it is difficult to definitively isolate the behaviors directly related to the PDGM implementation after CY 2022, we were only finalizing a permanent adjustment based on data from CYs 2020 through 2022. Because of that decision, the finalized mapping of OASIS–E to OASIS–D is not used for calculations related to the proposed payment adjustments in this final rule. While we are not implementing a permanent adjustment in this final rule, we still follow this process to provide the calculation for the illustrative permanent adjustments presented in tables 2 and 3, in order to comply with statutory requirements.

Comment: Several commenters stated that data from CYs 2020 through 2022 should also not be used to isolate PDGM-related behavior change and that consequently, those years should not be used to calculate permanent or temporary adjustments. Other commenters suggested that CMS not use CY 2022 claims as part of the repricing methodology. Commenters stated that annual recalibration began in CY 2022, not CY 2023 using disrupted CY 2020 data and that CMS should recalculate the total permanent adjustments excluding 2022 claims. Commenters noted their belief that CMS should at a minimum, not finalize the proposed −3.0 percent temporary adjustment for CY 2027, exclude the data for CY 2022, and recalculate the total permanent adjustments determined based on only the data from CYs 2020 and 2021.

Response: We remind commenters that repricing compares expenditures paid under the PDGM and pre-PDGM systems to determine if we are paying differently under the PDGM than we otherwise would have absent the new payment system (that is, the 153-group system). In the CY 2023 HH PPS proposed rule (87 FR 37615), we described an analysis that showed the decline in the average case-mix weight for simulated 60-day episodes was largely driven by reductions in therapy utilization instead of the clinical score (which may be impacted by diagnoses).

We acknowledge that the CY 2022 HH PPS final rule included recalibration of case-mix weights using CY 2020 claims and reassignment of certain ICD–10–CM codes to PDGM clinical and comorbidity groups. It is important to note that these policy changes do not affect aggregate expenditures under the PDGM. In contrast, updating LUPA visit thresholds in the CY 2023 HH PPS final rule (87 FR 66815 through 66816) did affect aggregate expenditures. In the CY 2023 final rule, we finalized our proposal to recalibrate the PDGM case-mix weights, updated points for functional impairment levels, reassigned certain ICD–10–CM codes related to the PDGM clinical groups and comorbidity groups, and updated LUPA visit thresholds using CY 2021 data (87 FR 66815 through 66846). Our data analysis indicated that visits in CY 2021 were similar to visits in CY 2020. We believed that CY 2021 data would be more indicative of visit patterns in CY 2023 rather than continuing to use the LUPA thresholds derived from the CY 2018 data pre-PDGM. Therefore, we finalized updates to the LUPA thresholds for CY 2023 using data from CY 2021.

We also remind commenters that recalibration is done in a budget neutral manner, as we apply a case-mix weight recalibration budget neutrality factor to the national standardized 30-day payment rate. Regarding concerns from commenters about using claims data from CY 2022, we provided analysis in the CY 2026 HH PPS final rule (90 FR 55364 through 55366) that suggested that provider behavior changed more significantly in the years immediately following the implementation of the PDGM, but decreased in magnitude overall starting in CY 2023. These changes, that may indicate HHAs were adapting to the implementation of a new case-mix system, have decreased in magnitude (90 FR 29121 through 29125) to the extent that we believe the implementation of the PDGM is the reason for these changes through CY 2022.

We remind commenters when analyzing the overall home health trends, such as the distribution of 30-day periods of care by the twelve PDGM clinical groups, distribution of 30-day periods of care by admission source and timing, distribution of 30-day periods of care by functional impairment level, distribution of 30-day periods with therapy and non-therapy visits, and average therapy visits per 30-day period by clinical group (Tables 6, 8, 9, and 10 and Figure 3 in the CY 2026 HH PPS proposed rule (90 FR 29121 through 29125)), we see indicators that suggest provider behavior changed more significantly in the years immediately following the implementation of the PDGM, but has decreased in magnitude overall starting in CY 2023.

MedPAC's analysis of home health trends after implementation of the PDGM is consistent with our findings. In its March 2026 Report to Congress, MedPAC provided a mandated report on the impact of the implementation of the PDGM.[4] The report examined outcomes from home health care services regardless of whether they were preceded by a hospitalization. MedPAC stated that fewer therapy visits per episode were directionally consistent with the PDGM's exclusion of the number of therapy visits as a payment factor and referenced CMS's concern for how the prior payment system encouraged therapy provision through financial incentives rather than patient need. Overall, MedPAC found that the implementation of the PDGM did not substantially affect overall access to home health care and that the transition to the new case-mix system did not negatively affect beneficiaries. As presented in Figures 14–3 and 14–4 of the report, our conclusion regarding the majority of behavior change occurring in CYs 2020 through 2022 is supported by MedPAC's findings, with declining trends for the share of Medicare beneficiaries with at least one home health stay and reduction of average number of visits per stay during CYs 2020 through 2022. That is, the most substantial declines occurred in the first few years after the implementation of the PDGM (that is, CYs 2020–2022).

For the reasons discussed earlier, we continue to acknowledge the difficulty in attributing any behavior change occurring from CYs 2023 through 2025 directly to the PDGM implementation and its effects on expenditures from the other policy changes occurring in those years. As discussed in the CY 2026 final rule (90 FR 55365), our analysis supports that the observed behavior changes in CYs 2020 through 2022 are attributable to the implementation of the PDGM and the 30-day unit of payment. Therefore, since the observed behavior changes directly attributable to the implementation of the PDGM occurred in CYs 2020 through 2022, we will continue to calculate the permanent adjustment for CYs 2020 through 2022. In response to commenters' request that CMS not finalize the proposed −3 percent temporary adjustment in CY 2027, we decline to do so as we continue to believe that applying a temporary adjustment in CY 2027 mitigates the need for a larger temporary adjustment in the future. Finalizing a −3 percent temporary adjustment

[4] *https://www.medpac.gov/wp-content/uploads/2026/03/Mar26_Ch14_MedPAC_Report_To_Congress_SEC.pdf.*

ensures that CMS continues to recoup retrospective overpayments as required by law and ensures financial stewardship of the Medicare Trust Funds.

Final Decision: We continue to adhere to the methodology finalized in the CY 2026 HH PPS final rule (90 FR 55365 through 55367) and reiterate that it complies with the statutory requirement to evaluate and adjust payments based on actual behavior changes on estimated aggregate expenditures. In this final rule, we exercise our authority under section 1895(b)(3)(D)(iii) of the Act to apply ''one or more'' temporary adjustments to begin recoupment of the retrospective overpayments for CYs 2020 through 2025. We are finalizing a 3.0 percent temporary reduction in CY 2027, that is equivalent to a 0.9700 temporary adjustment factor, to the CY 2027 national, 30-day payment rate. By implementing a −3.0 percent temporary adjustment, we can begin recoupment of retrospective overpayments. We determined that the total temporary adjustment dollar amount is approximately $4.9 billion through CY 2025, and we estimate that implementing a −3.0 percent temporary adjustment will allow us to recoup $500 million of this total dollar amount.

C. CY 2027 Home Health Low Utilization Payment Adjustment (LUPA) Thresholds, Functional Impairment Levels, Comorbidity Sub-Groups, and Case-Mix Weights

1. Final CY 2027 PDGM LUPA Thresholds

Under the HH PPS, LUPAs are paid when a certain visit threshold for a payment group during a 30-day period of care is not met. In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized a policy setting the LUPA thresholds at the 10th percentile of visits or two visits, whichever is higher, for each PDGM payment group. This means the LUPA threshold for each 30-day period of care varies depending on the PDGM payment group to which it is assigned. If the LUPA threshold for the payment group is met under the PDGM, the 30-day period of care will be paid the full 30-day period case-mix adjusted payment amount (subject to any partial payment adjustment or outlier adjustments). If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment will be made using the per-visit payment amounts as described in section II.E.4.c. of this final rule. For example, if the LUPA visit threshold is four, and a 30-day period of care has four or more visits, it is paid the full 30-day period payment amount; if the period of care has three or fewer visits, payment is made using the per-visit payment amounts.

In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized our policy that the LUPA thresholds for each PDGM payment group will be reevaluated every year based on the most current utilization data available at the time of rulemaking. However, as CY 2020 was the first year of the new case-mix adjustment methodology, we stated in the CY 2021 HH PPS final rule (85 FR 70305, 70306) that we will maintain the LUPA thresholds that were finalized and shown in table 17 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes. We stated that at that time, we did not have sufficient CY 2020 data to reevaluate the LUPA thresholds for CY 2021.

In the CY 2022 HH PPS final rule with comment period (86 FR 62249), we finalized the proposal to recalibrate the PDGM case-mix weights, functional impairment levels, and comorbidity subgroups while maintaining the LUPA thresholds for CY 2022. We stated that because there are several factors that contribute to how the case-mix weight is set for a particular case-mix group (such as the number of visits, length of visits, types of disciplines providing visits, and non-routine supplies) and the case-mix weight is derived by comparing the average resource use for the case-mix group relative to the average resource use across all groups, we believe the COVID–19 PHE would have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the COVID–19 PHE on the calculation of the case-mix weight will be minimized since the impact will be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight. However, in contrast, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (like what is used to generate the case-mix weight) that will control for the impacts of the COVID–19 PHE. We noted that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. Therefore, to mitigate any potential future and significant short-term variability in the LUPA thresholds due to the COVID–19 PHE, we finalized the proposal to maintain the LUPA thresholds finalized and displayed in table 17 in the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2022 payment purposes.

For CY 2024, we proposed to update the LUPA thresholds using CY 2022 Medicare home health claims (as of March 17, 2023) linked to OASIS assessment data. We believed that CY 2022 data would be more indicative of visit patterns in CY 2024 rather than continuing to use the LUPA thresholds derived from the CY 2018 data pre-PDGM. Therefore, we finalized a policy to update the LUPA thresholds for CY 2024 using data from CY 2022.

For CY 2027, we proposed to update the LUPA thresholds using CY 2025 home health claims utilization data (using more complete CY 2025 claims data as of July 14, 2026), in accordance with our policy to annually recalibrate the case-mix weights and update the LUPA thresholds, functional impairment levels, and comorbidity subgroups. After reviewing the CY 2025 home health claims utilization data, we determined that LUPA visit patterns in 2025 were similar to visits in 2024 and a total of 10 case-mix groups had a decline in their LUPA threshold of a single visit and one case-mix group had their LUPA threshold increase by a single visit. The proposed LUPA thresholds for the CY 2027 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights can be found in the CY 2027 HH PPS proposed rule (91 FR 41255).

We solicited public comment on the proposed updates to the LUPA thresholds for CY 2027. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed support for CMS's continued practice of annually recalibrating LUPA thresholds using the most recent complete claims data and characterized the proposed threshold reductions across 18 payment groups as ''modest but directionally favorable''. Two commenters identified a proposed LUPA threshold of 3.5 visits for HIPPS Code 4LC11 in the ''CY 2027 Proposed HH PDGM Case Mix Weights and LUPA Thresholds'' file (as posted on the HHA Center web page, located at *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center*), and asked CMS to clarify whether this should be read as 3 visits, 4 visits, or whether it reflects a true partial threshold.

Response: We thank commenters for their support and feedback on the annual recalibration for LUPA thresholds. We calculated the proposed CY 2027 LUPA thresholds using CY

2025 home health claims utilization data as of March 15, 2026, which identified 18 case-mix groups with a one-visit decrease. We are finalizing CY 2027 LUPA thresholds using more complete CY 2025 home health claims utilization data as of July 14, 2026, which shifted the visit distribution for eight of the 18 proposed groups and reduced the final count to 10 case-mix groups with a one-visit decrease.

Additionally, we reviewed the case-mix weight and LUPA thresholds published in the CY 2027 HH PPS proposed rule (91 FR 41261) in response to these comments and can confirm that the value of 3.5 visits listed for HIPPS Code 4LC11 was the result of an inadvertent technical error. LUPA visit thresholds are calculated as whole numbers, consistent with all other case-mix groups. We are publishing the corrected, finalized whole number LUPA threshold for HIPPS Code 4LC11 of three for CY 2027 in this final rule and are correcting this error in the technical files accompanying the final rule. We are otherwise finalizing the LUPA thresholds contained in table 11 using more complete CY 2025 claims data as of July 14, 2026.

Comment: Some commenters raised concerns that CMS is basing updates to the proposed LUPA thresholds on potentially fraudulent data, pointing specifically to clinically complex, short duration episodes and what they describe as high fraud areas such as Los Angeles County. These commenters stated that this distortion disadvantages legitimate HHAs that serve genuinely high-cost patients as fraudulent, low-acuity, high-volume billing skews the ratio's underlying data.

Response: We appreciate commenters' concerns about potential fraudulent billing and its impact on the proposed LUPA thresholds. However, we remind commenters that outlier billing patterns do not necessarily indicate fraudulent practice. We did not propose, and are not adopting, a geographic exclusion or separate modeling approach for identified outliers in calculating the CY 2027 LUPA thresholds. As such, we include the most recent and complete claims data available when it updates the LUPA thresholds. Nevertheless, we thank commenters for sharing their insight on how CMS can address fraud concerns in the home health market. Depending on the circumstances, an anomalous pattern can prompt further review and may trigger an investigation into fraud, waste, and abuse. Specifically, cost report fraud and abusive billing behavior require action through the appropriate channels that hold enforcement authority and we encourage commenters to report suspected fraud at: *https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reporting-fraud.*

Comment: One commenter recommended that when CMS adjusts clinical group assignments or comorbidity subgroups affecting LUPA thresholds, CMS should release revised grouper specifications and testing files at least 90–120 days prior to the January 1 effective date, to prevent claims disruption across clearinghouses and billing vendors.

Response: We thank the commenter for this feedback. The ICD–10–CM diagnosis code mappings used by the grouper (clinical groupings, comorbidity adjustments) and the LUPA thresholds are typically previewed in the proposed rule (published around late June/early July) so stakeholders can comment, and are then finalized in the final rule (published in early November). Each update of the Home Health Grouper software is available for beta testing approximately 6–8 weeks prior to the implementation date, and shortly before the final rule is published. To sign up to beta test the home health software release, stakeholders can email *hhppsgrouperemail@solventum.com* and provide their contact information. However, because we are still finalizing edits to diagnosis mapping based on comments received on the elements that make up the home health grouper that are previewed in the proposed rule, CMS cannot release the beta testing any sooner than 6–8 weeks prior to the implementation date.

Final Decision: We are finalizing the LUPA threshold updates as proposed for CY 2027 using CY 2025 home health claims utilization data (using more complete CY 2025 claims data as of July 14, 2026), including the one-visit decrease for ten case-mix groups and the one-visit increase for one case-mix group. The final LUPA thresholds for the CY 2027 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in table 11 and are also available on the HHA Center web page, located at *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center.* We will continue to monitor national LUPA rates and data indicators through routine program monitoring.

2. Final CY 2027 Functional Impairment Levels

Under the PDGM, the functional impairment level is determined by responses to certain OASIS items associated with activities of daily living and risk of hospitalization; that is, responses to OASIS items M1800–M1860 and M1033. A home health period of care receives points based on each of the responses associated with these functional OASIS items, which are then converted into a table of points corresponding to increased resource use. The sum of all these points results in a functional impairment score which is used to group home health periods into a functional level with similar resource use. That is, the higher the points, the more the response is associated with increased resource use, or increased impairment. The three functional impairment levels of low, medium, and high were designed so that approximately one-third of home health periods from each clinical group falls within each level. This means home health periods in the low impairment level have responses for the functional OASIS items that are associated with the lowest resource use, on average. Home health periods in the high impairment level have responses for the functional OASIS items that are associated with the highest resource use on average.

For CY 2027, we proposed using CY 2025 claims data to update the functional points and functional impairment levels by clinical group. The CY 2018 HH PPS proposed rule (82 FR 35320) and the technical report from December 2016, posted on the Home Health PPS Archive web page, located at *https://www.cms.gov/medicare/home-health-pps/home-health-pps-archive,* provide a more detailed explanation as to the construction of the functional impairment levels using the OASIS items. We proposed to use the same methodology previously finalized to update the functional impairment levels for CY 2027. The final updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2027 are listed in tables 6 and 7, respectively.

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TABLE 6: FINAL OASIS POINTS TABLE FOR CY 2027

	Responses	CY 2027 Points	Percent of Periods with this Response Category*
M1800: Grooming	0 or 1	**0**	**21.5%**
	2 or 3	**3**	**78.5%**
M1810: Current Ability to Dress Upper Body	0 or 1	**0**	**15.9%**
	2 or 3	**5**	**84.1%**
M1820: Current Ability to Dress Lower Body	0 or 1	**0**	**7.7%**
	2	**4**	**63.5%**
	3	**11**	**28.8%**
M1830: Bathing	0 or 1	**0**	**2.0%**
	2	**2**	**8.6%**
	3 or 4	**8**	**48.0%**
	5 or 6	**16**	**41.3%**
M1840: Toilet Transferring	0 or 1	**0**	**58.3%**
	2, 3 or 4	**6**	**41.7%**
M1850: Transferring	0	**0**	**1.0%**
	1	**3**	**16.4%**
	2, 3, 4 or 5	**5**	**82.6%**
M1860: Ambulation/Locomotion	0 or 1	**0**	**2.7%**
	2	**4**	**13.3%**
	3	**0**	**66.2%**
	4, 5 or 6	**19**	**17.8%**
M1033: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	**0**	**52.9%**
	Four or more items marked (Excluding responses 8, 9 or 10)	**11**	**47.1%**

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.
Note: *For item M1860, the point values for response 2 is worth more than the point values for response 3. There may be times in which the resource use for certain OASIS items associated with functional impairment will result in a seemingly inverse relationship to the response reported. However, this is the result of the direct association between the responses reported on the OASIS items and actual resource use. For item M1033, responses 8,9 and 10 represent "currently reports exhaustion", "other risk(s) not listed in 1-8", and "none of the above", respectively.*

TABLE 7: FINAL THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, FOR CY 2027

Clinical Group	Level of Impairment	CY 2027 Points
MMTA - Other	Low	**0-30**
	Medium	**31-42**
	High	**43+**
Behavioral Health	Low	**0-31**
	Medium	**32-44**
	High	**45+**
Complex Nursing Interventions	Low	**0-31**
	Medium	**32-55**
	High	**56+**
Musculoskeletal Rehabilitation	Low	**0-31**
	Medium	**32-44**
	High	**45+**
Neuro Rehabilitation	Low	**0-33**
	Medium	**34-50**
	High	**51+**
Wound	Low	**0-32**
	Medium	**33-50**
	High	**51+**
MMTA - Surgical Aftercare	Low	**0-30**
	Medium	**31-42**
	High	**43+**
MMTA - Cardiac and Circulatory	Low	**0-29**
	Medium	**30-42**
	High	**43+**
MMTA - Endocrine	Low	**0-27**
	Medium	**28-42**
	High	**43+**
MMTA - Gastrointestinal tract and Genitourinary system	Low	**0-33**
	Medium	**34-46**
	High	**47+**
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	**0-31**
	Medium	**32-44**
	High	**45+**
MMTA - Respiratory	Low	**0-32**
	Medium	**33-44**
	High	**45+**

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

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We solicited public comment on the proposed updates to the functional points and the functional impairment levels by clinical group. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed CMS's proposal to reduce the point value assigned to OASIS item M1860 response ''3'' (*for* ''*able to walk only with the supervision or assistance of another person at all times*'') to zero points for CY 2027, which is down from 1 point in CY 2026 and down from 6 points as recently as CY 2022. These commenters stated that M1860 response ''3'' covers a wide and clinically meaningful range of ambulation impairment (ranging from contact guard assistance to maximum assist) and that collapsing it to zero points equates it with no impairment at all and resultingly makes it appear progressively less resource intensive solely as a result of annual recalibration. Commenters requested that CMS explain the basis for the change and commit to a stable and anchored scoring approach for M1860 response ''3'' going forward. Other commenters raised similar concerns that the proposed functional impairment thresholds could shift a meaningful number of patient episodes from high to medium and medium to low functional impairment classifications, even though the underlying clinical needs of those patients have not changed. A few commenters identified specific proposed point reductions, including point values for M1830 (*bathing*) and for M1820 (*ability to dress lower body*) at low to moderate impairment levels, while severe impairment levels remain largely unchanged.

Commenters stated that this pattern in which response categories that encompass wide and clinically meaningful ranges of impairment are reduced in points, effectively equating those levels of impairment with no impairment at all and, consequently, making them appear progressively less resource intensive even though the underlying clinical needs of the patients have not changed concentrates payment recognition only on the most severely

dependent patients and undervalues resources devoted to patients with low to moderate limitations. To counter this, commenters recommended CMS implement greater stability in the functional scoring methodology by implementing fixed functional point values for a multiyear period, recalibrating only when CMS identifies statistically/clinically meaningful changes in patient needs rather than through full annual recalibration.

Response: We proposed the revised M1860, M1830 and M1820 point values based on updated regression analysis of CY 2025 claims and OASIS data reflecting the empirical association between OASIS responses and resource utilization, consistent with the same methodology CMS has applied in each annual PDGM recalibration cycle since implementation. CMS recognizes that HHAs whose patient populations differ from the national distribution may experience varied effects from the nationally calibrated set of functional impairment thresholds. However, functional impairment levels are calibrated using national data to ensure the methodology reflects resource use across the Medicare home health population as a whole, as we believe annual recalibration using the most recent complete data year is necessary to ensure functional impairment scoring continues to reflect current clinical and utilization patterns. As such CMS declines to propose or implement a floor or multiyear fix on point values for any individual OASIS response.

Comment: Several commenters recommended that CMS transition away from OASIS M items toward the exclusive use of GG functional items in order to determine functional impairment levels, highlighting that GG items would provide more clinically precise measurement and would better differentiate differences in resource use that the current OASIS M item categories collapse into a single data point.

Response: We appreciate commenters' interest in a potential transition to Section GG items for functional impairment scoring. We will continue to evaluate the feasibility of using the GG items for payment.

Comment: A few commenters challenged the structural basis of CMS's functional impairment methodology, under which point values and thresholds are calibrated so that approximately one third of periods within each clinical group fall into the low, medium, and high functional impairment categories, characterizing this as ''arbitrary''.

Response: We thank commenters for their feedback and note that the functional impairment levels are structured so that approximately one-third of periods within each clinical group are assigned to low, medium, and high categories, as this ensures that the case-mix system appropriately reflects differences in functional impairment. This classification of functional impairment has been a fundamental component of the HH PPS since its implementation and remains essential under the PDGM. Previously, the HH PPS grouped home health episodes using functional scores based on functional OASIS items with similar average resource use within the same functional level, with approximately a third of episodes classified as low, a third classified as medium, and a third classified as high functional impairment. Likewise, the PDGM groups home health periods of care using functional impairment scores based on functional OASIS items with similar resource use and has three levels of functional impairment severity: low, medium, and high. However, the PDGM differs from the previous HH PPS functional variable in that the three functional impairment level thresholds in the PDGM vary between the clinical groups. As such, the PDGM functional impairment structure accounts for patient characteristics within each clinical group that are associated with increased resource use due to functional impairment. This ensures that payment is more accurately aligned with patient characteristics, including beneficiaries who have greater need with activities of daily living (ADLs) and who are more functionally impaired. Updating the functional impairment levels based on the most current OASIS and claims data ensures that the payment system captures changes in functional impairment and the associated increases in resource use. Regardless of whether patients entering home health are more impaired due to shifts in the broader health care system or any other influence, the functional levels capture the relationship between functional status as indicated on the OASIS with resource use captured on claims. While we acknowledge commenters' concerns, we emphasize that the proposed recalibration is designed to strengthen the alignment between payment and patient characteristics, not to diminish access to medically necessary services. As such, updating the functional levels would specifically capture any changes in functional impairment and any changes in resource use associated with ADLs.

Final Decision: We are finalizing the functional points and functional impairment level updates for CY 2027 as proposed, using updated CY 2025 claims data (as of July 14, 2026).

3. Final CY 2027 Comorbidity Subgroups

Thirty-day periods of care receive a comorbidity adjustment category based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home-health specific list of clinically and statistically significant secondary diagnosis subgroups with similar resource use, meaning the diagnoses have at least as high as the median resource use and are reported in more than 0.1 percent of 30-day periods of care. Home health 30-day periods of care can receive a comorbidity adjustment under the following circumstances:

- *High comorbidity adjustment:* There are two or more secondary diagnoses on the home health-specific comorbidity subgroup interaction list that are associated with higher resource use when both are reported together compared to when they are reported separately. That is, the two diagnoses may interact with one another, resulting in higher resource use.
- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the home health-specific comorbidity subgroup list that is associated with higher resource use.
- *No comorbidity adjustment:* A 30-day period of care receives no comorbidity adjustment if no secondary diagnoses exist or do not meet the criteria for a low or high comorbidity adjustment.

In the CY 2019 HH PPS final rule with comment period (83 FR 56406), we stated that we will continue to examine the relationship of reported comorbidities on resource utilization and make the appropriate payment refinements to help ensure that payment is in alignment with the actual costs of providing care. For CY 2027, we proposed to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using CY 2025 home health data with linked OASIS data.

For CY 2027, we proposed to update the comorbidity subgroups to include 21 low comorbidity adjustment subgroups and 100 high comorbidity adjustment interaction subgroups. The proposed CY 2027 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments were

included in tables 21 and 22 in the CY 2027 HH PPS proposed rule (91 FR 41245).

Using more updated claims data for this final rule, there are 22 low comorbidity subgroups, and 103 high comorbidity subgroups for CY 2027 as shown in tables 8 and 9.

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TABLE 8: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2027

Low Comorbidity Subgroup	Description
Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
Circulatory 10	Varicose Veins and Lymphedema
Circulatory 2	Hemolytic, Aplastic, and Other Anemias
Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension
Circulatory 9	Other Venous Embolism and Thrombosis
Endocrine 3	Type 1, Type 2, and Other Specified Diabetes
Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
Gastrointestinal 2	Intestinal Obstruction and Ileus
Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
Heart 11	Heart Failure
Heart 5	Atherosclerotic Heart Disease with Angina
Neoplasms 17	Secondary neoplasms of respiratory and GI systems.
Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
Neurological 10	Diabetes with neuropathy
Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
Respiratory 10	2019 Novel Coronavirus
Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

TABLE 9: HIGH COMORBIDITY ADJUSTMENT INTERACTIONS FOR CY 2027

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
1	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
2	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
3	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
4	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
5	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
6	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
7	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
8	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
9	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
10	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
11	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
12	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias
13	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension
14	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 9	Other Venous Embolism and Thrombosis
15	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
16	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 11	Heart Failure
17	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Infectious 1	C-diff, MRSA, E-coli
18	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 10	Diabetes with neuropathy
19	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
20	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
21	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
22	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
23	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
24	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
25	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 1	Hypothyroidism
26	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
27	Circulatory 10	Varicose Veins and Lymphedema	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
28	Circulatory 10	Varicose Veins and Lymphedema	Heart 12	Other Heart Diseases
29	Circulatory 10	Varicose Veins and Lymphedema	Heart 8	Other Pulmonary Heart Diseases
30	Circulatory 10	Varicose Veins and Lymphedema	Infectious 1	C-diff, MRSA, E-coli
31	Circulatory 10	Varicose Veins and Lymphedema	Musculoskeletal 2	Rheumatoid Arthritis
32	Circulatory 10	Varicose Veins and Lymphedema	Neurological 12	Nondiabetic neuropathy
33	Circulatory 10	Varicose Veins and Lymphedema	Renal 1	Chronic kidney disease and ESRD
34	Circulatory 10	Varicose Veins and Lymphedema	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
35	Circulatory 10	Varicose Veins and Lymphedema	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
36	Circulatory 10	Varicose Veins and Lymphedema	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
37	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neoplasms 9	Malignant neoplasm of breast
38	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
39	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
40	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
41	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
42	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
43	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
44	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
45	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
46	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes
47	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
48	Circulatory 9	Other Venous Embolism and Thrombosis	Heart 11	Heart Failure
49	Circulatory 9	Other Venous Embolism and Thrombosis	Musculoskeletal 4	Lumbar Spinal Stenosis
50	Circulatory 9	Other Venous Embolism and Thrombosis	Respiratory 4	Bronchitis, Emphysema, and Interstitial Lung Disease
51	Circulatory 9	Other Venous Embolism and Thrombosis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
52	Endocrine 1	Hypothyroidism	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
53	Endocrine 1	Hypothyroidism	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
54	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
55	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
56	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
57	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
58	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
59	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
60	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
61	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
62	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
63	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
64	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
65	Gastrointestinal 4	Alcoholic Liver Disease, Chronic Hepatitis, Fibrosis and Cirrhosis of the Liver	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
66	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
67	Heart 11	Heart Failure	Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
68	Heart 11	Heart Failure	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
69	Heart 11	Heart Failure	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
70	Heart 11	Heart Failure	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
71	Heart 12	Other Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
72	Heart 7	Chronic Ischemic Heart Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
73	Heart 8	Other Pulmonary Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
74	Heart 9	Valve Disorders	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
75	Infectious 1	C-diff, MRSA, E-coli	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
76	Infectious 1	C-diff, MRSA, E-coli	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
77	Infectious 1	C-diff, MRSA, E-coli	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
78	Musculoskeletal 3	Joint Pain	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
79	Musculoskeletal 3	Joint Pain	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
80	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
81	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
82	Neurological 10	Diabetes with neuropathy	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
83	Neurological 10	Diabetes with neuropathy	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
84	Neurological 12	Nondiabetic neuropathy	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
85	Neurological 12	Nondiabetic neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
86	Neurological 4	Alzheimer's disease and related dementias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
87	Neurological 4	Alzheimer's disease and related dementias	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
88	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Renal 1	Chronic kidney disease and ESRD
89	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Respiratory 9	Respiratory Failure and Atelectasis
90	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Neurological 8	Epilepsy
91	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
92	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
93	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Respiratory 9	Respiratory Failure and Atelectasis
94	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
95	Neurological 8	Epilepsy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
96	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
97	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
98	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
99	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
100	Respiratory 9	Respiratory Failure and Atelectasis	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
101	Respiratory 9	Respiratory Failure and Atelectasis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
102	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
103	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

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We invited comments on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment

interactions for CY 2027. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed general support for CMS's proposed CY 2027 comorbidity subgroup structure, agreeing the proposed changes generally align payment with the cost of caring for patients with multiple interacting diagnoses and recommended CMS continue evaluating the reimbursement impact of comorbidity revisions for diabetes and chronic wound patients.

Response: We appreciate commenters' support and comments regarding the reimbursement impacts of the proposed comorbidity revisions for patients with diabetes and chronic wounds. CMS will continue to evaluate the effects of these revisions through annual recalibration using the most recently available data.

Comment: Some commenters raised concerns regarding proposed modifications that would lower certain wound-related high comorbidity interactions and stated this may not fully account for the skilled nursing resources required to manage patients with chronic wounds who also have diabetes, peripheral vascular disease, or renal disease, since such conditions significantly influence wound healing/hospitalization risk and require frequent clinical assessment and medication management. These commenters noted this may disproportionately affect HHAs serving medically complex wound care populations if the final subgroup structure does not adequately capture such interactions.

Response: We appreciate commenters' concerns regarding resource needs of certain patient populations. However, we proposed the revised high comorbidity interaction subgroups based on updated analysis of CY 2025 claims data, which is most appropriate as it reflects the current empirical relationship between specific diagnosis combinations and resource utilization across the Medicare home health population. We also note that the Wounds clinical group still has some of the highest case-mix weights, which should account for the resource intensity of caring for patients with wounds. We will continue to annually analyze the reported comorbidities along with the associated resource use to determine if any policy changes are necessary and appropriate in the future.

Final Decision: We are finalizing the updated comorbidity adjustment subgroups and the high comorbidity adjustment interactions using CY 2025 home health data. For CY 2027, the final updated comorbidity adjustment subgroups include 22 low comorbidity adjustment subgroups as identified in table 8 and 103 high comorbidity adjustment interaction subgroups as identified in table 9. The final CY 2027 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments will also be posted on the HHA Center web page at *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

4. Final CY 2027 PDGM Case-Mix Weights

As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56502), the PDGM places patients into meaningful payment categories based on patient and other characteristics, such as timing, admission source, clinical grouping using the reported principal diagnosis, functional impairment level, and comorbid conditions. The PDGM case-mix methodology results in 432 unique case-mix groups called home health resource groups (HHRGs). We also finalized a policy in the CY 2019 HH PPS final rule with comment period (83 FR 56515) to annually recalibrate the PDGM case-mix weights using a fixed effects model with the most recent and complete utilization data available at the time of annual rulemaking. Annual recalibration of the PDGM case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns. To generate the proposed recalibrated CY 2027 case-mix weights, we used CY 2025 home health claims data with linked OASIS data (as of March 15, 2026). We included the proposed case-mix weights in table 11 of the proposed rule (91 FR 41255). In this final rule, we updated these case-mix weights with claims data as of July 14, 2026, as shown in table 11. These data are the most current and complete data available at the time of this rulemaking.

The claims data provide visit-level data and data on whether non-routine supplies (NRS) were provided during the period and the total charges of NRS. We determine the case-mix weight for each of the 432 different PDGM payment groups by regressing resource use on a series of indicator variables for each of the categories using a fixed effects model as described in the following steps:

Step 1: Estimate a regression model to assign a functional impairment level to each 30-day period. The regression model estimates the relationship between a 30-day period's resource use and the functional status and risk of hospitalization items included in the PDGM, which are obtained from certain OASIS items. We refer readers to table 12 of the proposed rule for further information on the OASIS items used for the functional impairment level under the PDGM. We measure resource use with the cost-per-minute + NRS approach that uses information from 2022 home health cost reports. Other variables in the regression model include the 30-day period's admission source, clinical group, and 30-day period timing. We also include home health agency level fixed effects in the regression model. After estimating the regression model using 30-day periods, we divide the coefficients that correspond to the functional status and risk of hospitalization items by 10 and round to the nearest whole number. Those rounded numbers are used to compute a functional score for each 30-day period by summing together the rounded numbers for the functional status and risk of hospitalization items that are applicable to each 30-day period. Next, each 30-day period is assigned to a functional impairment level (low, medium, or high) depending on the 30-day period's total functional score. Each clinical group has a separate set of functional thresholds used to assign 30-day periods into a low, medium, or high functional impairment level. We set those thresholds so that we assign roughly a third of 30-day periods within each clinical group to each functional impairment level (low, medium, or high).

Step 2: A second regression model estimates the relationship between a 30-day period's resource use and indicator variables for the presence of any of the comorbidities and comorbidity interactions that were originally examined for inclusion in the PDGM. Like the first regression model, this model also includes home health agency level fixed effects and includes control variables for each 30-day period's admission source, clinical group, timing, and functional impairment level. After we estimate the model, we assign comorbidities to the low comorbidity adjustment if any comorbidities have a coefficient that is statistically significant (p-value of 0.05 or less) and which have a coefficient that is larger than the 50th percentile of positive and statistically significant comorbidity coefficients. If two comorbidities in the model and their interaction term have coefficients that sum together to exceed $150 and the interaction term is statistically significant (p-value of 0.05 or less), we

assign the two comorbidities together to the high comorbidity adjustment.

Step 3: After Step 2, each 30-day period is assigned to a clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. For each combination of those variables (which represent the 432 different payment groups that comprise the PDGM), we then calculate the 10th percentile of visits across all 30-day periods within a particular payment group. If a 30-day period's number of visits is less than the 10th percentile for their payment group, the 30-day period is classified as a Low Utilization Payment Adjustment (LUPA). If a payment group has a 10th percentile of visits that is less than two, we set the LUPA threshold for that payment group to be equal to two. That means if a 30-day period has one visit, it is classified as a LUPA and if it has two or more visits, it is not classified as a LUPA.

Step 4: Take all non-LUPA 30-day periods and regress resource use on the 30-day period's clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. The regression includes fixed effects at the level of the home health agency. After we estimate the model, the model coefficients are used to predict each 30-day period's resource use. To create the case-mix weight for each 30-day period, the predicted resource use is divided by the overall resource use of the 30-day periods used to estimate the regression.

The case-mix weight is then used to adjust the base payment rate to determine each 30-day period's payment. Table 10 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

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TABLE 10: COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE

Variable	Coefficient	Percentage of 30-Day Periods for this Model	Coefficient Divided by Average Resource Use
Clinical Group and Functional Impairment Level (MMTA - Other - Low is excluded)			
MMTA - Other - Medium Functional	$132.26	1.3%	0.0779
MMTA - Other - High Functional	$291.87	1.3%	0.1718
MMTA - Surgical Aftercare - Low Functional	-$36.01	1.2%	-0.0212
MMTA - Surgical Aftercare - Medium Functional	$142.03	1.2%	0.0836
MMTA - Surgical Aftercare - High Functional	$352.51	1.1%	0.2075
MMTA - Cardiac and Circulatory - Low Functional	-$23.85	5.7%	-0.0140
MMTA - Cardiac and Circulatory - Medium Functional	$127.63	5.9%	0.0751
MMTA - Cardiac and Circulatory - High Functional	$301.22	5.5%	0.1773
MMTA - Endocrine - Low Functional	$466.30	2.6%	0.2745
MMTA - Endocrine - Medium Functional	$547.02	2.6%	0.3220
MMTA - Endocrine - High Functional	$697.64	2.2%	0.4107
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$38.73	1.8%	-0.0228
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$125.51	1.6%	0.0739
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$294.04	1.7%	0.1731
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-$7.38	1.6%	-0.0043
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	$144.32	1.7%	0.0850
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$364.31	1.5%	0.2144
MMTA - Respiratory - Low Functional	-$21.03	2.2%	-0.0124
MMTA - Respiratory - Medium Functional	$146.62	2.3%	0.0863
MMTA - Respiratory - High Functional	$310.30	2.1%	0.1826
Behavioral Health - Low Functional	-$97.93	0.8%	-0.0576
Behavioral Health - Medium Functional	$120.06	0.7%	0.0707
Behavioral Health - High Functional	$244.39	0.7%	0.1439
Complex - Low Functional	-$25.88	0.9%	-0.0152
Complex - Medium Functional	$161.43	0.9%	0.0950
Complex - High Functional	$123.33	0.9%	0.0726
MS Rehab - Low Functional	$47.59	7.7%	0.0280
MS Rehab - Medium Functional	$188.20	7.5%	0.1108
MS Rehab - High Functional	$410.51	6.3%	0.2416
Neuro - Low Functional	$185.07	3.6%	0.1089
Neuro - Medium Functional	$350.88	4.0%	0.2065
Neuro - High Functional	$592.50	3.2%	0.3488
Wound - Low Functional	$620.23	4.8%	0.3651
Wound - Medium Functional	$780.37	4.9%	0.4593
Wound - High Functional	$995.20	4.6%	0.5858
Admission Source with Timing (Community Early is excluded)			
Community - Late	-$549.30	64.2%	-0.3233
Institutional - Early	$360.59	18.3%	0.2123
Institutional - Late	$237.01	6.1%	0.1395
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)			
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$96.98	58.7%	0.0571
Comorbidity Adjustment - Has at least one interaction from interaction list	$354.77	16.7%	0.2088

Variable	Coefficient	Percentage of 30-Day Periods for this Model	Coefficient Divided by Average Resource Use
Constant	$1,554.78		
Average Resource Use	$1,698.88		
Number of 30-day Periods	7,795.221		
Adjusted R-Squared	0.3142		

Source: *CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.*

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The final updated case-mix weights for CY 2027 are listed in table 11 and will also be posted on the HHA Center web page upon display of this final rule.

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TABLE B11: CASE-MIX WEIGHTS AND LUPA THRESHOLDS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1FC11	Behavioral Health - High	Early - Community	0	1.0590	4
1FC21	Behavioral Health - High	Early - Community	1	1.1161	4
1FC31	Behavioral Health - High	Early - Community	2	1.2679	4
2FC11	Behavioral Health - High	Early - Institutional	0	1.2713	3
2FC21	Behavioral Health - High	Early - Institutional	1	1.3284	3
2FC31	Behavioral Health - High	Early - Institutional	2	1.4801	4
3FC11	Behavioral Health - High	Late - Community	0	0.7357	2
3FC21	Behavioral Health - High	Late - Community	1	0.7928	2
3FC31	Behavioral Health - High	Late - Community	2	0.9445	2
4FC11	Behavioral Health - High	Late - Institutional	0	1.1985	3
4FC21	Behavioral Health - High	Late - Institutional	1	1.2556	3
4FC31	Behavioral Health - High	Late - Institutional	2	1.4074	3
1FA11	Behavioral Health - Low	Early - Community	0	0.8575	3
1FA21	Behavioral Health - Low	Early - Community	1	0.9146	3
1FA31	Behavioral Health - Low	Early - Community	2	1.0664	3
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0698	3
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1269	3
2FA31	Behavioral Health - Low	Early - Institutional	2	1.2786	3
3FA11	Behavioral Health - Low	Late - Community	0	0.5342	2
3FA21	Behavioral Health - Low	Late - Community	1	0.5913	2
3FA31	Behavioral Health - Low	Late - Community	2	0.7430	2
4FA11	Behavioral Health - Low	Late - Institutional	0	0.9970	3
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0541	2
4FA31	Behavioral Health - Low	Late - Institutional	2	1.2059	3
1FB11	Behavioral Health - Medium	Early - Community	0	0.9859	4
1FB21	Behavioral Health - Medium	Early - Community	1	1.0429	4
1FB31	Behavioral Health - Medium	Early - Community	2	1.1947	3
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.1981	3
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.2552	4
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4069	4
3FB11	Behavioral Health - Medium	Late - Community	0	0.6625	2
3FB21	Behavioral Health - Medium	Late - Community	1	0.7196	2
3FB31	Behavioral Health - Medium	Late - Community	2	0.8713	2
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1254	3
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.1824	3
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3342	3
1DC11	Complex - High	Early - Community	0	0.9878	2
1DC21	Complex - High	Early - Community	1	1.0449	2
1DC31	Complex - High	Early - Community	2	1.1966	2
2DC11	Complex - High	Early - Institutional	0	1.2000	3
2DC21	Complex - High	Early - Institutional	1	1.2571	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2DC31	Complex - High	Early - Institutional	2	1.4089	3
3DC11	Complex - High	Late - Community	0	0.6644	2
3DC21	Complex - High	Late - Community	1	0.7215	2
3DC31	Complex - High	Late - Community	2	0.8733	2
4DC11	Complex - High	Late - Institutional	0	1.1273	2
4DC21	Complex - High	Late - Institutional	1	1.1844	2
4DC31	Complex - High	Late - Institutional	2	1.3361	2
1DA11	Complex - Low	Early - Community	0	0.8999	2
1DA21	Complex - Low	Early - Community	1	0.9570	2
1DA31	Complex - Low	Early - Community	2	1.1088	2
2DA11	Complex - Low	Early - Institutional	0	1.1122	3
2DA21	Complex - Low	Early - Institutional	1	1.1693	3
2DA31	Complex - Low	Early - Institutional	2	1.3210	3
3DA11	Complex - Low	Late - Community	0	0.5766	2
3DA21	Complex - Low	Late - Community	1	0.6337	2
3DA31	Complex - Low	Late - Community	2	0.7854	2
4DA11	Complex - Low	Late - Institutional	0	1.0395	3
4DA21	Complex - Low	Late - Institutional	1	1.0965	2
4DA31	Complex - Low	Late - Institutional	2	1.2483	2
1DB11	Complex - Medium	Early - Community	0	1.0102	2
1DB21	Complex - Medium	Early - Community	1	1.0673	2
1DB31	Complex - Medium	Early - Community	2	1.2190	2
2DB11	Complex - Medium	Early - Institutional	0	1.2225	3
2DB21	Complex - Medium	Early - Institutional	1	1.2795	3
2DB31	Complex - Medium	Early - Institutional	2	1.4313	3
3DB11	Complex - Medium	Late - Community	0	0.6869	2
3DB21	Complex - Medium	Late - Community	1	0.7440	2
3DB31	Complex - Medium	Late - Community	2	0.8957	2
4DB11	Complex - Medium	Late - Institutional	0	1.1497	3
4DB21	Complex - Medium	Late - Institutional	1	1.2068	3
4DB31	Complex - Medium	Late - Institutional	2	1.3585	3
1HC11	MMTA - Cardiac - High	Early - Community	0	1.0925	4
1HC21	MMTA - Cardiac - High	Early - Community	1	1.1496	4
1HC31	MMTA - Cardiac - High	Early - Community	2	1.3013	3
2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.3047	4
2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.3618	4
2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.5136	4
3HC11	MMTA - Cardiac - High	Late - Community	0	0.7691	2
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8262	2
3HC31	MMTA - Cardiac - High	Late - Community	2	0.9780	3
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2320	3
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.2891	3
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4408	3
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9011	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1HA21	MMTA - Cardiac - Low	Early - Community	1	0.9582	3
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.1100	4
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	1.1134	3
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	1.1705	3
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	1.3222	4
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5778	3
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.6349	2
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7866	2
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	1.0406	3
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	1.0977	3
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	1.2495	3
1HB11	MMTA - Cardiac - Medium	Early - Community	0	0.9903	4
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.0474	4
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.1991	3
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	1.2026	4
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	1.2596	4
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	1.4114	4
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.6670	2
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7241	2
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.8758	2
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1298	3
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.1869	3
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3386	3
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3258	4
1IC21	MMTA - Endocrine - High	Early - Community	1	1.3829	4
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5347	4
2IC11	MMTA - Endocrine - High	Early - Institutional	0	1.5381	4
2IC21	MMTA - Endocrine - High	Early - Institutional	1	1.5952	4
2IC31	MMTA - Endocrine - High	Early - Institutional	2	1.7469	4
3IC11	MMTA - Endocrine - High	Late - Community	0	1.0025	3
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0596	3
3IC31	MMTA - Endocrine - High	Late - Community	2	1.2113	3
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4653	4
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.5224	4
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6742	4
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.1897	4
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.2467	4
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.3985	4
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	1.4019	3
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	1.4590	4
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	1.6107	4
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.8663	3
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.9234	3
3IA31	MMTA - Endocrine - Low	Late - Community	2	1.0752	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.3292	4
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.3863	3
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.5380	3
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2372	5
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.2943	4
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4460	4
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	1.4494	4
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	1.5065	4
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	1.6582	4
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.9138	3
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9709	3
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.1227	3
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.3767	4
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.4338	4
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.5855	4
1JC11	MMTA - GI/GU - High	Early - Community	0	1.0883	3
1JC21	MMTA - GI/GU - High	Early - Community	1	1.1453	2
1JC31	MMTA - GI/GU - High	Early - Community	2	1.2971	2
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3005	3
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.3576	3
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5093	3
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7649	2
3JC21	MMTA - GI/GU - High	Late - Community	1	0.8220	2
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9738	2
4JC11	MMTA - GI/GU - High	Late - Institutional	0	1.2278	3
4JC21	MMTA - GI/GU - High	Late - Institutional	1	1.2849	3
4JC31	MMTA - GI/GU - High	Late - Institutional	2	1.4366	3
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.8924	3
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9495	2
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.1012	2
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	1.1046	3
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	1.1617	3
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.3135	3
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5691	2
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.6261	2
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7779	2
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	1.0319	3
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	1.0890	3
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	1.2407	3
1JB11	MMTA - GI/GU - Medium	Early - Community	0	0.9891	3
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.0461	3
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.1979	3
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2013	3
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.2584	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4101	3
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6657	2
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7228	2
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8746	2
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1286	3
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.1857	3
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3374	3
1KC11	MMTA - Infectious - High	Early - Community	0	1.1296	2
1KC21	MMTA - Infectious - High	Early - Community	1	1.1867	2
1KC31	MMTA - Infectious - High	Early - Community	2	1.3384	2
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3419	3
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.3990	3
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.5507	3
3KC11	MMTA - Infectious - High	Late - Community	0	0.8063	2
3KC21	MMTA - Infectious - High	Late - Community	1	0.8634	2
3KC31	MMTA - Infectious - High	Late - Community	2	1.0151	2
4KC11	MMTA - Infectious - High	Late - Institutional	0	1.2691	3
4KC21	MMTA - Infectious - High	Late - Institutional	1	1.3262	3
4KC31	MMTA - Infectious - High	Late - Institutional	2	1.4780	3
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9108	2
1KA21	MMTA - Infectious - Low	Early - Community	1	0.9679	2
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1197	2
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1231	3
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.1802	3
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3319	3
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5875	2
3KA21	MMTA - Infectious - Low	Late - Community	1	0.6446	2
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7963	2
4KA11	MMTA - Infectious - Low	Late - Institutional	0	1.0503	3
4KA21	MMTA - Infectious - Low	Late - Institutional	1	1.1074	3
4KA31	MMTA - Infectious - Low	Late - Institutional	2	1.2592	3
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0001	3
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.0572	2
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2090	2
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2124	3
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.2695	3
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4212	3
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6768	2
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7339	2
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8856	2
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1396	3
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.1967	3
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3485	3
1AC11	MMTA - Other - High	Early - Community	0	1.0870	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1AC21	MMTA - Other - High	Early - Community	1	1.1441	3
1AC31	MMTA - Other - High	Early - Community	2	1.2958	3
2AC11	MMTA - Other - High	Early - Institutional	0	1.2992	4
2AC21	MMTA - Other - High	Early - Institutional	1	1.3563	4
2AC31	MMTA - Other - High	Early - Institutional	2	1.5081	4
3AC11	MMTA - Other - High	Late - Community	0	0.7636	2
3AC21	MMTA - Other - High	Late - Community	1	0.8207	2
3AC31	MMTA - Other - High	Late - Community	2	0.9725	2
4AC11	MMTA - Other - High	Late - Institutional	0	1.2265	3
4AC21	MMTA - Other - High	Late - Institutional	1	1.2836	3
4AC31	MMTA - Other - High	Late - Institutional	2	1.4353	3
1AA11	MMTA - Other - Low	Early - Community	0	0.9152	3
1AA21	MMTA - Other - Low	Early - Community	1	0.9723	3
1AA31	MMTA - Other - Low	Early - Community	2	1.1240	3
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1274	3
2AA21	MMTA - Other - Low	Early - Institutional	1	1.1845	3
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3363	4
3AA11	MMTA - Other - Low	Late - Community	0	0.5918	2
3AA21	MMTA - Other - Low	Late - Community	1	0.6489	2
3AA31	MMTA - Other - Low	Late - Community	2	0.8007	2
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0547	3
4AA21	MMTA - Other - Low	Late - Institutional	1	1.1118	3
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2635	3
1AB11	MMTA - Other - Medium	Early - Community	0	0.9930	4
1AB21	MMTA - Other - Medium	Early - Community	1	1.0501	4
1AB31	MMTA - Other - Medium	Early - Community	2	1.2019	4
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.2053	4
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.2624	4
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.4141	4
3AB11	MMTA - Other - Medium	Late - Community	0	0.6697	2
3AB21	MMTA - Other - Medium	Late - Community	1	0.7268	2
3AB31	MMTA - Other - Medium	Late - Community	2	0.8785	2
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1325	3
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.1896	3
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.3414	4
1LC11	MMTA - Respiratory - High	Early - Community	0	1.0978	3
1LC21	MMTA - Respiratory - High	Early - Community	1	1.1549	3
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3067	3
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3101	4
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.3672	3
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5189	4
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7745	2
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8316	2
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9833	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4LC11	MMTA - Respiratory - High	Late - Institutional	0	1.2373	3
4LC21	MMTA - Respiratory - High	Late - Institutional	1	1.2944	3
4LC31	MMTA - Respiratory - High	Late - Institutional	2	1.4462	3
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9028	3
1LA21	MMTA - Respiratory - Low	Early - Community	1	0.9599	2
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1116	2
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1151	3
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.1721	3
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3239	3
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5795	2
3LA21	MMTA - Respiratory - Low	Late - Community	1	0.6366	2
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7883	2
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	1.0423	3
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	1.0994	3
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	1.2511	3
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0015	3
1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.0586	3
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2103	3
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2137	4
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.2708	4
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4226	4
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6781	2
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7352	2
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8870	2
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1410	3
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.1981	3
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3498	3
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	1.1227	3
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	1.1798	2
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	1.3315	2
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	1.3349	4
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	1.3920	4
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	1.5438	4
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	0.7993	2
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	0.8564	2
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	1.0082	2
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	1.2622	3
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	1.3193	3
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	1.4710	4
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	0.8940	2
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	0.9511	2
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	1.1028	2
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	1.1062	3
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	1.1633	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	1.3151	4
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	0.5706	2
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	0.6277	2
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	0.7795	2
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	1.0335	2
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	1.0906	3
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	1.2423	3
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	0.9988	3
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.0559	2
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2076	2
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2110	3
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.2681	4
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4199	4
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6755	2
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7325	2
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8843	2
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.1383	3
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.1954	3
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.3471	4
1EC11	MS Rehab - High	Early - Community	0	1.1568	5
1EC21	MS Rehab - High	Early - Community	1	1.2139	4
1EC31	MS Rehab - High	Early - Community	2	1.3656	4
2EC11	MS Rehab - High	Early - Institutional	0	1.3691	5
2EC21	MS Rehab - High	Early - Institutional	1	1.4262	5
2EC31	MS Rehab - High	Early - Institutional	2	1.5779	5
3EC11	MS Rehab - High	Late - Community	0	0.8335	2
3EC21	MS Rehab - High	Late - Community	1	0.8906	2
3EC31	MS Rehab - High	Late - Community	2	1.0423	3
4EC11	MS Rehab - High	Late - Institutional	0	1.2963	4
4EC21	MS Rehab - High	Late - Institutional	1	1.3534	4
4EC31	MS Rehab - High	Late - Institutional	2	1.5051	4
1EA11	MS Rehab - Low	Early - Community	0	0.9432	4
1EA21	MS Rehab - Low	Early - Community	1	1.0003	4
1EA31	MS Rehab - Low	Early - Community	2	1.1520	4
2EA11	MS Rehab - Low	Early - Institutional	0	1.1554	4
2EA21	MS Rehab - Low	Early - Institutional	1	1.2125	4
2EA31	MS Rehab - Low	Early - Institutional	2	1.3643	5
3EA11	MS Rehab - Low	Late - Community	0	0.6199	2
3EA21	MS Rehab - Low	Late - Community	1	0.6769	2
3EA31	MS Rehab - Low	Late - Community	2	0.8287	2
4EA11	MS Rehab - Low	Late - Institutional	0	1.0827	4
4EA21	MS Rehab - Low	Late - Institutional	1	1.1398	4
4EA31	MS Rehab - Low	Late - Institutional	2	1.2915	4
1EB11	MS Rehab - Medium	Early - Community	0	1.0260	5

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1EB21	MS Rehab - Medium	Early - Community	1	1.0830	4
1EB31	MS Rehab - Medium	Early - Community	2	1.2348	4
2EB11	MS Rehab - Medium	Early - Institutional	0	1.2382	5
2EB21	MS Rehab - Medium	Early - Institutional	1	1.2953	5
2EB31	MS Rehab - Medium	Early - Institutional	2	1.4470	5
3EB11	MS Rehab - Medium	Late - Community	0	0.7026	2
3EB21	MS Rehab - Medium	Late - Community	1	0.7597	2
3EB31	MS Rehab - Medium	Late - Community	2	0.9115	2
4EB11	MS Rehab - Medium	Late - Institutional	0	1.1655	4
4EB21	MS Rehab - Medium	Late - Institutional	1	1.2226	4
4EB31	MS Rehab - Medium	Late - Institutional	2	1.3743	4
1BC11	Neuro - High	Early - Community	0	1.2639	4
1BC21	Neuro - High	Early - Community	1	1.3210	4
1BC31	Neuro - High	Early - Community	2	1.4728	4
2BC11	Neuro - High	Early - Institutional	0	1.4762	4
2BC21	Neuro - High	Early - Institutional	1	1.5333	4
2BC31	Neuro - High	Early - Institutional	2	1.6850	4
3BC11	Neuro - High	Late - Community	0	0.9406	2
3BC21	Neuro - High	Late - Community	1	0.9977	3
3BC31	Neuro - High	Late - Community	2	1.1494	3
4BC11	Neuro - High	Late - Institutional	0	1.4034	4
4BC21	Neuro - High	Late - Institutional	1	1.4605	4
4BC31	Neuro - High	Late - Institutional	2	1.6123	4
1BA11	Neuro - Low	Early - Community	0	1.0241	4
1BA21	Neuro - Low	Early - Community	1	1.0812	4
1BA31	Neuro - Low	Early - Community	2	1.2329	4
2BA11	Neuro - Low	Early - Institutional	0	1.2364	4
2BA21	Neuro - Low	Early - Institutional	1	1.2935	4
2BA31	Neuro - Low	Early - Institutional	2	1.4452	4
3BA11	Neuro - Low	Late - Community	0	0.7008	2
3BA21	Neuro - Low	Late - Community	1	0.7579	2
3BA31	Neuro - Low	Late - Community	2	0.9096	2
4BA11	Neuro - Low	Late - Institutional	0	1.1636	3
4BA21	Neuro - Low	Late - Institutional	1	1.2207	3
4BA31	Neuro - Low	Late - Institutional	2	1.3724	3
1BB11	Neuro - Medium	Early - Community	0	1.1217	4
1BB21	Neuro - Medium	Early - Community	1	1.1788	4
1BB31	Neuro - Medium	Early - Community	2	1.3305	4
2BB11	Neuro - Medium	Early - Institutional	0	1.3340	4
2BB21	Neuro - Medium	Early - Institutional	1	1.3911	4
2BB31	Neuro - Medium	Early - Institutional	2	1.5428	4
3BB11	Neuro - Medium	Late - Community	0	0.7984	2
3BB21	Neuro - Medium	Late - Community	1	0.8555	2
3BB31	Neuro - Medium	Late - Community	2	1.0072	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4BB11	Neuro - Medium	Late - Institutional	0	1.2612	4
4BB21	Neuro - Medium	Late - Institutional	1	1.3183	4
4BB31	Neuro - Medium	Late - Institutional	2	1.4701	4
1CC11	Wound - High	Early - Community	0	1.5010	4
1CC21	Wound - High	Early - Community	1	1.5581	4
1CC31	Wound - High	Early - Community	2	1.7098	4
2CC11	Wound - High	Early - Institutional	0	1.7132	4
2CC21	Wound - High	Early - Institutional	1	1.7703	4
2CC31	Wound - High	Early - Institutional	2	1.9221	4
3CC11	Wound - High	Late - Community	0	1.1776	3
3CC21	Wound - High	Late - Community	1	1.2347	3
3CC31	Wound - High	Late - Community	2	1.3865	3
4CC11	Wound - High	Late - Institutional	0	1.6405	4
4CC21	Wound - High	Late - Institutional	1	1.6976	4
4CC31	Wound - High	Late - Institutional	2	1.8493	4
1CA11	Wound - Low	Early - Community	0	1.2803	4
1CA21	Wound - Low	Early - Community	1	1.3373	4
1CA31	Wound - Low	Early - Community	2	1.4891	4
2CA11	Wound - Low	Early - Institutional	0	1.4925	4
2CA21	Wound - Low	Early - Institutional	1	1.5496	4
2CA31	Wound - Low	Early - Institutional	2	1.7013	4
3CA11	Wound - Low	Late - Community	0	0.9569	2
3CA21	Wound - Low	Late - Community	1	1.0140	3
3CA31	Wound - Low	Late - Community	2	1.1658	3
4CA11	Wound - Low	Late - Institutional	0	1.4198	4
4CA21	Wound - Low	Late - Institutional	1	1.4769	4
4CA31	Wound - Low	Late - Institutional	2	1.6286	4
1CB11	Wound - Medium	Early - Community	0	1.3745	4
1CB21	Wound - Medium	Early - Community	1	1.4316	4
1CB31	Wound - Medium	Early - Community	2	1.5833	4
2CB11	Wound - Medium	Early - Institutional	0	1.5868	4
2CB21	Wound - Medium	Early - Institutional	1	1.6439	4
2CB31	Wound - Medium	Early - Institutional	2	1.7956	4
3CB11	Wound - Medium	Late - Community	0	1.0512	3
3CB21	Wound - Medium	Late - Community	1	1.1083	3
3CB31	Wound - Medium	Late - Community	2	1.2600	3
4CB11	Wound - Medium	Late - Institutional	0	1.5140	4
4CB21	Wound - Medium	Late - Institutional	1	1.5711	4
4CB31	Wound - Medium	Late - Institutional	2	1.7229	4

Source: *CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.*

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Changes to the PDGM case-mix weights are implemented in a budget neutral manner by multiplying the CY 2027 national standardized 30-day period payment rate by a case-mix budget neutrality factor. Typically, the case-mix weight budget neutrality factor is also calculated using the most recent, complete home health claims data available. For CY 2027, we will continue the practice of using the most

recent complete home health claims data at the time of rulemaking, which is CY 2025 data. The case-mix budget neutrality factor is calculated as the ratio of 30-day base payment rates such that total payments when the CY 2027 PDGM case-mix weights (developed using CY 2025 home health claims data) are applied to CY 2025 utilization (claims) data are equal to total payments when CY 2026 PDGM case-mix weights (developed using CY 2024 home health claims data) are applied to CY 2025 utilization data. This produces a case-mix budget neutrality factor for CY 2027 of 1.0045.

We invited public comments on the CY 2027 proposed case-mix weights and proposed case-mix weight budget neutrality factor. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed support for CMS's practice of annually recalibrating case-mix weights using the most recent complete claims and OASIS data and generally agreed this practice is necessary to keep payment aligned with current utilization and clinical patterns.

Response: CMS appreciates commenters' support for the annual recalibration methodology required to maintain payment accuracy under the PDGM.

Comment: Some commenters raised concerns that recalibration may systematically underpay for high complexity, caregiver intensive patients (Alzheimer's disease and related dementias, wound care, high-acuity/dual-eligible populations), potentially discouraging HHAs from accepting them. Specifically, a commenter stated that the Wound clinical group, a high-acuity home health population, appears to take the largest case-mix cut. While, by contrast, MMTA–Endocrine sees a comparatively favorable increase. This commenter expressed concern that this shifts care away from HHAs who accept more complex patients, while rewarding low-acuity billing patterns.

Commenters also suggested that historical claims data used for recalibration may be distorted by what they describe as fraud/outlier billing (particularly in Los Angeles County) and COVID–19 PHE anomalies, which results in annual volatility in thresholds that ultimately creates operational/planning challenges. Commenters stated that this is especially the case for those HHAs whose patients differ from national averages leading to disproportionate payment shifts unrelated to actual patient needs.

Response: CMS notes that case-mix weights are derived from resource use patterns reflected in the most recent complete claims and assessment data, consistent with the statutory requirement to base weights on actual utilization. CMS also reminds stakeholders that the use of percentile trimming methodologies currently applied to claims data are designed to limit the influence of individual outlier claims. That said, for CY 2027, the use of CY 2025 claims represents the most complete and current data available. Also, as it relates to stakeholders' concerns regarding fraudulent/anomalous claims, we note that the recalibration methodology finalized in the CY 2019 HH PPS rule (83 FR 56502) is applied nationally and is based on the aggregate relationship between patient characteristics and observed resource use. To add, the program integrity issues are addressed through separate oversight channels and do not alter the statutory requirement for recalibrations to be implemented in a budget-neutral manner, as required by section 1895(b)(3)(A)(i) of the Act. We acknowledge that annual recalibration may contribute to year-to-year variability, but the overarching intent is to align payments as closely as possible with actual resource use. Finally, we note that the case-mix weights for high-intensity clinical and functional groups such as complex nursing, wound care, and the rehabilitation groups remain among the highest weighted case-mix weight categories for the finalized CY 2027 Home Health recalibration update. For example, the Wound-High Functional Impairment-Early-Institutional-High Comorbidity carries a case-mix weight of 1.9221, and the MMTA-Endocrine-High Functional Impairment-Early-Institutional-High Comorbidity has a case-mix weight of 1.7469. This indicates that recalibrated weights continue to account for the increased resource needs and costs associated with providing care to high-acuity patients, helping to ensure the adequate provision of needed home health services. Moreover, fraud, waste and abuse cannot be determined through claims data analysis alone. Thus, targeted program integrity efforts (which may involve examining individual providers and claims via established processes) remain the appropriate mechanism to identify and address fraud, waste and abuse. When providers are removed from the Medicare program, their claims are no longer reflected in subsequent rate-setting data. However, removal from the Medicare program for fraud, waste and abuse requires adjudicatory process. CMS cannot presumptively exclude all claims from the recalibration data set based on geographic location (such as Los Angeles County, as raised by commenters) or general utilization patterns (such as anomalous or outlier claims), and deem them as fraudulent absent this adjudicatory process or simply because of stakeholders' assertions alone. Nevertheless, CMS will continue to evaluate ways to improve transparency while monitoring broader system trends such as rising acuity, workforce shortages, and operational costs, as appropriate.

Comment: One commenter raised a distinct case-mix-adjacent concern regarding the admission-source variable used in the HH PPS case-mix adjustment methodology. This commenter noted that the CY 2026 Hospital Outpatient Prospective Payment System final rule finalized a three-year phasing out of the inpatient only list with an expansion of procedures permitted in ambulatory surgical centers. The commenter stated that as care continues shifting from inpatient to outpatient settings, the admission source distribution used in case-mix adjustment will change in ways not fully captured by historical home health claims data, and asked CMS to continue monitoring and assessing whether refinements to the admission-source variable are warranted.

Response: We acknowledge this comment and reiterate our commitment to continue monitoring whether refinements to the admission-source variable are warranted for consideration in future rulemaking as appropriate.

Final Decision: We are finalizing the recalibrated case-mix weights for CY 2027, updated with claims data as of July 14, 2026. We did not receive any comments on the proposed case-mix weight budget neutrality factor. Therefore, we are finalizing the proposal to implement the changes to the PDGM case-mix weights in a budget neutral manner by applying a case-mix budget neutrality factor to the CY 2027 national, standardized 30-day period payment rate. As stated previously, the final case-mix budget neutrality factor for CY 2027 is 1.0047.

E. Final CY 2027 Home Health Payment Rate Updates

1. Final CY 2027 Home Health Market Basket Update for HHAs

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for home health be increased by a factor equal to the applicable home health market basket update for those HHAs that submit

quality data as required by the Secretary. In the CY 2024 HH PPS final rule (88 FR 77726), we finalized a rebasing of the home health market basket to reflect 2021 cost report data. We also finalized a policy for CY 2024 and subsequent years that the labor-related share is 74.9 percent, and the non-labor-related share is 25.1 percent. A detailed description of how we rebased the home health market basket and labor-related share is available in the CY 2024 HH PPS final rule (88 FR 77726 through 77742).

In the CY 2015 HH PPS final rule (79 FR 38384), we finalized our methodology for calculating and applying the productivity adjustment. As we explained in that rule, section 1895(b)(3)(B)(vi) of the Act, requires that, in CY 2015 (and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015)) and CY 2020 (under section 53110 of the Balanced Budget Act of 2018)), the market basket percentage under the HH PPS as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is published by BLS as private nonfarm business total factor productivity (TFP) (previously referred to as multifactor productivity).[5] We refer readers to *https://www.bls.gov/productivity* for the BLS historical published TFP data. A complete description of IHS Global Inc.'s (IGI) TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.*

The proposed home health update percentage for CY 2027 was based on the estimated home health market basket percentage increase, specified at section 1895(b)(3)(B)(iii) of the Act, of 3.1 percent (based on IHS Global Inc.'s first quarter 2026 forecast with historical data through fourth quarter 2025). The estimated CY 2027 proposed home health market basket percentage increase of 3.1 percent was then reduced by a productivity adjustment, in accordance with section 1895(b)(3)(B)(vi) of the Act. Based on IGI's first quarter 2026 forecast, the proposed productivity adjustment was estimated to be 1.0 percentage point for CY 2027. Therefore, the proposed productivity-adjusted CY 2027 home health market basket update was 2.1 percent (proposed 3.1 percent market basket percentage increase, reduced by a proposed 1.0 percentage point productivity adjustment). Furthermore, we proposed that if more recent data became available (for example, a more recent estimate of the market basket percentage increase and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 market basket percentage increase and productivity adjustment in the final rule.

Section 1895(b)(3)(B)(v) of the Act requires that the home health percentage update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2027, the proposed home health payment update percentage was 0.1 percent (2.1 percent minus 2 percentage points).

We invited public comments on the proposed CY 2027 home health market basket percentage increase and productivity adjustment.

We received public comments on the proposed home health update percentage. The following is a summary of the comments we received and our responses.

Comment: While several commenters expressed support for the proposed 2.1 percent market basket update, many expressed that the proposed market basket percentage increase is inadequate to offset actual growth in the cost of furnishing home health care. Commenters most frequently cited rising labor costs (including wages, benefits, and recruitment/retention expenses), transportation and fuel costs, medical supply and pharmaceutical costs, and technology, cybersecurity, and regulatory compliance costs as exceeding the rate of the proposed market basket update.

A few commenters noted that cumulative market basket updates from CY 2020 through CY 2027 have lagged behind overall inflation indices such as the Employer Cost Index for Total Compensation and the Producer Price Index for All Commodities over the same period.

A few commenters requested that CMS clarify its market basket forecasting methodology and publish underlying data supporting the update calculation.

Response: Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. The home health market basket is a fixed-weight, Laspeyres-type price index, which measures the change in price, over time, of the mix of goods and services included in home health services that were purchased in the base period. Therefore, the market basket is designed to measure price inflation for HHAs and does not reflect increases in costs associated with changes in the volume or intensity of input goods and services. The home health market basket was last rebased to reflect a 2021 base year effective for CY 2024. We refer commenters to the CY 2024 HH PPS final rule (88 FR 77726) for a detailed description of the methodology used to rebase the home health market basket.

CMS understands that the market basket updates may differ from other overall inflation indexes; however, we reiterate that these topline indexes are not comparable since they measure different mixes of products, services, or wages than the legislatively defined CMS home health market basket. CMS welcomes feedback on alternative data sources for the market basket price proxies that appropriately measure price inflation and not costs. Suggestions can be emailed to *cmsdnhs@cms.hhs.gov.*

We acknowledge commenters' requests for CMS to provide additional information on the assumptions and inputs that go into developing a market basket update. As previously noted, the detailed market basket cost weights (including the methodology) and price proxies used in the market baskets were set forth in the CY 2024 HH PPS final rule (88 FR 77726). Additionally, we continually make available on the CMS website (*https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-data*) the detailed historical growth rates for the market baskets as well as price forecasts for the aggregated cost weights (such as compensation and utilities). We reiterate that the price proxy forecasts that underlie the home health market basket percentage increase (and all CMS market baskets) are derived from proprietary data produced by IHS

[5] *https://www.bls.gov/productivity/notices/2021/mfp-to-tfp-term-change.htm.*

Global Inc. (IGI), a nationally recognized economic and financial forecasting firm. Because these forecasts are proprietary to IGI, CMS cannot make the full underlying data publicly available. CMS uses independent, third-party forecasting services such as IGI specifically to ensure that the market basket projections reflect sound, objective economic analysis. We also note that when developing its forecast for the various price indexes used in the home health market basket, IGI considers industry-specific and overall macroeconomic factors that influence pricing trends. We strive for transparency regarding our methods and note that general inquiries on the forecasting methodology can be emailed to *cmsdnhs@cms.hhs.gov.*

Comment: Several commenters identified a cumulative home health market basket forecast error of approximately 7.3 to 7.6 percentage points for calendar years 2021 through 2025. Commenters assert that this forecast error has been permanently embedded in the home health payment rates contributing to the chronic underfunding of home health services relative to actual costs incurred.

Some commenters requested that CMS finalize a one-time forecast error correction of approximately 7.6 percentage points to remedy this cumulative underpayment.

Response: While the projected home health market basket updates have recently been underforecast (actual increases less forecasted increases were positive), over longer periods the forecasts have generally averaged close to the historical measures. The cumulative forecast error since HH PPS inception (fiscal year 2002 to CY 2025, excluding CY 2018 and CY 2020 when the market basket update was statutorily mandated) is 0.5 percent. CMS will continue to monitor the methods associated with the market basket forecasts as appropriate to ensure there are not underlying systematic issues in the forecasting approach.

We note that the recent underforecast of the home health market basket increase was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID–19 PHE. However, an analysis of the forecast error of the home health market basket over a longer period of time shows the forecast error has been both positive and negative. Only considering the forecast error for years when the final home health market basket update was lower than the actual market basket update does not consider the full experience and impact of forecast error, in particular the numerous years that providers benefited from the forecast error.

For these reasons, we continue to believe it is not appropriate to include adjustments to the market basket update for future years based on the difference between the actual and forecasted market basket increase in prior years.

Comment: Several commenters stated that the statutorily required 1.0 percentage point productivity adjustment does not reflect the operational realities of home health care delivery. These commenters characterized home health as a labor-intensive service delivered to one patient at a time in dispersed geographic settings, arguing that meaningful productivity gains of the magnitude assumed by the broader economy-wide total factor productivity measure are not achievable in this care setting.

A few commenters cited an analysis by the CMS Office of the Actuary suggesting that only approximately 0.1 percentage point of productivity gain is realistically achievable for home health, which is substantially less than the proposed 1.0 percentage point reduction.

A few commenters noted that the proposed 1.0 percent home health productivity adjustment is inconsistent with the 0.9 percent productivity adjustment applied to hospice payments, despite the similarity of the two programs' labor-intensive, in-home workforce models, and requested that CMS reconcile this discrepancy.

One commenter stated that the productivity adjustment has been applied asymmetrically over time, noting that CMS set the productivity adjustment to zero in FY 2021 a year when application of the standard methodology would have increased (not decreased) payments, and asserted that this asymmetry has widened the gap between home health payments and actual provider costs over time.

A few commenters suggested that CMS work with Congress or use its ''special exceptions and adjustments'' authority to reduce or waive the 1.0 percent productivity adjustment for CY 2027 in light of workforce shortages and rising patient acuity.

Response: Section 1895(b)(3)(B)(vi) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the HH PPS market basket increase factor. As required by statute, the CY 2027 productivity adjustment is derived based on the 10-year moving average growth in economy-wide nonfarm business TFP for the period ending in CY 2027. We recognize the concerns of commenters regarding the appropriateness of the productivity adjustment; however, we are required under section 1895(b)(3)(B)(vi) of the Act to apply the specific productivity adjustment described here.

We note that the differing productivity adjustments between home health and hospice that commenters identified are due to timing and data availability rather than industry characteristics. Both productivity adjustments use the most recent published BLS historical TFP data (*https://www.bls.gov/productivity*) at the time of rulemaking, and IGI's projection model (*https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/tfp_methodology.pdf*) is used to derive annual TFP growth rates for 2026 and 2027. The annual index level derived from this method is then interpolated to quarterly levels, and the FY 2027, or hospice, productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending September 30, 2027 relative to the 40-quarter moving average projected level for the period ending September 30, 2026. For more information on the FY 2027 productivity adjustment used to update hospice rates, refer to the FY 2027 Hospital Inpatient Prospective Payment System Final Rule (91 FR 49931). Similarly, the CY 2027, or home health, productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending December 31, 2027 relative to the 40-quarter moving average projected level for the period ending December 31, 2026. We believe our methodology for the productivity adjustment is consistent with section 1886(b)(3)(B)(xi)(II) of the Act, which states that the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

At the time of this final rule, the 2027 productivity adjustment reflects BLS historical TFP data through 2025 (released on March 19, 2026) and IGI's forecasted TFP growth for 2026 and 2027. The average annual growth rate of historical TFP published by BLS for 2018 through 2025 is currently 1.0 percent and IGI is projecting average TFP growth of about 0.9 percent for 2026 and 2027 based on IGI's third quarter 2026 forecast. Combining the

historical and projected TFP data over the entire 10-year time period and interpolating into quarterly index levels results in a 10-year moving average growth rate of TFP of 1.0 percent for CY 2027 (unchanged from the CY 2027 HH PPS proposed rule).

In response to commenters' concerns about the productivity adjustment only being applied if it reduces the payment update, we note that the productivity adjustment was established under the Affordable Care Act with a specific policy intent to encourage efficiency improvements in healthcare delivery by linking Medicare payment updates to economy-wide productivity gains. The statutory language in section 1895(b)(3)(B)(vi) of the Act requires that the Secretary reduce the market basket percentage increase by changes in economy-wide productivity; therefore, only productivity adjustments that reduce the market basket percentage increase in a given year are applied.

Furthermore, we appreciate the commenters' recommendations for CMS to work with Congress or use its ''special exceptions and adjustments'' authority to reduce or waive the 1.0 percent productivity adjustment for CY 2027 in light of workforce shortages and rising patient acuity. However, the productivity adjustment is required by statute and is not subject to the Secretary's discretion. Any change to how the productivity adjustment is calculated or applied would require a legislative change, not a regulatory one.

We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing, as proposed, to use more recent data to determine the CY 2027 productivity adjustment for the final rule.

Final Decision: Consistent with section 1895(b)(3)(B)(vi) of the Act, we are finalizing the home health payment update methodology. The market basket percentage increase for CY 2027 for the HH PPS is based on IGI's third quarter 2026 forecast of the home health market basket percentage increase, which is estimated to be 3.1 percent. As outlined earlier in this section, we are applying a 1.0 percentage point productivity adjustment to the CY 2027 home health market basket percentage increase. Therefore, the final CY 2027 home health market basket update is equal to 2.1 percent for HHAs that submit quality data and 0.1 percent for HHAs that do not submit quality data.

2. Final CY 2027 Home Health Wage Index

a. Background

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to home health payments. We proposed to continue this practice for CY 2027, as it is our belief that, in the absence of home health-specific wage data that accounts for area differences, using inpatient hospital wage data, including taking into account any changes made by the Office of Management and Budget (OMB) to Metropolitan Statistical Area (MSA) definitions, is appropriate and reasonable for the HH PPS.

In general, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017, OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018, OMB Bulletin No. 18–03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.* In the CY 2021 HH PPS final rule (85 FR 70298), we finalized our proposal to adopt the revised OMB delineations with a 5 percent cap on wage index decreases in CY 2021.

On July 21, 2023, OMB issued Bulletin No. 23–01, which updates and supersedes OMB Bulletin No. 20–01, issued on March 6, 2020. OMB Bulletin No. 23–01 establishes revised delineations for the MSAs, Micropolitan Statistical Areas, Combined Statistical Areas, and Metropolitan Divisions, collectively referred to as Core Based Statistical Areas (CBSAs). A copy of OMB Bulletin No. 23–01 is available online at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.*

According to OMB, the delineations from OMB Bulletin 23–01 reflect the 2020 Standards for Delineating Core Based Statistical Areas (CBSAs) (the ''2020 Standards''), which appeared in the **Federal Register** (86 FR 37770 through 37778) on July 16, 2021, and application of those standards to Census Bureau population and journey-to-work data (for example, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). The OMB ''2020 Standards'' define a ''Metropolitan Statistical Area'' as being associated with at least one Urban Area that has a population of at least 50,000 and a ''Micropolitan Statistical Area'' as being associated with at least one Urban Area that has a population of at least 10,000, but less than 50,000 (86 FR 37778).

In the CY 2025 HH PPS final rule (89 FR 88354), we finalized our proposal to adopt the revised OMB delineations from OMB Bulletin 23–01 with a 5 percent cap on wage index decreases at the CBSA level as well as at the county level. In that final rule we stated that we believe it is important for the HH PPS wage index to use the latest OMB delineations available in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We also stated that we believe using the most current OMB delineations will increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels. In conjunction with our implementation of the revised labor market delineations beginning in CY 2025, and consistent with the treatment of Micropolitan Statistical Areas under the Inpatient Prospective Payment System (IPPS), we also finalized continuing to treat Micropolitan Statistical Areas as ''rural'' and including Micropolitan Statistical Areas in the calculation of each state's statewide rural wage index. Therefore, the HH PPS statewide rural wage index is determined using IPPS hospital data from hospitals located in Micropolitan Statistical Areas and the HH PPS wage index for each CBSA is determined using IPPS hospital data from hospitals located in Metropolitan Statistical Areas.

b. Five Percent Cap on Wage Index Decreases

In the CY 2023 HH PPS final rule (87 FR 66851 through 66853), we finalized a policy that the CY HH PPS wage index will include a permanent 5 percent cap on wage index decreases for CY 2023

and each subsequent year. Specifically, we finalized, for CY 2023 and subsequent years, the application of a permanent 5 percent cap on any decrease to a geographic area's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, we finalized a policy requiring that a geographic area's wage index for CY 2023 will not be less than 95 percent of its final wage index for CY 2022, regardless of whether the geographic area is part of an updated CBSA, and that for subsequent years, a geographic area's wage index will not be less than 95 percent of its wage index calculated in the prior CY.

Previously this methodology was applied to all counties that make up a CBSA or statewide rural area. However, in the CY 2025 HH PPS final rule (89 FR 88418 through 88421), because of the adoption of the revised OMB delineations from OMB Bulletin 23–01, we finalized a policy applying this methodology to individual counties. Specifically, we finalized a policy applying the 5 percent cap to counties that moved from a CBSA or statewide rural area with a higher wage index value into a new CBSA or statewide rural area with a lower wage index value, so that the county's CY 2025 wage index would not be less than 95 percent of the county's CY 2024 wage index value under the old delineation despite moving into a new delineation with a lower wage index.

Due to the way that we proposed calculating the 5 percent cap for counties that experienced an OMB designation change, some CBSAs and statewide rural areas could have had more than one wage index value. Specifically, some counties that changed OMB designations had a wage index value that was different than the wage index value assigned to the other constituent counties that made up that CBSA or statewide rural area that they moved into after the application of the 5 percent cap. However, for home health claims processing, each CBSA or statewide rural area can have only one wage index value assigned to that CBSA or statewide rural area. Therefore, we finalized a policy, beginning in CY 2025, that counties that have a different wage index value than the CBSA or rural area into which they are designated after the application of the 5 percent cap will use a wage index transition code. These special codes are five digits in length and begin with ''50'' and the remaining digits are unique for that code. The 50XXX wage index transition codes are used only in specific counties; counties located in CBSAs and rural areas that do not correspond to a different transition wage index value will still use the CBSA number.

We also finalized a policy applying the 5 percent cap to these specific counties that correspond to a different wage index value due to a delineation change until the county's new wage index is more than 95 percent of the wage index from the previous calendar year. In order to capture the correct wage index value, an HHA will continue to use the assigned 50XXX transition code on home health claims for services in these counties until the county's wage index value calculated for that calendar year using the new OMB delineations is not less than 95 percent of the county's capped wage index from the previous calendar year.

For CY 2027, the 5 percent cap on wage index decreases will continue to be calculated at the county level as well as the CBSA and statewide rural area level. While some counties that required a transition code for CY 2025 and CY 2026 will continue to use the same transition code for CY 2027, other counties that required a transition code in CY 2025 and CY 2026 will no longer require a transition code in CY 2027. The counties that will no longer require a transition code beginning in CY 2027 have a CY 2027 wage index value in the CBSA or rural area that the county was redesignated into that is higher than 95 percent of the county's CY 2026 wage index. Therefore, these counties will use the CBSA or rural county code of the area into which they were redesignated based on OMB Bulletin No. 23–01.

While we did not propose any changes to the 5 percent cap policy for CY 2027, we did receive a few comments on the finalized policies. The following is a summary of the comments we received and our responses:

Comment: A few commenters expressed support for the finalized 5 percent cap policy.

Response: We thank the commenters for their support.

Comment: Some commenters recommended changes to the finalized cap percentage. Specifically, some commenters suggested reducing the cap percentage. These commenters suggested that even wage-index declines within the 5 percent cap can erase most of the annual payment update in competitive markets like Pennsylvania, Northern California, and Michigan, leaving providers with net increases of only 0.4 to 0.5 percent. Therefore, a commenter recommended lowering the cap percentage to 2 percent, while another commenter requested a provider-level floor limiting total revenue loss to 1 percent. Another commenter suggested that CMS could limit a provider's wage-index-related payment loss relative to the overall annual payment update or adopt another methodology that provides a more gradual transition where updated geographic data produce substantial reductions.

Response: We appreciate commenters' recommendations for changes to the finalized 5 percent cap policy. However, we did not propose to make changes to this policy in the CY 2027 HH PPS proposed rule. Therefore, these comments are outside the scope of the proposed rule. Any changes to the finalized 5 percent cap policy would need to go through notice and comment rulemaking. However, consistent with our finalized 5-percent cap policy outlined in the CY 2023 HH PPS final rule (66851 through 66853), we continue to believe that 5 percent is a reasonable level for the cap because it would more effectively mitigate any significant decreases in a geographic area's wage index for a calendar year, while still balancing the importance of ensuring that area wage index values accurately reflect relative differences in area wage levels. Furthermore, we believe that the 5 percent cap on wage index decreases provides a degree of predictability in payment changes for providers and allows providers time to adjust to any significant decreases they may face year to year.

Final Decision: We did not propose any changes to the finalized 5 percent cap policy in the proposed rule. Therefore, the CY 2027 HH PPS wage index will continue to include the 5 percent cap on wage index decreases. For CY 2027, the 5 percent cap on wage index decreases will also continue to be calculated at the county level. While some counties that required a transition code for CY 2025 and CY 2026 will continue to use the same transition code for CY 2027, other counties that previously required a transition code will no longer require a transition code in CY 2027. These counties will use the CBSA or rural county code of the area they were redesignated into based on OMB Bulletin No. 23–01. The complete list of counties and corresponding transition codes can be found as a separate tab in the calendar year's wage index file located on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health-pps/home-health-pps-wage-index.*

c. Final CY 2027 HH PPS Wage Index

The appropriate wage index value is applied to the labor portion of the HH

PPS rates based on the site of service for the beneficiary (defined in section 1861(m) of the Act as the beneficiary's place of residence). For CY 2027, we proposed to base the HH PPS wage index on the FY 2027 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023 (FY 2023 cost report data). The CY 2027 HH PPS wage index would not take into account any geographic reclassification of hospitals, including those in accordance with sections 1886(d)(8)(B) or 1886(d)(10) of the Act but would include the 5 percent cap on wage index decreases as discussed previously.

There exist some geographic areas where there are no hospitals, and thus, no hospital wage data on which to base the calculation of the HH PPS wage index. To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2027 HH PPS wage index, we proposed to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals.

For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the State as a reasonable proxy for the wage index for that CBSA. For CY 2027, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). Using the average wage index of all urban areas in Georgia as a proxy, we proposed the CY 2027 wage index value for Hinesville, GA, would be 0.8797. With updated wage data, the final CY 2027 HH PPS wage index value for Hinesville, GA will be 0.8798.

For rural areas that do not have inpatient hospitals, we use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. The term ''contiguous'' means sharing a border (72 FR 49859). In the CY 2025 HH PPS final rule (89 FR 88422), we finalized a policy that rural North Dakota would become a rural area without a hospital from which hospital wage data can be derived. Therefore, in order to calculate the wage index for rural area 99935, North Dakota, we finalized using as a proxy, the average pre-floor, pre-reclassified hospital wage data from the contiguous CBSAs: CBSA 13900-Bismark, ND, CBSA 22020-Fargo, ND–MN, CBSA 24220-Grand Forks, ND–MN, and CBSA 33500, Minot, ND. Using this methodology, we proposed that the CY 2027 HH PPS wage index for rural North Dakota would be 0.8210. With updated wage data, the final CY 2027 HH PPS wage index for rural North Dakota is 0.8209.

Previously, the only rural area without a hospital from which hospital wage data could be derived was rural Puerto Rico. However, for rural Puerto Rico, we did not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the proximity of almost all of Puerto Rico's various urban and non-urban areas to one another, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we used the most recent wage index previously available for that area, which was 0.4047. Beginning in CY 2025, due to the adoption of the revised OMB delineations, there is now a hospital in rural Puerto Rico from which hospital wage data can be derived. Therefore, we finalized a policy that the wage index for rural Puerto Rico would now be based on the hospital wage data for the area instead of the previously available wage index of 0.4047.

The unadjusted CY 2027 proposed wage index for rural Puerto Rico is 0.2577. However, because 0.2577 is more than a 5 percent decline in the CY 2026 wage index, we proposed that the CY 2027 5 percent cap adjusted wage index for rural Puerto Rico be set equal to 95 percent of the CY 2026 wage index of 0.3653, which resulted in a proposed wage index value of 0.3470. With updated wage data, the unadjusted CY 2027 final wage index for rural Puerto Rico is 0.2576. However, because 0.2576 is more than a 5 percent decline in the CY 2026 wage index, the CY 2027 5 percent cap adjusted wage index for rural Puerto Rico will be set equal to 95 percent of the CY 2026 wage index of 0.3653, which results in a final wage index value of 0.3470.

Additionally, due to the adoption of the revised OMB delineations in the CY 2025 HH PPS final rule, Delaware, which was previously an all-urban state, now has one rural area with a hospital from which hospital wage data can be derived. As such, we proposed that the CY 2027 wage index for rural Delaware would be 0.9590. With updated wage data, the final CY 2027 wage index for rural Delaware is 0.9590.

Finally, the Northern Mariana Islands and American Samoa are rural areas with no hospital data from which a wage index can be calculated. In the CY 2026 HH PPS final rule (90 FR 55405), using our established methodology for rural areas with no hospitals, we finalized that for CY 2026 and subsequent years, HHAs that provide services in the Northern Mariana Islands and American Samoa would use CBSA 99965 (Guam) and receive the wage index assigned to CBSA 99965 (Guam) of 0.9611. While we appreciate that the islands of the Pacific Rim are not actually contiguous, we believe that same principle applies here, and that Guam is a reasonable proxy for American Samoa and the Northern Mariana Islands. We believe that CBSA 99965 (Guam) represents a reasonable proxy because the islands are located within the Pacific Rim and share a common status as United States Territories.

The final HH PPS wage index file applicable for CY 2027 (January 1, 2027, through December 31, 2027) is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health-pps/home-health-pps-wage-index.*

We received public comments on the proposed HH PPS wage index. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for the proposed CY 2027 HH PPS wage index.

Response: We thank the commenters for their support.

Comment: Commenters broadly criticized the current methodology of using the inpatient hospital pre-floor, pre-reclassified wage index as an inaccurate proxy for home health labor costs. With respect to Maryland, several commenters stated that the current wage index methodology imports the effects of Maryland's hospital cost-containment incentives into Medicare payment for home health providers, which creates a policy spillover where hospital wage data affected by Maryland's Total Cost of Care Model is used to reduce payment to providers that are outside the hospital global budget system. These commenters recommended that CMS avoid exporting hospital-specific budget incentives into the payment methodology for independent home health and other post-acute providers.

Response: We continue to believe that in the absence of home health specific data, the pre-floor, pre-reclassified hospital wage index is appropriate for the geographic adjustment of home health claims. While we did not propose any changes to the CY 2027 HH PPS wage index methodology in the proposed rule, we did request information on changes to the home health wage index methodology and may consider these recommendations and the comments received on the RFI in future rulemaking as appropriate. A discussion of the comments received on the RFI for a new home health specific

wage index can be found in section III.F. of this final rule.

Comment: Several commenters expressed concern that home health providers are unable to benefit from IPPS hospital wage index policies such as reclassification and the rural floor. A commenter recommended that CMS modify the agency's wage index policy to use the final FY 2027 hospital wage index, including geographic reclassifications and rural floor adjustments.

Response: While we appreciate the commenters' concerns that HHAs are unable to benefit from IPPS hospital wage index policies, we continue to believe that the regulations and statutes that govern the HH PPS differ from the hospital regulations and statutes, such that there would be differences between how these payment systems apply wage index policies including geographic reclassification, or the rural floor. Section 4410(a) of the Balanced Budget Act of 1997 provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that State. This rural floor provision is specific to hospitals. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Medicare Geographic Classification Review Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification for purposes of payment under the IPPS. This reclassification provision is only applicable to hospitals as defined in section 1886(d) of the Act. Therefore, we do not believe that using hospital reclassification data would be appropriate as these data are specific to the requesting hospitals.

Comment: Some commenters expressed concern that the current wage index methodology often fails to accurately capture the labor market realities experienced by rural HHAs. These commenters suggested that the current wage index ignores drive time, low population density, and travel expenses that increase rural care costs. One commenter noted that the wage index for Maine shows a 20 percent urban-rural wage gap when actual wages differ by less than 5 percent. Another commenter expressed concern that staff working for rural HHAs drive up to 600 miles a week without adequate mileage reimbursement. A commenter stated that due to the lower population density, more miles are driven between patients, increasing both direct costs and indirect costs through lower productivity.

Response: We appreciate commenters' concerns regarding the wage index values assigned to rural areas. As discussed in the CY 2022 HH PPS final rule (86 FR 62285), we do not believe that a population density adjustment is appropriate at this time. Rural HHAs continually cite the need for higher reimbursement due to the added cost of traveling from one patient to the next. However, urban HHAs cite the need for higher reimbursement due to the added costs associated with needed security measures and traffic congestion. The home health wage index values in rural areas are not necessarily lower than the home health wage index values in urban areas. The home health wage index reflects the wages that inpatient hospitals pay in their local geographic areas. Regarding the commenter's concern with the wage index values assigned to rural Maine versus the wage index values assigned to Maine's urban CBSAs, we believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the cost reports of hospitals in those specific labor market areas. The wage index values are based on data submitted on the inpatient hospital cost reports. Therefore, as previously stated, in the absence of home health specific data we believe that the pre-floor, pre-reclassified hospital wage index is an appropriate proxy for the home health wage index.

Comment: A commenter stated that although the aggregate effect of wage index changes may be budget neutral nationally, the distributional impact can create substantial financial challenges for providers operating in markets where reimbursement does not align with the costs of attracting and retaining qualified staff.

Response: We appreciate the commenter's concern that despite the wage index being budget neural nationally there may be distributional impacts to individual providers that can create substantial financial challenges. However, we reiterate that we believe the 5 percent cap on wage index decreases should provide a degree of predictability in payment changes for individual providers and allows providers time to adjust to any significant decreases they may face year to year.

Final Decision: After consideration of public comments, we are finalizing our proposal to base the HH PPS wage index on the FY 2027 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023 (FY 2023 cost report data). The final CY 2027 HH PPS wage index will include the 5 percent cap on wage index decreases. The final HH PPS wage index file applicable for CY 2027 (January 1, 2027, through December 31, 2027) is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health-pps/home-health-pps-wage-index.*

3. Final CY 2027 Home Health Payment Update

a. Background

The HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000, HH PPS final rule (65 FR 41128), the base unit of payment under the HH PPS was a national, standardized 60-day episode payment rate. As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), and as described in the CY 2020 HH PPS final rule with comment period (84 FR 60478), the unit of home health payment changed from a 60-day episode to a 30-day period effective for those 30-day periods beginning on or after January 1, 2020.

As set forth in § 484.220, we adjust the national, standardized prospective payment rates by a case-mix relative weight and a wage index value based on the site of service for the beneficiary. To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. In the CY 2024 HH PPS final rule (88 FR 77676), we finalized the rebasing of the home health market basket to reflect 2021 Medicare cost report data. We also finalized a policy that, for CY 2024 and subsequent years, the labor-related share is 74.9 percent, and the non-labor-related share is 25.1 percent. The following are the steps we take to compute the case-mix and wage-adjusted 30-day period payment amount for CY 2027:

- Multiply the national, standardized 30-day period rate by the patient's applicable case-mix weight.
- Divide the case-mix adjusted amount into a labor (74.9 percent) and a non-labor portion (25.1 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 30-day period payment amount, subject to any additional applicable adjustments.

We provide annual updates of the HH PPS rate in accordance with section 1895(b)(3)(B) of the Act. Section 484.225

sets forth the specific annual percentage update methodology. In accordance with section 1895(b)(3)(B)(v) of the Act and § 484.225(i), for an HHA that does not submit home health quality data, as specified by the Secretary, the unadjusted national prospective 30-day period rate is equal to the rate for the previous calendar year increased by the applicable home health payment update percentage, minus two percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will not be considered in computing the prospective payment amount for a subsequent calendar year.

The final claim that the HHA submits for payment determines the total payment amount for the period and whether we make an applicable adjustment to the 30-day case-mix and wage-adjusted payment amount. The end date of the 30-day period, as reported on the claim, determines which calendar year rates Medicare would use to pay the claim.

We may adjust a 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect the following:

- A LUPA is provided on a per-visit basis as set forth in §§ 484.205(d)(1) and 484.230.
- A partial payment adjustment as set forth in §§ 484.205(d)(2) and 484.235.
- An outlier payment as set forth in §§ 484.205(d)(3) and 484.240.

b. Final CY 2027 National, Standardized 30-Day Period Payment Amount

Section 1895(b)(3)(A)(i) of the Act requires that the standard prospective payment rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different HHAs in a budget-neutral manner. We stated in the proposed rule that to determine the CY 2027 national, standardized 30-day period payment rate, we would continue our practice of using the most recent, complete utilization data at the time of rulemaking; that is, we are using CY 2025 claims data for CY 2027 payment rate updates.

As discussed in section II.C.1. of the CY 2026 HH PPS final rule (90 FR 55406), we finalized the implementation of a temporary 3.0 percent reduction to the CY 2026 base payment rate that was equivalent to a final temporary adjustment factor of 0.97000. Per section 1895(b)(3)(D)(iii) of the Act, a temporary adjustment is to be applied for the applicable year and not included when computing a payment rate for a subsequent year. In other words, the temporary adjustment factor for CY 2026 will not be included in the starting payment rate for CY 2027. Therefore, we calculated the CY 2026 national, standardized 30-day period payment with and without the temporary adjustment factor.

To calculate the CY 2027 national, standardized 30-day period payment amount, we began with the actual CY 2026 national standardized 30-day period payment amount (with the temporary adjustment factor included) and applied an adjustment factor of 1.03093 (which is equal to 1 divided by the CY 2026 temporary adjustment factor of 0.97000) to remove the temporary adjustment factor as shown in table 12.

TABLE B12: CY 2026 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT (WITHOUT TEMPORARY ADJUSTMENT)

CY 2026 National Standardized 30-Day Period Payment (With Temporary Adjustment)	Removing CY 2026 Temporary Adjustment Factor	CY 2026 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)
$2,038.22	1.03093	$2,101.26

We applied a case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor, the home health payment update percentage, and a temporary adjustment factor to update the CY 2027 payment rate. As discussed previously, to ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we applied a case-mix weight budget neutrality factor to the CY 2027 national, standardized 30-day period payment rate. The proposed case-mix weight budget neutrality factor for CY 2027 was 1.0045. Based on updated CY 2025 claims data as of July 14, 2026, the final case-mix weight budget neutrality factor for CY 2027 is 1.0047.

Additionally, we applied a wage index budget neutrality factor to ensure that wage index updates and revisions are implemented in a budget neutral manner. To calculate the wage index budget neutrality factor, we first determine the payment rate needed for non-LUPA 30-day periods using the CY 2027 wage index (with the 5 percent cap) so those total payments are equivalent to the total payments for non-LUPA 30-day periods using the CY 2026 wage index (with the 5 percent cap) and the CY 2026 national standardized 30-day period payment rate adjusted by the case-mix weights recalibration neutrality factor. Then, by dividing the payment rate for non-LUPA 30-day periods using the CY 2027 wage index with the 5 percent cap on wage index decreases) by the payment rate for non-LUPA 30-day periods using the CY 2026 wage index (with the 5 percent cap on wage index decreases), we obtain a wage index budget neutrality factor of 1.0009. We then apply the wage index budget neutrality factor of 1.0009 to the 30-day period payment rate.

Next, we update the 30-day period payment rate by the proposed CY 2027 home health payment update percentage of 2.1 percent. As discussed in section II.C.1. of this final rule, we are finalizing our proposal to apply the temporary 3.0 percent reduction to the CY 2027 base payment rate. The proposed temporary adjustment factor is 0.97000. As discussed previously, per section 1895(b)(3)(D)(iii) of the Act, the temporary adjustment is to be applied

for the applicable year and not included when computing a payment rate for a subsequent year. In other words, the temporary adjustment factor for CY 2027 should not be included in the starting payment rate for CY 2028. Therefore, we have calculated the CY 2027 national, standardized 30-day period payment with and without the temporary adjustment factor. The CY 2027 national standardized 30-day period payment rate without a temporary adjustment is only for illustrative purposes. The actual CY 2027 national standardized 30-day period payment rate includes the temporary adjustment and is calculated in table 13.

TABLE B13: FINAL CY 2027 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2026 National Standardized 30-Day Period Payment Without Temporary Adjustment	CY 2027 Case-Mix Weights Recalibration Neutrality Factor	CY 2027 Wage Index Budget Neutrality Factor	CY 2027 HH Payment Update Factor	CY 2027 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)	Temporary Adjustment Factor	CY 2027 National, Standardized 30-Day Period Payment (With Temporary Adjustment)
$2,101.26	1.0047	1.0009	1.0210	$2,157.41	0.9700	$2,092.69

The CY 2027 national standardized 30-day period payment rate for an HHA that does not submit the required quality data will be updated by 0.1 percent (the final CY 2027 home health payment update percentage of 2.1 percent minus 2 percentage points) and is shown in table 14.

TABLE B14: FINAL CY 2027 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2026 National Standardized 30-Day Period Payment Without Temporary Adjustment	CY 2027 Case-Mix Weights Recalibration Neutrality Factor	CY 2027 Wage Index Budget Neutrality Factor	CY 2027 HH Payment Update Factor Minus 2 Percentage Points	CY 2027 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)	Temporary Adjustment Factor	CY 2027 National, Standardized 30-Day Period Payment (With Temporary Adjustment)
$2,101.26	1.0047	1.0009	1.0010	$2,115.15	0.9700	$2,051.70

c. Final CY 2027 National Per-Visit Rates for 30-Day Periods of Care

The national per-visit rates are used to pay LUPAs and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or home health discipline. The six home health disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).
- Physical therapy (PT).
- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the final CY 2027 national per-visit rates, we started with the CY 2026 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA 30-day periods of care using the CY 2027 wage index with the 5 percent cap on wage index decreases and comparing it to simulated total payments for LUPA 30-day periods of care using the CY 2026 wage index with the 5 percent cap. By dividing the total payments for LUPA 30-day periods of care using the CY 2027 wage index by the total payments for LUPA 30-day periods of care using the CY 2026 wage index, we obtain a wage index budget neutrality factor of 0.9999. As a reminder, the wage index budget neutrality factors for the national, standardized 30-day period amount and

the national LUPA per-visit rates are not equal because they are calculated differently. The wage index budget neutrality factor for the LUPA per-visit payments is calculated by simulating total payments for LUPA 30-day periods while the 30-day period budget neutrality factor is calculated by simulating payments for non-LUPA 30-day periods.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weight budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Additionally, we are not applying the permanent adjustment or the temporary adjustment to the LUPA per-visit payment rates but only to the case-mix adjusted 30-day payment rate. Lastly, the per-visit rates for each discipline are updated by the CY 2027 home health payment update percentage of 2.1 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for periods that occur as the only period or initial period in a sequence of adjacent periods. The final CY 2027 national per-visit rates for HHAs that submit the required quality data are updated by the final CY 2027 home health payment update percentage of 2.1 percent and are shown in table 15.

TABLE 15: FINAL CY 2027 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2026 Per-Visit Payment Amount	CY 2027 Wage Index Budget Neutrality Factor	CY 2027 HH Payment Update Factor	CY 2027 Per-Visit Payment Amount
Home Health Aide	$80.12	0.9999	1.0210	$81.79
Medical Social Services	$283.64	0.9999	1.0210	$289.57
Occupational Therapy	$194.74	0.9999	1.0210	$198.81
Physical Therapy	$193.42	0.9999	1.0210	$197.46
Skilled Nursing	$176.96	0.9999	1.0210	$180.66
Speech-Language Pathology	$210.25	0.9999	1.0210	$214.64

The CY 2027 per-visit payment rates for HHAs that do not submit the required quality data will be updated by 0.1 percent, which is the final CY 2027 home health payment update percentage of 2.1 percent minus 2 percentage points and are shown in table 16.

TABLE 16: FINAL CY 2027 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2026 Per-Visit Payment Amount	CY 2027 Wage Index Budget Neutrality Factor	CY 2027 HH Payment Update Factor Minus 2 Percentage Points	CY 2027 Per-Visit Payment Amount
Home Health Aide	$80.12	0.9999	1.0010	$80.19
Medical Social Services	$283.64	0.9999	1.0010	$283.90
Occupational Therapy	$194.74	0.9999	1.0010	$194.92
Physical Therapy	$193.42	0.9999	1.0010	$193.59
Skilled Nursing	$176.96	0.9999	1.0010	$177.12
Speech-Language Pathology	$210.25	0.9999	1.0010	$210.44

We solicited comments on the proposed CY 2027 30-day home health payment rates and the per-visit payment rates but did not receive comments on this proposal.

Final Decision: We are finalizing the updates to the CY 2027 national, standardized 30-day period payment rates and the CY 2027 national per-visit payment amounts as proposed, using the final CY 2027 market basket update.

d. LUPA Add-On Factors

Prior to the implementation of the 30-day unit of payment, LUPA episodes were eligible for a LUPA add-on payment if the episode of care was the first or only episode in a sequence of adjacent episodes. As described in the CY 2008 HH PPS final rule, the average visit lengths in these initial LUPAs are 16 to 18 percent higher than the average visit lengths in initial non-LUPA episodes (72 FR 49848). LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA

payment before adjusting for area wage differences.

In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount, whereby we finalized the approach of multiplying the per-visit payment amount for the first skilled nursing (SN), physical therapy (PT), or speech language pathology (SLP) visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by 1 + the proportional increase in minutes for an initial visit over non-initial visits. Specifically, we updated the analysis using 100 percent of LUPA episodes and a 20 percent sample of non-LUPA first episodes from CY 2012 claims data. At that time, we finalized add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. In the CY 2019 HH PPS final rule with comment period (83 FR 56440), in addition to finalizing a 30-day unit of payment, we finalized our policy of continuing to multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (using the already established LUPA add-on factors of 1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM.

In the CY 2025 HH PPS final rule (89 FR 88426 through 88427), in an effort to enhance the accuracy and relevance of LUPA add-on factors to reflect current healthcare practices and costs, we finalized updates to the LUPA add-on factors for PT, SN, and SLP, which had not been revised since the CY 2014 HH PPS final rule (using CY 2012 claims data). We finalized using the same methodology to establish the LUPA add-on amount as used for CY 2014, using updated claims data.

Specifically, in CY 2025, we updated the LUPA add-on factors by using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data (as of September 11, 2024). Our analysis found that the average excess of minutes for the first visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods are 29.91 minutes for the first visit if SN, 28.08 minutes for the first visit if PT, and 31.57 minutes for the first visit if SLP. The average minutes for all non-first visits in non-LUPA episodes are 41.54 minutes for SN, 45.11 minutes for PT, and 47.15 minutes for SLP. To determine the LUPA add-on factors for each discipline, we calculated the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. We then added one to these ratios to obtain the final add on factors. Therefore, beginning in CY 2025 the final LUPA add on factors for SN, PT, and SLP are 1.7200 for SN; 1.6225 for PT; and 1.6696 for SLP.

Additionally, as outlined in the CY 2025 HH PPS proposed rule (89 FR 55378), in order to implement Division CC, section 115, of the Consolidation Appropriations Act (CAA), 2021, CMS finalized changes to the regulations at § 484.55(a)(2) and (b)(3) that allowed occupational therapists to conduct initial and comprehensive assessments for all Medicare beneficiaries under the home health benefit when the plan of care does not initially include skilled nursing care, but included OT, as well as either PT or SLP (86 FR 62351). This change necessitated the establishment of a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled OT visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care. However, at the time of the implementation, we stated in the CY 2022 HH PPS final rule (86 FR 62289), there was not sufficient data regarding the average excess minutes for the first visit in LUPA periods when the initial and comprehensive assessments are conducted by occupational therapists. Therefore, we finalized a policy using the PT LUPA add-on factor as a proxy. We also stated in the CY 2022 final rule that we will use the PT LUPA add-on factor as a proxy until we have CY 2022 data to establish a more accurate OT add-on factor for the LUPA add-on payment amounts (86 FR 62289). Ultimately, we refrained from using CY 2022 data (and instead utilized the PT LUPA add-on factor as a proxy for the OT LUPA add-on factor), as we marked the first year that occupational therapists were permitted to conduct the initial assessment. We wanted to extend our analysis to ensure we had sufficient data to reflect OT time spent conducting initial assessments to establish a discrete OT LUPA add-on factor (86 FR 62240).

In the CY 2025 HH PPS final rule (89 FR 88427), we finalized discontinuing the use of the PT LUPA add-on factor as a proxy and established a definitive LUPA add-on factor for OT. We used the same methodology used to establish the LUPA add-on amount for CY 2014, as described previously for the SN, PT, and SLP add-on factors. Specifically, we updated the analysis using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data. Using updated analysis (as of September 11, 2024), we found that the average excess of minutes for the first OT visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods is 33.28 minutes for the first visit. The average number of minutes for all non-first visits in non-LUPA periods is 45.98 minutes for OT. To determine the LUPA add-on factor for OT to account for the excess minutes during the first visit in a LUPA period, we finalized calculating the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. We then added one to this ratio to obtain the final add on factor of 1.7238 for OT. Therefore, the OT LUPA factor of 1.7238 is used when occupational therapy is the first skilled visit in a LUPA period that occurs as the only period or an initial period in a sequence of adjacent periods.

TABLE B17: LUPA ADD-ON FACTORS

Discipline	LUPA Add-on Factors
SN	1.7200
PT	1.6225
SLP	1.6696
OT	1.7238

4. Payments for High-Cost Outliers Under the HH PPS

a. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS and the previous unit of payment (that is, 60-day episodes), outlier payments were made for 60-day episodes whose estimated costs exceed a threshold amount for each HHRG. The episode's estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or PEP adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the home health FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined as a proportion of the wage-adjusted estimated cost that surpasses the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act to require that the Secretary reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act and revised the language to state that the total amount of the additional payments or payment adjustments for outlier episodes could not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act, which capped outlier payments as a percent of total payments for each HHA for each year at 10 percent.

As such, beginning in CY 2011, we reduced payment rates by 5 percent and targeted up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we targeted up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10-percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care in order to surpass the outlier threshold and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim would receive an outlier payment and the amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

In the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, the per unit rates used to estimate an episode's cost were updated by the home health update percentage each year, meaning we would start with the national per visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727). We stated that we would continue to monitor the visit length by discipline as more recent data becomes available and may propose updating the rates as needed in the future.

In the CY 2019 HH PPS final rule with comment period (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of PDGM beginning in CY 2020 and calculated payment for high-cost outliers based upon 30-day period of care. Upon implementation of the PDGM and 30-day unit of payment, we finalized the FDL ratio of 0.56 for 30-day periods of care in CY 2020.

In the CY 2021 HH PPS final rule (85 FR 70322), given that CY 2020 was the first year of the PDGM and the change to a 30-day unit of payment, we finalized maintaining the same FDL ratio of 0.56 for CY 2021 as we did not have sufficient CY 2020 data at the time of CY 2021 rulemaking to propose a change to the FDL ratio for CY 2021. In the CY 2022 HH PPS final rule with comment period (86 FR 62292), we estimated that outlier payments would be approximately 1.8 percent of total HH PPS payments in CY 2022 if we maintained an FDL of 0.56. Therefore, in order to pay up to, but no more than, 2.5 percent of total payments as outlier payments we finalized an FDL of 0.40 for CY 2022. In the CY 2023 HH PPS final rule (87 FR 66875), using CY 2021 claims utilization data, we finalized an FDL of 0.35 in order to pay up to, but no more than, 2.5 percent of the total payment as outlier payments in CY 2023. In the CY 2024 HH PPS final rule (88 FR 77749), using CY 2022 claims utilization data, we finalized an FDL of 0.27 for CY 2024. In the CY 2025 HH PPS final rule (89 FR 88354), using CY 2023 claims data (as of July 11, 2024) we finalized an FDL ratio of 0.35 for CY 2025. In the CY 2026 HH PPS final rule (90 FR 55411), using CY 2024 claims data (as of July 11, 2025) we finalized an FDL ratio of 0.37 for CY 2026.

b. Final FDL Ratio for CY 2027

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of periods that can receive outlier payments but makes it possible to select a higher loss-sharing ratio, and

therefore, increase outlier payments for qualifying outlier periods. Alternatively, a lower FDL ratio means that more periods can qualify for outlier payments, but outlier payments per period must be lower.

The FDL ratio and the loss-sharing ratio are selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). We use a value of 0.80 for the loss-sharing ratio, which we believe preserves incentives for HHAs to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs that exceed the outlier threshold amount.

Using CY 2025 claims data (as of March 12, 2026) and given the statutory requirement that total outlier payments do not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we proposed an FDL ratio of 0.29 for CY 2027. We also proposed to update the FDL ratio in the final rule based on more complete CY 2025 claims data.

We solicited comments on the proposed CY 2027 FDL. The following is a summary of the comments we received and our responses:

Comment: Most commenters expressed support for CMS's proposal to lower the fixed-dollar loss ratio. These commenters stated that this proposed update to the FDL would appropriately expand access to outlier payments for high-cost, medically complex care.

Response: We thank the commenters for their support.

Comment: A few commenters opposed the proposed update to the CY 2027 FDL and requested more transparency with the data surrounding the FDL and home health outlier payments. A commenter suggested that successive FDL decreases correlate with declining visit volumes, suggesting HHAs may be reducing visits to avoid disqualifying themselves from outlier payments rather than accepting costly patients as intended. This commenter requested deeper analysis of the 10 percent agency-level outlier cap and its relationship to visit-intensity trends. Multiple commenters requested that CMS publish detailed year-by-year reconciliation data from CY 2011–2027 comparing the 5 percent outlier set-aside, the 2.5 percent statutory ceiling, and actual outlier payments made. These commenters stated that the persistent gap suggests systemic underfunding of the home health benefit and requested that CMS quantify this trade-off for Congress, with one commenter recommending Congress consider eliminating the outlier provision entirely. One commenter asked CMS to confirm that high-complexity, caregiver-intensive episodes with respect to ADRD (Alzheimer's disease and related dementia) retain meaningful outlier access as the FDL is recalibrated.

Response: We remind commenters that, as established in section 1895(b)(5) of the Act, both the 2.5 percent target of outlier payments to total home health payments and the 10-percent cap on outlier payments at the home health agency level are statutory requirements. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or the 2.5-percent target amount. We appreciate commenters' recommendation to provide a detailed analysis that compares the 2.5 percent statutory ceiling and the actual outlier payments made; however, we are not required by statute to reconcile the 2.5 percent target of outlier payments. Because the FDL is calculated prospectively such that outlier payments do not exceed 2.5 percent of total home health payments, there are some years we may reach the 2.5 percent target and some years we may not. However, we believe that our current methodology for calculating the FDL remains appropriate. A high FDL ratio reduces the number of episodes that can receive outlier payments but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower. In the CY 2019 HH PPS final rule with comment period (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of the PDGM beginning in CY 2020 and calculated payment for high-cost outliers based upon 30-day periods of care. We have used the most recent claims data to calculate the FDL ratio since that time. In the CY 2027 HH PPS proposed rule, we stated that we would use the most recent claims data available, which is CY 2025 claims data. Using CY 2025 claims data (as of July 14, 2026), we found that the FDL ratio would need to be lowered from the final CY 2026 FDL of 0.37 to 0.29.

We appreciate the commenters' concerns regarding the successive decreases in the FDL and the impact that it may have on visit patterns and the impact to high intensity periods of care and recommendations to provide more transparency regarding the data used to calculate the FDL. We believe that outlier payments are beneficial in helping to mitigate the incentive for HHAs to avoid patients that need higher levels of medical care. We will continue to evaluate changes to the FDL, analyze patterns in home health outlier payments, and monitor for any impacts, particularly for those beneficiaries with clinically complex conditions, and may include the results of such efforts in future rulemaking as appropriate.

Comment: Some commenters expressed concern that CMS is updating the FDL based on potentially fraudulent data, specifically in what they describe as high fraud areas such as Los Angeles County. These commenters stated that fraudulent, low-acuity, high-volume billing distorts the ratio's underlying math and disadvantages legitimate HHAs serving genuinely high-cost patients. Some commenters requested that CMS withhold finalizing the update to the FDL until this fraudulent data is removed.

Response: We appreciate the commenters' concerns regarding potential fraudulent billing and its potential impact on the proposed FDL. However, as discussed previously, outlier billing patterns are not always indicative of fraudulent practice. Further evidence would be required to determine definitively whether their activities can be connected to fraudulent practices. Depending on the circumstance, anomalous patterns can prompt further review and initiate investigation for evidence of fraud, waste, and abuse. CMS currently includes the most recent and complete claims data when updating the FDL. If CMS excluded the claims the commenters view as outliers from the calculation of the FDL, CMS would need to make thresholds for determining what qualifies as an outlier to be excluded from the analytical sample; and the available aggregate data do not establish that these outlier claims are in fact improper and should be excluded. In addition, dropping providers with anomalous billing patterns can cause the sample to be much smaller relative to the most recent and complete claims for that given year. LA County is not the only area with unusual utilization patterns, and a blanket geographic exclusion for any geographic area showing varying utilization patterns would potentially remove a large number of legitimate claims with any potentially improper claims. CMS will continue to analyze utilization patterns due to commenter concern regarding fraudulent data; however, thus far these patterns do not establish fraud or the necessity to remove claims from rulemaking analysis.

We appreciate commenters sharing insight into how we can address concerns about potential fraud in the home health market. Cost report fraud and abusive billing behavior are concerns that need to be addressed through the appropriate channels with the authority to pursue enforcement action, such as the hotline for reporting fraud at the following website: *https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reporting-fraud.*

Final Decision: With updated CY 2025 claims data (as of July 14, 2026) and given the statutory requirement that total outlier payments do not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we are finalizing an FDL ratio of 0.29 for CY 2027.

F. Palliative Care Services as Home Health Services

In the proposed rule, CMS noted that it is seeking to advance its broader goal of promoting access to and utilization of palliative care services, with a particular focus on expanding opportunities for beneficiaries to receive these services under the Medicare home health benefit. As part of this effort, CMS included a Request for Information (RFI) in the FY 2027 Hospice Wage Index and Payment Rate Update proposed rule (91 FR 17359) to solicit public input on potential policy, operational, and payment approaches to strengthen and enhance the delivery of palliative care services outside of the hospice benefit. We were especially interested in hearing more about how Medicare practitioners and post-acute care providers furnish community-based palliative care, well as opportunities for improvement. We stated we believe that, as palliative care is a method of care delivery that is provided throughout the continuum of illness, it can be furnished under various Medicare benefits. We also stated that the home is an ideal environment for individuals to receive palliative care services, as remaining in the home during a serious illness may help alleviate psychological and mental distress and allow for more intimate caregiving to be provided by family members. As such, we believe the Medicare home health benefit can be an important step in the care continuum when a patient needs palliative care, either during episodes of serious illness or near end of life, before choosing hospice care.

In accordance with § 409.42(c), to qualify for Medicare coverage of home health services, a beneficiary must need skilled services as set out at § 409.32. Section 409.32(a) states that ''[t]o be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel.'' Under the home health benefit, a beneficiary's unique condition and individual needs should be considered in deciding whether skilled nursing care is reasonable and necessary, without regard to whether the illness or injury is acute, chronic, terminal, or expected to extend over a long period of time. There are no expectations that life-prolonging therapies will be avoided or that the patient must be considered terminally ill, and the restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities. Further, as discussed in chapter seven of the Medicare Benefit Policy Manual (BPM),[6] it is a physician or an allowed practitioner, as defined at *§ 484.2,* who is familiar with the patient who determines whether a skilled service is reasonable and necessary based on the patient's individual care needs and goals, and accepted standards of medical and nursing practice. Therefore, if the beneficiary meets the qualifications for coverage of services as set out at § 409.42, he or she could receive palliative care services under the home health benefit, if ordered by a physician or an allowed practitioner.

Often skilled services are determined to be reasonable and necessary when a patient has multiple medications and comorbidities, with resultant functional impairments, that leave them homebound with a need for skilled observation of the patient's condition and medication management. A discussion on palliative care delivery in the home emphasizes the importance of home-based care for patients with multiple morbidities and limited mobility.[7] The structure of the PDGM allows, in general, for palliative care services to be most appropriately grouped into the medication, management, teaching, and assessment (MMTA) clinical group. As discussed in the CY 2019 HH PPS proposed rule (83 FR 32402), health teaching; guidance and counseling; case management, treatments and procedures; and surveillance are integral to the care of most home health patients. Palliative care is defined at § 418.3 to mean ''patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.'' We noted that we believe this definition encompasses all the services provided under the Medicare home health benefit. Additionally, these important interventions are often the primary reason for home health services. Section 1861(m) of the Act requires the 30-day period to include all covered home health services: skilled nursing; home health aide; physical therapy; speech-language pathology; occupational therapy; medical social services, and medical supplies. Skilled nursing services can address advanced symptom management, including specialized care to manage pain, nausea and vomiting, depression and anxiety, and respiratory distress. This may also include medication management to monitor therapeutic and adverse effects and review and adjust medications in coordination with allowed practitioners. Medical social services can help address advance care planning needs (including discussion on transition to hospice) as well as offer referrals for social and emotional support for families and caregivers. Physical therapists (PTs), occupational therapists (OTs), and speech language pathologists (SLPs) enhance patient quality of life, comfort, and dignity by maximizing functional independence and managing symptoms. PTs focus on mobility, pain management, and safe transfers, while OTs specialize in adapting activities of daily living (ADLs) and environments to maintain independence for as long as possible. SLPs support safe eating and drinking and help facilitate communication and decision making for those patients with deficits.

We reiterated that, like other skilled services, comprehensive home health clinical notes are expected to substantiate the need for palliative care necessitating medication management, teaching, and assessment through documentation of the patient's achievement of care needs and goals as

[6] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf.*

[7] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Board on Health Care Services; Roundtable on Quality Care for People with Serious Illness. Models and Strategies to Integrate Palliative Care Principles into Care for People with Serious Illness: Proceedings of a Workshop. Washington (DC): National Academies Press (US); 2017 Oct 24. Proceedings of a Workshop. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK538355/.*

outlined in the plan of care. Accordingly, we pointed to chapter seven of the BPM that includes an example of a patient with malignant melanoma who is terminally ill and requires skilled observation, assessment, teaching, and treatment, and who has not elected hospice care. This example explains that the documentation should describe the goal of the skilled nursing intervention, and at each visit the services provided should support that goal. The skilled nursing care that the patient requires would be covered, notwithstanding that the condition is terminal, because the documentation and description must support that the needed services required the skills of a nurse. We stated that a palliative care plan for this type of patient would likely include medication and symptom management, including expected treatment responses for pain, anxiety, constipation, nausea, or dyspnea; education and caregiver training on managing symptoms at home; assessing social risk factors including caregiver burden and emotional and psychosocial distress; and skilled therapy for non-pharmacologic pain management strategies and interventions to maximize functional status and independence.

We noted in the proposed rule that we plan on adding additional palliative care examples of skilled care to the BPM following publication of this final rule to support our goal of encouraging community-based palliative care services, particularly under the Medicare home health benefit.

We solicited public comments on any concerns or suggestions reaching this goal. The following is a summary of the comments received and our responses:

Comment: The majority of commenters expressed support for CMS's goal of expanding community-based palliative care under the existing Medicare home health benefit, recognizing its potential to improve symptom management, caregiver support, and quality of life for seriously ill beneficiaries. Most of these commenters affirmed that skilled palliative services, including pain and symptom control, caregiver education, medication management, and care coordination are already authorized under chapter seven of the Medicare Benefit Policy Manual (BPM).[8]

However, many raised significant concerns regarding the disincentives created by current quality measurement and reimbursement frameworks that may penalize HHAs for serving patients who primarily require palliative care services. Specifically, commenters stated outcome measures tied to hospitalization and functional improvement in mobility and self-care may systematically disadvantage HHAs that appropriately prioritize comfort and quality of life over curative or rehabilitative goals. Commenters emphasized that for palliative care patients, a decline in these areas is often expected due to the natural progression of advanced disease and should not be interpreted as poor quality of care. Commenters expressed concern that as a result, HHAs that appropriately accept and manage these patients may receive lower performance scores and lower Star Ratings despite delivering high-quality, patient-centered care. Some commenters suggested CMS consider excluding palliative care patients from outcome measures that are based on functional improvement, discharge to community, and potentially preventable hospitalizations, or alternatively, implementing additional risk adjustment methodologies that account for the expected decline associated with serious progressive illness. Other commenters suggested a palliative track within the Home Health Quality Reporting Program, updating quality measures to distinguish between traditional home health patients and those receiving palliative care services.

Other commenters expressed concern regarding audit denials without specific, clinically realistic sub-regulatory guidance. Commenters consistently urged CMS to act quickly to update chapter seven of the BPM with concrete palliative care examples to avoid a scenario where policy encouragement exists in theory but is undermined in practice by audit risk, payment penalties, or lack of interdisciplinary infrastructure. Some commenters asked CMS to clarify how the homebound requirement applies to seriously ill patients who leave home for palliative-intent outpatient treatment (for example, palliative radiation or infusions), where leaving the home requires a considerable and taxing effort. These commenters also encouraged CMS to ensure Medicare Administrative Contractor (MAC) medical review aligns with new guidance.

Several commenters raised regulatory concerns that the homebound requirement is a barrier to earlier palliative intervention and suggested a potential non-homebound pathway to home-based palliative care; the need for nurse and nurse practitioner (NP) reimbursement integration within the home health interdisciplinary team; distinct Part B payment pathways for a community-based palliative care benefit, including the possibility of an add-on payment or development of specific CPT codes; and revising the regulations to explicitly include palliative care among covered home health services. Additionally, we received some comments indicating confusion regarding whether this discussion on palliative care was indicative of a new benefit or distinct service model under Medicare. Other commenters emphasized that CMS should avoid establishing separate palliative care eligibility criteria, duplicative assessments, or additional documentation standards that could discourage providers from furnishing these services. Additionally, a commenter asked whether the clarification of the provision of palliative care services under the home health benefit would require other providers or suppliers to enroll or be certified as an HHA in order to furnish palliative care.

One commenter cautioned that expanding palliative care without competency standards risks diluting specialty palliative care and further delays appropriate hospice referrals. A commenter specifically noted that HHAs do not have the resources to furnish these services at scale to beneficiaries with such complex and serious illness; that these patients require much more comprehensive, longitudinal, and coordinated care than can be provided by HHAs. This commenter pointed to the Home-Based Primary Care (HBPC) model as the standard for which palliative care should be provided in the community and stated that CMS discussing palliative care provision under the home health benefit understates the complex nature of palliative care and the importance of home-based primary care clinicians as the primary coordinators of palliative care services in the home. Several commenters urged CMS to maintain a clear boundary between the home health and hospice benefits, recognizing that the home health benefit is not a substitute for hospice, but may be a bridge for those seriously ill beneficiaries who are not ready to elect hospice. These commenters stressed that home health does not support the same intensity of interdisciplinary care that the hospice benefit provides.

And finally, some commenters requested that CMS clarify that palliative care can be provided across all disciplines and all PDGM clinical groups and is not only limited to the MMTA clinical group, and that we study the resource use of palliative and

[8] *https://www.cms.gov/files/document/bp102c07pdf.*

maintenance periods of care and pay commensurately.

Response: CMS thanks all commenters for their thoughtful and detailed input on the provision of community-based palliative care under the Medicare home health benefit. The breadth and quality of these comments reflect the deep commitment of clinicians, advocates, caregivers, and health systems to improving care for seriously ill beneficiaries, and CMS acknowledges the broad commenter support for its goal of expanding access to community-based palliative care by acknowledging its provision under the existing home health benefit. We agree that seriously ill beneficiaries stand to benefit significantly from improved pain and symptom management, caregiver support, and enhanced quality of life when palliative care principles are integrated into home health services. CMS remains committed to advancing this goal in a manner that is clinically sound, operationally feasible, and equitable across the beneficiary population.

We recognize concerns regarding current quality measures including improvement standards, which are less likely to occur in palliative care patients. We agree this would not indicate poor quality of care but rather could be expected in this population as a result of the natural progression of serious illness. With current discussions about opportunities for potential alignment between the expanded Home Health Value-Based Purchasing (HHVBP) Model and the Home Health Quality Reporting Program (HH QRP), the home health measure sets used for both the HH QRP and the expanded HHVBP Model will emphasize measures that address expected functional outcomes instead of an emphasis on functional improvement. For example, the Discharge Function measure used in the HH QRP and the expanded HHVBP Model assesses each patient's expected functional status at discharge based on the patient's clinical profile and then evaluates management of functional status based on whether the patient is expected to improve, maintain or decline in function. Over time, the functional status measures used in the expanded HHVBP Model and HH QRP measure sets will focus more on a patient's expected outcome and not simply assess functional improvement.

CMS recognizes commenter concerns that palliative requires specialized clinical skills, including advanced symptom assessment, goals-of-care communication, and interdisciplinary coordination; however, we believe that HHAs are well-positioned to provide these services given their existing infrastructure for interdisciplinary care planning, skilled nursing and therapy, and coordination with physicians, as part of comprehensive, home-based care. CMS will explore the development of minimum competency expectations for HHA staff providing palliative care services, in consultation with relevant clinical and professional organizations. Any future guidance will seek to preserve the integrity of specialized clinical skills in palliative care while enabling broader access to these services at the community level. Further, CMS recognizes the critical role NPs play in expanding access to care, particularly in underserved communities, and we note that ''allowed practitioners'' include NPs, physician assistants (PAs), and clinical nurse specialists (CNSs). These types of providers are allowed to certify patients for Medicare home health services and establish the plan of care, affording them the ability to participate in and manage community-based palliative care delivery under the home health benefit. CMS disagrees, however, that supporting home-based primary care and strengthening HHAs palliative care capacity are competing strategies. The regulatory framework already governing Medicare-certified HHAs makes them a well-suited, and readily scalable, environment for furnishing palliative care, consistent with the goals underlying this rule. The Conditions of Participation (CoPs) at CFR 42 part 484 require HHAs to conduct a comprehensive patient assessment, develop an individualized plan of care, and deliver services through an interdisciplinary group encompassing skilled nursing, therapy, medical social services, and aide support. These same requirements, symptom management, psychosocial and caregiver support, and coordinated interdisciplinary planning are the operational building blocks of palliative care.

CMS is not proposing a new service delivery model or a new benefit in this rule; rather, this clarification is intended to confirm that HHAs may furnish palliative care as a component of a skilled service already covered under the home health benefit, such as skilled nursing visits for pain and symptom management, patient and caregiver education, or care planning. It does not create a new, distinct benefit category or service type, and it does not modify the existing HH PPS payment methodology. Accordingly, CMS is not establishing a separate payment, add-on payment, or billing code specific to palliative care furnished under the home health benefit. HHAs should continue to bill for these services consistent with existing home health billing and coverage requirements, and any palliative care activities performed by home health staff must fit within the scope of a covered skilled service and be included in the individualized plan of care.

Additionally, this rule does not modify the eligibility requirements for the home health benefit or require any provider or supplier to enroll or be certified as an HHA in order to furnish palliative care. All home health eligibility requirements (homebound status, a qualifying skilled need, an allowed-practitioner order, a plan of care, and a face-to-face encounter) all still apply to palliative care patients. Regarding homebound status, the same criteria exist for determining whether a patient is confined to the home, meaning a patient can still be considered homebound if absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment. Additionally, nothing in this rule alters the requirement that home health services be furnished under a physician or allowed practitioner established plan of care. These clinicians, often the patient's primary care provider, retain full authority over diagnosis, treatment planning, and goals-of-care decisions. Enhancing HHAs' palliative care role would extend that plan of care into more frequent, hands-on interdisciplinary contact, complementing, not substituting for, the clinician relationship present in the HBPC model. Further, while we stated in the proposed rule that MMTA would likely be the most appropriate grouping for palliative care services, we recognize that these services can be applied across all home health disciplines and as outlined in the care plan.

Regarding concerns that CMS may be indicating these services are substitutes for hospice care, we agree that the home health and hospice benefits, while complementary, serve distinct purposes and beneficiary populations. We recognized in the proposed rule that the home health benefit can be an important step in the care continuum when a patient needs palliative care, either during episodes of serious illness or near end of life, before choosing hospice care. However, we do not intend for this clarification to blur the distinction between home health and hospice care, and we will continue to monitor program data and beneficiary experience to ensure that beneficiaries are directed to the benefit that best matches their care needs.

And finally, CMS agrees that consistent review and implementation across MACs is essential to the success of any palliative care policy initiative. CMS will work with MACs to ensure that medical review criteria, documentation expectations, and coverage determinations reflect updated guidance. We will issue specific MAC instructions and education materials in conjunction with BPM updates to promote national consistency and reduce audit-related and claims denial deterrents to palliative care delivery. We also thank commenters for submitting suggested examples for the BPM and will update this sub-regulatory guidance promptly to represent the various palliative care services we believe HHAs can provide under the home health benefit.

G. Request for Information on the Construction of a Home Health Specific Wage Index

For CY 2027, we are finalizing our proposal to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the HH PPS wage index. We continue to believe that this is the best available Medicare data to estimate costs per day, in accordance with our longstanding wage index policy at § 412.424(a)(2). The purpose of this comment solicitation was to gain information from the public regarding the appropriateness of alternative data sources consistent with our statutory authority and regulatory requirements. We noted that other payment systems have explored and are exploring alternative wage index methodologies under their specific programmatic and statutory circumstances. For example, CMS finalized changes to the ESRD PPS wage index using Bureau of Labor Statistics (BLS) occupation-level wage data in the CY 2025 ESRD PPS final rule (89 FR 89116). We noted that while this approach was developed under the specific programmatic and statutory circumstances of the ESRD PPS and may not be directly transferable to the HH PPS, CMS is interested in exploring whether similar methodologies using publicly available wage data could be used to better reflect the geographic variation in labor costs for HHAs. In addition, we noted that we are also considering the potential use of alternative data sources in other payment systems, including with respect to hospices (91 FR 17361 through 17363), the Inpatient Rehabilitation Facilities PPS (91 FR 17206 and 17207), and the Skilled Nursing Facilities PPS (91 FR 17692).

Furthermore, in its 2023 Report to the Congress,[9] MedPAC discussed various conceptual approaches to Medicare wage indexes, including the use of county-level wage data from BLS with an occupational mix to construct wage indexes that are more specific to the payment setting. MedPAC has previously written about using all-employer, occupation-level wage data to establish different weights for setting-specific occupational labor mixes as one approach to geographic adjustments.

We solicited public comments on whether we should consider using alternative data sources to construct an HHA specific wage index for potential use in future years. CMS sought feedback to understand the potential advantages and limitations of using alternative data sources, such as BLS data and home health Medicare cost reports, as well as other methodologies that stakeholders believe could appropriately reflect the geographic variation in labor costs for HHAs. We also sought feedback on the unique considerations applicable to HHAs that should inform how CMS considers the potential use of alternative data sources.

The following is a summary of the comments we received and our responses.

Comment: Overall, commenters expressed support for an approach that would more closely represent the geographic variation of wages related to occupations used in home health. Commenters requested that CMS provide more information on the potential methodology to calculate a home health specific wage index using alternate data sources and home health specific occupational mix, and recommended CMS convene a Technical Expert Panel to seek broader input based on presented analysis. Many commenters stated that any occupational mix must extend beyond RNs and therapists to include home health aides, medical social workers, LPNs, and community health workers. Commenters were split on data sources: many favored BLS Occupational Employment and Wage Statistics as independent and more current, while others raised concerns that BLS data is not home-health-specific, excludes benefits, dilutes the labor pool with non-Medicare providers, and relies on unverifiable survey samples. Some commenters stated that home health cost reports have serious data-quality problems, such as inconsistent contract-labor reporting, lack of audits, and distortion from what they describe as high-fraud cohorts such as Los Angeles County. All commenters supported publishing a detailed prototype/RFI with methodology, occupational weights, and provider/county-level impact files before implementation; convening a Technical Expert Panel; multi-year phase-in with continuation of the 5 percent cap on decreases; and robust stakeholder/industry engagement.

Response: We thank commenters for their feedback. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this information to inform future development of a home health specific wage index and for potential future rulemaking as appropriate.

III. Home Health Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

The HH QRP is authorized by section 1895(b)(3)(B)(v) of the Act. Section 1895(b)(3)(B)(v)(II) of the Act requires that, for 2007 and subsequent years, each home health agency (HHA) submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary shall reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points pursuant to section 1895(b)(3)(B)(v)(I) of the Act. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, as further reduced by the productivity adjustment (except in 2018 and 2020) described in section 1886(b)(3)(B)(xi)(II) of the Act, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the HH PPS for a year being less than payment rates for the preceding year. Section 1890A of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890 of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the HH QRP. The HH QRP regulations can be found at 42 CFR 484.245 and 484.250.

[9] *https://www.medpac.gov/document/chapter-9-reforming-medicares-wage-index-systems-june-2023-report/.*

B. Summary of the Proposed Rule and Responses to Public Comments

In accordance with the statutory authority at section 1895(b)(3)(B)(v) of the Act, we proposed the following policies in the proposed rule:

First, we summarized potential initiatives to improve alignment between the HH QRP and expanded HHVBP Model. We also proposed to revise the HH QRP data submission deadlines beginning with the CY 2027 HH QRP. In addition, we proposed to revise the HH QRP OASIS and HHCAHPs annual payment update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). We proposed some revisions to regulatory text in support of rule proposals and to improve digital transfer of information during the reconsiderations process. Finally, we solicited public comments on one Request for Information (RFI) on future measure concepts for the HH QRP.

For a detailed discussion of the considerations that we historically have used for measure selection for the HH QRP quality, resource use, and other measures, we refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68696). In the CY 2019 HH PPS final rule with comment period (83 FR 56548 through 56550), we finalized the factors we consider for removing previously adopted HH QRP measures.

C. Quality Measures Currently Adopted for the CY 2026 HH QRP

The HH QRP currently includes 18 measures for the CY 2027 program year. As finalized in the CY 2026 HH PPS final rule, the HH QRP currently uses thirteen OASIS-based measures, four claims-based measures, and a HHCAHPS Survey-based composite measure (see table 18).

D. Opportunities for Potential Alignment Between the HH QRP and the Expanded HHVBP Model

As discussed in the proposed rule, CMS has identified substantial opportunities to better align the HH QRP and the expanded HHVBP Model. While the HH QRP and expanded HHVBP Model share similar goals and measures, differences in measure sets, reporting periods, and performance assessment processes may create unnecessary complexity and administrative burden for HHAs. For example, misalignment between HH QRP APU reporting periods and the expanded HHVBP Model's annual performance period may contribute to confusion. Greater alignment would support more consistent evaluation of HHA quality performance and advance CMS quality priorities. Greater alignment is also consistent with CMS's priority of reducing provider burden and creating efficiencies across CMS programs. Opportunities for potential alignment between the HH QRP and expanded HHVBP Model include the following:

- Increasing alignment in expanded HHVBP Model and HH QRP Quality of Patient Care (QoPC) Star Ratings measure sets.
- Aligning HH QRP and expanded HHVBP Model measure reporting periods.
- Aligning HH QRP APU and expanded HHVBP Model annual payment reporting periods.
- Aligning expanded HHVBP Model Interim Performance and HH QRP QoPC Star Rating Reports.
- Aligning timeframe of appeals/suppression review processes for the expanded HHVBP Model and HH QRP.
- Updating scoring methodology to incorporate HH QRP APU penalties in expanded HHVBP Model payment adjustments and factoring HH QRP Quality Assessments Only (QAO) values into QoPC Star Ratings scoring.

We convened a Technical Expert Panel (TEP) meeting addressing HH QRP and expanded HHVBP Model alignment in December 2025. Please see the 2025 TEP Summary Report for more information (*www.cms.gov/priorities/innovation/files/hhvbp-tep-summary-report.pdf*).

Table 18 reflects current and expected usage of measures for both the expanded HHVBP Model and the HH QRP.

TABLE 18: QUALITY MEASURE USAGE IN HHVBP AND HH QRP COMPONENTS

Measures	Included in HHVBP Performance Measures	Used in HHQRP QoPC/ Patient Survey Star Ratings	Expected Inclusion in both HHVBP and HHQRP Star Ratings	HHQRP Non-QoPC Star Ratings QMs
OASIS-based Measures				
Discharge Function Score*^	Yes	No	Yes	Yes
Improvement in Bathing**	Yes	Yes	Yes	No
Improvement in Upper Body Dressing**	Yes	No	No	Yes
Improvement in Lower Body Dressing**	Yes	No	No	Yes
Improvement in Bed Transferring	No	Yes	No	No
Improvement in Ambulation/Locomotion	No	Yes	No	No
Improvement in Dyspnea	Yes	Yes	Yes	No
Improvement in Management of Oral Medications	Yes	Yes	Yes	No
Timely Initiation of Care	No	Yes	No	No
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury - HH	No	No	No	Yes
Falls with Major Injury	No	No	No	Yes
Transfer of Health Information to Provider	No	No	No	Yes
Transfer of Health Information to Patient	No	No	No	Yes
Influenza Immunization Received	No	No	No	Yes
Drug Regimen Review	No	No	No	Yes
Claims-based Measures				
Potentially Preventable Hospitalizations (PPH)*	Yes	Yes	Yes	No
Discharge to Community – Post Acute Care (DTC-PAC)* ^	Yes	Yes	Yes	Yes
Medicare Spending per Beneficiary- Post Acute Care (MSPB-PAC) **	Yes	No	No	Yes
Potentially Preventable Readmission	No	No	No	Yes
HHCAHPS Survey-based Measures				
Care of Patients***	Yes	Yes	No	Yes
Communication Between Providers and Patients***	Yes	Yes	No	Yes
Talk About Home Safety****	No	No	No	Yes
Review Medicines****	No	No	No	Yes
Talk About Medicine Side Effects****	No	No	No	Yes
Overall Rating of Care Provided by the Home Health Agency	Yes	Yes	Yes	Yes
Willingness to Recommend the Home Health Agency	Yes	No	No	Yes

^ Measures expected to be added to QoPC Star Ratings in the near future.
* Measure added to the expanded HHVBP Model starting with the CY 2025 applicable measure set.
** Measure added to the expanded HHVBP Model starting with the CY 2026 applicable measure set.
*** Measure removed from the expanded HHVBP Model starting with the CY 2026 applicable measure set.
****Measure added to HH QRP Non-QoPC CY 2026 measure set to replace the Specific Care Issues measure.

Though we did not seek comments on the list of opportunities for potential alignment between the HH QRP and the expanded HHVBP Model, numerous commenters offered feedback. The following is a summary of the comments we received and our responses.

Comment: Commenters broadly supported potential efforts to align the HH QRP with the expanded HHVBP Model, emphasizing the potential to reduce duplicative reporting, administrative complexity, and provider burden. Many commenters urged CMS to ensure that potential alignment efforts account for the unique needs of high-acuity and palliative-intent patients, recommending mechanisms such as palliative-status exclusions, refined risk adjustment, and the development of outcome measures appropriate for patients with declining trajectories to prevent HHAs from being unfairly penalized. Several commenters advocated for greater transparency, public engagement, and adequate lead time in implementing any potential future changes, as well as the inclusion of functional, caregiver-facing, and clinically relevant measures—particularly for populations with dementia, neurological diseases, or serious illness.

Response: We thank commenters for their input and will take this feedback into consideration as appropriate.

E. Form, Manner, and Timing of Data Submission Under the HH QRP

1. Revise HH QRP Data Submission Deadlines Beginning With the CY 2027 HH QRP

a. Background

Section 1899B(f)(1) of the Act also requires the Secretary to provide confidential feedback reports to PAC providers on the performance of such PAC providers for quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning 1 year after the applicable specified application date. Further, section 1899B(g) of the Act requires the Secretary to establish procedures for making available to the public information regarding the performance

of individual PAC providers for quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning not later than 2 years after the applicable specified application date. The procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act for similar purposes, that each PAC provider has the opportunity to review and submit corrections to the data and information that are to be made public for the PAC provider prior to such data being made public.

Although assessment data submission, quarterly performance reports, and public reporting are required by statute, timing of data submission under the HH QRP was not initially specified. Thus, in the CY 2017 HHS PPS final rule (81 FR 76784) we finalized our proposal to comply with the requirements of section 1899B(g) of the Act, that HHAs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, HHAs could review and perform corrections to errors in the assessment data used to calculate the measures.

Public reporting of data collected under our quality reporting programs, such as the HH QRP, is designed to provide consumers and their families with the most current information to empower them to make quality-informed decisions about where to receive their care. We have identified that the time between when data on measures is submitted to us and when those data are publicly reported (approximately nine months) may be too long to provide the most accurate and up to date information for the public. We have received feedback from the provider community and TEPs that the aged data used in publicly reported quality measures diminishes their value to consumers. Furthermore, we have heard from HHAs that the HH QRP measure results they receive prior to public reporting are less useful for their quality improvement efforts due to the aged data and the delay in when they receive these reports.

Currently, the largest contributing factor to the 9-month lag between the end of the data collection period and when measures are publicly reported is the 4.5-month timeframe for data submission. Reducing the data submission timeframe from 4.5 months to the 15th day of the second month after the end of the calendar quarter could reduce this lag by up to 3 months, resulting in more timely public reporting of data for consumers and increasing the value of publicly reported data. Additionally, this timeframe provides HHAs with more recent data in support of their quality improvement activities.

In the CY 2026 HH PPS proposed rule, we included a request for information (RFI) on reducing the OASIS assessment data submission deadline from 4.5 months to 45 days (90 FR 29182). We refer readers to the CY 2026 HH PPS final rule (90 FR 55429 and 55430) for a full summary of the public comments received.

b. Revise the HH QRP Assessment Data Submission Deadline

Beginning with the CY 2027 HH QRP, we proposed that HHAs be required to complete their data submissions and make corrections to their OASIS assessment data where necessary no later than the 15th day of the second month after the end of the calendar quarter. However, if the 15th day of the second month fell on a Friday, weekend, or Federal holiday, the date would be delayed until 11:59 p.m. EST on the next business day. We proposed that HHAs follow the deadlines presented in Table 19 for the CY 2027 HH QRP. We also proposed that similar calendar year data submission deadlines apply to future years' payment determinations.

TABLE 19: DATA COLLECTION TIMEFRAME AND DATA SUBMISSION DEADLINES FOR OASIS ASSESSMENT DATA AFFECTING THE CY 2029 PAYMENT DETERMINATION

Calendar Year (CY) Quarter	Data Collection Timeframe	Final Data Submission Deadlines for CY 2029 Payment Determination*
CY 2027 Quarter 1	January 1–March 31, 2027	May 17, 2027
CY 2027 Quarter 2	April 1–June 30, 2027	August 16, 2027
CY 2027 Quarter 3	July 1–September 30, 2027	November 15, 2027
CY 2027 Quarter 4	October 1–December 31, 2027	February 15, 2028

* Data submission deadlines will follow a similar quarterly schedule for subsequent CYs.

We believe that requiring HHAs to submit OASIS assessment data by the 15th day of the second month after the end of the calendar quarter is reasonable. We conducted an analysis on the potential impact of reducing the timeframe by determining how many assessments are currently being submitted by this deadline, which is approximately within 45 days of the end of the quarter. Using 2024 data, we determined that 99.27 percent of all OASIS assessments were submitted to CMS within a 45-day timeframe. Of the remaining 0.73 percent submitted beyond 45 days, 0.24 percent of the total (that is, about one third of the post-45 day timeframe) were submitted after the current 4.5-month data submission deadline and would not be further impacted by a change in the data submission deadline. Therefore, only 0.49 percent of OASIS assessments will be impacted by changing the data submission deadline from 4.5 months to require data submission by the 15th day of the second month after the end of the calendar quarter.

We received public comments on the proposal to require that HHAs complete their data submissions and make corrections to their OASIS assessment data where necessary no later than the 15th day of the second month after the end of the calendar quarter beginning with the CY 2027 HH QRP. The following is a summary of the comments we received and our responses.

Comment: A majority of commenters supported CMS' proposal to revise the OASIS data submission deadline, stating that more timely reporting of

HHQRP data could help HHAs implement quality improvement initiatives and beneficiaries and their caregivers make better-informed decisions when selecting HHAs. Several commenters supported the proposal based on data showing that most HHAs are already meeting the 45-day submission requirement. Many commenters who supported the proposal urged CMS to ensure clear guidance and training is in place to support the implementation of this proposal.

Response: We thank commenters for their support and agree that this proposal would give patients and consumers more timely access to quality data and give HHAs better data for quality improvement. Clear guidance around the new submission deadline will be available through the range of communication channels used to reach HHAs.

Comment: Some commenters supported the proposal and the goal of improving the timeliness of publicly reported data, but had concerns about operational and staffing challenges, administrative burden, and data validation, especially for small or rural HHAs that may struggle with staffing challenges and operational issues. A few commenters expressed concerns that providers continue to experience staffing shortages and turnover of HH staff. Some commenters that supported the proposal noted the current clinical and administrative burden around implementing OASIS all-payer submissions and changing payment requirements. Several commenters encouraged CMS to establish a phased implementation or grace period to meet submission requirements, to provide flexibility for the first several data submission cycles. A few other commenters cited recent implementation of the HOPE tool to stress the benefits of a phased implementation.

Response: We appreciate the commenters' concerns about operational and staffing challenges, especially for small or rural HHAs. However, we do not believe that the proposal adds burden for HHA staff by changing the data submission deadline; rather, it shifts the existing workflow from 4.5 months after each quarterly data collection period to the 15th day of the second month after the end of the calendar quarter. Since workflows are in place for the necessary processes, we do not believe a phased implementation approach is necessary. As previously stated in the CY 2027 HH PPS proposed rule, our internal analysis showed that 99.27 percent of all OASIS assessments are already being submitted within a 45-day timeframe, which suggests that data submission within this timeframe is the current practice for most HHAs. Further, we believe a phased implementation approach would add operational complexity, as providers would have to update workflows and modify staffing numerous times over the implementation period. We will continue to monitor data submission compliance rates as part of already implemented program monitoring.

Comment: Some commenters were concerned that the proposed timeline may not provide adequate time for agencies to validate data to identify and correct errors, particularly for new admissions near the end of a reporting quarter. They raised concerns that review processes are critical to ensuring high-quality data but may no longer be feasible within a 45-day submission window.

Response: We believe that we are providing HHAs sufficient time to adjust staffing and workflow operations that will allow them to validate data and make any corrections needed by the new deadline. In general, we believe data validation and quality checks to be complete with the initial data submission, with better proximity to the patient. We would also like to note that this proposal will benefit HHAs by allowing them to have access to more timely data for quality improvement efforts.

Comment: A few commenters supported the proposal but recommended allowing HHAs to request an extension if there are circumstances out of the HHA's control impacted the HHA's ability to submit data in a timely manner.

Response: Currently, in the event they were unable to submit quality data due to extraordinary circumstances beyond their control, we provide HHAs with the opportunity to request an exception or extension from the program's reporting requirements. HHAs affected by a natural or man-made disaster or other extraordinary circumstances may request an exception or extension using instructions provided on the HH QRP website: *https://www.cms.gov/medicare/quality/home-health/home-health-quality-reporting-reconsideration-and-exception-extension.*

Comment: Some commenters recommended that CMS provide enhanced technical assistance and support as part of the transition to the new reporting timeframe. Several commenters suggested updated training resources and outreach to HHAs to ensure providers have sufficient support to implement this proposal. A few commenters requested the ability for vendors to have a test period for submissions.

Response: We appreciate commenters' input and recommendations for implementation of this proposal. We would like to note that we currently conduct national outreach (such as email communications) about upcoming data submission deadlines. We also provide guidance and technical manuals, data submission deadline documents, and training resources. We intend to make updates to our outreach processes, manuals, data submission deadline documents and training resources related to this change. Regarding technical assistance and support, we list resources and on our website: *https://www.cms.gov/medicare/quality/home-health/home-health-quality-reporting-training.* We do not anticipate that the new submission timeframe will require data processing since the submission processes have not been changed with this proposal.

After consideration of public comments, we are finalizing as proposed to require that HHAs submit their OASIS assessments and make corrections to their OASIS assessment data where necessary no later than the 15th day of the second month after the end of the calendar quarter beginning with the CY 2027 HHQRP.

2. Revise the OASIS Annual Payment Update Reporting Timeframe

a. Background

HHAs are required to submit OASIS data in a timely manner as outlined under section 1895(b)(3)(B)(v) of the Act, as amended by the Deficit Reduction Act (Pub. L. 109–117). Failure to submit OASIS data in a timely manner with respect to a HH QRP year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. This annual payment update (APU) was initiated for the HH QRP on January 1, 2007. The HH QRP APU requirements were finalized in the CY 2007 HH PPS Final Rule (71 FR 44087 through 44088) outlining data collection of 12 months of data beginning July 1, 2005 and running through July 1, 2026. This timeframe allowed a full 12 months of data and provided CMS the time necessary to analyze and make any necessary payment adjustments to the CY 2007 payment rates (71 FR 44087 through 44088). The timing for APU reporting

has remained on this data calculation cadence since this update.

The current OASIS APU reporting timeframe differs from that used by other major CMS payment updates. Notably, the expanded HHVBP Model annual payment adjustment and the HH PPS updates are both based on a calendar year timeline. To improve alignment between HH payment policies and OASIS QRP reporting requirements, CMS proposed to revise the OASIS APU data reporting timeframe to reflect a January 1 through December 31 reporting timeframe, or the calendar year. We believe this update would provide clarity to HH payment updates and facilitate the alignment of the HH pay-for-reporting policies with other HH payment policies.

b. Revise the OASIS Annual Payment Update Reporting Timeframe

The revision of the OASIS APU data reporting to a calendar year timeframe would require a transition year in which the current reporting timeframe was moved to the new proposed reporting timeframe. We proposed the transition occur with the 2028 APU and further proposed that the 6 months data collected from July 1, 2026 through December 31, 2026 would serve as the OASIS APU data reporting timeframe to determine the HH QRP 2028 OASIS APU. We also proposed that the 2029 OASIS APU would be the first iteration in which the OASIS APU data reporting timeframe will be based on the calendar year, from January 1, 2027 through December 31, 2027. We would continue this new pattern for each subsequent OASIS APU with effective dates for data reporting of January 1 through December 31. OASIS assessments will be considered complete if they comply with the HH Conditions for Payment (COPs) that apply to the applicable year. Please see table 20 that outlines the current OASIS APU data reporting timeframe, the proposed transition reporting timeframe, and the revised OASIS APU timeframe used for the CY 2029 APU and later.

TABLE 20: DATA REPORTING TIMEFRAMES ASSOCIATED WITH UPCOMING HHQRP OASIS APU

OASIS APU Issued	Data Reporting Timeframe
January 2027	July 1, 2025 – June 30, 2026
January 2028 transition	July 1, 2026 - December 31, 2026
January 2029	January 1, 2027 – December 31, 2027

In the CY 2024 HH PPS final rule, CMS finalized adding the following language to the regulatory text at § 484.245(b)(2)(ii)(A): ''A home health agency must meet or exceed the data submission threshold for each submission year (July 1–June 30) set at 90 percent of all required OASIS or successor instrument records and submitted through the CMS designated data submission systems'' (88 FR 77676). With the proposed change to a calendar year reporting timeframe, CMS proposed to revise the language in § 484.245(b)(2)(ii)(A) that currently states ''(July 1–June 30)'' to state ''(January 1 through December 31)''.

We received public comment on the proposal to revise the OASIS APU reporting timeframes to a calendar year period beginning with the CY 2027 HH QRP. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed strong support for CMS's proposal to align the OASIS Annual Payment Update (APU) reporting period with the calendar year, citing anticipated benefits such as improved administrative efficiency, consistency across payment and quality reporting programs, and reduced confusion for providers.

Response: We thank commenters for their support for our proposal to revise the OASIS APU reporting period to calendar year. We seek to align reporting periods, where possible, to provide clearer reporting processes across HH programs.

Comment: Several commenters who supported the CMS proposal also emphasized the importance of clear and timely guidance regarding the new reporting timeframe, standardized reporting specifications, and transition support to ensure HHAs can comply with the new requirements and avoid unintended payment penalties. Some commenters highlighted concerns about a potential increase in operational burden, particularly regarding the inclusion of all-payer OASIS data and the risks associated with a shortened reporting period during the transition year. They recommended either an extended transition period or additional compliance resources. Several expressed concerns that there may be an increase in APU failure during the transition to the new calendar reporting timeframe.

Response: We thank commenters for their support of this proposal and for sharing criteria that would assist with implementation of revised calendar proposal. We will ensure that clear guidance around the implementation of revisions of the reporting timeframe for the OASIS APU will be shared via multiple means of communication, including the official HHQRP website. We will also work to ensure training materials related to the HHQRP APU addresses OASIS all-payer data submission. Our goal is to limit burden associated with a transition to calendar year reporting of the OASIS APU.

After consideration of public comments, we are finalizing as proposed to revise the OASIS APU reporting timeframe to a calendar year period effective January 1, 2027. We are also finalizing the transition period in which the six months of data collected from July 1, 2026 through December 31, 2026 would serve as the OASIS APU data reporting timeframe to determine the HHQRP 2028 APU. We are finalizing the 2029 OASIS APU data reporting timeframe would be the first iteration in which the OASIS APU data reporting timeframe would be for a calendar year, from January 1, 2027 through December 31, 2027.

3. Revise the HHCAHPS Annual Payment Update Reporting Timeframe

a. Background

HHAs are required to submit quality data in a timely manner as outlined under section 1895(b)(3)(B)(v) of the Act. Failure to submit HHCAHPS data in a timely manner with respect to a HH QRP year could result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. HHCAHPS data

inclusion in the HH QRP was finalized with the CY 2010 HH PPS Final Rule (FR 74 58098 through 58104). Adding a HHCAHPS annual payment update (APU) to the current HH QRP requirements was also finalized with the CY 2010 HH PPS Final Rule where CMS finalized the policy that HHCAHPS will be included in the APU reporting for the CY 2012 APU based on 6 months of data from October 2010 to March 2011 (FR 74 58103). In the CY 2011 HH PPS final rule, CMS finalized a policy that HHCAHPS APU calculations would require four quarters of data collection from April 1, 2011 to March 31, 2012 for the CY 2013 HHCAHPS APU (FR 75 70406). The timing for HHCAHPS APU reporting has remained on this cadence since this update.

The current HHCAHPS APU reporting timeframe differs from that used by other annual HH CMS payment updates. The expanded HHVBP Model payment adjustment percentage and the HH PPS updates are both based on a calendar year timeline. The OASIS APU data reporting timeframe is also different from a calendar year timeline and we are also proposing an update to a calendar year timeframe in a previous proposal. To improve alignment between home health payment policies and HH QRP pay-for-reporting requirements, we proposed to revise the HHCAHPS APU data reporting timeframe to reflect a January 1 through December 31 reporting timeframe, or the calendar year. We believe this update would provide clarity related to HH payment updates and facilitate the alignment of CMS HH pay-for-reporting policies with other HH payment policies.

b. Revise the HHCAHPS Annual Payment Update Reporting Timeframe

The proposed revision of the HHCAHPS APU data reporting to a calendar year timeframe would require a transition year in which the current reporting timeframe was moved to the new proposed reporting timeframe. We proposed the transition occur with the 2028 HHCAHPS APU and further proposed that the nine months of data collected from April 1, 2026 through December 31, 2026 would serve as the HHCAHPS APU data reporting timeframe to determine the HHQRP 2028 APU. We also proposed that the 2029 HHCAHPS APU data reporting timeframe would be the first iteration in which the HHCAHPS APU data reporting timeframe would be for a calendar year, from January 1, 2027 through December 31, 2027. We would continue this new pattern for each subsequent HHCAHPS APU with effective dates for data reporting of January 1 through December 31. HHA OASIS assessments would be considered complete if they complied with the HH CoPs and Conditions for Payment that apply to the applicable year. Please see Table 21 that outlines the HHCAHPS current APU data reporting timeframe, the proposed transition reporting timeframe, and the revised APU timeframe used for the CY 2029 APU and later.

TABLE 21: DATA REPORTING TIMEFRAMES ASSOCIATED WITH UPCOMING HHQRP HHCAHPS APU

HHCAHPS APU Issued	Data Reporting Timeframe
January 2027	April 1, 2025 – March 31, 2026
January 2028 transition	April 1, 2026 - December 31, 2026
January 2029	January 1, 2027 – December 31, 2027

We received public comment on the proposal to revise the HHCAHPS APU reporting timeframes to a calendar year period beginning with the CY 2027 HH QRP. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported CMS's proposal to align the HHCAHPS APU reporting period with the calendar year. Commenters noted that this proposal could reduce confusion, improve compliance, and align the timing of HHQRP APU and the expanded HHVBP Model APR determinations. Commenters also shared the importance of clear implementation guidance and safeguards to ensure providers are not penalized for technical or vendor-related issues beyond their control during the transition from the current reporting schedule to a new reporting periods for the HHCAHPS APU.

Response: We thank commenters for their support for the proposal to revise the reporting timeframe for the HHCAHPS APU. We are working to improve alignment for HH program reporting requirements and simplifying program policies.

Comment: Some commenters who supported the HHCAHPS APU calendar update proposal raised the issue of burden associated moving to a new HHCAHPS calendar. They noted that to ensure an effective transition would require investments in quality assurance resources, data analytics, clinical education, software systems, and compliance oversight. One commenter supported the CMS proposal but requested that CMS clarify whether any scoring methodologies for HHQRP or the expanded HHVBP Model would change.

Response: We thank commenters for outlining potential burden issues related to this proposal. We will provide clear guidance around the implementation of this issue that we believe will limit undue costs associated with the transition and implementation of calendar year HHCAHPS APU reporting. Since no new processes are required and only a shift in the submission workflow, we do not anticipate the requirement for new investment of processing or validations systems. We also do not anticipate changes for the HH QRP or expanded HHVBP Model scoring methodologies associated with this transition to calendar year reporting of HHCAHPS APU calculations.

After consideration of public comments, we are finalizing as proposed to revise the HHCAHPS APU reporting timeframes to a calendar year period effective January 1, 2027. We are also finalizing the transition period in which the nine months of data collected from April 1, 2026 through December 31, 2026 would serve as the HHCAHPS APU data reporting timeframe to determine the HHQRP 2028 APU. We are finalizing the 2029 HHCAHPS APU data reporting timeframe would be the first iteration in which the HHCAHPS APU data reporting timeframe would be for a calendar year, from January 1, 2027 through December 31, 2027.

4. Updates To Regulation Text Related to Reconsiderations

In the CY2026 HH PPS final rule, CMS updated regulation text language to codify how a provider may request an

extension to file a request for reconsideration (90 FR 55342). We proposed to further clarify aspects of the reconsideration process to facilitate more timely, digital transmission of information. Specifically, § 484.245(d)(1)(i) currently states that HHAs that do not meet the quality reporting requirements under this section for a program year will receive a letter of noncompliance via the United States Postal Service and the CMS-designated data submission system. We proposed to revise this language to specify that HHAs that do not meet the quality reporting requirements under this section for a program year would receive a notification of noncompliance via the CMS-designated data submission system. Section 484.245(d)(1)(ii) currently states that an HHA may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance. We proposed to revise this language to state that an HHA may request reconsideration no later than 30 calendar days after the date identified on the notification of non-compliance. Section 484.245(d)(2)(v) currently states that CMS identified reason(s) for non-compliance as stated in the non-compliance letter. We proposed to revise this language to state, that CMS identified reason(s) for non-compliance as stated in the non-compliance notification.

Section 484.245(d)(4)(i) currently states that CMS notifies the HHA, in writing, of its final decision regarding any reconsideration request through at least one of the following methods:

- CMS designated data submission system.
- The United States Postal Service.
- Email from the CMS Medicare Administrative Contractor (MAC).

We proposed to revise this language to state that CMS would notify the HHA of its final decision regarding any reconsideration request through a CMS designated data submission system.

We received comments on the proposed updates to the regulations text related to the reconsideration process. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported CMS modernization and digital communications efforts but expressed concern that relying on a single portal could cause providers to miss important notices due to staff turnover, account-access issues, technical failures, emergencies, or system outages. They stressed that missing a notice could have significant financial consequences, including payment reductions.

Response: We thank commenters for their support of the proposed updates. Communication with providers via the CMS electronic systems has been in place for numerous years and has been effectively utilized across numerous CMS programs including the expanded HHVBP Model.

Comment: Several commenters recommended maintaining redundant notification methods. They proposed safeguards including sending email alerts to multiple designated contacts whenever a notice is posted, allowing optional text-message notifications, continuing mailed notices or allowing agencies to opt into them, maintaining auditable records of notice availability and retrieval, and ensuring appeal deadlines begin only after providers have been alerted that a notification is available. Commenters also urged CMS to account for outages or access failures that could prevent timely review of notices.

Response: The processes that will remain in place after this update has been implemented will continue to include multiple forms of outreach. These include electronic distribution to multiple designated contacts and through multiple distribution channels for HHA contacts.

Comment: Several commenters further emphasized the need for due-process protections and operational safeguards as the electronic system is implemented. They suggested allowing agencies to designate multiple authorized users, ensuring system accessibility and compliance with Section 508 standards, providing machine-readable notice formats, issuing receipts and timestamps for submissions, and retaining records throughout the appeal period.

Response: We appreciate these comments and agree that there is a need to have operational safeguards related to these important reconsideration processes. We believe that our current safeguards address the concerns raised by the commenters. HHAs can have confidence that their reconsideration requests will be processed effectively.

Comment: Commenters also raised concerns related to scenarios in which there was some CMS system failure. Commenters suggested extending deadlines during system downtime, offering alternative submission methods when technical issues occur, and providing a clear human point of contact for reconsideration-related questions. Overall, commenters support digital modernization but believe additional protections are necessary to ensure fairness and prevent avoidable payment penalties.

Response: We appreciate commenters addressing concerns when technical issues may occur during the reconsideration process. We have established policies and procedures to allow HHAs to receive timely communication about their compliance status and to expect consistent communication during reconsideration follow-up. Should technical issues arise, our policies in place to reach providers when contingencies are necessary.

After consideration of public comments, we are finalizing revising this language to state that we will notify the HHA of its final decision regarding any reconsideration request through a CMS designated data submission system.

F. HH QRP Measure Concepts Under Consideration for Future Years—Request for Information (RFI)

In the CY 2024 HH PPS proposed rule (88 FR 43738 through 43740), we included an RFI on a set of principles for selecting and prioritizing HH QRP measures, identifying measurement gaps, and suitable measures for filling these gaps. We refer readers to the CY 2024 HH PPS final rule (88 FR 77773 through 77774) for a summary of the public comments received in response to the RFI.

We sought input on the importance, relevance, appropriateness, and applicability of the quality measure concepts related to advance care planning (ACP). Advance care planning is a continuous process that supports people in understanding and communicating their goals, values, and preferences regarding future medical decisions.[10] The Patient Self Determination Act of 1990[11] supports this process by requiring healthcare facilities to inform patients of their rights regarding medical decisions, including advance directives and end of life care.[12] In post-acute care (PAC) settings, where patients recover from acute illness, injury, or major procedures, their needs and goals may evolve as their condition changes. Factors such as clinical stability, functional status, therapy tolerance, cognition function, prognosis, and

[10] McMahan, R. D., Tellez, I., & Sudore, R. L. (2021). Deconstructing the Complexities of Advance Care Planning Outcomes: What Do We Know and Where Do We Go? A Scoping Review.Journal of the American Geriatrics Society,69(1), 234–244. *https://doi.org/10.1111/jgs.16801.*

[11] Public Law 101–508, 4206, 4751.

[12] *https://www.congress.gov/bill/101st-congress/house-bill/4449https://www.congress.gov/bill/101st-congress/house-bill/5835.*

personal preferences can all shift during recovery. Regular reassessment and transparent communication are essential to maintaining person-centered care, while advance care planning facilitates shared decision-making by documenting patient preferences and ensuring goal-concordant care throughout care transitions.[13]

As we review new measure concepts, we will prioritize evidence-based outcome measures that promote person-centered care practices. We sought input on the relevant aspects of advance care planning and measures appropriate for the HH setting. We received public comments on this request for information, and the following is a summary of the comments we received.

Comment: Many commenters expressed support for CMS's exploration of an ACP quality measure within the HH QRP while emphasizing the need for a patient-centered, practical, and clinically meaningful approach. Most commenters agreed that ACP is an important component of quality home health care, particularly for individuals with serious illness, chronic conditions, cognitive impairment, or complex care needs. Commenters who supported an ACP measure emphasized that home health clinicians are uniquely positioned to facilitate discussions about goals of care because they work directly with patients and families in the home environment and often develop trusted relationships that provide insight into patient preferences, caregiver capacity, safety concerns, and evolving care needs.

Some commenters who supported the ACP concept for HH shared that ACP should be understood as an ongoing process rather than a one-time documentation exercise. They cautioned CMS against creating a measure that simply rewards the presence of an advance directive or other legal document. Instead, commenters recommended focusing on meaningful conversations, shared decision-making, identification of patient goals and values, and documentation that reflects patient preferences over time. Several commenters stressed that success should be measured by whether care is aligned with patient wishes rather than whether a specific form has been completed. They also suggested that patients must retain the right to decline ACP discussions or defer decisions without providers being penalized.

Some commenters who support an ACP QM linked ACP closely with palliative care and serious illness management. Organizations representing patients, providers, and palliative care advocates noted that ACP plays a critical role in helping individuals understand treatment options, manage symptoms, plan for future care needs, and make informed decisions throughout the course of illness. Commenters highlighted that home health agencies increasingly serve older, frail, and medically complex beneficiaries whose primary goals may include symptom management, quality of life maintenance, caregiver support, avoiding hospitalizations, and remaining at home.

Several commenters argued that current home health quality measures primarily reward functional improvement, which may not accurately reflect quality care for patients with progressive or terminal illnesses. They encouraged CMS to develop measures that recognize goal-concordant care, symptom management, stabilization, caregiver preparedness, and successful transitions to hospice when appropriate.

Other commenters linked the palliative care RFI in a separate section of the proposed rule with the ACP RFI. These commenters generally supported CMS's efforts to expand awareness and accessibility of palliative care and appreciate clarification that beneficiaries do not need to be terminally ill or forgo curative treatment to receive these services. They suggested that increased access to palliative care can improve symptom management, pain control, patient and caregiver support, care coordination, and overall quality of life. They also noted that earlier integration of palliative care may help patients better understand their treatment options and align care with individual goals and preferences.

Some commenters who expressed support for measuring ACP warned against creating additional documentation requirements that duplicate existing OASIS assessments, care planning processes, or regulatory obligations. Commenters recommended leveraging existing workflows and data whenever possible and ensuring that any new measure is operationally feasible for agencies of all sizes. Several organizations also noted that home health agencies currently lack reimbursement mechanisms akin to those available to physicians for conducting ACP conversations. They argued that meaningful ACP discussions require significant clinician time, training, and interdisciplinary collaboration and that CMS should consider payment pathways that support these activities in HH.

Several commenters emphasized that ACP information is most valuable when it can travel with patients across settings, including hospitals, rehabilitation facilities, home health agencies, palliative care programs, and hospice. Commenters urged CMS to align future ACP measures with national interoperability standards and structured electronic data exchange rather than relying solely on OASIS items or scanned documents. They argued that standardized, machine-readable ACP information would improve care transitions and increase the likelihood that patient preferences are known and honored across the continuum of care.

Despite this support, several commenters requested additional guidance regarding how palliative care should be operationalized within home health settings. Commenters sought clearer distinctions between palliative care and hospice services, more detailed eligibility criteria, clarification regarding documentation and reporting requirements, and practical examples illustrating when palliative care interventions would be appropriate. Concerns were also raised about potential confusion among providers, patients, and caregivers if definitions and expectations are not clearly communicated.

Several commenters also highlighted the importance of health equity, communication access, and caregiver engagement. Recommendations included accommodating individuals with communication disorders, cognitive impairment, limited English proficiency, low health literacy, cultural differences, and varying levels of caregiver support. Commenters stressed that family caregivers often play an essential role in decision-making, care coordination, and implementation of patient preferences and should be included in future quality measurement efforts. Some commenters recommended risk adjustment, stratification, and appropriate exclusions to ensure providers caring for complex or vulnerable populations are not unfairly disadvantaged. Commenters also consistently encouraged comprehensive testing, technical expert review, and ongoing collaboration before implementing any ACP measure in the HH QRP.

Commenters that supported ACP measure concept for HH also shared concerns regarding accountability and quality measurement. Commenters

[13] McMahan RD, Tellez I, Sudore RL. Deconstructing the Complexities of Advance Care Planning Outcomes: What Do We Know and Where Do We Go? A Scoping Review. J Am Geriatr Soc. 2021 Jan;69(1):234–244. doi: 10.1111/jgs.16801. Epub 2020 Sep 7. PMID: 32894787; PMCID: PMC7856112.

caution against measures that hold home health agencies' responsibility for outcomes outside their control, such as whether a patient completes an advanced care directive or changes previously established preferences. Commenters recommend that CMS develop measures that assess whether agencies offered information, facilitated discussions, and appropriately documented patient choices. Such an approach would more accurately reflect the quality of care provided while protecting patient choice and reducing unnecessary administrative burden.

Commenters who did not support an ACP concept in HH contend that home health agencies (HHAs) are not the most appropriate setting or provider type to lead ACP discussions. They also argue that home health services are typically short-term and intermittent, agency staff often lack the long-term relationship, clinical authority, and comprehensive knowledge of a patient's medical history needed to guide complex decisions regarding prognosis, treatment options, and end-of-life preferences. Commenters suggest that primary care physicians and other long-term care providers are better positioned to lead these conversations.

Commenters who do not support an ACP QM expressed concerns about proposed ACP measures that would require documentation of an advance care directive or a completed decision. They argued that such measures could create inappropriate pressure on vulnerable patients, raise privacy concerns, duplicate existing documentation requirements, and unfairly hold agencies accountable for outcomes beyond their control. Many recommend that CMS instead measure whether a goals-of-care discussion was offered, documented, and conducted, regardless of whether a formal directive or final decision resulted.

Several commenters emphasized the importance of correct reimbursement, training, and quality measurement infrastructure that does not exist in HH for an ACP QM. They note that meaningful ACP and palliative care require significant clinician time, expertise, and care coordination. They urge CMS to first develop appropriate payment and reporting mechanisms that appropriately recognize these activities before looking to develop a measure.

Response: We thank all the commenters for responding to this RFI. While we are not responding to specific comments in response to the RFI in this final rule, we will take this feedback into consideration for our future measure development efforts for the HH QRP.

IV. The Expanded Home Health Value-Based Purchasing (HHVBP) Model

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the Center for Medicare and Medicaid Innovation (Innovation Center) implemented the Home Health Value-Based Purchasing (HHVBP) Model (''original Model'') in nine states on January 1, 2016. The design of the original Model leveraged the successes and lessons learned from other CMS value-based purchasing programs and demonstrations to shift from volume-based payments to a model designed to promote the delivery of higher quality care to Medicare beneficiaries. The specific goals of the original Model were to—

- Provide higher incentives for better quality care with greater efficiency;
- Study new potential quality and efficiency measures for appropriateness in the home health setting; and
- Enhance the current public reporting process.

On January 8, 2021, CMS announced the certification of the HHVBP Model for expansion nationwide, as well as the intent to expand the Model through notice and comment rulemaking.[14] In the CY 2022 HH PPS final rule (86 FR 62292 through 62336), we finalized the decision to expand the HHVBP Model to all Medicare certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. CY 2022 was a pre-implementation year. Payment adjustments under the Model are calculated in the year after each performance year and applied 2 years following each performance year. Therefore, payment adjustments for the first performance year of CY 2023 were implemented in CY 2025. Our codified policies for the expanded HHVBP Model can be found in our regulations at 42 CFR part 484, subpart F, §§ 484.300 through 484.375. The following description of existing HHVBP performance feedback reports is included for background and to provide context for the discussion of potential alignment between the HH QRP and the expanded HHVBP Model in section III. of this final rule.

CMS publishes two types of routine performance feedback reports that provide HHAs with information on their measure performance:

- The first report type is the Interim Performance Report (IPR), which is issued quarterly. The information in the IPR reflects calculation of the TPS based on rolling data periods that are updated each quarter. CMS issues two versions of the IPR—a preliminary version and a final version that reflects any changes made as a result of the recalculation request process. The IPRs provide interim performance scores, achievement and improvement points, and TPS.
- The second report is the Annual Performance Report (APR). The APR provides HHAs with information on their measure performance using data from the prior calendar year. Like the IPR, the APR provides feedback to HHAs about performance relative to quality measure achievement thresholds, benchmarks, and improvement thresholds. Additionally, the APR includes the HHA's payment adjustment percentage for the upcoming CY, an explanation of when the adjustment will apply, and how CMS determined the adjustment.

For more information on the policies we have adopted previously for the expanded HHVBP Model, we refer readers to the following:

- CY 2022 HH PPS final rule (86 FR 62240).
- CY 2023 HH PPS final rule (87 FR 66790).
- CY 2024 HH PPS final rule (88 FR 77676).
- CY 2025 HH PPS final rule (89 FR 88354).
- CY 2026 HH PPS final rule (90 FR 55342).

CY 2027 will be the fifth performance year for the expanded HHVBP Model. As finalized in the CY 2026 HH PPS final rule, the expanded HHVBP Model currently uses six OASIS-based measures, three claims-based measures, and two HHCAHPS Survey-based measures (see Table 31 in section III. (HH QRP) of this final rule). We continue to address the number of measures needed to maximize the number of HHAs in each cohort eligible for a payment adjustment.

CMS has identified substantial opportunities to better align the HH QRP and the expanded HHVBP Model, including measure-set alignment. Table 31 in section III. of this final rule reflects current and expected usage of measures for both the expanded HHVBP Model and the HH QRP. For more details on the potential alignment between the HH QRP and expanded HHVBP Model, see section III.D. of this final rule.

Though we did not propose any changes specific to the expanded HHVBP Model in the proposed rule, we did receive several public comments. The following is a summary of the

[14] *https://www.cms.gov/newsroom/press-releases/cms-takes-action-improve-home-health-care-seniors-announces-intent-expand-home-health-value-based.*

comments we received and our responses.

Comment: Some commenters noted their appreciation that the proposed rule did not include new proposals related to the expanded HHVBP Model outside of outlining potential efforts to align the HH QRP and the expanded HHVBP Model. Several commenters submitted comments regarding potential updates to the expanded HHVBP Model's applicable measure set, cohort assignment, and the impact that HH QRP proposals and concepts discussed in HH QRP RFIs could have on the expanded HHVBP Model. Several commenters raised concerns about how additional emphasis on patients receiving palliative care via home health care could reflect negatively on HHA performance on HHVBP scores. Some commenters suggested that these patients should not be included in the expanded HHVBP Model if CMS further emphasizes palliative care in home health. Some commenters also suggested specific changes to the expanded HHVBP Model applicable measure set such as stratifying results by a patient's dual eligibility status for Medicare and Medicaid coverage. Other commenters noted that the expanded HHVBP Model should consider measures that do not only focus on functional improvement. A few commenters suggested that CMS should consider additional cohorts to better account for the differences in HHA characteristics.

Response: We thank commenters for their input. Since we did not propose any changes specific to the expanded HHVBP Model in the proposed rule, we are not responding to specific comments received in this final rule and will take this feedback into consideration as appropriate.

V. Durable Medical Equipment and Provider Enrollment Provisions

A. Overview

In this section of the final rule, we proposed changes and sought comment on the following DME and provider enrollment provisions:

- In section V.B. of the final rule, we will clarify the application of the DMEPOS face-to-face encounter requirements and the related documentation necessary to support the replacement of DMEPOS items.
- In section V.C. of the final rule, we proposed a number of Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process.
- In section V.D. of the final rule, we proposed to make changes to the Medicare Part B definition of DME regulations in accordance with the statutory changes implemented via section 6222(a) of the CAA, 2026.
- In section V.E. of the final rule, we discussed requesting revisions to the information collection requirements that will require DMEPOS CBP contract suppliers to report the country of origin for the lead items furnished during the contract's period of performance.

B. DMEPOS Encounter Requirements for Identical Replacement Items

1. Background

Section 1834(a)(11)(B)(ii) of the Social Security Act, as amended by section 504 of MACRA and codified in the Code of Federal Regulation (CFR) at 42 CFR 410.38, outlines a condition of payment for certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Specifically, it requires a physician, physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) (as these four terms are defined in section 1861 of the Act) to write an order that is communicated to the supplier prior to delivery and document that the physician, PA, practitioner, or specialist has had a face-to-face encounter (including through use of telehealth under section 1834(m) of the Act) with the individual involved, during the 6-month period preceding such written order.

On November 8, 2019 (84 FR 60648), we published a process whereby items identified as potential vulnerabilities to the Trust Fund may be placed on the *Master List of DMEPOS Items Potentially Subject to Face-to-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements* (''Master List''). We analyze the Master List and select items from the Master List to be placed on the *Required Face-to-Face Encounter and Written Orders Prior to Delivery List* (''Required F2F/WOPD List'') via **Federal Register** notice. The face-to-face encounter requirements outlined in 42 CFR 410.38 are only applicable to items that are selected and placed on the Required F2F/WOPD List via **Federal Register** notice.

For the identified items, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription. The regulation requires supporting documentation to include the subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

Separately, in our Medicare Benefit Policy Manual (100–02) (Chapter 15, Section 110.2—Repairs, Maintenance, Replacement, and Delivery) we define replacement as the provision of an identical or nearly identical item. Replacements may occur as a result of loss, theft, or irreparable damage, which may be due to a specific incident or event, or irreparable wear, in consideration of the reasonable useful lifetime of the equipment.

Section 414.210(f) discusses payment for replacement of equipment. As specified at 42 CFR 414.210(f)(1), the reasonable useful lifetime of durable medical equipment is generally determined through program instructions, or in the absence of program instructions, may be determined by the Medicare Administrative Contractors and be no less than 5 years. If the item of equipment has been in continuous use by the beneficiary for the equipment's useful lifetime or if the contractor determines that the item is lost, stolen, or irreparably damaged, the beneficiary may elect to obtain a new piece of equipment. Replacement may be paid when the practitioner reaffirms the medical necessity of the item through a new order.

2. Provisions of the Regulation and Responses to Public Comments

CMS proposed to clarify that while an order would continue to be required for replacement DMEPOS items, a new face-to-face encounter would not need to occur to support payment for these DMEPOS items. We further proposed to clarify that, for purposes of 42 CFR 410.38(d)(2)(iii), a ''replacement'' refers to the provision of an item that replaces an item falling under the same Healthcare Common Procedure Coding System (HCPCS) code; it does not include those situations involving the provision of a different item, for example, because of a change in medical condition. In other words, for paragraph(d) the replacement would be the same type of item (that is, the same HCPCS code as that originally ordered and rendered) with no change to the type of item ordered and rendered. When an order is written to replace an item falling under the same HCPCS code, requiring a new face-to-face examination to document subjective and objective beneficiary specific information regarding how the DMEPOS item will continue to be used in relation to the beneficiary's clinical condition seems burdensome and redundant. If

the item is not a replacement item identified by the same HCPCS code, then a new face-to-face encounter would continue to be required, as described in existing 42 CFR 410.38. This clarification does not eliminate the need for a new order, nor does it supersede or eliminate any other coverage instruction–including those iterated in national or local coverage determinations. In addition, we note that such claims may nonetheless be subject to medical review to ensure the appropriateness of claims billed for payment; particularly when there is concern for aberrant billing behaviors or potential fraud.

We received public comments on these proposals. In addition to the comments outlined below, CMS received some comments outside the scope of this regulation which will not be addressed. The following is a summary of the comments we received and our responses.

Comment: Commenters supported and encouraged finalization of CMS' proposal that a new face-to-face encounter would not need to occur to support payment for replacement DMEPOS items. Commenters acknowledged that the updates would prevent potential delays in the provision of replacement items, avoid unnecessary burdens and protect beneficiary access.

Response: We thank the commenters for their review and support of the proposed clarification.

Comment: A commenter suggested that CMS should consider establishing a reasonable timeframe after which a new face-to-face encounter would again be required to support continued use of the item. For example, if a replacement occurs many years after the original order, they shared their belief that a new clinical assessment may be appropriate to confirm that the beneficiary's condition, functional needs, and prescribed equipment remain consistent with current medical necessity requirements.

Response: We thank the commenter for their suggestion. We note that this clarification does not remove the need for the practitioner order, nor the need for the initial assessment to be provided, upon request, to support compliance with coverage requirements. We believe that these program integrity protections, coupled with regular clinical practice, will help ensure ongoing practitioner oversight of our beneficiary population.

Comment: Commenters requested that CMS look outside of the face-to-face requirements for evidence to support the item was initially medically necessary when such documentation is unavailable due to the lapse in time or other third-party documentation constraints.

Response: We appreciate the commenter's suggestion. We are finalizing the clarification that a face-to-face encounter does not need to be repeated for the sole purpose of ordering replacement items. However, we note that the regulation at 42 CFR 410.38 requires a face-to-face encounter for certain DMEPOS items. As such, documentation to support that the face-to-face encounter occurred when the item was initially furnished continues to be required.

Comment: A commenter requested CMS provide claim examples that define 'identical replacement' by HCPCS code, explain what documentation suppliers and treating practitioners should retain, and confirm that payment will not be denied solely because no new encounter occurred when the original encounter documentation remains valid and available.

Response: We do not believe that providing claim examples is necessary. The definition of 'identical replacement' is defined in this regulation as the same HCPCS code. In this regulation we clarify that when an identical DMEPOS item is being replaced, such claim will not be denied because a new encounter did not occur. However, we also clarify that the provider is expected to retain documentation to support that the original encounter occurred, as appropriate, when the item is initially furnished and that such documentation demonstrates compliance with our coverage requirements.

Comment: Commenters asked CMS to clarify that updated technologies, successor products, and newer device generations remain eligible for the replacement-item framework when they fall within the same HCPCS code and serve the same medical purpose.

Response: We agree. As stated in our proposal, it is our intent that this clarification would apply to the provision of an item that replaces an item falling under the same HCPCS code; it does not include those situations involving the provision of a different item, for example, because of a change in medical condition.

Comment: Commenters asked that CMS expand our current definition of an identical item as being the same HCPCS code to include any transitions within the same clinical product family, such as a beneficiary moving from a standard intermittent catheter to a hydrophilic-coated intermittent catheter. Likewise, commenters asked us to expand the definition to allow the provision of new accessory items, rendered with the replacement item, without a new face-to-face encounter being required.

Response: We thank the commenters for their feedback but are electing to retain our original language. As previously stated, we think that it is most appropriate to conduct a new face-to-face encounter when there is a change in or addition of HCPCS items, as such deviations may indicate a change in condition.

Comment: A commenter expressed their concern that this regulatory clarification created misalignment amongst DMEPOS items. Specifically, they shared their concern that certain replacement items would not require a face-to-face encounter, while continuous glucose monitors require ongoing practitioner oversight, as a condition of payment, for continued coverage. Likewise, another commenter asked for our clarification that this provision would not impact the item-specific coverage requirements for wheelchairs (such as specialty evaluations for wheelchairs). Relatedly, a commenter asked CMS to remind contractors that they have the flexibility to revise local coverage determination requirements that may necessitate additional provider visits when furnishing identical replacement items.

Response: We are emphasizing our prior statement that this clarification does not eliminate the need for a new order, nor does it supersede or eliminate any other coverage instruction—including those iterated in national or local coverage determinations. If the item specific coverage policies include practitioner oversight requirements, such requirements would continue to apply. This provision only clarifies the intent of the regulatory text at 42 CFR 410.38.

Comment: Commenters requested CMS confirmation that the regulatory clarification would specifically apply to speech generating devices.

Response: This clarification applies for all DMEPOS items that require a face-to-face encounter per 42 CFR 410.38. Commenters can review those items that are currently included on the Required Face-To-Face Encounter and Written Order Prior To Delivery List, available at: *https://www.cms.gov/files/document/required-face-face-encounter-written-order-prior-delivery-list.pdf.*

Final Decision: After consideration of the public comments, we are finalizing our regulation as proposed to clarify that a new face-to-face encounter would not need to occur to support payment for these DMEPOS replacement items.

C. Provider Enrollment

1. Background and Applicability

a. Enrollment Process

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers (hereafter collectively ''providers'' unless otherwise noted) seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.575 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS–855 (OMB Control No.: 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, PECOS), collects important information about the provider. Such data include, but are not limited to, general identifying information (for example, legal business name), licensure and certification data, and practice locations. The application is used for a variety of provider enrollment transactions, including the following:

- Initial enrollment—The provider is—(1) enrolling in Medicare for the first time; (2) enrolling in another Medicare contractor's jurisdiction; or (3) seeking to enroll in Medicare after having previously been enrolled.
- Change of ownership—The provider is reporting a change in its ownership.
- Revalidation—The provider is revalidating its Medicare enrollment information in accordance with § 424.515. (Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) must revalidate their enrollment every 3 years; all other providers and suppliers must do so every 5 years.)
- Reactivation—The provider is seeking to reactivate its Medicare billing privileges after it was deactivated in accordance with § 424.540.
- Change of information—The provider is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving the provider's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse.

As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers: (1) engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent therewith, and as we discuss in this section V.C. of this final rule, we proposed several changes to our existing Medicare provider enrollment regulations.

b. Legal Authorities

There are two principal categories of legal authorities for our proposed Medicare provider enrollment provisions:

- Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers; and
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

c. Applicable Provider and Supplier Types

The provisions in section V.C. of this final rule apply to all Medicare provider and supplier types except as specifically indicated otherwise. The most prominent proposed provisions that would apply only to certain types of providers or suppliers include the following:

- New § 424.530(a)(20), which would permit denial of a hospice's enrollment application for the reasons specified therein.
- New §§ 424.530(a)(22) and 424.535(a)(25), which would allow denial or revocation of a hospice's, home health agency's, or DMEPOS supplier's enrollment for failing to comply with the change in majority ownership provisions in §§ 424.550(b) or 424.551.
- Revised § 424.540(b)(3)(i), which would require reactivating hospices to undergo a State survey or accreditation prior to reactivation.
- Revisions to our DMEPOS accreditation requirements in § 424.58.

d. Comment Solicitation

We solicited and welcomed comments on all of the proposed provider enrollment provisions that follow. We received approximately 375 sets of comments from stakeholders. We thoroughly and carefully read, reviewed, and considered all of them in full. Most comments will be addressed within the subject-matter section to which the comment pertained. More general comments, as well as comments that seemingly pertained to multiple topics, will be addressed at the end of this section (V.C.) (For instance, sets of comments that expressed the same concerns across several provisions.) This will reduce repetition and facilitate both clarity and brevity.

We also note that in some cases, it was difficult to determine whether the stakeholder's comment referenced a particular enrollment proposal or our current enrollment process as a whole; for example, some commenters were unclear as to whether they were requesting changes to: (1) a proposed enrollment revocation reason; (2) how providers are currently revoked; or (3) both. We interpreted these comments as best we could based on their plain language.

2. Revocations and Denials of Enrollment

Under § 424.535(a), CMS may revoke a Medicare provider's enrollment for any of the reasons specified in that paragraph. These reasons include, for example, the provider's: (1) failure to adhere to Medicare enrollment requirements; (2) exclusion by the HHS Office of Inspector General (OIG); (3) felony conviction within the previous 10 years; (4) pattern of improper or abusive billing; and (5) termination by another Federal health care program. A revocation helps safeguard the Medicare program, the Trust Funds, and beneficiaries by removing from (and preventing payment to) Medicare providers that have engaged in

problematic or otherwise non-compliant behavior. When a provider is revoked, it is generally barred from reenrolling in Medicare for a period of 1 to 10 years.

CMS also has numerous reasons in § 424.530(a) for which it can deny a provider's enrollment application, some of which duplicate our revocation grounds in § 424.535(a) (for instance, OIG exclusion). The general rationale for a denial is akin to that for a revocation: to protect the Medicare program and its beneficiaries from potentially fraudulent or abusive activity.

We have previously finalized a number of regulations adding or revising revocation and denial reasons in subpart P to address particular program integrity vulnerabilities and types of provider conduct. We have also used rulemaking to refine other revocation and denial policies, such as the effective dates of revocations. With our continuing obligation to establish strong payment safeguards, we proposed several changes to our revocation and denial policies in subpart P.

a. Modifications of Current Revocation Provisions

(1) Abuse of Billing Privileges (§ 424.535(a)(8)(ii))

Section 424.535(a)(8) permits revocation based on the provider's abuse of billing privileges. Per § 424.535(a)(8)(ii), this includes situations where CMS determines that the provider has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following factors (outlined in § 424.535(a)(8)(ii)(A) through (D)):

- The percentage of submitted claims that were denied during the period under consideration (paragraph (a)(8)(ii)(A)).
- Whether the provider or supplier has any history of final adverse actions and the nature of any such actions (paragraph (a)(8)(ii)(B)).
- The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined) (paragraph (a)(8)(ii)(C)).
- Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination (paragraph (a)(8)(ii)(D)).

As we stated in the December 5, 2014, final rule that promulgated § 424.535(a)(8)(ii), a provider ''should be responsible for submitting valid claims at all times and that the provider or supplier's repeated failure to do so poses a risk to the Medicare Trust Funds.'' [15]

We proposed the following two revisions to § 424.535(a)(8)(ii):

- Removing all the factors in § 424.535(a)(8)(ii)(A) through (D).
- Removing the second sentence of § 424.535(a)(8)(ii) that reads ''In making this determination, CMS considers, as appropriate or applicable, the following''.

We have seen a wide variety of potential § 424.535(a)(8)(ii) cases over the years. However, our existing factors often constrain our ability to effectively address all these factual scenarios. We noted the following in the proposed rule:

- Final Adverse Actions—Most aberrant billing we have seen is done by providers with no history of adverse actions (for example, Medicare revocations or OIG exclusions). Yet the adverse action factor in § 424.535(a)(8)(ii) essentially requires us to weigh against a finding of improper billing for such providers. That is, this factor assists non-compliant providers so long as the provider lacks an adverse history, which it often will; this hinders our efforts to invoke § 424.535(a)(8)(ii) against the provider.
- Percentage of Claims Denied—This factor, too, is problematic. Non-compliant billing often occurs notwithstanding a low percentage of denied claims, especially with providers that submit many claims. Similar to the adverse history factor, the claim denial criterion thus makes it more difficult to use § 424.535(a)(8)(ii) even if a pattern of abusive billing exists. Moreover, the factor is limited to claim denials and does not consider other types of non-compliant claims (such as rejected claims). In our view, it is the lack of compliance itself, rather than the type of claim involved, that is pertinent.

In sum—and given our responsibility to protect the Trust Funds and taxpayers from improper billing—we must have the ability to address all possible § 424.535(a)(8)(ii) scenarios without the rigid constraints of our existing factors. Even with the ''as appropriate or applicable'' qualifier in the opening paragraph of § 424.535(a)(8)(ii), there could still be an implication that we must consider all the factors in our determinations, which, as indicated, hampers the usefulness of § 424.535(a)(8)(ii).

The following is a summary of the comments we received on this proposal and our responses.

[15] ''Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment'' (79 FR 72500).

Comment: Many commenters opposed our removal of factors from § 424.535(a)(8)(ii). They stated that clear criteria and thresholds (such as a minimum number of claims needed to constitute a ''pattern or practice'') are needed to foster transparency and certainty for providers. Some commenters stated that CMS should not only retain the current factors but also include new ones such as (though not limited to): (1) the statistical validity and representativeness of any claim sample that CMS reviews; (2) the dollar amount, frequency, nature, severity, and materiality of the alleged errors; (3) whether the provider knew or reasonably should have known of the noncompliance; (4) whether CMS or the MAC previously notified or educated the provider; (5) whether the provider promptly refunded overpayments and implemented corrective action; (6) the provider's compliance history and prompt rectification of errors; (7) the presence or absence of fraud, waste, abuse, or beneficiary harm; and (8) whether the pattern or practice involved final adjudicated claims rather than initial denials.

Response: We appreciate the commenters' concerns and suggestions. Yet as previously explained, specifically delineated and mandatory factors have inhibited our ability to effectively utilize § 424.535(a)(8)(ii). This said, we emphasize strongly that CMS will take into account the facts and circumstances of every evaluation under § 424.535(a)(8)(ii) and, as we currently do, will only revoke under this ground when genuinely warranted and not as a matter of course. Moreover, stakeholders should not assume that our removal of § 424.535(a)(8)(ii)'s factors means that we will never again consider matters such as the percentage of claims denied or the type of billing non-compliance in our § 424.535(a)(8)(ii) determinations. Our change to § 424.535(a)(8)(ii) simply reflects the program integrity need to move away from explicit factors and towards a broader, more flexible ''facts and circumstances'' approach. This is also partly why we have not established a fixed, regulatory definition of ''pattern or practice'' with numerical and time thresholds.

We stress that up through 2014, none of CMS' denial or revocation grounds contained enumerated, mandatory factors—and even today, a number of our grounds do not. Both then and now, a lack of factors does not mean providers will be treated unfairly. We have for decades reviewed every case with the utmost care and consideration, recognized the heavy consequences of a

revocation, and only taken this measure when necessary.

Comment: Commenters expressed concern about our statement in the proposed rule that § 424.535(a)(8)(ii) could be invoked if ''several of the provider's claims do not meet Medicare requirements.'' They contended that this represents an expansion of § 424.535(a)(8)(ii). They stated that occasional claim submission errors do not establish abusive billing and are largely unavoidable given, for example: (1) the complexity of Medicare billing; (2) that some providers submit thousands of claims; and (3) that small, independent practices do not have the billing staff and resources of larger providers. Several commenters requested that the final rule expressly state that isolated, inadvertent, immaterial, clerical, or promptly corrected claim errors—standing alone—do not constitute a pattern or practice of abusive billing. Others sought a CMS statement that a finding based only on ''several'' non-compliant claims should not invoke § 424.535(a)(8)(ii) unless the provider engaged in material and repeated non-compliance.

Response: We respectfully disagree that the quoted ''several'' statement is an expansion of § 424.535(a)(8)(ii). To the contrary, it represents CMS' position since the provision's inception in 2014. We have always had the authority to invoke § 424.535(a)(8)(ii) in such circumstances. For both this reason and the need to address many different factual scenarios, the unequivocal statements the commenters request are overbroad. On the other hand, we recognize and understand the commenters' concerns and, as we always have, will only use § 424.535(a)(8)(ii) when the facts and circumstances warrant it. The previously quoted statement and the removal of factors will not change this.

Comment: Commenters stated that instead of revoking a provider under § 424.535(a)(8)(ii), CMS should first: (1) use provider education and corrective action programs, including ''Targeted Probe and Educate''; and (2) allow providers to explain the erroneous claim submissions and to resubmit said claims.

Response: We again appreciate the commenters' concerns about § 424.535(a)(8)(ii)'s potential application. However, we have consistently maintained that providers are responsible for always submitting accurate and compliant claims. If we routinely allowed providers to simply resubmit non-compliant claims without any invocation of § 424.535(a)(8)(ii), we believe providers would have less incentive to initially submit correct claims, knowing that CMS will not take action against them.

This concept is especially true regarding pre-revocation opportunities to be heard, which we believe these commenters were requesting. (As addressed later, other commenters requested such a process for several of our other proposals.) We discussed this issue in the CY 2026 HH PPS final rule, published in the December 2, 2025, **Federal Register** (90 FR 55342).[16] We stated therein: ''We have always maintained that establishing an informal pre-revocation appeals process could encourage providers to disregard compliance with Medicare requirements until they are notified of the non-adherence, upon which they will remedy the issue and remain enrolled but then perhaps resume their prior behavior. In other words, allowing providers to always take corrective action and resume compliance before revocation gives them no incentive to remain adherent in the first place, which leaves the Medicare program at risk of billions of dollars in payments to non-compliant providers.'' [17] We hold this same position regarding § 424.535(a)(8)(ii).

Comment: A commenter suggested that if CMS views the § 424.535(a)(8)(ii) factors as constraining, it could make them optional by replacing the language ''CMS considers'' in § 424.535(a)(8)(ii)'s opening paragraph with ''CMS may consider''.

Response: While we appreciate this suggestion, we remain concerned that even the optional nature of public, regulatorily specified factors could convey the impression that CMS should still consider them. This would present largely the same previously discussed problem we have seen with mandatory criteria.

Comment: Several commenters requested that CMS clarify the following: (1) whether initial claim denials, technical denials, documentation deficiencies, or coding disagreements are considered claims that fail to meet Medicare requirements; (2) whether claims that are subsequently overturned on appeal remain part of the analysis; (3) whether CMS intends to establish numerical thresholds or materiality standards before revocation; and (4) how CMS will distinguish isolated operational errors from systemic abusive conduct.

Response: Concerning the first two requests, we did not propose to interpret or clarify either the phrase ''fails to meet Medicare requirements'' or the types of claims that fall within our analysis. Thus, we believe these requests are outside the scope of this final rule. The answer to the third question is no for reasons already indicated. Regarding the fourth, CMS, as it long has, will carefully evaluate the facts and circumstances of every § 424.535(a)(8)(ii) case and only taken revocation action when justified.

After considering the comments received, we are finalizing proposed revised § 424.535(a)(8)(ii) without modification.

(2) False or Misleading Information (§ 424.535(a)(4))

Section 424.535(a)(4) permits revocation if the provider or supplier certified as ''true'' misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. We proposed to revise § 424.535(a)(4) to allow revocation based on the submission of false or misleading information on or associated with any CMS or Medicare enrollment-related form. This would include but not be limited to: (1) enrollment-related forms created by and/or submitted to CMS contractors; (2) false or misleading documentation furnished as part of the completion or submission of the CMS or Medicare enrollment-related form; (3) the Form CMS–588 (Electronic Funds Transfer (EFT) Authorization Agreement; OMB Control Number 0938–0626), which must be submitted with the enrollment application; (4) documents required to demonstrate compliance with HHA capitalization requirements in § 489.28; (5) opt-out affidavits under 42 CFR part 405, subpart D; (6) letters from a provider demonstrating that a particular provider official qualifies as an authorized or delegated official under § 424.502; and (7) any other required or requested enrollment-related documentation.

We stated that providers and suppliers must always submit truthful enrollment and enrollment-related information to CMS and its contractors regardless of the form or document involved. Any false or misleading information could lead to serious doubts about the provider's veracity, a non-compliant provider being inadvertently enrolled in Medicare, or improper

[16] ''Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies''.

[17] Ibid.

payments based on inaccurately submitted data. With this in mind, we also stressed that under revised § 424.535(a)(4):

- The submission need not be intended to gain or maintain Medicare enrollment. For § 424.535(a)(4) purposes, the ultimate aim of the submission—be it to enroll, revalidate enrollment, reactivate enrollment, voluntarily terminate enrollment, report changed EFT data, etc.—is not as crucial as the truthfulness of the submission. If we continued to limit § 424.535(a)(4) to ''gain or maintain enrollment'' situations, providers might believe they can submit false information on other enrollment-related documents without concern about possible revocation.
- The information need not have been certified as ''true'' for § 424.535(a)(4) to apply. The correctness of the information is the salient point and not whether it was certified as ''true.''

We believe that our § 424.535(a)(4) expansion would help ensure that providers furnish truthful and accurate enrollment-related data to Medicare.

The following is a summary of the comments we received on this proposal and our responses. Note that some of these comments and responses also pertain to proposed revised § 424.530(a)(4), which would permit denial based on the same grounds identified in proposed § 424.535(a)(4). Our final decision regarding § 424.530(a)(4) will be addressed later.

Comment: Numerous commenters stated that our proposed expansion of §§ 424.530(a)(4) and 424.535(a)(4) could result in denials and revocations based on inadvertent or immaterial administrative errors. They stated that CMS should distinguish between intentional fraud and technical or minor mistakes that are promptly corrected. They added that CMS should: (1) include a materiality-based standard—like ''knowing and material misrepresentation''—and other factors in §§ 424.530(a)(4) and 424.535(a)(4) (for example, whether the information is relevant to program integrity); (2) permit providers to cure any unintentional or clerical errors before revocation (such as a 30-day correction timeframe); and (3) always consider mitigating circumstances in its paragraph (a)(4) determinations.

Response: We appreciate these comments and address them as follows.

First, our proposal was not intended to change the standard we always apply when reviewing potential §§ 424.530(a)(4) and 424.535(a)(4) situations. We will continue to carefully consider the facts and circumstances of each case and only deny or revoke when truly justified.

Second, we respectfully decline to establish knowledge, materiality, or other regulatorily specified criteria or thresholds. Sections 424.530(a)(4) and 424.535(a)(4) have never had a knowledge or intent standard or required the data to be material, and we did not propose in this rule to establish such requirements. If we required knowledge or intent, providers might submit false data believing they could later simply disavow awareness thereof to avoid denial or revocation. A materiality threshold, meanwhile, would enable providers to, knowingly or unknowingly, submit incorrect information without fear of consequences so long as it is not deemed material. As for establishing new factors, we reiterate our previously noted concerns about required criteria that constrain our ability to take denial or revocation action when necessary. We also stress that it has long been CMS policy that the enrolling or enrolled provider bears ultimate legal responsibility for the accuracy and thoroughness of all submitted data, a point we reiterated in the CY 2026 HH PPS final rule.

Third, and consistent with our aforementioned quoted statement from the CY 2026 HH PPS final rule, we believe that permitting a pre-revocation correction period and/or quasi-appeals process could disincentivize providers to submit correct and truthful information in their initial submission.

Comment: Some commenters were concerned that the increased number of documents and communications covered by § 424.535(a)(4) could concomitantly increase the chances of a revocation based on an innocent error. This could prove especially problematic for large providers that submit many such documents.

Response: While we appreciate these concerns, the central issue is the submission of the false or misleading information itself and not the number of potential documents on which it could be furnished. All enrollment-related data provided to CMS and the MACs—irrespective of the volume of documents involved—must be truthful and accurate. To restate, though, CMS will evaluate the facts and circumstances of every situation and only deny or revoke when genuinely warranted.

Comment: Several commenters requested clarification on which types of forms and communications are ''associated with'' a provider's enrollment.

Response: We identify in revised § 424.535(a)(4) various types of forms and documents that fall within this category. We will, if needed, issue guidance to further elucidate this term.

Comment: Several commenters recommended that CMS define ''false or misleading information.''

Response: We respectfully believe this comment is outside the scope of this final rule because we did not propose to define this term, which already appears in the current versions of §§ 424.530(a)(4) and 424.535(a)(4). Nonetheless, we can state that the terms ''false'' and ''misleading'' in the context of §§ 424.530(a)(4) and 424.535(a)(4) have—and have always had—their plain meanings.

Comment: A commenter requested that CMS ensure that any technical or automated mechanism used by CMS to detect false information be configured so as not to flag providers that use different acronyms, abbreviations, or spellings for addresses or other demographic information.

Response: We appreciate this comment and stress that CMS in its §§ 424.530(a)(4) and 424.535(a)(4) determinations takes into account the facts and circumstances of the situation.

Comment: A commenter sought confirmation that claims corrected through routine adjustments, self-audits, or voluntary refunds will not independently be treated as evidence of providing false or misleading information.

Response: Sections 424.530(a)(4) and 424.535(a)(4) only apply to enrollment-related submissions.

After considering the comments received, we are finalizing proposed revised § 424.535(a)(4) without modification.

(3) Extension of Revocation (§ 424.535(i))

Section 424.535(i) states that if a provider's enrollment is revoked under § 424.535(a), CMS may revoke any and all of the provider's other enrollments. This provision is designed to ensure that, if circumstances warrant, individuals and entities revoked for inappropriate behavior do not remain enrolled in Medicare—and, hence, potentially able to continue their conduct via their other Medicare enrollments—in any capacity. We proposed to expand § 424.535(i) such that we could also revoke a provider's other enrollments if the provider's triggering enrollment is denied under § 424.530(a).

Numerous commenters opposed our proposal. Their principal contention was that enrollment denials can sometimes be for purely innocuous reasons and should therefore not trigger

revocations of the provider's other enrollments.

After reviewing the comments received, we are not finalizing our proposed revision to § 424.535(i).

(4) Expansion and Reorganization of Retroactive Revocation Grounds (§ 424.535(g))

Section 424.535(g) addresses revocation effective dates. Current paragraph (g)(1) states that except as described in paragraphs (g)(2) and (g)(3), a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider; the revocation is thus prospective. Existing paragraphs (g)(2)(i) through (xv) list situations where the revocation effective date is retroactive. This generally means that the revocation's effective date is retroactive back to the date on which the provider's non-adherence to Medicare requirements commenced.

The purpose of paragraph (g)(2) is to prevent payments to a provider while it is out of compliance. Using an example we included in the proposed rule, assume a provider's medical license is revoked by the State on March 1. CMS learns of this and sends a revocation notice to the provider on March 15. If we applied the prospective ''30 days after mailing'' timeframe in paragraph (g)(1), the provider could bill and be paid for services furnished between March 1 and April 15 while unlicensed, resulting in potentially thousands of dollars in improper Medicare payments. Preventing improper payments is a cornerstone of provider enrollment, and retroactive revocation effective dates are vital mechanisms for ensuring that taxpayer monies are paid only to compliant providers. As § 424.500 makes clear: ''Providers and suppliers must meet and maintain [part 424, subpart P's] enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare-covered services or supplies.'' This means, by extension, that if said requirements are not met, the provider cannot bill—or, in turn, receive payment—for Medicare services or supplies.

Our concerns about paying non-adherent providers are why we have increased the number of retroactive revocation grounds over the years. In the CY 2026 HH PPS final rule, we finalized numerous revisions to § 424.535(g) such that many of our existing revocation reasons are now retroactive.[18] So critical is it to make payments only to qualified providers and to be consistent with §§ 424.500 and 424.505 that we proposed in the CY 2027 HH PPS final rule to make the remainder of current prospective revocation grounds retroactive. We also believe that the prospect of a retroactive revocation no matter the § 424.535(a) reason could help spur providers to ensure constant compliance with Medicare requirements.

We proposed two sets of changes to § 424.535(g). First, we would add new retroactive revocation bases. Second, we proposed to restructure § 424.535(g) to remove current § 424.535(g)(1) (which addresses prospective revocations) and realign the existing retroactive grounds to correspond to the numerical order of our § 424.535(a) revocation reasons. The following summarizes our proposed provisions in revised § 424.535(g)(1).

(a) General Non-Compliance, Licensure, and Provider Agreements

CMS may revoke a provider under § 424.535(a)(1) if the provider is not in compliance with the enrollment requirements in Title 42 of the Act or in the enrollment application applicable to its provider type. We proposed in new § 424.535(g)(1)(i)(A) that said revocation would be effective on the date the non-compliance began (per CMS' or the CMS contractor's determination). This comports with several other current retroactive grounds for which the commencement of non-compliance is the effective date; for said current grounds—as well as proposed § 424.535(g)(1)(i)(A)—the rationale is that payments should not be made to non-adherent providers.

State licensure revocations, suspensions, and surrenders (in lieu of further disciplinary action) are also grounds for revocation. As stated in existing § 424.535(g)(2)(iii) and (v), these revocation effective dates are the dates of the revocation, suspension, or surrender. We proposed to consolidate paragraphs (g)(2)(iii) and (v) within new § 424.535(g)(1)(i)(B), retaining their current effective dates.

Current § 424.535(g)(2)(vii) addresses effective dates for revocations based on a provider agreement termination under part 489. We proposed to retain these dates and incorporate them into new § 424.535(g)(1)(i)(C).

(b) Exclusions/Debarments, Felony Convictions, False Information, and Non-Operational Status

These revocation grounds are addressed in § 424.535(a)(2), (3), (4), and (5)(i), with their concomitant effective dates outlined in existing § 424.535(g)(2)(i), (ii), (ix), and (iv), respectively. Per § 424.535(g)'s proposed reorganization, § 424.535(g)(2)(i), (ii), (ix), and (iv) would become new § 424.535(g)(1)(ii), (iii), (iv), and (v)(A), respectively.

(Due to our aforementioned expansion of § 424.535(a)(4), we proposed that new § 424.535(g)(1)(iv) would include an additional effective date for paragraph (a)(4) revocations based on the submission of false or misleading data not involving the signature of a provider enrollment application certification statement. For these other false/misleading communications, the revocation effective date would be the date the false/misleading information was submitted.)

(c) Failure To Satisfy Enrollment Requirements

Section 424.535(a)(5)(ii) permits revocation if the provider fails to satisfy any Medicare enrollment requirement. We proposed in new § 424.535(g)(1)(v)(B) that a § 424.535(a)(5)(ii) revocation becomes effective on the date the Medicare enrollment requirement was not satisfied.

(d) Application Fee Payment

CMS can revoke a provider's enrollment under § 424.535(a)(6) in various situations concerning the required payment of a provider application fee under § 424.514. We proposed in new § 424.535(g)(1)(vi) that a § 424.535(a)(6) revocation is effective on the date on which CMS or its contractor determines that the provider or supplier should be revoked under this paragraph.

(e) Misuse of Billing Number

CMS may revoke a provider's enrollment under § 424.535(a)(7) if the provider knowingly sells to or allows another individual or entity to use its billing number. (This excludes providers who enter into a valid reassignment of benefits under § 424.80 or a § 489.18 change of ownership.) Given the seriousness of this conduct—with its significant potential for fraud—we proposed in new § 424.535(g)(1)(vii) that the revocation effective date should be the date on which the conduct resulting in the revocation occurred.

(f) Abuse of Billing Privileges

The effective dates for revocations under § 424.535(a)(8)(i) and (ii) are addressed in § 424.535(a)(8)(iii). So that all revocation effective dates can be located in one paragraph, we proposed to move and redesignate § 424.535(a)(8)(iii) as new § 424.535(g)(1)(viii). Paragraph (iii) would be deleted from § 424.535(a)(8).

[18] Ibid.

(g) Reporting Enrollment Data Changes

Section 424.535(a)(9) permits revocation if the provider failed to comply with the change of information reporting requirements in §§ 424.516(d) or (e), 410.33(g)(2), or 424.57(c)(2). These four paragraphs collectively address all Medicare provider and supplier types (except Medicare Diabetes Prevention Programs (MDPPs), which are dealt with in § 424.205)) and all types of enrollment data changes. Current § 424.535(g)(2)(x) partially addresses the effective date of a § 424.535(a)(9) revocation. For revocations based on the provider's failure to timely report a change of ownership or adverse legal action (or a change, addition, or deletion of a practice location), the effective date under § 424.535(g)(2)(x) is the day following the date by which the provider was required to report the change, addition, or deletion. All other changes are prospective under current § 424.535(g)(1).

We proposed in new § 424.535(g)(1)(ix) to make all § 424.535(a)(9) revocations retroactive to the day following the due date for reporting the change. While ownership, adverse legal action, and practice location changes are important (hence their inclusion in existing § 424.535(g)(2)(x)), other data changes are as well. A failure to timely report a new managing employee or corporate officer, for example, could result in CMS unknowingly paying a provider with a high-level official who poses a program integrity risk based on past or current conduct. If we do not timely learn of a provider's new bank, billing agency, or correspondence address, CMS risks sending funds or information to—or receiving claims from—the wrong entity or individual; this could lead to incorrect payments or the inadvertent release of confidential data. As we emphasized in the proposed rule: (1) outdated or erroneous enrollment information of any type—not simply ownership, adverse action, or location data—can threaten the Trust Funds; and (2) any failure to timely report such changes means the provider is non-compliant with enrollment requirements. For these reasons—and because the prospect of a retroactive revocation could encourage providers to timely report all enrollment changes—we believed that § 424.535(g)(1)(ix) is warranted.

Although the provider is ultimately responsible for ensuring that its enrollment data is timely updated and always accurate, we solicited stakeholder comment on any administrative difficulties in reporting changes in enrollment information and how they could be addressed.

(h) Failure To Document or Furnish Documentation

CMS can revoke a provider under § 424.535(a)(10) if the provider fails to comply with the documentation or CMS access requirements in § 424.516(f). In general, § 424.516(f) requires providers (including physicians and eligible professionals) to: (1) retain for 7 years all documents regarding written orders, certifications, referrals, prescriptions and requests for payments for Part A or B services, items, or drugs; and (2) furnish access to that documentation upon CMS or CMS contractor request.

We proposed in new § 424.535(g)(1)(x)(A) and (B) that a § 424.535(a)(10) effective date is as follows:

- For revocations based on a failure to retain documentation, the date on which CMS or the CMS contractor determines that the provider has not complied with this retention requirement.
- For revocations based on a failure to provide access to that documentation, the day after the date by which the provider was required to give access.

We believed that proposed § 424.535(g)(1)(x)(A) and (B) balance the need for retroactivity—due to, for instance, the provider's non-compliance and our inability to make payment to non-adherent providers—and the need for a clear effective date. To illustrate, suppose CMS discovered several years after a particular service was ordered or certified that the provider lacks documentation thereof. CMS would have no means of knowing whether the documentation was never kept, discarded after 2 years or 4 years, etc. Therefore, it is difficult to establish an effective date in this scenario, hence the need to use the proposed—and much more precise—§ 424.535(g)(1)(x)(A) date. Regarding § 424.535(g)(1)(x)(B), the provider's failure to provide the documentation constitutes non-compliance, similar to a provider's failure to timely report changes of information. Thus, we believe that the day after the due date for furnishing access is an appropriate effective date.

(i) Initial Reserve Operating Funds (IROF)

Under 42 CFR 489.28, HHAs must demonstrate that they have sufficient available funds upon application submission and for the 3-month period following the conveyance of Medicare billing privileges to operate the HHA for this 3-month timeframe. CMS can revoke the HHA under § 424.535(a)(11) if, within 30 days of a CMS or Medicare contractor request, the HHA cannot furnish supporting documentation verifying that it meets the IROF requirement. For the same reasons behind proposed § 424.535(g)(1)(x)(B)—specifically, the provider's non-compliance with § 489.28 based on its failure to demonstrate adequate funds—we proposed in new § 424.535(g)(1)(xi) that the § 424.535(a)(11) revocation effective date is the day after the date by which the HHA was required to submit the requested documentation.

(j) Other Program Termination

CMS under § 424.535(a)(12) may revoke a provider's Medicare enrollment if the provider is terminated, revoked, or otherwise barred from participation in a State Medicaid program or any other Federal health care program. The effective date of a § 424.535(a)(12) revocation is, consistent with existing § 424.535(g)(2)(vi), the date of the termination, revocation, or bar (from the other program). As part of our restructuring of § 424.535(g), we proposed to redesignate § 424.535(g)(2)(vi) as new § 424.535(g)(1)(xii); however, we would include the terms ''revocation'' and ''bar'' within the latter to correspond to § 424.535(a)(12). (Current § 424.535(g)(1)(vi) only references terminations.)

(k) Drug Enforcement Administration (DEA) Certificates

Section 424.535(a)(13)(i) and (ii) permit revocation if—

- A physician or other eligible professional's DEA Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to a show cause order; or
- The applicable licensing or administrative body for any State in which the physician or eligible professional practices suspends or revokes the individual's ability to prescribe one or more drugs.

Existing § 424.535(g)(2)(xi) permits retroactive revocation based on the surrender of the provider's DEA certificate of registration in response to a show cause order. (The revocation effective date is the date the certificate was surrendered.) We proposed to include DEA certificate revocations and suspensions within this paragraph, with the date of the revocation or suspension as the effective date. It is the permanent or temporary loss of the certificate itself—rather than the form of loss (for example, revocation or surrender)—that is important for program integrity

purposes; it would be illogical for certificate surrenders to be part of paragraph (g)(2)(xi) but not revocations or suspensions. As we stated in the CY 2026 HH PPS final rule that promulgated paragraph (g)(2)(xi), meeting all applicable Federal and State requirements is necessary for enrollment.[19] If a provider is prescribing or dispensing drugs while non-compliant, we believe the risk this presents to beneficiaries after the certificate loss warrants a revocation back to the date said loss occurred.

Per current § 424.535(g)(2)(xii), the effective date of a revocation based on a State's suspension or revocation of the physician's or practitioner's ability to prescribe one or more drugs is the date of the suspension or revocation. We proposed to redesignate this paragraph without change as new paragraph (g)(1)(xiii)(B), with existing (g)(2)(xi) redesignated as new paragraph (g)(1)(xiii)(A).

(l) Improper Prescribing Practices

Section 424.535(a)(14) permits revocation if the physician or practitioner has a pattern or practice of prescribing Medicare-covered drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements. We proposed in new § 424.535(g)(1)(xiv) that the effective date of a § 424.535(a)(14) revocation would be the last date of the prescription(s) in question. (This approach mirrors that for § 424.535(a)(8)(ii)'s revocation effective date, which, as noted, is the last date of service on the claims in question.) Applying a prospective effective date to a § 424.535(a)(14) would essentially allow the individual to continue prescribing for at least another 30 days, during which time additional beneficiaries might be placed as risk.

(m) False Claims Act (FCA)

Revocation is permissible under § 424.535(a)(15) if the provider (or owner, managing employee or organization, officer, or director thereof) has had an FCA civil judgment against them within the previous 10 years. We proposed in new paragraph (g)(1)(xv) a retroactive revocation effective date back to the date of the judgment.

(Proposed new § 424.535(g)(1)(xvi) is addressed later in this section V.C. of this final rule.)

(n) Debts Referred to Treasury

Section 424.535(a)(17) permits revocation if the provider failed to repay a debt that CMS appropriately referred to the United States Department of Treasury. (Paragraph (a)(17) does not apply if: (1) the debt has been discharged by a bankruptcy court; or (2) the administrative appeals process regarding the debt has not been exhausted or the timeframe for filing the appeal (at the appropriate appeal level) has not expired.)

All providers are responsible for satisfying their financial obligations to Medicare. Consistent with our rationale for the original promulgation of § 424.535(a)(17), we believe that referral to the Department of Treasury may indicate the provider's unwillingness to repay a debt, which raises doubts regarding whether the provider is a reliable participant in the Medicare program.

With the need to protect the Medicare program's financial integrity, we proposed in new § 424.535(g)(1)(xvii) that the effective date of a § 424.535(a)(17) revocation would be retroactive back to the date on which CMS referred the debt to Treasury. As we explained in the proposed rule, a prospective effective date would give the provider more time to incur additional debts that it also might not repay, placing the taxpayers at considerable financial risk. We also believe that the prospect of a retroactive revocation under § 424.535(g)(1)(xvii) could spur providers to ensure that they repay all debts before the latter are sent to Treasury.

(o) Revoked Under Different Name or Identity

CMS under § 424.535(a)(18) may revoke a provider that is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period under § 424.535(c) has not expired. The objective is to prevent situations where a revoked provider changes its identity in order to re-enter Medicare and thus circumvent its existing bar on reenrollment. In light of such improper conduct, we proposed in new § 424.535(g)(1)(xviii) that a § 424.535(a)(18) revocation effective date would be the same as the effective date of the provider's current enrollment.

(p) Undue Risk

Per § 424.535(a)(19), CMS may revoke a provider or supplier that has or has had an affiliation under § 424.519 that poses an undue risk of fraud, waste, or abuse to the Medicare program. Due to the many different scenarios that could fall within § 424.535(a)(19)'s purview, we proposed in new § 424.535(g)(1)(xix) that a revocation under § 424.535(a)(19) is effective on the date on which CMS or its contractor determines that the provider or supplier should be revoked under this paragraph.

(q) Billing From Non-Compliant Location

CMS may revoke enrollment under § 424.535(a)(20) if the provider billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements. Given the importance of maintaining constant compliance with enrollment requirements, we proposed that a § 424.535(a)(20) revocation's effective date would be the earliest date on the claims for the non-compliant location that are triggering the revocation.

(r) Abusive Ordering, Certifying, Referring, or Prescribing

Section 424.535(a)(21) permits revocation if the physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements. As with proposed § 424.535(g)(1)(xiv) regarding § 424.535(a)(14), the seriousness of the conduct described in § 424.535(a)(21) and the threats it can present to Medicare patients and the Trust Funds (for instance, ordering unnecessary tests) warrants a retroactive effective date. This date under proposed § 424.535(g)(1)(xxi) would be the date of the last order, certification, referral, or prescription in the applicable pattern or practice, akin to the proposed § 424.535(a)(14) effective date.

(s) Patient Harm

Revocation under § 424.535(a)(22) is permissible if the physician or other eligible professional has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper conduct that led to patient harm. Considering the need to protect Medicare beneficiaries from potential harm, we proposed that this effective date per new § 424.535(g)(1)(xxii) would be the date of the prior action that resulted in the revocation.

[19] 90 FR 55342.

(t) Supplier Standard and Condition Violation

Several provider and supplier types have certain standards and conditions they must meet in addition to all other enrollment requirements. These types—and their corresponding standard/condition regulatory sections—include independent diagnostic testing facilities (IDTFs) (§ 410.33(g)), DMEPOS suppliers (§ 424.57(b) and (c)), opioid treatment programs (OTP) (§ 424.67(b) and (e)), home infusion therapy suppliers (§ 424.68(c) and (e)), and MDPPs (§ 424.205(b) and (c)). Except for § 424.57(b) violations, CMS under § 424.535(a)(23) may revoke the provider or supplier for non-compliance with any of the standards or conditions applicable to their provider/supplier type. (Revocation is permissible for § 424.57(b) violations (as well as § 424.57(c) non-compliance) under § 424.57(e)(1).) The current § 424.535(a)(23) revocation effective dates (outlined in § 424.535(g)(2)(xv)(A) through (D), respectively) are as follows:

- For standard or condition violations involving the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's Federal or State license, certification, accreditation, or MDPP recognition, the date of the suspension, revocation, termination, or surrender.
- For standard or condition violations involving a non-operational practice location, the date the non-operational status began.
- For OTP standard violations involving a felony conviction of a party described in § 424.67(b)(6)(i), the date of the felony conviction.
- For all standard violations not addressed in existing paragraph (g)(2) (which, as discussed, would be incorporated within revised (g)(1)), the prospective effective date in current paragraph (g)(1) applies if the effective date in existing paragraph (g)(3) (discussed shortly) does not.

We proposed to retain the dates in § 424.535(g)(2)(xv)(A) through (C), though we would re-designate them as new § 424.535(g)(1)(xxiii)(A)(*1*) through (*3*). In new § 424.535(g)(1)(xxiii)(B)—and consistent with the foregoing concerns about paying non-compliant providers—we proposed that the effective date of all other revocations based on a condition or standard violation would be the date of non-compliance with the condition or standard.

We proposed three other organizational changes. First, existing § 424.535(g)(2)(viii) states that the effective date of a revocation based on a lapse in the IDTF's comprehensive liability insurance under § 410.33(g)(6) is the date the insurance lapsed. We did not propose to include a separate effective date for this revocation in revised § 424.535(g)(1) because we believe it would fall within new § 424.535(g)(1)(xxiii)(B), with the lapse date being the standard violation date. Second, existing § 424.535(g)(2)(xiv) states that the effective date of a revocation based on a DMEPOS supplier's non-compliance with a condition or standard in § 424.57(b) or (c) is the date on which the non-compliance began. This provision would not be included in revised § 424.535(g)(1), for new § 424.535(g)(1)(xxiii) would cover § 424.57(b) or (c) violations. Third, existing paragraph (g)(3) would be re-designated as revised § 424.535(g)(2).

(u) Extension of Revocation

As already noted, § 424.535(i) states that if a provider's Medicare enrollment is revoked, CMS may revoke any and all of the provider's Medicare enrollments, including those under different names, numerical identifiers or business identities and those under different types. The effective date of the revocation(s) of the other enrollment(s) is—per existing § 424.535(g)(2)(xiii)—the effective date of the revocation that triggered the other revocation(s). We proposed to retain this effective date provision but would redesignate it as new § 424.535(g)(2)(xxvi).

(Proposed new § 424.535(g)(1)(xxiv) and (xxv) will be addressed later.)

The following is a summary of the comments we received on our retroactive revocation proposals and our responses.

Comment: Many commenters opposed CMS' proposal to extend its retroactive revocation authority to all revocations and recommended that it not be finalized. They stated that retroactive revocations can impose severe and disproportionate financial consequences on otherwise legitimate providers and suppliers.

Response: We appreciate and understand the concerns expressed. We respond as follows.

First, and as previously noted, in past years we have gradually expanded the reasons for which we may retroactively revoke providers. In last year's CY 2026 HH PPS final rule, we added roughly 10 new retroactive grounds. Accordingly, retroactive revocations are not a novel concept but have been used to a considerable degree for some time. Our retroactive revocation proposals in this year's rule are consistent with current practice.

Second, we explained to commenters in last year's CY 2026 HH PPS final rule that retroactive revocations are intended to recoup payments to which the provider is not entitled due to its non-compliance. Generally, once the provider is non-adherent to Medicare enrollment requirements, it cannot receive payment for services furnished beginning on or after the point the non-compliance began. We especially emphasized in that rule that: (1) our allowance of prospective dates for certain revocation grounds has resulted in hundreds of millions of dollars in payments to non-compliant providers; and (2) we have an obligation to the American taxpayers to halt this.[20] We maintain this position in the present final rule; taxpayer monies must be protected against improper payments.

Third, retroactive liability under § 424.535(g) does not occur without a revocation. This may seem obvious, but it is critical for stakeholders to understand that revocations are actually quite rare when weighed against the universe of well over 2 million Medicare providers and suppliers. In fact, only about 3 percent of providers are ever revoked. It is never a step we wish to take—partly because, like the commenters, we fully recognize its consequences and the potential retroactive financial liability—and in many cases we instead apply more modest actions such as deactivations under § 424.540 and stays of enrollment under § 424.541; indeed, we promulgated the latter action in the CY 2024 Physician Fee Schedule final rule (88 FR 78818)[21] to give us greater flexibility to address certain instances of comparatively minor non-compliance without having to pursue revocation.

In sum, despite our recognition of the commenters' concerns, we are unable to make payment to providers that are not compliant with Medicare enrollment requirements. This is consistent with the requirements of §§ 424.500 and 424.505 and underlies the need for our proposed expansion of retroactive revocation grounds. Yet because we recognize the consequences of a retroactive revocation, we seek to assure providers that revocations are not only infrequent but also are only imposed when genuinely warranted. This will not change under revised § 424.535(g).

[20] Ibid.

[21] "Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program".

Comment: Several commenters stated that retroactive revocations can impair or interrupt beneficiary access to care.

Response: Our expansion of retroactive revocation grounds in past years has not, to our knowledge, resulted in the material prevention or disruption of beneficiary care. Thus, we have no reason to believe said hindrances will occur with our revisions to § 424.535(g); this is especially true given, again, the infrequency of revocations. Nonetheless, we will, as we always have, remain watchful for any access to care issues.

Comment: Numerous commenters expressed concern that CMS' proposal would, in essence, unfairly convert technical or minor provider errors into a finding that every covered service during the period in question is unpayable. They stated that such deficiencies should not trigger a retroactive revocation, the current prospective dates for these reasons should remain (for example, reporting a change of information), and retroactive revocations should be reserved for serious misconduct, such as, but not limited to: (1) criminal activity; (2) intentional or systemic provider fraud, waste, or abuse; (3) material non-compliance; or (4) patient harm.

Response: While we appreciate these comments, they appear to presume that every minor error does or will automatically result in a revocation. This has never been the case. As explained earlier, we frequently use other actions (for example, stays) to address such situations. On the other hand, we reiterate that non-compliance with enrollment requirements—even if the provider believes it is a mere technical or inconsequential violation—should result in non-payment. The current prospective effective date in § 424.535(g) for certain revocations is directly antithetical to this, which is why: (1) a retroactive date is needed if we believe the non-compliance warrants a revocation; and (2) we cannot restrict retroactive revocations to matters such as criminal or fraudulent behavior or beneficiary harm. Non-compliance at any level and to any degree remains non-compliance.

Comment: A few commenters stated that CMS' retroactive revocation proposals lack clear, explicit congressional authorization and fail the independent statutory interpretation standard.

Response: We respectfully disagree. We previously stated that sections 1102 and 1871 of the Act give the Secretary discretion to promulgate regulations that are necessary for the efficient administration of the Medicare program; section 1866(j), meanwhile, states in paragraph (1) that the Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title. In our view, establishing revocation effective dates and ensuring that Medicare payments are made correctly and only to compliant providers and suppliers—which is the central purpose of retroactive revocations—clearly falls within the scopes of sections 1102, 1871, and 1866(j) of the Act. Hence, we believe—as we have with our prior regulatory expansions of retroactive revocations—that sections 1102, 1871, and 1866(j) of the Act furnish sufficient authority for our § 424.535(g) proposal.

Comment: Several commenters stated that CMS' proposed expansion of § 424.535(g) is inconsistent with certain aspects of section 1866(b)(2) of the Act. Under section 1866(b)(2)(i) and (ii), CMS may refuse to enter into a provider agreement or—upon such reasonable notice to the provider and the public—may refuse to renew or may terminate such an agreement if CMS determines that the provider fails to: (1) comply substantially with the provisions of the agreement, with the provisions of Title XVIII and regulations thereunder, or with a corrective action required under section 1886(f)(2)(B); or (2) substantially meet the applicable provisions of section 1861 of the Act. The commenters appeared to contend that a provider that is retroactively revoked has not been given ''reasonable notice'' of its non-compliance because, in effect, the provider: (1) might not have realized it is non-compliant; (2) had thus been furnishing legitimate services in good-faith; (3) only belatedly learned of its non-adherence; and (4) is now responsible for repaying Medicare. Accordingly, they concluded that the revocation's retroactive nature violates section 1866(b)(2) of the Act. Another contention seemingly was that so long as the provider ''substantially'' (as that term is used in section 1866(b)(2) of the Act) complies with enrollment requirements, a retroactive revocation is impermissible.

Other commenters stated that section 1866(b)(2) would be violated if CMS applied one of its proposed retroactive revocation grounds to a time period prior to January 1, 2027. This is because, the commenters contended, the section 1866(b)(2) of the Act requirement of ''reasonable notice'' to the provider will not have been met—particularly if the revocation effective date goes back several years.

Response: Provider enrollment and provider agreements are different concepts operating under different authorities and requirements. In general, Medicare provider enrollment is the process by which providers and suppliers seek to obtain and maintain Medicare billing privileges; it is largely governed by section 1866(j) of the Act and 42 CFR 424.500 through 424.575. A provider agreement, as defined in 42 CFR 489.3, is an agreement between CMS and a provider identified in § 489.2(b) to furnish services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act. Subparts A and B of part 489 address provider agreements. The provisions and parameters of section 1866(b)(2) of the Act, in short, do not apply to provider enrollment, and we emphasize that complete compliance with enrollment provisions—rather than merely ''substantial'' compliance—is required to obtain and maintain billing privileges.

Comment: Several commenters stated that retroactive revocations under § 424.535(a)(8)(ii) and any associated recoupment could violate section 1879(a)(2) of the Act whereby, the commenters contended, a provider need not reimburse any overpayment if it ''did not know, and could not reasonably have been expected to know, that payment would not be made.''

Response: We respectfully disagree with this comment. Section 1879(a)(2) of the Act is only one of two requirements needed for section 1879(a) of the Act to apply. The other, section 1879(a)(1) of the Act, requires a CMS determination that—based on section 1862(a)(1) or (9) of the Act or by reason of a coverage denial described in section 1862(g) of the Act—Part A or Part B payment may not be made for any expenses incurred for items or services furnished by a provider of services or by another person pursuant to an assignment under section 1842(b)(3)(B)(ii) of the Act. Section 1879(a)(1) of the Act does not apply to retroactive revocations because, among other things, the specific denial reasons listed in that section are not applicable to the overpayment determination.

Comment: A commenter stated that retroactive revocations could disincentivize providers from self-disclosure and prompt remediation of non-compliance out of concern that CMS will revoke the provider based on said non-adherence.

Response: We respectfully disagree. We saw no evidence of this following previous expansions of retroactive revocation grounds. In fact, we believe it will encourage providers to be more vigilant in their reporting responsibilities.

Comment: A few commenters maintained that our retroactive revocation provisions would violate section 1866(b)(3) of the Act. Section 1866(b)(3) of the Act states that the effective date of a termination or refusal to renew a provider agreement shall become effective on the same date and in the same manner as an exclusion from participation under section 1128(c) of the Act. Section 1128(c)(1) of the Act conditions such an exclusion on ''reasonable notice,'' and section 1128(c)(2)(A) of the Act limits this exclusion to services furnished to an individual on or after the effective date. Moreover, section 1128(c)(2)(B)(ii) of the Act provides that—absent a health and safety determination—an exclusion does not apply to payment for home health services and hospice care furnished to an individual under a plan of care established before the date of the exclusion. It follows, the commenters concluded, that: (1) under these statutes, a provider must first receive adequate notice prior to the effective date of any such termination action, including revocation; and (2) proposed § 424.535(g) would violate this requirement because the termination effective date would precede notice and apply retroactively to services already provided.

Response: We respectfully disagree with these contentions for two reasons. First, section 1866(b)(3) of the Act, like section 1866(b)(2) of the Act, is inapplicable to provider enrollment. As discussed earlier, provider enrollment and provider agreements are different concepts operating under different authorities and requirements, and termination of a provider agreement is distinct from a denial or revocation of enrollment in Medicare. Second, section 1128(c) does not apply to Medicare denials and revocations but only to OIG exclusions. Consequently, these retroactive revocation provisions do not violate section 1866(b)(3) of the Act.

Comment: Commenters recommended that in its retroactive revocation determinations, CMS should consider whether: (1) the provider reasonably believed it was compliant with enrollment requirements when it provided the services; and (2) the services were medically necessary, documented, and otherwise covered (including whether CMS or its contractor possessed the relevant information while continuing to process claims).

Response: We appreciate these suggestions but decline to commit to them. As we stated in the CY 2026 HH PPS final rule and have noted in other provider enrollment rules, it is ultimately the provider's responsibility to ensure constant adherence to Medicare enrollment requirements.[22] While we say this most respectfully, simply having a reasonable or good-faith belief that is it compliant with these requirements does not exempt the provider from the obligation to actually be compliant. Payments to a non-adherent provider are inappropriate irrespective of: (1) the provider's belief in its compliance; or (2) whether the furnished services were otherwise proper.

Comment: Several commenters stated that CMS should limit recoupment to claims causally related to the identified noncompliance. Another commenter requested that accredited Complex Rehabilitation Technology suppliers be exempt from retroactive revocation effective dates.

Response: We respectfully refer these commenters to our previous response. The issue is the submission of claims for services furnished while the provider is non-compliant, irrespective of whether the claim is related to the non-compliance or to the type of provider or supplier involved; it is partly for this latter reason that we cannot exempt certain provider or supplier types from retroactive revocation application.

Comment: A commenter supported our retroactive revocation proposals. The commenter stated that prospective revocations create a window during which noncompliant providers can continue billing Medicare after the basis for revocation has been identified; retroactive revocations close this gap. The commenter also recommended that CMS supplement this provision with standardized documentation requirements that establish what evidence must be collected and maintained before a retroactive revocation decision is made.

Response: We appreciate the commenter's support and entirely concur with the concerns expressed about prospective revocation effective dates. However, we respectfully decline the commenter's documentation recommendation because we must retain the operational flexibility to address all types of potential retroactive revocations; given the very different facts of each case, a fixed, required form of documentation might not fit all scenarios.

Comment: A few commenters stated that providers should not be retroactively revoked based on requirements that were ambiguous, newly articulated, or not reasonably understood at the time services were furnished. They stated that before enforcing any expanded retroactive revocation authority, CMS should, among other things: (1) issue detailed guidance and practical examples; and (2) furnish education to providers and the MACs.

Response: We are respectfully uncertain as to which specific requirements the commenters believe are unclear or the matters on which the commenters seek guidance. We note that CMS cannot automatically exempt providers from retroactive revocations simply because the provider states that it did not understand certain requirements. If we granted such exceptions in all cases, each potentially revoked provider might claim said misunderstanding to avoid revocation. It is also each provider's responsibility to ensure that it comprehends all requirements. That said, and as later discussed, we expect—to the extent needed—to issue additional guidance regarding our new provisions following the publication of this final rule.

Comment: Numerous commenters stated that CMS should: (1) furnish a reasonable opportunity to cure technical deficiencies before CMS retroactively revokes a provider and begins recoupment; and (2) ensure that the consequence is proportionate to the conduct.

Response: Regarding cure opportunities, we respectfully refer the commenters to our earlier statements—both in the CY 2026 HH PPS final rule and the present rule—about informal pre-revocation appeals processes and our inability to make payment for services furnished while the provider is non-compliant, even if the issue is later corrected. As for the second comment, we reiterate that we: (1) often apply more modest actions (for instance, deactivations and stays) to help ensure proportionality; and (2) only undertake revocation when genuinely justified.

Comment: Numerous commenters stated that CMS should not commence retroactive revocation recoupment until after provider has exhausted its appeal rights or otherwise has had an opportunity for administrative review. Some commenters also questioned whether recouped payments would be returned to the provider if the revocation is reversed on appeal.

[22] ''Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies''.

Response: We thank the commenters for their feedback and note that we addressed these same issues in the CY 2026 HH PPS final rule. In response to comments, we stated that we historically have not delayed implementing retroactive revocations or commencing collections while appeals are pending.[23] We explained that because the appeals process can take some time, delayed revocation and recoupment implementation could result in many millions of dollars in continued payments to non-compliant providers as well as postponed repayment of monies to which Medicare and the taxpayers are entitled.[24] We stressed, though, that if the revocation is reversed is appeal, repayment of any collected monies to the provider can be facilitated.[25] These remain our stances with respect to our § 424.535(g) proposal in the current final rule.

Comment: A commenter stated that CMS should not have a retroactive effective date for § 424.535(a)(17) until it clarifies: (1) the circumstances under which a provider is treated as having failed to repay a debt referred to the Department of the Treasury; (2) the period a provider has before that determination is made; and (3) the number of contacts CMS will attempt beforehand.

Response: We refer the commenter to CMS Publication 100–06 (Financial Management Manual), Chapter 4 for information on these three issues.[26]

Comment: Commenters stated that retroactive revocations should require an individualized CMS determination of the provider's relative risk or non-compliance.

Response: With each potential revocation, CMS carefully reviews the facts and circumstances of the case. We view this as an individualized finding regarding the provider's conduct.

Comment: Several commenters recommended a maximum lookback period for retroactive recoupment, with a few commenters suggesting 3 years.

Response: We respectfully disagree. When a provider furnishes services while non-compliant, it is largely immaterial whether, for instance, the service was provided two weeks before the provider received the revocation letter, one year prior, or even three years prior. Payments cannot be made to non-adherent providers.

Comment: Commenters stated that all retroactive revocation notices to providers should explain: (1) the factual and legal basis for—and identify the evidence behind—any retroactive effective date; (2) the available rebuttal, corrective-action, and appeal options; (3) why the provider was noncompliant as of that date; (4) why retroactivity, rather than prospective revocation or a corrective action, is warranted; and (5) the timeframe for (and details of) recoupment.

Response: We appreciate these comments. CMS does not make a separate, individualized determination as to whether a revocation should or should not be retroactive. Retroactivity or prospectivity is determined by the applicable regulatory provision. For example, existing § 424.535(g)(2)(xii) requires that a revocation based on a State's suspension of a physician's prescribing ability be retroactive to the date of the suspension; the date cannot be made prospective. However, each revocation letter always identifies: (1) the factual and legal basis for the revocation; (2) the effective date as specified in § 424.535(g); and (3) appeal rights and procedures. We also separately notify providers of the recoupment process and its timing. Such will remain so under revised § 424.535(g).

Comment: A commenter requested that CMS not apply retroactive revocation effective dates to: (1) reporting-only State deficiencies absent intentional concealment; or (2) condition- or standard-level findings that the provider corrects through an accepted plan of correction.

Response: We believe the commenter is referencing State survey findings and deficiencies. There is no existing ground in § 424.535(a) (nor did we propose one in this rule) under which CMS takes revocation action based solely and exclusively on such findings or deficiencies.

Comment: Commenters recommended that CMS define and provide examples and objective standards of ''non-compliance'' in this rule for cases where the revocation effective date is the date of non-compliance; several commenters requested the same for retroactive effective dates such as, but not limited to, ''the date a Medicare enrollment requirement was no longer met'' and the last date of improper billing. Second, commenters requested that CMS document (and provide evidence for) the factual basis for any CMS conclusion that the provider was noncompliant as of a particular date.

Response: Given the very large number of factual scenarios that can involve non-compliance, no longer meeting Medicare requirements, etc., and our need to have the flexibility to address them all based on their individual circumstances, we are unable to accommodate the commenters' first request.

We note that we currently have various revocation grounds and effective dates in § 424.535 based on non-compliance. The concept is not new. When revoking on this basis (such as non-compliance with a DMEPOS supplier standard under § 424.57(c)), we explain the reason for the action and how we determined the effective date. This will continue under revised § 424.535(g).

Comment: Several commenters stated that a retroactive revocation effective date based on the date that CMS determines that the provider should be revoked is overly vague.

Response: We respectfully disagree. To the contrary, we believe that the date on which CMS decides that the provider should be revoked is the clearest, most definitive date we can utilize given, as explained, the challenge of establishing precisely when the event generating the revocation occurred.

Comment: A commenter expressed concern about retroactive effective dates for § 424.535(a)(22) revocations. Since a State's investigation of patient harm could take considerable time, the commenter stated that the physician or practitioner—though furnishing legitimate services while licensed and reasonably believing that no adverse State finding would occur—may ultimately be responsible for substantial overpayments. The commenter added that the physician or practitioner, concerned about retroactive liability, might even cease treating patients pending the State's decision.

Response: We appreciate the commenter's concerns. However, patient harm is a serious matter that we believe warrants an effective date that coincides with the date of the prior action from the State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program.

While the issue of whether a physician or practitioner may continue treating patients pending a State investigation for patient harm is outside the scope of this final rule, we again do not anticipate an impact on access to care; this is based on what we have seen after previous establishments of new retroactive revocation grounds.

After reviewing the comments received, we are finalizing our proposed revisions to § 424.535(g) without modification.

[23] Ibid.

[24] Ibid.

[25] Ibid.

[26] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms019018.*

(5) Claim Submissions After Revocation (§ 424.535(h))

Under § 424.535(h)(1)(i) (and excluding HHAs), a revoked provider must—within 60 calendar days after the revocation's effective date—submit all claims for items and services furnished before the date of the revocation letter. For revoked HHAs, § 424.535(h)(1)(ii) states that claims must be submitted within 60 days after the later of the following: (1) the revocation effective date; and (2) the date that the HHA's last payable episode ends.

Prior to 2009, the post-revocation claim submittal period was up to 27 months. It was changed to 60 days for certain provider and supplier types in the CY 2009 Physician Fee Schedule final rule (73 FR 69726).[27] It was later made applicable to all provider and supplier types in a December 5, 2014, final rule (79 FR 72500).[28] In both rules, we explained that the reduction to 60 days was necessary because the prior 27-month period posed significant risk to the Medicare program; it gave problematic providers over 2 years to potentially continue their conduct via the submission of inappropriate claims.

Although the current 60-day period is far less than the prior 27-month timeframe, we have long remained concerned about possible fraudulent, improper, or other non-compliant activity by revoked providers. If a provider engaged in such conduct before the revocation, it may continue it afterwards—and 2 months is still an extensive timeframe in which to do so. Indeed, a revoked provider could submit hundreds of improper claims for hundreds of thousands of dollars during this period. If other providers did the same after their revocations, many millions of Trust Fund dollars would be threatened. With the need to protect taxpayer monies from such parties, we believe that further reducing the submission timeframe could correspondingly lessen the program integrity risk, for providers would have less time to engage in inappropriate billing. For these reasons, we proposed to change the 60-day timeframe referenced in § 424.535(h) to 15 days. While we recognized in the proposed rule that this would be a substantial time reduction, we believed the risk warrants it.

We proposed an additional change to § 424.535(h). We previously explained our proposal to make the remainder of our prospective revocation reasons retrospective. Under existing § 424.535(h), though, if a provider had 60 days from the revocation effective date to submit its claims but the effective date was more than 60 days retroactive, the submission period might well have expired before the provider even received the revocation letter. To ensure that the provider actually has an opportunity to submit its claims, we proposed to change:

- Section 424.535(h)(1)(i) to state that a revoked provider must—within 15 calendar days of the date of the revocation letter—submit all claims for items and services furnished before the revocation effective date.
- Section 424.535(h)(1)(ii) to state that a revoked HHA must—within 15 calendar days of the date of the revocation letter—submit all claims for items and services furnished before the later of the following:

(We did not propose to change §§ 424.535(h)(1)(i)(A) and (B) or (h)(2) (which references the timely filing requirements of § 424.44).)

The following is a summary of the comments we received on this proposal and our responses.

Comment: Numerous commenters opposed the reduction to 15 days, citing two principal concerns. First, larger and moderate-sized providers would need more than 15 days to submit all outstanding claims given the amount of time it would take to identify and prepare potentially many claims. Second, certain provider types are subject to monthly billing cycles, notices of admission, minimum data sets (MDS), and other provider-specific requirements that would make it very difficult (if not impossible) to submit within 15 days all claims for all the services they furnished before the revocation effective date. They stated that CMS should retain the 60-day period or at least give providers and suppliers 30 days or 45 days with extensions for good cause or other special circumstances. Examples of the latter could include (but not be limited to): (1) when billing data cannot be completed and accepted by CMS systems within the filing window; and (2) claims cannot be finalized for periods of care already in progress. A few commenters suggested that if CMS wants to use a 15-day period, it should be 15 business days instead of calendar days.

Response: While we appreciate and understand these concerns, we believe that the seriousness of a revocation—and the program integrity risks that revoked providers pose—require a submission period of much less than 60 days. The risk of continued inappropriate conduct for a 2-month period and the potential loss of many thousands of taxpayer dollars is simply too great to permit a timeframe greater than 15 days, which is why we are also unable to grant the commenters' requested extensions and a change to business days.

Comment: Commenters stated that the 60-day period should be retained for: (1) certain provider types (such as SNFs and HHAs) based on their billing cycles; or (2) providers not revoked for fraud, beneficiary harm, intentional misrepresentation, billing for services not rendered, or similar conduct.

Response: Excluding § 424.535(h)'s longstanding provision regarding HHAs' last payable episodes (previously noted), we do not believe that certain providers—either by type or based on the revocation reason—should be exempt from the ''15-day after the revocation letter date'' requirement. This is because any revocation of any provider presents a heightened program integrity risk [29]—and with it, the potential for improper post-revocation claims to be submitted, even if fraud, patient harm, etc., did not trigger the revocation.

Comment: Several commenters stated that CMS should toll any post-revocation claims submission deadline: (1) pending completion of the revocation appeals process; and (2) for system outages and disasters.

Response: We respectfully disagree. This could result in a delay of many months—far beyond 15 and even 60 days—due to the stoppage of the submission period clock; it would give revoked providers much more opportunity to potentially submit inappropriate claims. This would be contrary to our need to protect the American taxpayers and the Medicare program at large against improper activity.

Comment: Several commenters stated that the 15-day period should begin when the revocation notice is received rather than on the date of the notice.

Response: We respectfully disagree. Using the date of the notice adds far

[27] ''Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)'', published in the **Federal Register** on November 19, 2008.

[28] ''Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment''.

[29] To illustrate this risk, revoked providers—irrespective of their type or the conduct underlying the revocation—are subject to: (1) a minimum 1-year minimum reenrollment bar; and (2) the strictest level of enrollment screening under § 424.518 should they seek to reenroll once their bar expires.

more certainty to when the timeframe actually began than the receipt date; the latter can depend on a variety of factors and be subject to different interpretations. (For this same reason, the 15-day timeframe for submitting stay of enrollment and deactivation rebuttals under §§ 424.541 and 424.546, respectively, is based on the notification letter date, not the receipt date.)

Comment: Multiple commenters questioned whether a provider may resubmit pre-revocation claims without being impacted by the reduced filing period if the revocation is reversed on appeal.

Response: Although it was unclear to us, it appeared the commenters were asking whether any 15-day deadline applies for the resubmission of any pre-revocation claims after a reversal occurs. If so, the answer is no.

Comment: A commenter requested that CMS: (1) explain how rejected claims submitted within § 424.535(h)'s timeframe are treated and whether providers can resubmit those claims; and (2) establish a minimum claims submission period rather than permit retroactive revocations.

Response: Regarding the second comment, merely adjusting the claim submission period in lieu of retroactive revocation would fail to address the aforementioned need to recoup payments that were made to non-compliant providers. For the first, rejected claims would be handled in the same manner they are under existing § 424.535(h).

Comment: Several commenters requested that CMS explain how the 15-day period would apply to SNFs, HHAs, and other provider types with specific billing requirements such as minimum data sets and monthly billing.

Response: We will, as appropriate, issue guidance on this matter.

Comment: A few commenters expressed concern that the provider may not receive the revocation letter, in which case the 15-day period might expire before the provider learns of the revocation.

Response: While we appreciate this concern, CMS and the MACs strive to take appropriate steps for affected providers to receive revocation letters timely.

Comment: A commenter expressed support for our proposed change to § 424.535(h).

Response: We appreciate the commenter's support.

After considering the comments received, we are finalizing our revisions to § 424.535(h) without modification.

(6) New Revocation Reasons

We also proposed to add several new grounds for revocation in § 424.535(a).

(a) High-Risk Enrollments (§ 424.535(a)(24))

As explained in the proposed rule, we have seen an alarming increase in situations where an unusually and disproportionately large number of providers and suppliers—sometimes of the same type—are simultaneously operating within a very small geographic area (for instance, a multi-block sector), the same complex or building, or even the same suite. Examples include: (1) several dozen hospices within a four-block area of Los Angeles County; (2) 18 HHAs within the same building in Columbus, Ohio; (3) at least nine cases in Ohio where at least five HHAs have the same practice location address, with four of these nine situations involving at least nine HHAs in one location; and (4) similar situations with several certified providers of the same type operating out of one building in Michigan, Nevada, North Carolina, and Texas. Per CMS data, the number of HHAs in Los Angeles County between 2019 and 2023 rose over 45 percent, and at least 1,400 new HHAs have enrolled in the county since 2019. There was no medical need for such an enormous rise, which was entirely out of proportion with any increase in the county's beneficiary population and can be a strong indicator of widespread fraud. Others share our concerns about this, including the Medicare Payment Advisory Commission,[30] members of Congress,[31] and even several national HHA and hospice organizations.[32]

We recognize that many medical facilities, complexes, and geographic areas have large numbers of providers and suppliers located therein. To illustrate, a medical building on a hospital campus may have seven physician practices with different specialties, two laboratories, etc. Also, some areas may have several types of providers and suppliers within a particular neighborhood. The vast preponderance of these situations do not, in and of themselves, necessarily mean that fraud, waste, and abuse exists or that program integrity risks are otherwise present. Yet we believe those cases mentioned in the previous paragraph—as well as other situations—can and do. Fraud schemes can indeed involve problematic (or potentially problematic) providers operating in same general vicinity, as shown in the Los Angeles County and Columbus situations. Although having, for example, four organizational providers/suppliers of the same type (such as ambulance companies) in a seven-block area does not automatically signify fraud, waste, and abuse, it does—based on our experience—raise questions as to whether there is a patient need for all these providers or whether other considerations, such as fraud, are involved.

With tens of millions of Medicare dollars at risk in any fraud scheme, our role in safeguarding the Trust Funds requires the ability to take revocation action—if circumstances warrant—to address such situations. This is especially important because we currently lack authority under § 424.535(a) to revoke providers/suppliers based on program integrity threats stemming from an excessive number of enrolled providers/suppliers within a particular area. We accordingly proposed in new § 424.535(a)(24) that CMS may revoke a provider's or supplier's enrollment if it deems the enrollment as presenting a high risk of fraud, waste, or abuse due to the provider's or supplier's location within a limited geographic area that has an excessive number of providers and suppliers. We noted the following regarding § 424.535(a)(24) in the proposed rule.

First, the term ''high risk'' for purposes of § 424.535(a)(24) does not mean the provider must be in: (1) the ''high'' screening level under § 424.518(c); or (2) a region that has traditionally posed a high risk of fraud, waste, and abuse, such as south Florida. To be sure, § 424.518(c) providers—as well as providers in known program integrity hotspots—pose elevated risks, a matter we may consider in § 424.535(a)(24) determinations. Yet other provider types in other areas can present threats as well. The risk that a particular provider poses based on its proximity to other providers—somewhat more so than the provider type and historic geographic risk—is the main consideration under proposed § 424.535(a)(24).

[30] *https://www.medpac.gov/wp-content/uploads/2025/12/Tab-H-HHA-update-Dec-2025.pdf.*

[31] Letter from United States House Representatives Brett Guthrie, John Joyce, M.D., Morgan Griffith, Jason Smith, David Schweikert, and Vern Buchanan to T. March Bell, Inspector General, HHS–OIG, January 9, 2026, *https://energycommerce.house.gov/posts/chairmen-guthrie-joyce-griffith-smith-schweikert-and-buchanan-ask-hhs-oig-about-ongoing-hha-and-hospice-fraud-in-los-angeles-county-1.*

[32] Letter from LeadingAge and the National Alliance for Care at Home Letter to Dr. Mehmet Oz, CMS Administrator, December 22, 2025, *https://allianceforcareathome.org/wp-content/uploads/Final-Alliance-and-LeadingAge-Home-Health-and-Hospice-Program-Integrity-Recommendations.pdf.*

Second, a potential fraud scheme can involve multiple provider and supplier types; for example, several HHAs, hospices, DMEPOS suppliers, physicians, etc., might be participating in a single operation. A § 424.535(a)(24) revocation therefore would not require the provider in question and the other providers/suppliers in the area to be of the same type.

Third, the terms ''limited geographic area'' or ''excessive number'' in the context of § 424.535(a)(24) will have their ordinary, plain-language meanings. This is due to the many factual situations that could arise and our need to address them—something that thresholds such as minimum/maximum distance or numbers of providers would obstruct. Moreover, such thresholds would alert potentially problematic providers as to how to circumvent a § 424.535(a)(24) revocation. If, to illustrate, we stated that § 424.535(a)(24) only applies if there are at least X number of providers within a radius of Y miles, providers seeking to engage in fraud might enroll immediately outside said radius and/or within an area with fewer providers. This would defeat the purpose of § 424.535(a)(24). That said, our primary focus is on providers in smaller areas—common buildings and complexes, city and town blocks, neighborhoods, etc. Although we reserve the right to apply § 424.535(a)(24) to providers in larger areas (especially if there is an abnormally high number of providers therein), § 424.535(a)(24)'s application would typically be relatively narrow in scope.

Fourth, an actual finding of fraud, waste, or abuse by the provider or another provider in the area would not be required for a § 424.535(a)(24) revocation. This is akin to section 1866(j)(5) of the Act (codified in § 424.519), which permits denial or revocation if (1) the provider has or has had a certain type of affiliation with another provider or supplier, and (2) the affiliation poses an undue risk of fraud, waste, or abuse; no determination of actual fraud, waste, or abuse is needed. Section 424.535(a)(24) revocations would be based on the assessed risk and not whether the provider or nearby providers have actually engaged in fraudulent conduct.

Fifth, while several existing revocation reasons in § 424.535(a) require CMS to consider specified factors in its revocation decisions, we are not proposing the same for § 424.535(a)(24). Consistent with our prior discussion regarding § 424.535(a)(8)(ii), we must be able to address all potential § 424.535(a)(24) scenarios without the rigid restrictions of required criteria and based solely on the unique facts and circumstances of each case.

Sixth, some interested parties may detect certain similarities between § 424.535(a)(24) and our authority under section 1866(j)(7) of the Act (codified in § 424.570) to impose a temporary enrollment moratorium. Although we address temporary moratoria in greater detail later in section V.C.1.f.(2).(b). of this final rule, we state here that a moratorium differs from § 424.535(a)(24) in many ways. The latter, for instance: (1) is a revocation reason rather a prohibition on new enrollments; and (2) takes into account the provider's proximity to other providers of all types, not simply the number of (or risk posed by) providers of the same type.

As much as anything else, though, we emphasized that proposed § 424.535(a)(24) was not principally designed to revoke good-faith providers who otherwise present no apparent risks even though they might, for example, be in an area with numerous other providers. Providers should not at all assume they would be revoked under § 424.535(a)(24) merely because they operate near other providers. Indeed, the overwhelming preponderance would not be. Section 424.535(a)(24) would only be applied in exceptional instances where, based on the facts and circumstances, the risk genuinely justifies it.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Many commenters opposed our proposal. They noted that providers—urban and rural, large and small—are frequently located near other providers for reasons such as: (1) administrative and financial efficiency (for example, sharing a building to reduce costs); and (2) the facilitation of patient care as part of multi-provider, comprehensive treatment. A provider's mere presence among other providers, they contended, does not by itself indicate program integrity risk. While, in certain instances, they stated that proximity might be a basis for closer CMS review or investigation, it should never be grounds for revocation. They urged CMS to withdraw proposed § 424.535(a)(24) and instead use other means of addressing geographic concentration, such as enhanced screening and oversight.

Response: We appreciate these comments and respond as follows.

First, and as we have stated, we acknowledge that hospitals, medical complexes, office buildings, densely populated communities, etc., frequently have numerous providers and provider types operating within and around them. Many of these situations by themselves do not involve fraud, waste, or abuse, or risks thereof, and we do not believe the proposed rule stated otherwise. Our principal focus is instead on isolated cases we have seen where, for instance, there are obvious, extremely heavy, and highly aberrant clusters of providers—frequently of the same provider type—operating within a very small area similar to that we saw in our aforementioned Los Angeles and Columbus examples. Established health care systems, hospital campuses, medical complexes, etc., are not the targets of § 424.535(a)(24). We fully understand the concerns that commenters expressed about § 424.535(a)(24). We wish to again reassure providers and suppliers that, by and large, we are not seeking to target legitimate, common, and standard concentrations of providers in places such as hospital medical centers and health system complexes that would normally have a greater number of providers and suppliers therein. It is the unusual situations that we seek to address—and even in some of these cases, revocation might not occur.

Second, and on the other hand, we disagree that concentration must never be a reason for revocation. Such a position, in our view, disregards the crucial concept of risk. While, as stated, concentration does not automatically mean that a program integrity risk exists—it very frequently will not—this does not mean that said risk can never exist. Consider the Columbus situation, where, inexplicably, there were 18 HHAs operating within one building and the program integrity risk was accordingly very high. If we took the stance that no action could be taken because concentration never means risk, we effectively must wait until we learn that fraud has actually occurred before taking measures—by which point millions of dollars in taxpayer monies may have been lost. This would reflect the pay-and-chase formula that has proven far less effective in halting fraud, waste, and abuse than the approach of stopping fraud before it begins. We believe that our duty to the American people to protect the Trust Funds and beneficiaries requires us be preventive and proactive—not reactive—in response to program integrity risks, hence the need for § 424.535(a)(24). Hence we respectfully decline to withdraw our proposal and maintain that it would be the most effective way—more so than other potential

program integrity mechanisms—to address this particular vulnerability.

Comment: Commenters requested that CMS establish regulatory factors or standards that CMS must consider in determining risk and, in turn, whether to revoke a provider under § 424.535(a)(24). Criteria and parameters that commenters suggested included (but were not limited to): (1) the provider's ownership, billing patterns, adverse legal history, compliance history, history of timely responses to CMS inquiries, operational status, physical capacity, and specific conduct; (2) whether the provider furnished services inconsistent with beneficiary diagnoses; (3) the provider's relationships (if any) with other providers within the concentrated area; (4) beneficiary complaints against the provider; (5) beneficiary demand and market access needs; (6) whether the provider engaged in patient harm; (7) numerical thresholds for a revocation to occur—such as a certain number of providers of a particular type within a regulatorily specified geographic area (for instance, within X number of square miles or neighborhood blocks; X square feet of a building or medical center size; (8) defining ''limited area'' and ''excessive number'' (potentially after consulting with the applicable State agency regarding provider need and market saturation); (9) referral sources and beneficiary overlap; and (10) the degree of concentration, including sub-factors CMS should consider in determining this. The commenters stated that having required factors will ensure objectivity and transparency and, a commenter contended, facilitate a ''totality of the circumstances'' approach.

Response: We appreciate these recommendations and reiterate that we will consider the facts and circumstances of every potential § 424.535(a)(24) case. This could, if warranted, include some of the data the commenters recommended. Yet as previously explained, we must have flexibility in potential denial and revocation determinations under §§ 424.530 424.535 in light of the wide range of factual situations that can and do arise. Having explicit, inflexible factors and numerical thresholds that we must consider in every case significantly hinders this ability. It can also, as already noted, alert dishonest providers as to what CMS contemplates in its denial and revocation decisions, hence enabling them to adjust their behavior to circumvent these criteria and thresholds; to illustrate, if we defined ''excessive number'' as meaning the particular cluster must have at least X number of providers within less than X square miles for § 424.535(a)(24) to apply, providers in a fraud scheme could position their locations so as to avoid this threshold. For all these reasons, § 424.535(a)(24) will not contain regulatorily-specified factors, parameters, or definitions.

Comment: Several commenters requested that CMS clarify a number of operational considerations regarding § 424.535(a)(24). These included, but were not limited to: (1) the data CMS will use in its determination and whether the provider may review it; (2) whether CMS' methodology and the criteria CMS used will be made public; (3) the frequency with which CMS will re-review and, if needed, update said determination; and (4) whether a provider that is revoked under § 424.535(a)(24) based strictly on saturation may enroll in a different but non-saturated area.

Response: We will explain the basis for each revocation in our revocation letter to the provider. However, consistent with our decades-long revocation processes, we do not plan to disclose to the public the specific facts, data, and methodology used in each case. Furthermore, except as specified in the appeal process described in 42 CFR part 498, CMS also will not re-review § 424.535(a)(24) revocations. As for the fourth issue, we respectfully cannot pre-determine a particular situation based on hypothetical facts.

Comment: Commenters stated that § 424.535(a)(24) raises due process concerns because an otherwise compliant and legitimate provider could be revoked simply because of its location. They stated that in any § 424.535(a)(24) case, CMS should: (1) require clear evidence and an individualized finding of the provider's specific conduct (rather than mere location within a certain area), with several commenters requesting a formal finding of fraud, waste, or abuse; and (2) allow the provider to challenge and submit evidence to rebut CMS' decision—and to cure any deficiencies—before the revocation occurs.

We appreciate these comments, understand the concerns expressed, and state as follows.

First, we respectfully disagree with the apparent assertion that a § 424.535(a)(24) revocation is based entirely on the provider's location per se. The basis, rather, is the fraud, waste, and abuse risk the enrollment poses within the context of the area in question. Explained otherwise, risk, not location, is the central issue. This distinction is important. For purposes of § 424.535(a)(24), a provider and its physical location—standing alone—typically do not raise concerns. When viewed in conjunction with other providers' nearby locations, though, a program integrity risk can arise, and this risk is what triggers the revocation. As noted, this situation is not considerably different from that addressed in section 1866(j)(5) of the Act and § 424.519, whereby denial or revocation can occur if the provider has or has had a certain type of affiliation that poses an undue risk of fraud, waste, or abuse. In both cases, the provider in question need not have engaged in fraud, waste, abuse, or other misconduct. The focus instead is the risk that either the affiliation or, with § 424.535(a)(24), the enrollment (based on proximity and concentration) poses. Likewise, we disagree that an actual fraud, waste, or abuse finding should be required since this would involve reverting to a ''pay-and-chase'' formula. We must take measures when risk arises instead of only doing so after the improper conduct occurs.

Second, in considering the facts and circumstances in a § 424.535(a)(24) situation, the provider's conduct may, if CMS deems it warranted, be a consideration in its decision. Yet because the issue is risk and because we are not establishing mandatory factors, we respectfully decline to require an assessment or individualized finding of the provider's behavior. Our finding will involve determining the risk described in § 424.535(a)(24).

Third, we are unable to establish the requested pre-revocation appeals process or cure opportunity for reasons previously stated. We believe that our current appeals process under 42 CFR part 489 affords providers adequate due process for revocations and denials.

Comment: Several commenters maintained that in any § 424.535(a)(24) revocation, CMS should: (1) furnish specific written findings (including, for example, (i) methodology, (ii) the legal basis for the action, (iii) the reasons why CMS believes a high risk exists, and (iv) the time period, comparator group, provider density, claims, locations, individuals, ownership relationships, etc. on which CMS relies); (2) give the provider access to the supporting evidence; (3) grant expedited review if the action threatens beneficiary access; (4) ensure that any review is performed by a CMS official who did not make the original decision; (5) stay any revocation and recoupment during a timely administrative appeal; and (6) explain, if applicable, the recoupment and repayment period and schedule.

Response: CMS in every revocation sends a letter to the provider explaining,

among other things, the basis for revocation (including the legal basis) and the provider's appeal rights; the latter includes a statement that the appeals/reconsideration review is performed by a CMS official who did not make the original decision. We also separately inform providers of the process and timing of recoupment.

We previously explained why we do not postpone revocations or recoupment pending the completion of appeals. In addition, the appeals process in 42 CFR part 498 does not provide for expedited provider enrollment appeals for certain types of providers or situations. To do so, we believe, would be unfair to those without expedited appeal rights. All providers and suppliers are, and should be, subject to the same appeals procedures and timeframes.

Comment: Commenters recommended that CMS establish a safe harbor or rebuttable presumption of ''no high risk'' under § 424.535(a)(24) for legitimate providers that, for example, maintain bona fide locations, appropriate personnel, no problematic ownership relationships, etc. Some commenters went further and stated that providers with a passed site visit, an active State license and accreditation, and no adverse history should be explicitly excluded from (a)(24)'s purview. Other commenters urged CMS to explicitly state in the rule (including in the regulatory text) that: (1) provider concentration can be an investigative factor but cannot alone be grounds for revocation; and (2) § 424.535(a)(24) requires documented and individualized evidence that the provider presents a material and specific risk of fraud, waste, abuse, or beneficiary harm.

Response: We thank the commenters for these recommendations but must respectfully decline them. Formally establishing the requested presumption in the rule would hamstring our efforts to address the Los Angeles and Columbus-type situations heretofore mentioned. We would be stating at the outset of any potential § 424.535(a)(24) situation that the provider very likely presents no risk if the criteria the commenters reference (for example, operational locations) are met. We cannot make such pre-judgments before the facts and circumstances are reviewed, and we again remind commenters that the central question is not the risk the individual provider actually presents but the risk posed by the scenario in § 424.535(a)(24). Merely because we earlier recognized that provider proximity often does not present material program integrity concerns does not mean we must or should create an official presumption in this rule that this is so. Furthermore, we have seen instances where a licensed or accredited provider's location, ownership, management, services, background, etc., appeared legitimate, but the provider later engaged in fraud, waste, or abuse as part of a larger scheme. In brief, we are unable to establish formal carve-outs or suppositions with respect to § 424.535(a)(24) since every situation will be different and will require an objective analysis of the facts and circumstances without preexisting assumptions.

Concerning the last comment regarding individualized findings, we refer the commenters to our earlier statements on this topic.

Comment: Several commenters believed that CMS' reference in the proposed rule to section 1866(j)(5) of the Act when explaining proposed § 424.535(a)(24) is erroneous. They contended that: (1) under section 1866(j)(5) of the act, the provider has an affiliation with an entity that had previously been suspended or excluded, whereas § 424.535(a)(24) permits revocation absent an affiliation or a prior adverse finding; and (2) neither section 1866(j)(5) nor any other statute allows the action that § 424.535(a)(24) contemplates.

Response: We stated in the proposed rule that a § 424.535(a)(24) situation ''is not considerably different from'' that addressed in section 1866(j)(5) of the Act and § 424.519. This is correct, for in both cases, the provider in question need not have engaged in fraud, waste, abuse, or other misconduct. The focus instead is the risk that either the affiliation or, with § 424.535(a)(24), the enrollment (based on proximity and concentration) poses.'' [33] The quoted statement merely aimed to show that § 424.535(a)(24)'s concept of revocation based on risk is not new. Respectfully, it neither stated nor implied that we were relying upon section 1866(j)(5) as authority for § 424.535(a)(24); the relevant authorities for this provision are sections 1102, 1871, and 1866(j) of the Act.

Comment: Several commenters stated that § 424.535(a)(24) could: (1) restrict beneficiaries' access to care and limit their choice of providers; (2) discourage providers from locating in certain areas or associating with other providers; and (3) make it more difficult for smaller, independent providers to compete with larger health care organizations that have greater resources, thus leading the former to be acquired by the latter.

Response: We respectfully disagree with these contentions. We reiterate that we always carefully examine the facts of the case before undertaking revocation action, and that § 424.535(a)(24) revocations would largely be limited to exceptional situations. Accordingly, we do not believe patient care or choice will be impacted. Second, we have over the years increased the number and scopes of our revocation reasons; this included expanding the types of provider relationships and affiliations that could result in revocations. To our knowledge, none of these regulatory revisions led to the second and third events the commenters cited, and there is no evidence to suggest they will with respect to § 424.535(a)(24).

Comment: A few commenters questioned how § 424.535(a)(24) would apply to fixed-site institutional providers, with other commenters requesting that they be formally exempted from § 424.535(a)(24).

Response: The provision will apply to all providers in the same manner irrespective of provider size and type, and for reasons already noted we cannot establish carve-outs or exceptions to § 424.535(a)(24).

Comment: Some commenters contended that § 424.535(a)(24) inappropriately amounts to: (1) a certificate of need program (whereby, within some States and territories, certain new or expanding providers must demonstrate a need for their services); (2) a § 424.570-type temporary moratorium on the enrollment of specific new provider types within a particular area; and (3) a CMS-enforced limit on the number of providers an area may have, with revocations of all providers that exceed that threshold.

Response: We respectfully disagree. Section 424.535(a)(24) does not prohibit enrollment, require a demonstration of need, or impose strict numerical limits. It is solely limited to the isolated and very individualized situations previously described involving a provider excess in a limited area leading to a high risk of fraud, waste, or abuse.

Comment: A few commenters stated that the scenario described in § 424.535(a)(24) is not among the grounds in section 1866(b)(2) of the Act for provider agreements terminations. Hence, § 424.535(a)(24) violates this statutory provision.

Response: We disagree because, as previously explained, section 1866(b)(2) of the Act pertains to provider agreements. It does not apply to provider enrollment.

After considering the comments received, we are finalizing § 424.535(a)(24) without modification.

[33] 91 FR 41216.

(b) Certain Misdemeanor Convictions (§ 424.535(a)(16))

In the CY 2024 PFS proposed rule (88 FR 52262), we proposed in new §§ 424.530(a)(16) and 424.535(a)(16) to deny or revoke enrollment if the provider—or any owner, managing employee or organization, officer, or director thereof—was convicted of a Federal or State misdemeanor within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. We stated that offenses would include (but not be limited in scope or severity) to the following:

- Fraud or other criminal misconduct involving the provider's participation in a Federal or State health care program or the delivery of services or items thereunder.
- Assault, battery, neglect, or abuse of a patient (including sexual offenses).
- Any other misdemeanor that places the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.[34]

We outlined in that CY 2024 proposed rule our increasing concern about providers convicted of misdemeanors for conduct that could endanger the Trust Funds and beneficiaries. We stated that our oversight of the Medicare program requires that we be able to take protective action in such instances.

We also noted that while some States may designate a particular crime as a misdemeanor while others deem it a felony, this does not lessen the risk that the former can pose to Medicare and its beneficiaries.[35] It is the conduct itself, not its classification under State law, that concerns us. This is particularly true since restricting our revocation authority for criminal convictions to felonies could leave us unable to address situations where a felony charge results in a misdemeanor plea.

We did not finalize this proposal in the CY 2024 PFS final rule (88 FR 78818).[36] However, we emphasized in that final rule that: (1) we would continue to monitor cases of misdemeanor convictions involving significant misconduct; (2) we might pursue future rulemaking to address them; and (3) many misdemeanors—especially those involving assault, battery, neglect, or abuse of a patient (including sexual offenses)—can involve disturbing activity.[37]

As explained in the CY 2027 HH PPS proposed rule, two particularly disconcerting categories of misdemeanor convictions we have recently seen involve sexual assault and financial misconduct. The former can endanger Medicare beneficiaries while the latter can threaten the Trust Funds—both of which we must safeguard. In line with our aforementioned willingness to pursue future rulemaking if warranted, we proposed in § 424.535(a)(16) (currently designated as ''Reserved'') to revoke enrollment if the provider or supplier—or any owner, managing employee or organization, officer, or director thereof—was convicted of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

While parts of this proposal duplicate those in the CY 2024 proposed rule (for example, the 10-year period, the applicability to owners, directors, etc.), there is one critical difference: it is much narrower in scope. Whereas the CY 2024 proposal was rather open-ended in terms of potential misdemeanors, the present one is limited to sexual assault and financial misconduct. We believe this would reduce stakeholders' possible concerns that proposed § 424.535(a)(16) is too broad. In addition, we stress that: (1) terms such as ''financial misconduct'' would be based on their plain meanings; and (2) the misdemeanor convictions described in this paragraph must be detrimental to Medicare's (and Medicare beneficiaries') best interests, meaning that not every such conviction would result in revocation.

The following is a summary of the comments we received on this proposal and our responses. Some of these comments and responses also reference proposed revised § 424.530(a)(16), which would permit denial based on the same grounds identified in proposed § 424.535(a)(16). Our final decision regarding § 424.530(a)(16) will be addressed later.

Comment: Commenters requested guidance on how CMS will determine whether a misdemeanor: (1) is detrimental to the best interests of the Medicare program; and (2) constitutes ''financial misconduct.'' The commenters also requested that CMS define this latter term (as well as ''sexual assault'') and outline all offenses that could fall within either category.

Response: As we do with the same ''detrimental to the best interests standard'' in §§ 424.530(a) and 424.535(a) for felony convictions, CMS considers the facts and circumstances of the case. Also, and as previously indicated, ''financial misconduct'' and ''sexual assault'' will have their plain meanings. Considering that the scope of offenses that fit within these two categories can vary by state, we are unable to list all of them.

Comment: Commenters requested that CMS establish regulatory factors and criteria it must consider in every potential §§ 424.530(a)(16) and 424.535(a)(16) case. Among commenters' suggested standards were: (1) whether any evidence of rehabilitation exists; (2) whether there is a connection between the provider and the behavior leading to the revocation; (3) whether a nexus exists between the criminal conviction on the one hand and either the Trust Funds or the provider's health care operations on the other; (4) how long ago the conviction occurred; (5) the nature of the offense; (6) the convicted party's current role within the organization; and (7) whether the underlying conduct leading to the misdemeanor has already been reviewed by the applicable State licensing or regulatory authority.

Response: We appreciate this request but reiterate our previously explained concerns about the restraints that factors pose. These concerns apply to §§ 424.530(a)(16) and 424.535(a)(16), too. Thus, we respectfully decline to include specific criteria in these two regulatory provisions.

Comment: Several commenters supported this proposed revocation and denial reason.

Response: We appreciate the commenters' support.

Comment: A commenter recommended that CMS confirm that the actions of an unpaid board member would not invoke §§ 424.530(a)(16) or 424.535(a)(16).

Response: Although it is somewhat unclear, we believe the commenter is referencing ''directors'' as that term is defined in § 424.502. A person can qualify as a director regardless of whether they are paid or unpaid. Sexual assault and financial misconduct misdemeanors by unpaid board

[34] ''Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program'', published in the **Federal Register** on August 7, 2023.

[35] Ibid.

[36] ''Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program'', published in the **Federal Register** on November 16, 2023.

[37] Ibid.

members consequently fall within the scope of §§ 424.530(a)(16) and 424.535(a)(16).

Comment: Some commenters stated that CMS should: (1) explain how providers are expected to identify potentially qualifying convictions; (2) identify the safeguards that would apply before an individual's conduct results in the organization's revocation; (3) establish reasonable due diligence expectations, provider notification procedures, and clear responsibilities when a potentially qualifying conviction becomes known but CMS has not yet determined whether it is detrimental to Medicare; and (4) explain what a provider must do upon discovering a potentially disqualifying misdemeanor conviction.

Response: We were unclear as to certain aspects of these comments. Based on our best reading, we address them as follows. First, this provision (like §§ 424.530(a)(3) and 424.535(a)(3)) does not require providers to review their personnel for potential convictions as part of the provider enrollment process. Whether they choose to do so is the provider's internal, independent business decision. Second, the principal safeguard is that CMS will, as always, consider the facts and circumstances of the case before taking action. (We are uncertain as to which other ''safeguards'' the commenters were referencing or seeking.) Third, if, as we suspect, the commenters are asking how much research they must perform regarding their employees' backgrounds, we refer them to our response to the first comment. Fourth, providers are notified by letter of any denial or revocation (regardless of the specific denial or revocation reason). Fifth, we believe the commenters are asking whether the provider must take certain action if CMS is reviewing a potential §§ 424.530(a)(16) or 424.535(a)(16) situation. If so, the answer is no—assuming the question's context is limited to the mere fact that the case is under CMS review. Sixth, CMS cannot direct providers on a particular course of action in the scenario described in the fourth comment. That, too, is an internal provider decision. We can only state that CMS would have the ability to utilize §§ 424.530(a)(16) or 424.535(a)(16) as circumstances warrant.

We wish to expound upon our responses to the first and third comments because, as discussed later, additional commenters raised similar issues concerning other provider enrollment proposals. Although the provider is not required under subpart P of part 424 to conduct these personnel reviews, this does not absolve the provider of ultimate responsibility if one of its owners, managing employees, etc., engages in conduct that could generate a revocation or denial. In addition, CMS cannot establish a ''due diligence'' standard that prohibits CMS from denying or revoking the provider so long as the provider conducted a certain degree of review and did not find any prior adverse history, but CMS later found that the owner, director, etc., has such history. This has for decades been CMS' position for every denial or revocation reason that involves conduct by an owning or managing party. Applying a due diligence standard would mean that a provider could always avoid denial or revocation by simply stating that it examined the owner's or manager's background but found nothing. This would leave the Medicare program, the Trust Funds, and beneficiaries at tremendous risk; under this scenario, program integrity would be based strictly on the provider's actual or purported review of its affiliated parties rather than actual or potential threats to the program and its patients. Put otherwise, while we understand commenters' concerns about unknown adverse actions, we cannot predicate our payment safeguard efforts on the extent of providers' internal investigative activities (should they wish to perform them).

Comment: Some commenters requested that the proposed 10-year lookback period be reduced to, for example, 5 years.

Response: We believe the proposed 10-year period is appropriate. It achieves consistency the 10-year period in §§ 424.530(a)(3) or 424.535(a)(3), and convictions from as long as 10 years ago can still raise program integrity concerns.

Comment: A few commenters stated that ''financial misconduct'' misdemeanors should be limited to those involving the delivery of a health care item or service as described in section 1128 of the Act.

Response: We respectfully disagree. Considering our need to protect the Trust Funds against fraud, waste, and abuse, it is the conviction itself—and the financial misconduct behind it—that must take precedence over the precise forum in which the behavior occurred.

Comment: Several commenters questioned whether §§ 424.530(a)(16) and 424.535(a)(16) will be applied prospectively or retroactively in terms of when the conviction occurred.

Response: The interpretation of the terms ''within the preceding 10 years'' will generally be similar to the identical language appearing in §§ 424.530(a)(3) and 424.535(a)(3)(i). CMS, as appropriate, may issue public guidance on this issue.

Comment: A few commenters stated that CMS in proposed §§ 424.530(a)(16) and 424.535(a)(16) is effectively requiring providers to research their organizations for parties with financial misconduct and sexual assault misdemeanor convictions without providing a mechanism for providers to obtain this data.

Response: Consistent with our earlier statements—as well as with prior rulemaking efforts where we expanded the scope of various denial and revocation reasons to include additional parties—§§ 424.530(a)(16) and 424.535(a)(16) do not require providers to perform the research the commenters indicate.

Comment: Several commenters supported proposed §§ 424.530(a)(16) and 424.535(a)(16).

Response: We appreciate the commenters' support.

After considering the comments received, we are finalizing §§ 424.5355(a)(16) without modification.

(c) Effective Dates of New Revocation Reasons

Consistent with our proposed retroactive effective dates for all revocation reasons, we proposed the following effective dates for proposed § 424.535(a)(16) and (24). The § 424.535(a)(16) effective date would be the date of the conviction; this date would be referenced in new § 424.535(g)(1)(xvi). For § 424.535(a)(24), we proposed in new § 424.535(g)(1)(xxiv) an effective date that is the date on which CMS or its contractor determines that the provider should be revoked under § 424.535(a)(24); this is due to the difficulty in establishing a concrete date as to when the risk addressed in § 424.535(g)(1)(xxiv) commenced.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Numerous commenters opposed these proposed retroactive effective dates. They maintained that a misdemeanor conviction occurring some time ago should not require the provider to repay potentially years of Medicare payments. Regarding § 424.535(a)(24), they believed it would be unfair to recoup payments simply because the provider's location is near other providers. The commenters, in short, believed these retroactive dates could financially harm providers and cause beneficiary access issues.

Response: We appreciate this feedback. Concerning § 424.535(a)(16), the proposed effective date is the same as that for felony convictions § 424.535(a)(3). In both cases, the conviction presents a risk regardless of when it occurred. Hence, we believe it is appropriate to use the date it occurred as the revocation effective date. With respect to § 424.535(a)(24), we reiterate that: (1) as with § 424.535(a)(19), the issue is the risk presented and not the provider's location per se; and (2) § 424.535(a)(24) will only be used in exceptional situations. We add that even if the risk under § 424.535(a)(24) began years ago, the revocation effective date only goes back to the date on which CMS determines that the provider should be revoked. Given that the provider in most cases would receive the revocation letter comparatively soon after this determination is made, the recoupment period could be rather short.

Our prior responses to comments on revised § 424.535(g) also apply to those regarding § 424.535(a)(16) and (a)(24).

After considering the comments received, we are finalizing §§ 424.535(g)(xvi) and (xxiv) without modification.

(7) Revised and New Denial Reasons (§ 424.530(a))

We also proposed a number of revised and new denial reasons in § 424.530(a).

(a) Changes to Existing Denial Reasons

Some of the following proposed denial reasons would be expanded to include actions by managing employees and managing organizations. We received comments from stakeholders: (1) regarding the meaning of ''managing employee'' in the context of these denial reasons; and (2) expressing concern that a broad interpretation of ''managing employee'' could result in an increased number of denials. These comments will be addressed in our later discussion of our proposed revision to § 424.502's ''managing employee'' definition.

(i) Debt (§ 424.530(a)(6))

Current § 424.530(a)(6)(i) and (ii) permit denial if the enrolling provider or owner (as defined in § 424.502) thereof—

- Has an existing Medicare debt; or
- Was previously the owner of a provider that had a Medicare debt when the latter provider's enrollment was voluntarily terminated, involuntarily terminated, or revoked (and additional criteria in § 424.530(a)(6)(ii)(A) through (C) are met).

We proposed to include within the scope of § 424.530(a)(6) the provider's managing employees, managing organizations, and individuals and entities with any other form of business or financial relationship with the provider.

As noted in prior rulemaking efforts, managing employees and managing organizations (as defined in § 424.502) often have as much or more influence over a provider's day-to-day operations as an owner. Yet § 424.530(a)(6) only references the provider itself and its owners. Section 424.530(a)(6) thus cannot prevent enrollment if, for instance, a managing employee or organization of the prior provider ran its daily operations, was responsible for its accumulation of large debts, and now seeks to re-enter Medicare through their ownership of the new provider. Too, we have seen instances where parties other than owners and managing employees and organizations were involved with the former provider in some capacity. Therefore, the central issue is not the precise form or label of the relationship with the former provider—that is, whether it was ownership, financial, etc. It is instead the relationship itself and the party's effort to enroll new locations or reenter Medicare through the new provider.

We received a number of comments on our proposal.

Comment: Some commenters stated that before denying a provider under § 424.530(a)(6)(i) or (ii) based on the debt of another party (for instance, managing employee), CMS should add required factors to both paragraphs. Other commenters maintained that CMS's proposed § 424.530(a)(6) expansion could deny enrollment to providers based on financial obligations of parties that might only be minimally involved with the provider.

Response: After reviewing the comments received, we are not finalizing our proposed revisions to § 424.530(a)(6).

(ii) Payment Suspension (§ 424.530(a)(7))

Denial is permitted under § 424.530(a)(7) if the provider, or any owning or managing employee or organization of the provider, is currently under a Medicare or Medicaid payment suspension (as defined in §§ 405.370 through 405.372 or in § 455.23). We proposed to expand § 424.530(a)(7) to include individuals and entities with any other form of business or financial relationship with the provider. We explained that because a payment suspension is a serious matter, relationships other than those involving ownership and management should be considered under § 424.530(a)(7).

As with proposed § 424.530(a)(6), commenters expressed concern that the ''any other form of business or financial relationship'' category is unclear and potentially very wide in applicability. After reviewing these and other comments, we have decided not to finalize our proposed revisions to § 424.530(a)(7).

(iii) Program Terminations/Suspensions (§ 424.530(a)(14))

CMS may deny enrollment under current § 424.530(a)(14)(i) if—

- The provider is currently terminated or suspended (or otherwise barred) from participation in a State Medicaid program or any other Federal health care program; or
- The provider's license is currently revoked or suspended in a State other than that in which the provider is enrolling.

We proposed two changes to § 424.530(a)(14)(i). One would include the provider's owners, managing employees, and managing organizations within its scope. This aligns with several other denial reasons—such as existing § 424.530(a)(3) and, as noted, (a)(7)—that include actions against owners and managing employees/organizations. Similar to these other denial grounds, revised § 424.530(a)(14)(i) would help prevent situations where the owning/managing party's conduct that led to the licensure action or the other program termination/suspension could be repeated with the prospective Medicare provider, especially considering the influence such parties typically have over a provider's operations. Furthermore, it could keep such parties from entering Medicare via a new provider, hoping to shield themselves from § 424.530(a)(14)(i)'s application due to the provision's current limitation to providers.

The other change would expand licenses to include those voluntarily surrendered in lieu of further disciplinary action. We have provisions in §§ 424.530 and 424.535 whose purview includes voluntary surrenders, and we believe the same approach for § 424.530(a)(14)(i) is needed because our overriding concern is the loss of the license rather than the type of loss. Voluntary surrenders in lieu of further disciplinary action, in our view, are as much a threat to the Trust Funds and beneficiaries as revocations and suspensions, since they all involve problematic conduct.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Commenters questioned how CMS would apply § 424.530(a)(14)(i) in light of our proposed expansion of § 424.502's ''managing employee'' definition. They believed that a § 424.530(a)(14)(i) denial could stem from situations where: (1) the managing employee with the termination or suspension does not have close involvement with the provider's operations; and (2) there is little nexus between the managing employee's action and the provider. They stated that CMS should require a substantial connection between the provider, the managing employee, and the employee's action. Others stated that the proposed expansion of § 424.530(a)(14)(i) is too broad and should not be finalized.

Response: As already stated, we consider the facts and circumstances of the case before denying a provider's enrollment. We note that there is no requirement that the managing employee's action be substantially connected to the provider's operations. This has long been our position for all denial and revocation grounds that can be based on an owner's or managing employee's conduct. For § 424.530(a)(14)(i) situations, the managing employee's program or license termination, suspension, or voluntary surrender alone poses considerable risk regardless of: (1) the relative degree of the person's involvement with the provider; or (2) the termination's, suspension's, or surrender's potential impact on the provider.

We also disagree that revised § 424.530(a)(14)(i) would be too broad. The addition of managing employee and organizations to its scope is consistent with other denial and revocation grounds pertaining to such parties.

Comment: Several commenters stated that providers should be able to remove a managing employee from their organization prior to any § 424.530(a)(14)(i) denial.

Response: Section 424.530(c) addresses the situation the commenters describe.

Comment: A commenter stated that because voluntary surrenders are not necessarily indicative of fraud, waste, or abuse, CMS should evaluate the circumstances and risk involving the surrender in § 424.530(a)(14)(i) determinations.

Response: CMS evaluates the facts and circumstances of the case in every potential denial or revocation situation.

Comment: A few commenters stated that if CMS revokes a provider under § 424.530(a)(14)(i) and the State reverses or overturns the Medicaid revocation, termination, or bar, CMS should reverse its § 424.530(a)(14)(i) revocation.

Response: As this comment appears to concern the general application of § 424.530(a)(14)(i) in the Medicaid context as opposed to the specifics of our proposed change, we respectfully believe it is outside the scope of this final rule.

After reviewing the comments received, we are finalizing our proposed revision to § 424.530(a)(14)(i) without modification.

(iv) False or Misleading Data (§ 424.530(a)(4))

Section 424.530(a)(4) allows denial based on the provider's/supplier's submission of false or misleading information on the enrollment application to gain enrollment in the Medicare program. We proposed to expand § 424.530(a)(4) in the same manner as with proposed § 424.535(a)(4) and for the same reasons. (The parenthetical concerning OIG referral would be retained in revised § 424.530(a)(4).)

The comments we received on this proposal were generally the same as those regarding § 424.535(a)(4), discussed previously. Our responses are likewise the same. We are accordingly finalizing proposed § 424.530(a)(4) without modification.

(b) New Denial Reasons

(i) Misdemeanor Convictions (§ 424.530(a)(16))

(A) New § 424.530(a)(16)

As previously noted, w proposed to duplicate proposed § 424.535(a)(16) in § 424.530(a)(16) (also presently designated as ''Reserved'') as a new denial ground. The same rationale is involved: the need to protect beneficiaries and the Trust Funds against parties convicted of sexual assault or financial misconduct misdemeanors.

The comments we received on this proposal mirrored those concerning § 424.535(a)(16), discussed earlier. Our responses are also the same. Thus, we are finalizing proposed § 424.530(a)(16) without modification.

(B) ''Final Adverse Action'' Definition

Section 424.502 defines ''final adverse action'' as any of the following: (1) Medicare revocation; (2) State health care license suspension or revocation; (3) revocation or suspension by an accreditation organization; (4) felony conviction; or (5) exclusion or debarment. Given our proposed denial and revocation reasons based on a misdemeanor conviction for sexual assault or financial misconduct, we proposed to add such misdemeanors as new paragraph (6) in the ''final adverse action'' definition. (As with felony convictions in paragraph (4), the 10-year period would be that preceding enrollment, revalidation, or reenrollment.)

The following is a summary of the comments we received on this proposal and our responses.

Comment: A commenter stated that CMS should delay this change (suggesting 2 years of non-enforcement) to enable providers to evaluate applicable individuals, obtain updated disclosures, and take corrective action where necessary.

Response: We respectfully are unable to delay the implementation or enforcement of this or any of our finalized provisions considering the important program safeguard issues they address.

Comment: A commenter requested that CMS explain the practical implications of our revision to the ''final adverse action'' definition.

Response: The principal implication is that under § 424.518(c)(3)(ii)(E), providers with a final adverse action within the past 10 years are screened at the ''high'' level. We believe providers with the misdemeanors in question would warrant this elevated screening.

After reviewing the comments received, we are finalizing our proposed revision to the ''final adverse action'' definition without modification.

(ii) Same Suite (§ 424.530(a)(19))

We proposed a new denial ground in § 424.530(a)(19) based on the provider having its practice location in the same suite or office as another provider whose Medicare enrollment has been revoked or denied. Sharing a suite or office with a provider who has been deemed non-compliant with Medicare requirements could spur concerns about the newly enrolling provider's own willingness to retain compliance if enrolled. This is particularly true when—in situations we have seen—several providers in the same suite engage (or seek to engage) in a fraud scheme, have their Medicare enrollments revoked or denied, and another provider aims to enroll in that same office. Considering the risks posed by the revoked or denied provider, we believe we must be able to prevent the new enrollment if circumstances justify it.

We explained in the proposed rule that § 424.530(a)(19) would differ from proposed § 424.535(a)(24). The latter is a revocation reason and not a denial ground; it is also partly based on the

number of nearby providers, whereas § 424.530(a)(19) is based on shared suites and offices. Sections 424.530(a)(19) and 424.535(a)(24) therefore complement but do not duplicate each other.

We recognize that, for example, physicians that are part of a group frequently share the same suite. If 10 physicians are in the group and one (Dr. X) has their enrollment revoked, this does not automatically mean that a prospective (and Medicare enrolling) 11th group member will be denied enrollment based on Dr X's revocation. Every situation is different, and CMS will only invoke § 424.530(a)(19) when proper.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Numerous commenters opposed our proposal. They stated that space and office sharing is extremely common—especially for purposes of cost-savings and strengthening of patient care—and not indicative of fraud, waste, or abuse. It would be improper, they added, to deny a provider on this ground, especially when the provider may have no knowledge of, connection to, or control over a neighboring provider's enrollment status.

Response: We appreciate and understand this feedback. As stated, we acknowledge that space-sharing (particularly involving physician practices) is very common and does not by itself raise serious program integrity concerns. Yet we reiterate that there have been situations where providers in a shared office or suite have engaged—or, based on the facts and circumstances of the case, may engage in—improper activity. The need to protect Medicare beneficiaries and the Trust Funds requires that we have the ability to address these situations. We believe that § 424.530(a)(19) could assist in this by enabling denial of an enrollment that might exacerbate the problem.

Comment: Commenters stated that CMS should establish regulatory factors, criteria, standards, and thresholds for potential § 424.530(a)(19) cases. These should include, for example, requiring: (1) a clear connection between the enrolling provider and the other provider's denied or revoked enrollment (and the conduct behind (or basis for) that other denial or revocation); (2) the enrolling provider's knowledge of the other denial or revocation; (3) common ownership, control, or coordination between the two providers; and (4) a lookback period, whereby § 424.530(a)(19) would not apply if the other provider's revocation or denial occurred more than a certain number of years ago.

Response: For reasons mentioned previously, we respectfully decline to add said criteria and thresholds to § 424.530(a)(19). As mentioned, though, CMS will only invoke § 424.530(a)(19) when warranted by the facts and circumstances of the case.

Comment: Commenters stated that instead of § 424.530(a)(19), CMS should concentrate on the individual behavior of each provider rather than tie the latter to a co-tenant's improper conduct. Additional commenters recommended that any § 424.530(a)(19) denial require a documented, individualized finding connecting the enrolling provider to fraud, waste, or abuse.

Response: While we appreciate the commenters' feedback, we have explained in this rule, the proposed rule, and prior rules that certain relationships and affiliations—whether organizational, managerial, business-based, geographic, etc.—can present significant risks to Medicare. This by no stretch means that all (or even most) of them do, but some can in certain circumstances. If we simply disregarded all potentially problematic relationships and arrangements and only took action after an individual provider engaged in fraud or misconduct, this would—as previously noted with respect to § 424.535(a)(24)—revert to a ''pay-and-chase'' model. In other words, we must: (1) proactively prevent improper activity before it happens; (2) treat the risk of misconduct as seriously as we do actual misconduct; and (3) deter possible wrongdoing involving relationships, multiple providers, and multiples parties as much as that involving a single provider. This is the basic reason for § 424.530(a)(19), § 424.535(a)(24), and certain other provisions promulgated in this and past rules. Even if the enrolling provider was not directly involved in its co-tenant's activities, we must have to ability to take action as needed to protect the Medicare program against potential threats.

Comment: Commenters stated that CMS should establish a safe harbor for providers that can demonstrate a legitimate, documented clinical or business rationale for co-location.

Response: While we appreciate this recommendation, the issue is not the need or rationale for the co-location; many such arrangements are for entirely legitimate purposes. Rather, it is the risk associated with the co-location due to the other provider's denial or revocation, which is why we must respectfully decline the commenters' safe-harbor request.

Comment: A commenter stated that because existing § 424.57(c)(29) prohibits DMEPOS suppliers from co-locating with another provider or supplier, § 424.530(a)(19) is unnecessary and duplicative.

Response: We respectfully disagree because the two provisions address different situations. Section 424.57(c)(29) is restricted to DMEPOS suppliers and prohibits co-location. Proposed § 424.530(a)(19) is not provider-type specific, does not itself bar space-sharing, and involves sharing an office or suite with a denied or revoked provider.

Comment: A few commenters contended that § 424.530(a)(19) should not apply if the enrolling provider has no ownership, management, financial, or operational relationship with the revoked or denied provider.

Response: We respectfully disagree. As stated elsewhere in this final rule section V.C., we cannot regulatorily exclude potential scenarios from our proposed denial and revocation provisions, for the facts of each case will vary. Indeed, such exemptions could impair program integrity if, to illustrate, the circumstances of a particular exempted situation warranted denial or revocation but the exception prohibited action on our part.

Comment: Some commenters stated that § 424.530(a)(19) could discourage physicians and practitioners from joining and co-locating with group practices out of concern that their enrollments may be denied if the group has a denied or revoked provider.

Response: We respectfully disagree for two reasons. First, denials on this ground will be the exception, not the norm. They will only occur when genuinely justified. Second, we have added and expanded numerous denial and revocation grounds over the past two decades to include certain relationships and affiliations. We are unaware of large numbers of providers and other parties avoiding such arrangements as a result. We believe this will hold true with § 424.530(a)(19), too.

Comment: A few commenters urged CMS to state in the regulatory text that § 424.530(a)(19) would not apply to situations where a physician is: (1) joining an established group practice; or (2) otherwise enrolling at a location where the revoked or denied provider is no longer present.

Response: For reasons already stated, we cannot exempt certain arrangements from § 424.530(a)(19)'s scope. Regarding the second comment, CMS will issue guidance on this matter.

Comment: Several commenters recommended that CMS define what constitutes the ''same suite or office''.

Response: We respectfully believe that this phrase's meaning is plain on its face.

Comment: Noting our earlier scenario of a 10-physician group, a commenter—seemingly believing this constituted an exception to § 424.530(a)(19)—requested that it be included in the regulatory text.

Response: While we appreciate this request, our scenario was not an exemption. It merely stated that § 424.530(a)(19) ''does not automatically mean that a prospective (and Medicare enrolling) 11th group member will be denied enrollment'' based on another group member's revocation. The purpose was to make clear that every case is different and will be evaluated on its own facts and circumstances.

After reviewing the comments received, we are finalizing proposed § 424.530(a)(19) without modification.

(iii) Hospice Medical Directors and Administrators (§ 424.530(a)(20))

We explained at length in the proposed rule the serious program integrity issues involving hospices. CMS in recent years has taken numerous steps to address them, including, for example:

- Under § 424.518(c), requiring persons who directly or indirectly own 5 percent or more of a newly enrolling hospice (or a hospice undergoing any ownership change) to submit fingerprints for a criminal background check.
- Requiring hospice medical directors who certify a patient's terminal illness under § 418.22(c) to be enrolled in or opted out of Medicare, which enables CMS to screen the medical director.
- Clarifying that hospice medical directors and administrators are ''managing employees'' (as that term is defined in § 424.502) and thus must be reported on the hospice's Form CMS–855A enrollment application (OMB Control No. 0938–0685). This helps ensure that CMS knows the identities of these parties and can vet them for potential issues.

In light of medical directors' and administrators' managing control over hospices, we believed that closer oversight of these individuals was necessary—particularly considering: (1) the criminal and False Claims Act cases we have seen involving hospice operators; [38] and (2) reports of physicians falsely certifying patients' terminal statuses.[39] Despite the aforementioned steps, we continue to have program integrity concerns about hospice operators. We still see instances of false physician certifications, kickbacks to certifying physicians, criminal cases involving administrators, hospices billing Medicare while non-compliant with enrollment requirements, etc. On a more specific level, we outlined in the proposed rule three particularly problematic issues.

First, there are individuals who serve as medical director or administrator of numerous hospices. Ensuring—(1) quality care to hospice patients; (2) the efficiency of the hospice's operations; (3) compliance with Medicare requirements; and (4) hospice program integrity requires the full attention and oversight of the medical director and administrator. We believe that having these roles at numerous facilities limits the time the individual can spend on each facility's operations and raises questions about the person's commitment to oversight. This places hospice beneficiaries and program integrity at risk.

Second, we have seen cases where the medical director or administrator is very far from the physical hospice facility; several instances, in fact, involved the hospice and medical director being on opposite sides of the country (for instance, the medical director is in New York, and the hospice is in California). This, too, generates significant concerns about the individual's oversight of the hospice.

Third, certain hospices have been using medical directors with inactive licenses. Section 418.22(c), as noted, requires the medical director who initially certifies the beneficiary's terminal status to be enrolled in or opted-out of Medicare. However, if the medical director is not certifying Medicare beneficiaries' terminal status—and said physician is neither billing Medicare nor ordering/certifying the services/items outlined in § 424.507—enrollment is not required. Therefore, CMS might not know whether the medical director's license is active and only learn of the inactive status later. Since the medical director Conditions of Participation (CoPs) at § 418.102 and personnel requirements for physicians at § 418.114(b)(1) require hospice medical directors to be physicians (and thus licensed), hospices that have medical directors with inactive licenses are not compliant with the CoP Medicare requirements.

To further address hospice medial director and administrator program integrity issues and to protect beneficiaries, we proposed new § 424.530(a)(20). This would permit denial of a hospice's enrollment application if any of the following apply:

- The enrolling hospice's medical director is—

++ The medical director of multiple other hospices, or

++ Practices at such a distance (for example, in a different state) from the enrolling hospice that the medical director cannot realistically perform all medical director functions required under 42 CFR part 418.

- The enrolling hospice's administrator is—

++ The administrator of multiple other hospices; or

++ Located at such a distance from the enrolling hospice that the administrator cannot realistically perform all administrator functions required under 42 CFR part 418.

- The hospice's medical director does not have an active physician medical license in the State in which they are practicing.

Section 424.530(a)(20) would not: (1) formally prohibit medical directors and administrators from serving at more than one hospice; or (2) change hospice CoPs or other hospice policies in 42 CFR part 418. It would simply help us address situations where the hospice's prospective enrollment raises the program integrity concerns outlined in this section V.C. of this final rule.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Commenters opposed the multiple hospice and distance provisions in § 424.530(a)(20). Some stated that rural and small hospices—as well as larger health systems—occasionally hire medical directors and administrators to provide consistent leadership and continuity of care across their service areas, partly because qualified candidates can be scarce. They believed our proposal could harm the ability of these hospices (particularly rural ones) to attract such officials. A

[38] See, for example, the proposed rule titled, ''Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements'' (88 FR 43654), published in the **Federal Register** on July, 10, 2023.

[39] See, for example, the proposed rule titled, ''Medicare Program; FY 2024 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice Quality Reporting Program Requirements, and Hospice Certifying Physician Provider Enrollment Requirements'' (88 FR 20022), published in the **Federal Register** on April 4, 2023.

commenter requested a specific exemption from § 424.530(a)(20) for hospices in a designated Health Professional Shortage Area (HPSA) by the Health Resources and Services Administration (HRSA).

Response: We thank the commenters for this feedback. As earlier stated, this provision establishes no actual or implied limits on the number of hospices a medical director or administrator can oversee. It also does not create mileage or other distance thresholds. We recognize the existence of the situations the commenters' raised, and our proposal is not intended to halt all arrangements involving either the direction of multiple hospices or direction from a considerable distance. It is instead aimed at isolated but highly disconcerting situations we have seen that involve, for instance, potential program integrity or beneficiary safety issues. We seek to assure hospices that—as with other denial and revocation grounds—we would only apply § 424.530(a)(20) in limited instances and after a careful review of the facts and circumstances involved. This said, we are respectfully unable to establish § 424.530(a)(20) carve-outs for certain hospices in this final rule (such as hospices in HPSAs), for we must be able to address a broad range of situations.

Comment: Commenters expressed concern that CMS did not define or establish thresholds for ''multiple other hospices.''

Response: As indicated in our previous response, we did not define ''multiple other hospices'' so we could retain the ability to address a wide range of factual scenarios. We also believed that requiring numerical thresholds would effectively place limits on how many hospices a medical director or administrator could oversee, something we were not seeking to do in this rule.

Comment: Commenters stated that CMS should evaluate whether required functions are actually being performed rather than presume inadequacy based principally on mileage or the number of hospices served. They urged CMS: (1) to define objective, evidence-based criteria for determining whether a medical director or administrator can fulfill required responsibilities; (2) not to use oversight of multiple hospices or geographic distance alone as a basis for denial; (3) to provide a reasonable cure period for a temporary or administrative licensure lapse when appropriate; (4) to phase in any new requirements and consider protections for existing, disclosed arrangements that comply with 42 CFR part 418; (5) to identify the process CMS will use and the data and factors it will consider—such as (but not limited to) the individual's regular availability, the scope of their role within the hospice, and the approximate number of patients the hospices in question have—in determining whether a § 424.530(a)(20) denial is warranted; and (6) allow hospices to demonstrate how their operations ensure compliance.

Response: We appreciate these suggestions. Regarding the first, second, and fifth, we reiterate that while we decline to include specific criteria within § 424.530(a)(20), we will thoroughly examine the facts and circumstances of every case and will not automatically assume either inadequacy or sufficiency. For the third, we refer commenters to our earlier statements regarding cure periods and the need for constant compliance with Medicare enrollment regulations; allowing the former could disincentivize hospice physicians from maintaining the latter. We respectfully decline the commenters' fourth request regarding staged implementation. Arrangements of significant concern to us might warrant a possible § 424.530(a)(20) denial of an enrolling hospice soon after the January 1, 2027, effective date. (We note that § 424.530(a)(20) only applies to denials and not revocations, which we believe addresses the comments regarding existing, disclosed arrangements.) We view the sixth recommendation as a request that CMS's § 424.530(a)(20) investigation include discussions with the hospice about its medical director and administrator operations. While we appreciate the suggestion, CMS cannot pre-commit to an official, mandatory means of investigation in a particular enrollment case.

Comment: Several commenters stated that physical distance is an imperfect proxy for effective oversight.

Response: Again, we recognize that distance does not necessarily equate to a lack of oversight. Yet we have seen cases where it has. These include instances where the medical director or administrator is part of a wider scheme where the person only superficially monitors the hospice—or, in some situations, has no involvement at all but is listed as the medical director or administrator merely for appearances' sake. Such cases require us to take steps to protect the Medicare program and beneficiaries and, if the facts warrant it, deny enrollment.

Comment: Several commenters appeared to question the need for § 424.530(a)(20) because the CoPs already establish responsibilities for hospice medical directors and administrators. Another commenter stated that proposed § 424.530(a)(20) should be withdrawn from this rule and addressed in the hospice CoPs after CMS meets with stakeholders to better understand: (1) the needs of rural hospices; and (2) how to develop CoPs that address key personnel working at multiple providers.

Response: We appreciate this feedback but note that CoPs are separate from the question of risk in the context of provider enrollment. Even if a CoP is met, this does not mean that the facility, medical director, or administrator can never present a program integrity or enrollment risk—especially considering the situations we have seen. We accordingly believe our provision is necessary.

Comment: A few commenters questioned whether CMS whether § 424.530(a)(20)'s licensure provision pertains to the State in which the medical director practices or the State in which the hospice is located.

Response: It pertains to the former.

Comment: A commenter stated that CMS should publish de-identified implementation data as well as the grounds for denials and their disposition.

Response: Although we respectfully are unclear as to the type of ''implementation data'' the commenter suggests, CMS does not publish the specific facts, evidence, and reasons behind individual denial cases.

Comment: A commenter questioned how § 424.530(a)(20) would apply to system-level chief medical officers, regional medical directors, alternate administrators, and other leadership models used by multi-site hospice organizations.

Response: We believe the commenter is requesting clarity on whether § 424.530(a)(20) would apply not only to medical directors and administrators but also to the other officials the commenter cited. Assuming so, the provision only pertains to the activities of medical directors and administrators.

After reviewing the comments received, we are finalizing proposed § 424.530(a)(20) without modification.

(iv) Misuse of Identity (§ 424.530(a)(21))

We noted previously that § 424.535(a)(7) permits revocation if the provider knowingly sells to or allows another individual or entity to use its billing number. (This does not include providers or suppliers who enter into a valid § 424.80 reassignment of benefits or a § 489.18 change of ownership.) Yet there is no denial reason that specifically addresses misuse of identifiers. This is troubling given situations that have occurred where a

party (X) steals the identity of another party (Y) (for example, another physician or practitioner) and enrolls Y without Y's knowledge and using Y's credentials and identifiers; X then bills and receives payment from Medicare under Y's name. To address this and other situations involving prospective enrollees using compromised identities, we proposed in new § 424.530(a)(21) that CMS can deny enrollment if the prospective provider or supplier is attempting to enroll under another party's identity.

The comments we received on this proposal were supportive. No opposition was expressed. Thus, we are finalizing § 424.530(a)(21) without modification.

(8) Reapplication Bar (§ 424.530(f))

Under § 424.530(f), CMS may prohibit a prospective provider from enrolling in Medicare for up to 10 years if its enrollment application is denied because the provider submitted false or misleading information on or with (or omitted information from) its application to gain enrollment in Medicare. The goal is to prevent dishonest providers from submitting false information on their initial application and, after being denied enrollment on this ground under § 424.530(a)(4), simply submitting a new application with correct data.

We believe that restricting § 424.530(f) to instances involving false information limits its potential effectiveness, for there are other § 424.530(a) denial reasons that could involve similarly inappropriate provider behavior. Assume a prospective provider's enrollment is denied because the provider is: (1) unlicensed; (2) OIG excluded or has a recent felony conviction; (3) using a false storefront as its practice location; (4) under a current Medicare and Medicaid payment suspension based on a credible allegation of fraud; (5) terminated from another Federal health care program; or (6) revoked from Medicare and attempting to enroll under a different identity. This casts serious doubt as to the provider's honesty and trustworthiness, since the provider likely knows it cannot enroll but is nonetheless hoping to somehow ''sneak into'' the program; indeed, without a reapplication bar in these and similar situations, the provider might routinely submit more such applications with this nefarious objective in mind.

Accordingly, and to safeguard the Medicare program, we proposed to revise the introductory text of § 424.530(f) to allow CMS to impose a reapplication bar for up to 10 years based on any § 424.530(a) denial reason (not merely § 424.530(a)(4)). We also proposed to delete factors at § 424.530(f)(2) that CMS currently must consider in determining whether to impose a reapplication bar (and the length thereof) for a § 424.530(a)(4) denial. There are two related reasons for this latter proposal. First, the current § 424.530(a)(4) factors pertain strictly to false or misleading data situations and would thus be inapplicable to other denial grounds. Second, proposing different § 424.530(a)(4) criteria would essentially present the same problem mentioned in the previous sentence—specifically, a single set of § 424.530(f) factors could not possibly apply to all § 424.530(a) denial reasons considering the varying facts of each.

Unlike reenrollment bars under § 424.535(c), reapplication bars are discretionary. CMS need not impose them, and we are not proposing to change this. We recognize that less serious denial situations—such as, but not limited to, failure to pay an application fee—might not warrant a reapplication bar. Our focus is mostly on providers whose conduct raises significant program integrity concerns.

We would retain current § 424.530(f)(1) and (f)(3), which address, respectively, the bar's: (1) applicability to the provider's other names, identities, etc.; and (2) impact on the ordering, referral, certification, or prescription of services, items, or drugs. Paragraph (f)(3), though, would be re-designated as revised paragraph (f)(2).

The following is a summary of the comments we received on this proposal and our responses.

Comment: Many commenters opposed our expansion of § 424.530(f) to include all denial grounds. They stated that 10 years is much too long a bar for what may be a comparatively modest reason for the denial and could effectively force the provider to cease operations.

Response: While we appreciate these concerns, we reiterate that a reapplication bar is completely discretionary; a bar may not be imposed in every case. Moreover, the 10-year period is a maximum, not a mandatory timeframe. It is not as though any bar we impose must be for 10 years. In fact, many bars will not be anywhere near this length. Only if a 10-year bar is truly necessary will it be imposed, and we will carefully consider the facts and circumstances in every reapplication bar case.

Comment: Commenters stated that when considering a reapplication bar and its length, CMS should distinguish between denials: (1) involving fraud, abuse, intentional misrepresentation, or patient safety concerns; and (2) arising from technical, administrative, or similar issues. They maintained that this would allow CMS to concentrate on more serious conduct without harming providers whose enrollments were denied for less significant reasons. They believed longer bars should be reserved for more serious conduct.

Response: We thank commenters for this recommendation. We recognize that not all denials are the same and that the facts and circumstances of each situation will differ. We seek to assure providers that every reapplication bar case will be carefully evaluated, and we will only impose longer bars when warranted.

Comment: Commenters recommended that CMS retain and add mandatory reapplication bar factors (including data that CMS must review in every case) in § 424.530(f) so that stakeholders understand the bases for CMS' determinations. Suggested additional factors included, but were not limited to, the severity of the conduct and whether there was any beneficiary harm.

Response: As previously explained, regulatorily specified criteria has at times inhibited our ability to take necessary program integrity measures. Therefore, we believe that our proposed removal of factors from § 424.530(f)—and our declination to add new ones—is necessary.

Comment: A commenter requested that CMS: (1) identify denials that are considered less serious than others; and (2) not apply a reapplication bar to providers that are denied enrollment under § 424.530(a)(1) based on a failure to respond timely to a revalidation request or other request for information.

Response: We respectfully decline these requests because they both effectively require CMS to make certain reapplication bar decisions before we have reviewed the facts of a particular case. For instance, if we stated in this final rule that Denial Reason X generally might not involve the misconduct that Denial Reason Y does, this could—as with having factors within our denial and revocation reasons—obstruct our efforts to apply a reapplication bar (and an extended one if needed) in Denial X cases. Likewise, we cannot formally exclude the § 424.530(a)(1) situation the commenter references because there could indeed be instances where a bar is warranted.

Comment: A commenter requested that CMS confirm that it will not issue a reapplication bar for a denial that has been reversed on appeal.

Response: No reapplication bar will be applied in this instance.

Comment: A commenter stated that: (1) providers must be able to challenge the imposition and length of a reapplication bar; and (2) the denial notice must explain why the selected duration is proportionate to the underlying conduct.

Response: The imposition of a reapplication bar and its length are not appealable matters because neither is an initial determination under 42 CFR 498.3. The denial letter describes the basis for the bar's length.

After reviewing the comments received, we are finalizing our proposed changes to § 424.530(f) without modification.

(9) Changes in Majority Ownership (CIMOs)

We previously mentioned § 424.550(b) and § 424.551, the former pertaining to HHAs and hospices and the latter to DMEPOS suppliers (hereafter collectively ''providers''). Under these provisions, if the provider undergoes a CIMO within 36 months of its initial enrollment—or within 36 months of its most recent CIMO—and no exception applies, the provider's enrollment is terminated. (For HHAs and hospices, the provider agreement is also terminated and does not transfer to the new owner.) The provider under its new majority ownership must enroll as a new provider and undergo a State survey or accreditation. (DMEPOS suppliers must obtain a new accreditation.)

There are two main purposes of this ''36-month rule''. First, it enables CMS to perform a complete screening and vetting of the provider under its new ownership. This is vital for ensuring that the provider is compliant with all Medicare enrollment requirements. Second, it helps prevent ''flipping''. This involves a party enrolling a provider for the sole purpose of quickly selling it to another party without the latter having to newly enroll or undergo a survey/accreditation. The seller's exclusive objective is profit and not patient care, which places beneficiaries and the Trust Funds at risk.

While the 36-month rule has helped to stem flipping and facilitate closer scrutiny of new owners, we have seen provider efforts to circumvent or ignore it. These include, but are not limited to:

- Failing to notify CMS of the ownership change—meaning the sale occurs and the buyer assumes ownership under the existing enrollment without enrolling the entity as a new provider with a new survey/accreditation. Only later does CMS learn of the sale.
- Using a management (or similar) agreement in lieu of a formal sales agreement. Here, the management agreement states that: (1) managerial (and effectively all other) authority over the provider is transferred to Party X; and (2) X intends to later purchase the provider. Once the 36-month period expires, the sale occurs. In essence, Party X is purchasing the provider within the 36-month period but under the guise of a ''management agreement''.

Such inappropriate attempts to avoid the 36-month rule undercut the rule's overriding objective of protecting beneficiaries and the Trust Funds from unvetted and potentially problematic entities. To deter these efforts, we proposed in new §§ 424.530(a)(22) and 424.535(a)(25) that we may deny or revoke enrollment if CMS determines that the HHA, hospice, or DMEPOS supplier failed to comply with the provisions and requirements of, as applicable, §§ 424.550(b) or 424.551. The § 424.535(a)(25) revocation effective date under new § 424.535(g)(1)(xxv) would be the date on which CMS or its contractor determined that the provider should be revoked.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Several commenters supported proposed §§ 424.530(a)(22) and 424.535(a)(25). A commenter stated that the strengthening of oversight of ownership changes via these provisions is well targeted, adding that ownership changes are a documented vehicle for fraud scheme expansion in home health and other high-risk provider categories.

Response: We appreciate the commenters' support.

Comment: Commenters recommended that CMS add factors and criteria (including, potentially, a materiality standard) for §§ 424.530(a)(22) and 424.535(a)(25) determinations. They believed this would retain the provision's focus on inappropriate behaviors without chilling legitimate transactions.

Response: We thank commenters for this suggestion but restate our earlier position on required factors and the need to be able to address a multitude of situations. Thus, we respectfully decline the commenters' recommendation.

Comment: Commenters stated that CMS should implement §§ 424.530(a)(22) and 424.535(a)(25) with safeguards for bona fide transactions.

Response: Our proposed grounds are not designed to deter or discourage CIMOs, and we do not believe providers will be disincentivized from engaging in them. We recognize that many such transactions are legitimate. Yet this does not mean we should ignore instances where compliance is not maintained, circumvention has been attempted, etc., for we must ensure that parties comply with our provider enrollment requirements. All this said, and as with our other denial and revocation grounds, we will take action under §§ 424.530(a)(22) and 424.535(a)(25) only when justified and after a thorough review of the case's facts and circumstances; this, in itself, is an important safeguard for providers.

Comment: Commenters stated that provider confusion about whether a transaction constitutes a CIMO should not result in revocation where the entity acted in good faith and promptly corrects a reporting or procedural deficiency.

Response: We repeat our prior response regarding our careful review of the facts and circumstances of every case. We note, though, that: (1) providers are ultimately responsible for understanding and adhering to the CIMO requirements; and (2) a provider's claimed misinterpretation of §§ 424.550(b) and 424.551 is not, by itself, sufficient basis for avoiding a denial or revocation under §§ 424.530(a)(22) and 424.535(a)(25).

Comment: Commenters stated that CMS should not apply §§ 424.530(a)(22) and 424.535(a)(25) except in cases of fraud, misconduct, deliberate circumvention, or other serious activity. Technical or minor errors—or when there was no purposeful circumvention—should be excluded, with a few commenters requesting a specific intent requirement for §§ 424.530(a)(22) and 424.535(a)(25) to be applicable. A commenter stated that no reapplication or reenrollment bar should be applied in §§ 424.530(a)(22) and 424.535(a)(25) situations if the CIMO was conducted in good faith but later found to be non-compliant.

Response: We respectfully disagree with these comments. Even if a provider believes its non-compliance is immaterial or was unintentional, it remains non-compliance. While we will, again, review every case on its own facts and circumstances, we are unable to promulgate a blanket exemption for situations not involving fraud, serious misbehavior, intentional circumvention, etc. This also applies to reenrollment bars, which are mandatory under § 424.535(c) (though the length of the bar is a matter of CMS discretion). Reapplication bars are discretionary, but CMS cannot exclude certain situations from § 424.530(f) given the need to

address various types of factual situations.

Comment: Several commenters expressed concern that our proposals appear to prohibit management agreements in CIMO situations. They stated that such arrangements are common and legitimate.

Response: Sections 424.530(a)(22) and 424.535(a)(25) do not prohibit such agreements *per se.* However, and depending on the situation's circumstances, they can involve improper efforts to sidestep the 36-month rule and its important protections—hence our citing it as an example of §§ 424.530(a)(22) and 424.535(a)(25)'s potential applicability.

Comment: A commenter requested that CMS identify which types of ownership arrangements it deems ''abusive'' under the 36-month rule.

Response: We respectfully decline the commenter's request because: (1) neither §§ 424.530(a)(22) nor 424.535(a)(25) use the term ''abusive'', nor did we do so in the proposed rule's preamble discussion of these two provisions; and (2) we cannot deem certain transactions as abusive or not abusive without assessing the case's specific and unique facts.

Comment: A commenter urged CMS to: (1) remove the reference to § 424.550(b) in § 424.535(a)(25); and (2) state that revocation is permissible if an HHA or hospice failed to report material ownership-related information within 30 days as required in § 424.516(e)(1). While it was somewhat unclear, the commenter appeared to contend that so long as the provider reported material data about the CIMO within 30 days, this should satisfy CMS' concerns about CIMO compliance.

Response: We respectfully disagree for two reasons. First, neither § 424.516(e)(1) nor § 424.550(b) contains a materiality standard. Required data must be reported regardless of its materiality. Second, and as explained in the proposed rule, our concerns go beyond the mere timely reporting of the change to include, for instance, non-compliance with other requirements as well as circumvention.

Comment: A few commenters stated that CMS should: (1) furnish additional guidance on what constitutes a CIMO and outline the facts that demonstrate a compliant CIMO; and (2) allow providers to obtain formal, pre-sale determinations directly from CMS or the MAC regarding whether their transaction (or potential transaction) triggers the 36-month rule's requirements.

Response: We appreciate the comments but believe they are outside the scope of this final rule.

Comment: A commenter recommended that CMS establish a risk-based ''Trusted Provider'' CIMO voluntary registration and recognition mechanism. Under this approach, vetted, good-faith HHAs and hospices—such as, the commenter believed, those with no adverse history or that are currently accredited—may complete a CIMO via expedited screening, with the provider agreement and billing privileges remaining intact; no new enrollment and survey would be required. The commenter maintained that this would be consistent with CMS' existing risk-based screening process under § 424.518.

Response: We appreciate this suggestion but believe it is outside the scope of this final rule.

Comment: A commenter opposed proposed § 424.535(g)(1)(xxv)'s revocation effective date of ''the date on which CMS or its contractor determined that the provider should be revoked.'' The commenter believed this: (1) is inconsistent with the more fixed effective dates in § 424.535(g); and (2) would give CMS complete discretion to make the effective date retroactive to the provider's initial enrollment date. The commenter stated that the effective date should instead be that of the management agreement or other event that triggered the § 424.550(b) violation.

Response: Most respectfully, we believe the commenter may be misinterpreting this effective date. The § 424.535(g)(1)(xxv) date is the date of CMS's decision to revoke, not any random date back to which CMS believes the revocation should be made retroactive. The decision date is, in fact, a fixed date—and as previously explained, it is necessary due to (1) the variety of situations that can arise under § 424.535(a)(25); and(2) the consequent difficulty of assigning a single effective date to cover all of them.

Comment: A commenter stated that a DMEPOS supplier should not be required to enroll as a new supplier and obtain a new accreditation after a CIMO.

Response: While we appreciate this comment, it appeared to relate to the CY 2026 HH PPS final rule wherein we finalized §§ 424.551. Hence, we believe it is outside the scope of the present final rule.

Comment: A few commenters stated that the following parties and situations should be exempt from §§ 424.530(a)(22) and 424.535(a)(25): (1) management or operating arrangements in connection with a bona fide joint venture—regardless of which joint venture participant holds the provider agreement or State license during the transition; (2) within-window providers as part of a bona fide package transaction not involving circumvention of § 424.550(b); and (3) management arrangements used to bridge CHOW processing for such packages.

Response: While we appreciate these requests, we are unable to formally exempt these and other transactions from the purview of §§ 424.530(a)(22) and 424.535(a)(25) because: (1) such situations can still involve §§ 424.550(b) and 424.551 non-compliance; and (2) doing so would involve CMS making determinations before reviewing the facts of a particular case.

After reviewing the comments received, we are finalizing proposed §§ 424.530(a)(22) and 424.535(a)(25) without modification.

3. Preclusion List (42 CFR 422.2 and 423.100)

Addressed primarily in 42 CFR 422.222 and 423.120, the preclusion list is a compilation of providers and prescribers who are prohibited from receiving payment for furnished, ordered, or prescribed MA items/services and Part D drugs. The list's objective is to effectively bar from the MA and Part D programs various entities and persons that pose program integrity risks. Per the definition of ''preclusion list'' in §§ 422.2 and 423.100, a party may be placed on said list if they fall into any of the following three categories:

- Currently revoked under Medicare for a reason other than that in § 424.535(a)(3) (which addresses felony convictions), the reenrollment bar has not expired, and CMS determines that the underlying conduct that led to the revocation is detrimental to the Medicare program's best interests.
- Engaged in behavior, other than that described in § 424.535(a)(3): (1) for which CMS could have revoked the provider/prescriber to the extent applicable had they been enrolled in Medicare; and (2) that CMS determines is detrimental to the Medicare program's best interests.
- Regardless of whether the provider/prescriber is or was enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the Medicare program's best interests.

We proposed to expand this third category to include felony convictions against the provider/prescriber's owner, managing employee, managing organization, corporate director, or corporate officer. As already stated,

these parties typically exercise considerable influence over a provider/prescriber's operations, and a felony conviction against said party greatly concerns us; indeed, this is precisely why §§ 424.530(a)(3) and 424.535(a)(3) permit denial or revocation based on felony convictions against owners, managing employees/organizations, and corporate officers/directors. Our proposed change would not only ensure greater consistency with §§ 424.530(a)(3) and 424.535(a)(3) but also help protect the MA and Part D programs from program integrity risks.

The specific regulatory revisions would be to paragraph (3) of the ''preclusion list'' definitions in §§ 422.2 and 423.100. The language therein stating that the prescriber/provider, ''regardless of whether they are or were enrolled in Medicare, has been convicted of a felony. . . '' would be changed to the prescriber/provider, ''regardless of whether they are or were enrolled in Medicare—or an owner, managing employee, managing organization, director, or officer (as those terms are defined in § 424.502) thereof—has been convicted of a felony . . .''.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Commenters disagreed with our proposed preclusion list expansion. They stated that providers could have difficulty identifying and verifying information regarding individuals associated with the provider. They requested that CMS: (1) establish reasonable due diligence expectations; and (2) ensure that providers are not penalized for information they could not reasonably have known or verified. Commenters further recommended that CMS promulgate factors for determining whether the provider should be added to the preclusion list. Recommended criteria included (but were not limited to) a nexus between the provider and the owning or managing party's action, the nature of the conviction, the risk posed to Medicare, when the conviction occurred, and the convicted party's role within the provider organization.

Response: Consistent with §§ 424.530(a)(3) and 424.535(a)(3)'s application to felony convictions of parties other than the provider, the primary consideration must always be the party's felony conviction itself and not: (1) the provider's efforts in screening personnel or associated parties; or (2) whether the provider knew of (or was involved in) the conduct. Similar to our earlier statements, we cannot base preclusion decisions under revised paragraph (3) on a knowledge or due diligence standard. If we did, providers could consistently avoid denial or revocation by simply asserting that they knew nothing of the conduct; this obviously would hamper our program integrity efforts, harm the Trust Funds, and potentially endanger beneficiaries. Hence, we respectfully decline to establish the requested knowledge or diligence standard.

Insofar as promulgating factors, we maintain our position that regulatorily-specified criteria hamstring our efforts to take required action against problematic providers. Therefore, we must decline to establish them with respect to revised paragraph (3) of the ''preclusion list'' definition.

Comment: Several commenters stated that it would be unfair to place a provider on the preclusion list based on a felony conviction of a party who may not have close, constant involvement with the provider's operations. They believed that CMS should not finalize its proposed expansion or, at a minimum, remove managing employees and organizations from the proposal.

Response: We disagree. Felony convictions are very serious matters, and the parties we propose to include within the preclusion list definition are sufficiently linked to the provider to—if warranted under the facts and circumstances—trigger the preclusion list's application.

Comment: A few commenters questioned whether a provider whose managing employee has a felony conviction would be added to or removed (as applicable) from the preclusion list if the provider terminated the person's employment. They requested that CMS allow providers to avoid the preclusion list by severing such relationships upon CMS notice of the issue.

Response: Section 424.535(e), in certain instances, affords a revoked provider a 15-day opportunity to remove from their organization the entity or individual whose action (for example, a managing employee's felony conviction) generated the provider's revocation. While there is no concomitant provision in our preclusion list regulations, we will consider this issue for future rulemaking.

Comment: A commenter requested that CMS explain why: (1) this preclusion list expansion is necessary; and (2) the problem cannot be addressed via existing means such as screening, denial, or revocation. The commenter added that a provider should only be included on the preclusion list per our proposal if a clear and ongoing program integrity risk exists.

Response: As we explained in the proposed rule, in this final rule, and when we promulgated (and later expanded) §§ 424.530(a)(3) and 424.535(a)(3), providers with owners and managing employees that have felony convictions have always generated serious and justifiable program integrity concerns. This is partly, but by no means exclusively, due to the possibility that the person's conduct may be replicated in the provider setting. Since there are no other statutory or regulatory means of addressing this vulnerability with respect to Medicare programs other than Parts A and B, our proposal is necessary.

Regarding the commenter's last statement, CMS: (1) reviews the facts and circumstances of every potential preclusion list case under current paragraph (3) of the ''preclusion list'' definition; (2) will do the same with our proposed change; and (3) takes action only when justified.

Comment: A comment stated that in light of the ''preclusion list'' definition expansion, CMS should—

- Explain how qualifying convictions will be identified and verified;
- Clarify how and when providers, prescribers, and MA and Part D plans will be notified;
- Identify when preclusion list updates and associated payment consequences will take effect;
- Identify w responsibilities plans will have before payment is affected;
- Ensure that affected providers receive timely notice and a meaningful opportunity to—

++ Correct erroneous information;

++ Demonstrate that the provision does not apply; or

++ Otherwise challenge the proposed placement on the preclusion; and

- Clarify how MA and Part D plans should proceed while a determination is disputed or under review so that payment is not improperly disrupted based on unresolved information.

Response: Our proposed expansion does not change any procedures regarding the six issues the commenter raised, though we note there is no pre-preclusion quasi-appeals system. Should the commenter have questions regarding the preclusion list process, we respectfully recommend visiting CMS' preclusion list website at *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos/preclusion-list.*

After reviewing the comments received, we are finalizing our proposed changes to the preclusion list

definitions in §§ 422.2 and 423.100 without modification.

4. Temporary Moratoria (§ 424.570)

Pursuant to section 1866(j)(7) of the Act and § 424.570, we imposed several temporary enrollment moratoria between 2013 and 2019, and—as of May 13, 2026—there are national moratoria on the enrollment of new HHAs and hospices.[40] All moratoria (including a moratorium extension) are announced via a notice published in the **Federal Register**. Under § 424.570(a)(1)(iii)(A) through (C), a temporary moratorium does not apply to any of the following:

- Changes in practice location (except if the location is changing from a location outside the moratorium area to a location inside the moratorium area).
- Changes in provider or supplier information, such as phone numbers.
- Changes in ownership (except changes in ownership of HHAs that would require an initial enrollment).

Since restarting the moratorium process in 2026 after more than 6 years, we have seen several issues that we believe must be addressed in regulation.

a. Effective Date

Per § 424.570(a)(1)(iv), a temporary moratorium does not apply to any enrollment application received by the Medicare contractor prior to the date the moratorium is imposed. We proposed to revise § 424.570(a)(1)(iv) as follows:

- Existing § 424.570(a)(1)(iv) would be redesignated as new § 424.570(a)(1)(iv)(A).
- New § 424.570(a)(1)(iv)(B) would state that the date the moratorium is imposed is the moratorium's effective date, which is the date on which the moratorium notice was filed for public inspection at the Office of the Federal Register (OFR).

There are often gaps between when a document (such as a proposed rule) is filed for OFR public inspection and when it is published in the **Federal Register**. If we used the latter as the moratorium's imposition/effective date, the affected providers/suppliers might have several days to submit their initial applications in order to ''beat the deadline.'' This would partly obstruct the moratorium's goal of halting all new enrollments and could lead to a rush of new applicants during this gap, some of whom may present program integrity threats. Using the OFR filing date would prevent this scenario, for the moratorium's imposition would be immediate.

b. Ownership Changes

We proposed to change the aforementioned parenthetical in § 424.570(a)(1)(iii)(C) from ''(except changes in ownership of home health agencies that would require an initial enrollment)'' to ''(except changes in ownership that require an initial enrollment, such as, but not limited to, an HHA, hospice, or DMEPOS supplier change in majority ownership under §§ 424.550(b) or 424.551)''. This update would codify existing CMS policy that—like HHAs—hospices and DMEPOS suppliers that undergo a non-exempt CIMO under §§ 424.550(b) or 424.551 must enroll as a new provider/supplier and are thus subject to the moratorium.

c. Other Applicability

Section 424.570(a)(1)(i) states that CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area. To clarify what qualifies as a ''new'' provider/supplier or practice location under the moratorium, we proposed to outline in new § 424.570(a)(1)(i)(A) through (E) the application types that—solely for purposes of § 424.570(a)—are considered ''new'' and to which a moratorium applies:

- Initial enrollment applications.
- Change of ownership applications that require an initial enrollment per § 424.570(a)(1)(iii)(C).
- Enrollment applications from revoked providers/suppliers whose reenrollment bars under § 424.535(c) have expired and are seeking to enroll again in the Medicare program.
- Reactivation applications.
- Enrollment applications from voluntarily terminated providers/suppliers seeking to enroll again in the Medicare program.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Commenters opposed making the moratorium effective date the date of filing at the OFR instead of the publication date. They stated that providers may not receive adequate notice of the moratorium when the notice is placed on display. They also disagreed with our statement that providers could quickly submit applications between the display and publication dates to get ahead of an effective date based on publication. They believed that using the latter date would be fairer and would give providers more time to prepare.

Response: We thank the commenters for their thoughts. Commenters can access the **Federal Register** website for newly displayed documents no less than for newly published ones; in both cases, the information is public and retrievable. Regarding application submission, providers can indeed attempt to send in applications before the notice is published—even if the application might be incomplete due to the abbreviated timeframe to prepare and submit it. Given the important program integrity aspects of a moratorium and the consequent need for immediate implementation, we cannot afford to assume that no providers will be able to submit applications during this period. We believe the OFR filing date is appropriate notwithstanding commenters' concerns about reasonable advance notice.

Comment: Commenters disagreed with including reactivations within § 424.570's purview. They maintained that deactivations can sometimes occur for what commenters stated were minor reasons—such as a failure to timely report certain information or 6 consecutive months of Medicare non-billing—or on grounds unrelated to fraud, waste, abuse, or other misconduct. They believed it would be unfair to prevent these providers from reactivating their enrollment based on the moratorium. In addition, they contended that reactivations do not involve the enrollment of a ''new'' provider because: (1) the provider remains enrolled during the deactivation period; and (2) the reactivation process is less onerous than initial enrollment. Another commenter stated that including reactivations within § 424.570 violates section 1866(j)(7) of the Act.

Response: We thank stakeholders for these comments. We addressed the reactivation matter in the proposed rule and restate our position here.

Deactivation means the provider's billing privileges are stopped but can be restored (or ''reactivated'') upon the submission of information required under § 424.540. While a deactivated provider is not revoked from Medicare, the provider's: (1) ability to bill Medicare is halted pending its reactivation; (2) enrollment is effectively shut down; and (3) participation in

[40] We also implemented a nationwide moratorium on DMEPOS medical supply companies in a notice placed on display at the **Federal Register** on February 25, 2026, and published in the **Federal Register** notice on February 27, 2026. (''Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Nationwide Temporary Moratoria on Enrollment of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Medical Supply Companies'' (91 FR 9855)). It expired on August 27, 2026, and was not extended.

Medicare is blocked in a manner akin to a revocation. The only material differences between a revoked and a deactivated provider are that the former: (1) is subject to a reenrollment bar and a potentially more exhaustive reentry process (for instance, undergoing a State survey or accreditation); and (2) involves appeal rights under 42 CFR part 498 whereas the latter triggers rebuttal rights. Also, the bases for both revocations and deactivations typically involve concerning provider behavior, such as non-compliance with enrollment requirements or a non-operational practice location. Even if the deactivation was based on non-billing with no nefarious conduct, said conduct could have ensued if, for example, an unscrupulous party attempted to access the provider's billing number during the non-billing period. We continue to believe that the significant similarities between deactivations and revocations warrant including reactivations within § 424.570(a)(1)(i).

We further maintain that: (1) we indeed have the legal authority to define in regulation the scope of the term ''new'' as used in section 1866(j)(7); and (2) we do not foresee beneficiary access issues arising from revised § 424.570 based on our past experience with moratoria.

Comment: Several commenters stated that CIMOs that (1) adhere to §§ 424.550(b) or 424.551, (2) involve compliant providers, or (3) pose no program integrity risk should be exempt from a moratorium.

Response: We respectfully disagree because non-exempt CIMOs under §§ 424.550(b) and 424.551 are—and have always been—considered new enrollments. This is because the provider must initially enroll and undergo a State survey or accreditation to bill Medicare under its new ownership. In addition, exempting certain CIMOs based on risk would require a CMS examination of said risk for each CIMO scenario and potentially result in case-by-case moratorium exceptions, which section 1866(j)(7) does not permit.

Comment: Several commenters stated that CMS' moratorium authority is too broad because a moratorium can impact bona fide providers as much as problematic ones. They recommended that CMS use more targeted means of addressing fraud, waste, and abuse that would not negatively impact honest providers and their patients.

Response: While we appreciate these comments, we believe they focused on our use of moratoria as a whole rather than our specific proposed revisions. Accordingly, we believe they are outside the scope of this final rule.

As an aside, we emphasize to stakeholders that moratoria under § 424.570(a)(1)(i) are actually very infrequent and typically limited. While our present hospice and HHA moratoria—as well as our 6-month long and now expired DMEPOS medical supply company moratorium—are nationwide—these three are the only national enrollment moratoria we have ever implemented going all the way back to 2011. Our moratoria from 2013 to 2019 were restricted to only a few provider and supplier types in certain regions. All this means that the overwhelming majority of providers and provider types—even newly enrolling ones—have not been impacted by § 424.570 to the extent it might appear to some.

Comment: Several commenters stated that including reactivating providers within § 424.570 could lead to access to care issues without improving program integrity.

Response: We respectfully disagree. Again, moratoria are, generally speaking, quite limited, meaning that comparatively few reactivating providers would be impacted and, consequently, patient care should not be affected. We also restate our position regarding the program integrity need for adding reactivations to § 424.570.

Comment: Several commenters stated that CMS should exempt from § 424.570: (1) service-line and other provider expansions involving legitimate providers; and (2) reenrollments.

Response: We are respectfully unclear as to the specific exemptions the commenter seeks. If, by ''service-line expansions'', the commenter is referencing practice location additions, these have previously been included in our moratoria because—depending in part on the provider or supplier type involved—they involve the establishment of a new site. Insofar as reenrollments, we believe the commenter is referencing situations where a provider has either voluntarily or involuntary departed the Medicare program and seeks to enroll in Medicare again. These have always been treated as initial enrollments and thus subject to our moratoria.

Comment: A commenter supported our proposed changes to § 424.570.

Response: We appreciate the commenter's support.

Comment: A commenter stated that CMS should complement any imposed temporary moratorium with the following: (1) issuing sub-regulatory guidance clarifying appropriate billing requirements for G0390 (a HCPCS code used to report trauma response team activation), including activation criteria and documentation expectations; (2) conducting targeted program integrity reviews focused on outlier billing patterns, rather than applying broad-based restrictions that may affect compliant providers; (3) increasing transparency regarding how CMS identifies and monitors high-risk utilization patterns; and (4) considering a revised reimbursement model for trauma services aligned with developing a national military and civilian system. The commenter also stated that CMS should impose a temporary moratorium on the enrollment of new trauma centers in geographic areas experiencing oversaturation.

Response: We appreciate these suggestions but believe they are outside the scope of this final rule.

Comment: A commenter requested that CMS establish a process by which reactivating providers can request an exemption from a moratorium's applicability based on administrative deactivation, contractor error, or deactivations under appeal.

Response: While we appreciate this request, we reiterate that section 1866(j)(7) of the Act does not permit individual, case-by-case exceptions to a moratorium.

After reviewing the comments received, we are finalizing our proposed changes to § 424.570 without modification.

5. Hospice Reactivations (§ 424.540(b)(3))

We mentioned earlier that hospices (like HHAs) that undergo a non-exempt CIMO within 36 months of their initial enrollment (or within 36 months of their previous CIMO) must initially enroll as a new hospice and have a State survey or accreditation. A new enrollment and survey/accreditation help confirm that the hospice under its new ownership is properly vetted, is committed to furnishing quality care, meets all enrollment requirements and CoPs, and does not pose program integrity risks. The program integrity and quality of care benefits of a State survey/accreditation are why in 2009 we promulgated § 424.540(b)(3)(i), which requires a deactivated HHA to obtain an initial survey/accreditation before it can be reactivated.

We believe the payment safeguard and patient care protections afforded by § 424.540(b)(3) should be extended to hospices. The previously noted hospice problems we have seen require, in our view, much closer scrutiny of reactivating hospices—particularly

since, deactivated hospices are essentially blocked from Medicare. We must ensure that the reentering hospice is compliant with all Medicare requirements. Thus, we proposed to revise § 424.540(b)(3)(i) to include hospices.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Several commenters supported our proposed change.

Response: We appreciate the commenters' support.

Comment: A commenter stated regarding our proposal that CMS has not demonstrated that: (1) current reactivation processes are inadequate; or (2) providers deactivated for administrative reasons pose a heightened quality or program integrity risk warranting additional survey requirements. Several other commenters contended that the hospice reactivation survey requirement should exclude hospices that were deactivated for reasons other than fraud, abuse, or patient harm.

Response: We respectfully disagree with these comments. In our view, the existing reactivation process for hospices is not entirely adequate because it lacks the protection that surveys provide. While we are uncertain as to which ''administrative'' reasons the commenter had in mind, all deactivated providers present a degree of risk based on the deactivation itself. This is especially the case with deactivated hospices in light of—as explained in the proposed rule—the high risk that hospices as a provider category present. Given all this, we must ensure that a reactivating hospice (that, as explained, is effectively seeking to reenter Medicare) meets the hospice CoPs via a new survey or accreditation. This protects both beneficiaries and the Trust Funds.

After reviewing the comments received, we are finalizing our proposed change to § 424.540(b)(3)(i) without modification.

6. Opt-Out (42 CFR Part 405, Subpart D)

Section 1802(b)(1) of the Act permits certain physicians and practitioners to opt-out of Medicare. Under opt-out, neither the physician/practitioner nor the beneficiary submits a bill to Medicare for services performed. Instead, the beneficiary pays the physician/practitioner out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician/practitioner and the beneficiary that states, in essence, that neither can receive payment from Medicare for the services performed. The physician/practitioner must also submit an affidavit to Medicare expressing a decision to opt-out of the program and confirming, as further described in § 405.420, compliance with opt-out requirements. Opt-out periods are for 2 years.

Provisions in 42 CFR part 405, subpart D, govern Medicare opt-out. We proposed the following two regulatory clarifications, both of which reflect current policy.

First, opt-out periods are automatically renewed pursuant to section 1802(b)(3) of the Act unless the physician/practitioner—consistent with § 405.445(a)—notifies the appropriate MAC not later than 30 days before the end of the 2-year period indicating that they do not want to extend the affidavit's extension for a subsequent 2-year period. In outlining the types of CMS opt-out determinations that are considered ''initial'' under § 498.3(b) (and thus appealable under 42 CFR part 498), § 405.450(a) includes the individual's failure to ''timely renew opt-out''. Since opt-out is automatically extended absent the occurrence in § 405.445(a), we proposed to change the quoted language in § 405.450(a) to ''timely cancel automatic renewal''; a similar change would be made to § 498.3(b)(19), which lists various initial opt-out-related determinations.

Second, § 405.400 defines ''opt-out period'' as meaning, in part—with respect to an affidavit that meets the requirements of § 405.420—a 2-year period beginning on the date the affidavit is signed (as specified by § 405.410(c)(1) or (2)). There are instances where the MAC, in reviewing and processing the physician/practitioner's submitted affidavit, needs and requests additional information or clarification from the physician/practitioner. Interested parties have asked whether—if a new affidavit must be submitted per the MAC's request and it is subsequently approved—the opt-out period begins on the signature date of the second or the first submitted affidavit. To address this, we proposed in § 405.400 to change the ''opt-out period'' definition that states ''the date the affidavit is signed'' to ''the date the first submitted affidavit is signed.'' This reflects our existing policy on this issue.

The comments we received on these proposed changes were supportive. No opposition was expressed. Hence, we are finalizing them without modification.

7. Affiliations

Consistent with section 1866(j)(5) of the Act, § 424.519 states that upon a CMS request, an initially enrolling or revalidating provider or supplier (hereafter collectively ''provider'' unless otherwise noted) must disclose any and all affiliations that it or any of its owning or managing employees or organizations (per § 424.502's definitions of ''owner'' and ''managing employee'') has or, within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider that has a disclosable event (as defined in § 424.502). If CMS determines that the affiliation poses an undue risk of fraud, waste, or abuse, CMS may deny or revoke the provider's enrollment under § 424.530(a)(13) or § 424.535(a)(19), respectively.

Section 424.502 defines a ''disclosable event'' as any of the following: (1) a current uncollected debt to Medicare, Medicaid, or CHIP; (2) a payment suspension under a Federal health care program; (3) an OIG exclusion; or (4) a denial, revocation or termination of a Medicare, Medicaid, or CHIP enrollment.

For purposes of § 424.519, an ''affiliation'' under § 424.502 includes any of the following (outlined in paragraphs (1) through (5) of the ''affiliation'' definition):

- A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
- A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
- An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including sole proprietorships)—either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization.
- An interest in which an individual is acting as an officer or director of a corporation.
- Any reassignment relationship under § 424.80.

These provisions were established in a final rule published in the **Federal Register** on September 10, 2019 (84 FR 47794).[41]

Since establishing these affiliation regulations, CMS has emphasized identifying current and past relationships between and among different providers and suppliers and, if an undue risk exists, denying or revoking the applicable provider(s).

[41] ''Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process.''

This helps protect the Trust Funds and beneficiaries from threats that certain provider associations can pose. Nevertheless, we have found three issues in § 424.519 that we believe hinder the provision's effectiveness.

One involves the 5-year lookback period. Situations have arisen where a relationship from more than 5 years ago still presents an undue risk of fraud, waste, abuse. In excluding consideration of these affiliations—and, in turn, being unable to deny or revoke enrollment under §§ 424.530(a)(13) or 424.535(a)(19)—we are effectively permitting a potentially significant fraud, waste, or abuse risk to remain. This is antithetical to our duty to protect the Medicare program.

The second pertains to the ''affiliation'' definition in § 424.502. While it covers several types of associations, there are other conceivably problematic relationships we have encountered in our program integrity efforts. We cited the following hypotheticals in the proposed rule:

- An individual or entity operates a small building with over 30 HHAs and hospices that list the building address as their practice location. Considering our earlier discussion of the high payment safeguard risk in such situations, the building operator might be involved with these providers in some type of fraud scheme.
- A provider had a relationship with a financial services company that had several high-level officials convicted of fraudulent activity.
- A provider hired Marketing Firm X. X had solicited beneficiaries for four DMEPOS suppliers, all of which were later revoked with a 10-year reenrollment bar.

These and other scenarios demonstrate that associations beyond those listed in the ''affiliation'' definition can endanger the Medicare program, for nefarious parties of all types constantly seek new means of perpetuating Medicare fraud.

The third issue also involves the ''affiliation'' definition, though on a narrower level—specifically, an aspect of paragraph (3) thereof warranting additional clarification. As noted, paragraph (3) addresses relationships where an individual or entity has operational or managerial control over (or directly or indirectly conducts) the day-to-day operations of another organization. (This mirrors our current definitions of ''managing employee'' and ''managing organization in § 424.502.) As explained in the proposed rule, a recent situation arose where an individual was a medical director (Dr. A) of two providers—B and C. C was revoked from Medicare. Since a medical director is a managing employee under § 424.502, B was revoked under § 424.535(a)(19) consistent with paragraph (3) of the affiliation definition; that is, Dr. X was an individual with operational or managerial control over another entity—Providers B and C. This established the affiliation between B and C, with Dr. X as the clear link—a view that aligns not only with our longstanding interpretation of paragraph (3) but also with section 1866(j)(5) of the Act. Furthermore, we believe our position helps ensure section 1866(j)(5)'s usefulness. A provider generally acts through its owners, managers, and other personnel. If we applied paragraph (3) only to situations where a provider operates or manages another provider, we would be unable to address other cases where the real fraud, waste, and abuse risk is posed by parties affiliated with both providers. In other words, we need the ability to go within the provider organization to the operators and managers to address threats they present.

With all three issues, we believe the fraud, waste, and abuse risk itself is much more important than when the relationship triggering the risk occurred, whether the provider entity poses the risk or, instead, the managing employee, etc. Hence, we proposed the following revisions to our affiliation provisions in part 424, subpart P:

- Removing the 5-year period from § 424.519(b).
- Adding new paragraph (6) to the ''affiliation'' definition. This paragraph would include any marketing, business, fulfillment, financial, managerial, or beneficiary relationship. (The ''managerial'' relationships in paragraph (6) would be those not otherwise falling within paragraph (3) of the ''affiliation'' definition.)
- Adding in paragraph (3) of the ''affiliation'' definition the following language between ''individual or entity,'' and ''exercises operational'': ''or any of its owning or managing employees or organizations,''.
- In §§ 424.530(a)(13) and § 424.535(a)(19), insert the following language between ''provider or supplier'' and ''has or has had'': ''or any of its owning or managing employees or organizations,''.

The following is a summary of the comments we received and our responses.

Comment: Many commenters opposed our changes to the affiliation provisions. They believed it would be extremely difficult, if not impossible, to detect various affiliations: (1) from more than 5 years ago; and (2) involving the provider's owners, managers, and other affiliated parties. It could also be challenging to obtain data from more distant parties. They stated that these revisions would impose a massive reporting burden and should either be significantly delayed or not finalized.

Response: We appreciate these comments. While we understand the concerns expressed, we emphasize that affiliation data need only be reported upon a CMS request—and CMS has, to date, never requested that a provider to do so; this is because we recognize the burden this could present to providers. In utilizing §§ 424.530(a)(13) and § 424.535(a)(19), CMS has instead relied upon its authority under §§ 424.519(i) to apply these two provisions even if the provider has not yet reported (or is not required at that time to report) the affiliation to CMS. To the maximum extent possible, we will continue this approach so as not to impose these disclosure obligations and the associated burden on providers.

Comment: Commenters maintained that regardless of whether our expanded affiliation data must be reported, there will be a substantial burden on providers because they must now research and constantly monitor all parties with whom they have or ever had an affiliation. A commenter stated that CMS in the aforementioned September 10, 2019, final rule with comment period estimated the annual cost of this activity to be $937,500—an amount that will be greatly increased if our proposed affiliation provisions are finalized.

Response: We disagree with these comments. Providers are under no obligation to perform this monitoring. If they choose to do so, that is an independent business decision. In addition, the cited $937,500 cost was for the compilation and reporting of affiliation information pursuant to a CMS request. It was unrelated to any internal monitoring that a provider wishes to undertake on its own volition.

Although discussed in more detail in the ICR and RIA sections of this final rule, we maintain our stance that our affiliation revisions would impose no burden on providers. This is because: (1) we do not at this time anticipate making requests for disclosures; and (2) providers are not required to undertake any form of regular research or tracking of actual or potential affiliations.

Comment: Commenters stated that if CMS finalizes its proposed affiliation changes, it should ensure that providers under §§ 424.530(c) and 424.535(e) can demonstrate termination of affiliations, managing employee relationships, or

business relationships—not simply for sanctions, exclusions, debts, or felonies of associated parties.

Response: We appreciate this comment and will consider clarifying this issue in post-final rule guidance.

Comment: Commenters expressed concern that the addition of parties and relationships to § 424.535(a)(19) and § 424.502's ''affiliation'' definition (and the resulting potential linkages to many different providers) could result in unwarranted revocations. A commenter stated that such downstream revocations should be prohibited under § 424.535(a)(19).

Response: We wish to assure providers that CMS reviews each potential § 424.535(a)(19) case individually, based on its own particular circumstances. This will remain so under revised § 424.535(a)(19). For this same reason, though, we cannot automatically bar these downstream revocations; if a particular case, judged on its own facts, warrants a § 424.535(a)(19) revocation, we must be able to take action regardless of whether it is downstream.

Comment: Commenters expressed concern about the meaning of ''any marketing, business, fulfillment, financial, manag-erial or beneficiary relationship'' and that CMS did not define these terms. They stated that this could include virtually any party with which the provider has any dealings, no matter how slight. They maintained that legitimate providers should not be penalized for very tenuous associations or held responsible for the actions of distant parties over which the provider has no control.

Response: We note several things. First, we believe that with respect to the affiliation definition, the six types of relationships in the previously quoted language have their plain meanings. Second, our addition of paragraph (6) to the affiliation definition does not mean that every such relationship will lead to the provider's denial or revocation if a disclosable event exists. We acknowledge that many of these affiliations do not involve an undue risk of fraud, waste, and abuse. As previously mentioned, though, we have seen instances where they do, and for this reason we believe our affiliation expansions are warranted. Third, and in a similar context, the main issue is not: (1) whether the provider could control or even knew of the actions of the other party; or (2) the organizational distance (or tenuousness or materiality of the relationship) between the provider and the affiliate. It is instead the risk the affiliation poses to the Medicare program. This is the main test for whether §§ 424.530(a)(13) and 424.535(a)(19) should apply in a particular situation and is consistent with the language in section 1866(j)(5) of the Act.

All this said, we agree with commenters' concerns about including beneficiary relationships within new paragraph (6) of the ''affiliation'' definition. We are therefore not finalizing said inclusion.

Comment: Commenters stated that CMS should: (1) limit the definition of ''affiliation'' to relationships that either have a meaningful nexus to Medicare program integrity or involve a material connection between the provider on the one hand and the other party and their disclosable event on the other; (2) define the scope of reportable affiliations; (3) require an individualized determination that the affiliation presents a current and undue risk; (4) establish reasonable due diligence expectations that reflect what providers can realistically know and verify through ordinary business practices; and (5) promulgate required factors and thresholds (such as common ownership and control). Some commenters requested that CMS explicitly exclude from reporting (and from potential denial or revocation) all routine commercial, patient care, referral, and vendor relationships. Other associations that commenters stated should be exempted included, but were not limited to, manufacturer, wholesaler, insurance, banking, accreditation, and other ordinary-course dealings. Additional commenters stated that the ''affiliation'' definition, the associated reporting requirements, and CMS' overall oversight of potentially problematic relationships should be restricted to more proximate associations involving, for example, ownership interests, governance authority, operational control, financial control, coordinated conduct, and program integrity threats. Without such parameters, they maintained, legitimate and routine business transactions could become reportable affiliations.

Response: While we appreciate these comments, we cannot exempt certain categories of affiliations beforehand simply because they might on the surface appear to lack a ''meaningful nexus'' or other significant connection, or do not meet a materiality (or similar) threshold. There are many types of affiliations—both involving close relationships and those more distant—that can present a program integrity threat. Our obligation to protect the Medicare program consequently requires that we broaden our affiliation definition to include more relationships. Indeed, if we restricted this definition in the manner the commenters requested (for example, ownership, close nexus, financial control, etc.) the hypothetical scenarios previously outlined would remain unaddressed, conceivably harming the Trust Funds and beneficiaries.

We address the scope of the affiliations within the definition of that term. If the commenters are referencing the scope of the ''any marketing, business . . .'', language, we restate that the categories of relationships within this term will—for purposes of §§ 424.530(a)(13) and 424.535(a)(19)—have their plain meaning.

While we are somewhat unclear as to the commenters' reference to ''individualized determinations'', we emphasize that—as with all §§ 424.530(a)(13) and 424.535(a)(19) decisions—CMS will carefully and thoroughly consider the facts of each case and only take action when justified under the circumstances.

We respectfully decline to establish a ''due diligence'' threshold for applying §§ 424.530(a)(13) and 424.535(a)(19) because, again, we do not at this time anticipate making disclosure requests, and providers are not required to conduct internal research of possible affiliations.

Regarding factors and thresholds, we repeat our earlier concerns about the restraints that fixed, inflexible criteria impose on our ability to assess each case based its own unique circumstances.

Comment: Numerous commenters opposed the removal of the 5-year lookback period. They stated, in general, that this would increase the burden and complexity of reporting without helping to identify fraud or promote program integrity.

Response: We respectfully disagree. We refer the commenters to our prior statements concerning disclosure requests, and we stress that affiliations older than 5 years can still present a current risk of fraud, waste, or abuse.

Comment: Commenters stated that before denial or revocation occurs, providers should be able to correct or add affiliation data that was inadvertently erroneous or missing in their disclosure submission.

Response: We refer the commenters to our prior statements regarding data disclosure.

Comment: Some commenters stated that CMS should be able to identify affiliations and disclosable events via internal systems without requiring providers to report this information. They noted that providers often will not have access to (or be able to obtain from associated parties) certain affiliation

data. Accordingly, provider disclosure of this data should not be necessary.

Response: While CMS may request submission of provider affiliation data at any time, we agree with the commenters' general position and will, to the extent feasible, utilize existing data when making §§ 424.530(a)(13) and 424.535(a)(19) determinations.

Comment: A commenter stated that CMS should request affiliation disclosures involving specified disclosable events and then evaluate whether an affiliation poses an undue risk (akin to the processes CMS outlined in the aforementioned September 10, 2019, final rule). The commenter believed that a revocation process where CMS assumes affiliations pose undue risk without some reasonable fact-finding in which CMS solicits information from the provider with the affiliation is punitive and unnecessary.

Response: We appreciate the commenter's feedback but note several things. First, and as stated, although we retain the right to do so under § 424.519, we do not anticipate requesting affiliation data due to the provider burden. Second, CMS does not revoke providers under § 424.535(a)(19) without having information on file—the overwhelming majority of which is already on file with CMS based on the provider's various Form CMS–855 submissions and is linked in PECOS to other providers' submissions (for instance, shared managing employees)—demonstrating an undue fraud, waste, and abuse risk. Third, we believe that whether the data is reported via a specific request under § 424.519(b) or is currently on file based on prior submissions or other information is less important than our need to alleviate provider burden.

After reviewing the comments received, we are finalizing our proposed revised affiliation provisions with two modifications, both of which involve proposed paragraph (6) of the ''affiliation'' definition. The first, as mentioned, is the removal of beneficiary relationshipstherefrom. The second involves adding the following language at the end of said paragraph: ''whether direct or indirect (including, for example, common use of the same organization to perform these services.'' In our view, this additional language—which we do not believe is different in intended scope from what we proposed and is primarily a clarification—will help stakeholders more clearly understand the concepts and examples outlined in the proposed and final rules. Such transparency is critical given: (1) the concerns that commenters expressed; and (2) what we perceived to be some provider confusion as to the meaning and scope of certain aspects of our proposal.

In closing, we do not believe that the non-finalization of our proposed changes to §§ 424.530(a)(6), 424.530(a)(7), and 424.535(i) is inconsistent with our finalization of revisions to some of our affiliation provisions. This is because they can address somewhat different factual situations; for example, proposed §§ 424.535(i) referenced a denied provider potentially having its other enrollment applications revoked, whereas our affiliation changes focused more on the wider question of undue risk of fraud, waste, and abuse involving certain relationships.

8. Private Equity Companies (PECs) and Real Estate Investment Trusts (REITs)

In a November 17, 2023, final rule published in the **Federal Register** titled, ''Medicare and Medicaid Programs; Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities; Medicare Providers' and Suppliers' Disclosure of Private Equity Companies and Real Estate Investment Trusts'' (88 FR 80141), we implemented section 1124(c) of the Act. This provision—promulgated in § 424.516(g)—requires SNFs to report detailed information about their ownership, management, and associated parties. The regulation's purpose was to gain further insight into the SNF's operators and affiliates—a vital need given concerns about nursing home quality of care.

We expressed particular concern in the November 17, 2023, final rule about the prevalence of PEC and REIT ownership of SNFs. We cited reports indicating links between such ownership and substandard SNF care, primarily due to these entities' emphasis on maximizing profits.[42] Hence, we stated in that final rule our intention to revise the Form CMS–855A enrollment application [43] to require all certified providers and certified suppliers (not simply SNFs) that complete said form to identify whether an entity they have disclosed thereon is a PEC or a REIT.[44]

The issue goes further, though. PECs and REITs are involved in other health care sectors, too, including physician practices. For instance, the May 2025 edition of the American Medical Association's (AMA) Journal of Ethics (JOE) noted the continued increase in PEC ownership of providers and suppliers. The AMA JOE website (via which the May 2025 edition could be accessed) stated that private equity ''aim(s) to maximize profitability while minimizing long-term holdings in such investments . . . One reason private equity investment in the health sector deserves close ethical attention is that private equity firms are, generally, not interested in managing patient panels, clinician personnel, or making service delivery streams work for patients. Another reason is that influx of private equity investment in health care tends to consolidate markets for health services, undermining competition and driving up costs for patients''.[45] Various articles in the May 2025 edition expounded on this theme. As noted in the proposed rule, such statements included:

- ''Physicians have fiduciary duties to respond with care to patient's clinical needs and vulnerabilities, whereas private equity companies have no such ethical or legal duties to patients and strive to maximize financial returns for their investors.'' [46]
- ''Studies on the impact of PE investment in health care have increased in the last decade, with the preponderance of data suggesting that PE acquisitions are associated with reduced staffing levels and on-hand medical supplies. A 2023 systematic review concluded that PE ownership was associated with increased costs to payers and patients.'' [47]
- ''Private equity firms' acquisition and management of health service delivery entities, such as specialty physicians' practices, have been associated with increased cost and diminished quality of care.'' [48]
- ''Private equity margin maximization and profit-making strategies focus on acquisition, short-term ownership, and sale of health care entities, including residency program opportunities. PE ownership durations generally have 3 purposes: reduce staff, sell assets, and refinance debt.'' [49]

As we explained in the FY 2024 Inpatient Prospective Payment System Long-Term Care Hospital Prospective

[42] 88 FR 80144.

[43] Medicare Enrollment Application—Institutional Providers (OMB Control No. 0938–0635).

[44] 88 FR 80146.

[45] *https://journalofethics.ama-assn.org/issue/private-equity-health-care.*

[46] Lucy Xu, MD, and Matthew R. Naunheim, MD; ''What Are Physicians' Duties to Patients When They Sell Their Practices?''; May 2025.

[47] Ibid.

[48] Cheryl Erwin and Sheryl Tatar Dacso; ''When and How Should Patients Be Informed About Clinicians' or Organizations' Sale of a Clinical Practice to a Private Equity Buyer?'' May 2025.

[49] Mark Varvares, MD, et al.; ''Should Private Equity Firms Own Residency Slots?'' May 2025.

Payment System proposed rule [50], given the linkage between PEC and REIT ownership and a decline in nursing home quality, we believed it was critical to collect this information from all providers and suppliers that complete the Form CMS–855A, not simply SNFs. Doing so would enable us to: (1) determine whether a similar connection exists with respect to non-SNF providers and suppliers; and (2) help us take measures to improve beneficiary quality of care to the extent such connections exist.[51]

In light of the foregoing, we believe CMS should ascertain the prevalence of PEC and REIT involvement with Medicare Part B suppliers no less than with Part A providers such as SNFs. This is a Medicare-wide issue. Consequently—and like our approach in the November 17, 2023, final rule—we announced in the CY 2027 HH PPS proposed rule our intention to revise the following provider enrollment applications to require all suppliers completing these forms to identify whether any organizations disclosed thereon are PECs or REITs:

- Form CMS–855B (Medicare Enrollment Application—Clinics/Group Practices and Certain Other Suppliers; OMB Control No. 0938–1377).
- Form CMS–855S (Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers; OMB Control No. 0938–1056).
- Form CMS–20134 (Medicare Diabetes Prevention Program (MDPP) Suppliers).

We note that we are relying upon sections 1102, 1866(j), and 1871 of the Act (rather than section 1124(c) of the Act) as authority for this proposal.

As with the November 17, 2023, final rule, our intended form revisions would not involve regulatory changes.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Some commenters supported our planned change, believing that transparency regarding owners of suppliers is important.

Response: We appreciate the commenters' support.

Comment: Several commenters expressed concern that CMS' intended change will require all suppliers that complete the Forms CMS–855B, CMS–855S, and CMS–20134 to now submit the same extensive data that section 1124(c) of the Act requires SNFs to provide on the Form CMS–855A. That is, they believed CMS was attempting to implement section 1124(c) (which only applies to SNFs) for Part B suppliers. Accordingly, they concluded that CMS lacks the statutory authority for its data collection.

Response: While we sincerely appreciate these comments, they are incorrect. We are not seeking to apply section 1124(c) to Part B suppliers or to require suppliers to submit the data referenced in section 1124(c). As we did when revising the Form CMS–855A in 2024, we plan to simply add a checkbox to Forms CMS–855B, CMS–855S, and CMS–20134 by which the supplier identifies whether a reported owner, managing organization, etc. is a PEC or REIT. This change would have no relation to section 1124(c) of the Act and would not require other provider or supplier types to complete the SNF attachment to the Form CMS–855A enrollment application or a similar attachment.

We also remind stakeholders that we were not relying upon section 1124(c) of Act in establishing the Form CMS–855A PEC and REIT checkboxes. We were instead utilizing our authority under section 1866(j) of the Act. We are doing the same here regarding our checkbox additions to the Forms CMS–855B, CMS–855S, and CMS–20134.

Comment: Some commenters maintained that our change would revise these forms without the public having an opportunity to comment thereon.

Response: Our Form CMS–855B, CMS–855S, and CMS–20134 revisions would be facilitated through the Paperwork Reduction Act (PRA) process. Stakeholders will have a 60-day period in which to comment on the revisions, followed by another 30-day comment period.

Comment: Several commenters stated that CMS in the proposed rule did not adequately justify the need for these checkboxes: (1) with respect to REITs; and (2) on CMS' Part B enrollment forms. They contended that there is insufficient evidence that REITs (and, for that matter, PECs) present program integrity risks to Medicare Part B health care and beneficiaries. They also stated that any collection of this data would unfairly impugn REITs and PECs, especially since such entities provide considerable benefit. They requested a CMS statement that PEC or REIT ownership (or profits stemming from) will not, by itself, result in a supplier's revocation, denial, higher-risk designation under § 424.518, etc.

Response: Our proposal was not intended to impugn PECs and REITs but simply to address the previously expressed concerns about their financial participation in the health-care sector. The checkboxes will give us a better understanding of the scope of such with respect to Medicare Part B; the reports we cited in the proposed rule indicate significant private equity involvement with physician practices, which complete the Form CMS–855B. The commenters noted that no specific examples of REIT involvement with Part B suppliers were included in the proposed rule. While true, the lack of provider enrollment data on REIT Part B prevalence is precisely why the REIT checkbox is needed given the aforementioned issues.

As of the date of this final rule, CMS does not have the regulatory authority to revoke a provider or raise its § 424.518 risk-level based solely and exclusively on the fact that it has PEC or REIT ownership.

Comment: Several commenters questioned how CMS will use this information and for what purposes.

Response: Like with the checkboxes on the Form CMS–855A, CMS will use it to examine the prevalence of private equity and REITs in the health-care sector in light of the quality of care concerns.

Comment: Several commenters stated that CMS must define the terms ''private equity company'' and ''real estate investment trust''—and provide clear reporting instructions (with examples)—on the three forms it intends to revise.

Response: CMS will include on these forms the same PEC and REIT definitions and instructions listed on the Form CMS–855A. These definitions are consistent with those in § 424.502.

Comment: Several commenters disagreed with the current definitions of ''private equity company'' and ''real estate investment trust.'' They believed the definitions should be revised to reflect the general understanding of PECs and REITs throughout the business and financial communities.

Response: As we did not propose to revise these definitions, we believe these comments are outside the scope of this final rule.

Comment: Several commenters stated that CMS should: (1) limit providers' reporting responsibilities to PEC and REIT data that can reasonably be identified (particularly a party's REIT status, which the commenters

[50] ''Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership'', published in the Federal Register on May 1, 2023.

[51] Ibid.

contended can be difficult to obtain); (2) furnish provider education, guidance, and examples; and (3) delay implementation to give providers time to understand the new requirements.

Response: Regarding the first recommendation, we refer commenters to our prior statements regarding a ''due diligence'' standard. CMS will, as deemed appropriate, issue guidance on the PEC and REIT checkboxes but respectfully declines to postpone these reporting requirements due to the importance of the information in question.

Comment: A commenter seemingly urged CMS to ensure that: (1) institutional and minority PEC and REIT investors are not inadvertently captured via our planned form changes; and (2) the reporting thresholds are proportionate.

Response: Although we were somewhat uncertain as to the commenter's specific requests, we again state that the provider must indicate via the planned checkboxes whether each disclosed organizational owning or managing party reported on the enrollment application is a PEC or REIT. There are no exceptions for minority or institutional parties, for sections 1124 and 1124A of the Act do not exempt providers from disclosing minority and institutional owners.

Comment: A few commenters stated that CMS should outline in this final rule the ICR burden on Part B suppliers in reporting REIT information, which the commenters believed would be excessive given the potential challenges in securing it.

Response: Akin to our approach in the aforementioned November 17, 2023, final rule, this burden estimate will be addressed in the PRA packages for the Forms CMS–855B, CMS–855S, and CMS–20134 rather than the final rule. Stakeholders will have the opportunity to comment on this projection as part of the PRA process.

After reviewing the comments received, we intend to proceed with proposed revisions to the three aforementioned enrollment applications to collect PEC and REIT data. We welcome additional stakeholder feedback during the PRA notice-and-comment process.

9. Managing Employees (§ 424.502)

The term ''managing employee'' is defined in § 424.502. It means, in part, a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider. Managing employees have long been required to be disclosed on the provider's Medicare enrollment application. Since managing employees sometimes have as much or more influence over a provider's daily operations as an owner, we must know whether such persons present risks to the Trust Funds.

Yet the risks are not strictly financial. We have repeatedly noted over the years our role in protecting the health and safety of Medicare beneficiaries. From a provider enrollment perspective, part of this involves our current collecting of information on certain medical professionals within a provider organization. This includes, for example: (1) IDTF supervising physicians, interpreting physicians, and technicians; (2) ordering OTP personnel; and (3) hospice and SNF medical directors. The purpose is to ensure that such persons not only pose no payment safeguard threats but also are qualified for their roles (such as meeting State licensure requirements). Unqualified or unvetted medical personnel can harm Medicare patients.

So great is our concern about this matter that we believe additional clinical parties should be disclosed on the provider enrollment application. Hence, we proposed to expand upon our aforementioned inclusion of hospice and SNF medical directors within the ''managing employee'' definition. The following persons would be added:

- Medical directors (not merely those at SNFs and hospices)
- Clinical directors
- Departmental heads (for example, a hospital's chief of cardiology)
- Supervising physicians (not simply those at IDTFs)
- Nursing directors
- Alternate administrators
- All other clinical personnel that meet the ''managing employee'' definition.

We noted four things in the proposed rule. First, these categories apply to all provider and supplier types, including SNFs and hospices. Second, we believe the persons in these categories already qualify as ''managing employees'' and should have always been reported. They clearly have direct or indirect control of the provider's day-to-day operations, and the fact that they are clinical personnel (rather than administrative) is irrelevant for purposes of determining whether a person is a managing employee. Our inclusion of them within the ''managing employee'' definition is, in large part, a reminder to stakeholders that clinical staff must be disclosed if the definition is met. Third, these seven new bulleted categories do not establish any minimum threshold for disclosure; for example, even if an individual has less influence than a departmental head, the person must still be reported as long as the managing employee definition is met. Fourth, and on the other hand, this does not mean that every clinical employee regardless of influence must be reported. Disclosure is only required if the person is a managing employee.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Many commenters opposed our proposed revision on several grounds. First, they did not believe these persons qualify as managing employees simply because of their title—with some commenters maintaining that they did not qualify at all because they do not fall within the generally understood meaning of ''managing employee''; they seemingly contended that the definition is restricted to administrative and non-clinical officials with very high-level leadership and supervisory authority over the provider's entire operation. Second, they stated that the burden of reporting these individuals as managing employees would be enormous, especially for larger providers with many clinical employees. Third, and in a similar vein, they disagreed with our assertions that (i) these individuals should always have been reported as managing employees and (ii) there would thus be no additional reporting burden (as we stated in the ICR and RIA sections of the proposed rule). Fourth, they maintained that our use of phrases such as ''additional clinical parties'' and ''expand upon'' when describing our change in the proposed rule was not only a contradiction but also a *de facto* CMS admission that: (i) these persons never qualified as managing employees; (ii) our revision constitutes a new reporting requirement; and (iii) CMS must calculate the reporting burden accordingly.

Response: We respectfully disagree with all these comments. We believe the clinical parties listed in our proposed revised definition clearly are managing employees. Even if one assumed that a person's title is not absolutely and conclusively dispositive as to whether they meet the ''managing employee'' definition, we have always viewed it as by far the strongest indicator of such. More importantly, we have long interpreted this definition much more broadly than the commenters apparently have. It has never been limited to the highest administrative officers in the organization, it has never excluded officials who oversee only certain parts or offices of a provider, and we have never indicated that clinical personnel

do not fall within its scope. Indeed, the definition encompasses not only those who exercise ''operational or managerial control over'' the provider's day-to-day operations but also persons ''who directly or indirectly conduct'' said operations. This covers—and has long covered—a wide range of parties; as an illustration, a clinical department head at a local hospital, in our view, unquestionably participates in conducting the provider's day-to-day operations. Given all this, we retain our stance that these individuals should always have been disclosed.

The phrases ''additional clinical parties'' and ''expand upon'' were merely references to our listing of more officials within the definition as a reminder that they qualify as managing employees. It was neither a contradiction nor an indication that they never before qualified, for we expressly stated in several places in the proposed rule that they already did. In short, it was an addition of language, not an addition or expansion of scope—two very different things, especially since the actual definition itself is not changing but only the listing of parties for clarity purposes. It was no different than our 2023 revision of this definition to list SNF and hospice medical directors and administrators; [52] this, too, was not an expansion and, we note, generated no public comments during the rulemaking process claiming an additional burden.

We refer commenters to the ICR section of this final rule for a discussion of burden.

Comment: Commenters stated that CMS should apply a due diligence standard to the reporting of clinical and other managing employees. So long as the provider made a reasonable effort to obtain all managing employee data, they believed this should be sufficient for CMS—and that CMS should take no denial, revocation, deactivation, or other measure against the provider. Several commenters believed this approach would comport with CMS' sub-regulatory guidance regarding the reporting of SNF additional disclosable party (ADP) information—whereby, the commenters maintained, SNFs can outline for MACs its ''maximum feasible'' but unsuccessful efforts to obtain ADP data.[53]

Response: We disagree with these comments. While we understand it can occasionally be challenging to secure certain managing employee data, CMS has never had a ''best efforts'' or similar allowance for this information. It must be reported, and CMS can take action if it is not.

The SNF guidance comparison is, most respectfully, somewhat fallacious because the ''maximum feasible efforts'' reference therein: (1) is limited to ADP data and does not apply to the reporting of managing employees; and (2) in no way means that CMS automatically accepts the failure to report certain ADP data so long as the provider made said efforts.

Comment: Several commenters stated that clinical directors, nursing leaders, department heads, and other clinicians may supervise patient care but do not necessarily exercise ownership-level or financial control and may have limited managerial authority over the provider.

Response: For reasons already stated, we believe the clinical parties identified in our proposed definition revision clearly qualify as managing employees. We add that one need not exercise ownership-level or financial control or wide-ranging, high-level managerial authority to fall within the very broad ''managing employee'' definition.

Comment: Commenters stated that the proposed ''managing employee'' definition should be significantly narrowed while containing a clear, minimum threshold for disclosure. Some recommended a threshold of actual decision-making or other substantial authority over, for instance, the provider's organizational operations and decision-making, financial matters, billing, policy, etc. A few added that clinical personnel with limited supervisory duties or who engage in temporary coverage should be excluded from the ''managing employee'' definition.

Response: We believe both the existing and proposed versions of the definition are plain on their face as to who must be reported. If the individual falls within the definition, they must be disclosed.

Comment: Commenters stated that a person's authority—not their title—should determine who is or is not a managing employee. They maintained that: (1) providers, not CMS, are in the best position to make this determination and that CMS should defer to providers on the matter; and (2) CMS should expressly state that the individuals CMS proposed to list in the ''managing employee'' definition are not managing employees based solely on their title.

Response: As stated previously, we believe titles are an extremely heavy indicator of one's authority, and, accordingly, that the clinical personnel in question are indeed managing employees; hence, we cannot make the unequivocal statement the commenters request. Moreover, if we deferred the reporting of managing employees entirely to the provider's judgment and prohibited ourselves from even questioning whether all the provider's managing employees were disclosed, providers would have every incentive to avoid reporting certain individuals.

Comment: Several commenters stated that the current ''managing employee'' definition only lists SNF and hospice medical directors. They implied that these were therefore the only clinical managing employees that traditionally had to be reported.

Response: We respectfully disagree. Our inclusion of SNF and hospice medical directors: (1) was merely a reminder that these persons are managing employees; and (2) never implied that these were only clinical personnel who needed to be disclosed.

Comment: A commenter stated that if CMS finalizes its proposed revised definition, it should increase the timeframe for reporting managing employee changes.

Response: We respectfully disagree. Such changes have long been required to be disclosed within 30 days given this data's vital importance to program integrity.

Comment: Several commenters stated that if CMS finalizes its proposal, it should: (1) provide clear examples of individuals who would and would not qualify as managing employees within different provider types and organizational structures; (2) establish an appropriate implementation timeframe and grace period before initiating enforcement actions, including giving providers time to review and update their enrollment records; and (3) hold providers harmless for failing to report individuals who—under what they believe is CMS' revised interpretation—would now be considered managing employees but were not previously understood to fall within the regulatory definition. Other commenters questioned whether all providers must submit enrollment applications to report clinical managing employees who were not previously disclosed.

[52] ''Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements'' (88 FR 77676), published in the **Federal Register** on November 13, 2023.

[53] *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos.*

Response: CMS will, if appropriate, issue guidance regarding the commenters' first request and the last question. However, we cannot commit to a ''hold harmless'' exception or a delayed implementation because, again, these clinical parties have long met the ''managing employee'' definition. (This is also why we disagree with the commenters' assertion that our proposal constitutes a ''revised interpretation'' of the definition.)

Comment: A few commenters stated that CMS' revision to the ''managing employee'' definition is unnecessary because many of these individuals are already disclosed to CMS via other means, such as certification or accreditation.

Response: We respectfully disagree because provider enrollment requirements—including the reporting of managing employees—are separate and distinct from other requirements (such as CoPs, accreditation requirements, etc.) and must be individually met.

Comment: A commenter urged CMS to clarify that community pharmacy personnel are managing employees only if they exercise actual operational or managerial control over the DMEPOS supplier's day-to-day operations and not merely because they (1) hold a clinical license; (2) supervise a pharmacy practice at a location; or (3) serve as a pharmacist-in-charge.

Response: While CMS cannot establish or commit to blanket ''managing employee'' exemptions in this final rule, we will, as appropriate, issue guidance on the matter the commenter raised.

After reviewing the comments received, we are finalizing our proposed revised ''managing employee'' definition without modification.

10. Definition of ''Operational'' (§ 424.502)

a. Background and Provisions

Per § 424.510(d)(6), a provider must be ''operational'' to obtain Medicare billing privileges. ''Operational'' is defined in § 424.502 as meaning the provider meets all of the following:

- Has a qualified physical practice location
- Is open to the public for the purpose of providing health care related services
- Is prepared to submit valid Medicare claims
- Is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered) to furnish these items or services.

The ''operational'' definition's core purpose is to help confirm that the provider is bona fide. Unfortunately, we have discovered instances where a provider appears to meet the definition but turns out to be a fraudulent operation. We believe stronger, broader, and clearer components of the definition would better ensure the provider's operational status and legitimacy and assist us in preventing sham providers from entering Medicare. Therefore, we proposed the following changes to our definition.

First, we proposed an opening sentence to the definition that would read ''*Operational* means (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered) the provider or supplier meets all of the following:''. The parenthetical—which is in the current definition—would elucidate for stakeholders that: (1) certain components of our revised definition may not apply to all provider types; and (2) CMS would account for this in applying the definition.

Second, the previously referenced four bulleted components of the existing definition would be designated as new paragraphs (1) through (4) therein. This would improve the definition's readability. (We did not propose changes to the first requirement concerning a qualified physical practice location.)

Third, proposed paragraph (2) would explain that the requirement that the provider ''[i]s open to the public for the purpose of providing health care related services'' includes, but is not limited to, all of the following:

- The provider's location is fully accessible to all patients and lacks safety hazards.
- The provider's hours of business are sufficient to regularly serve patients.
- Medicare beneficiaries can contact and locate the provider's location based on publicly available information (for example, the internet).

We believe these three requirements would help verify the provider's compliance with paragraph (2). In our view, a provider whose location threatens patient safety, is inaccessible to beneficiaries, or cannot be found via public means raises doubts as to whether the location is truly ''open.''

For purposes of the ''operational'' definition, we proposed to define ''accessible'' as meaning both of the following:

- The provider is located in an area and a building that patients can enter with reasonable ease.
- The location is compliant with all Federal Americans with Disabilities Act regulations and all applicable and equivalent State and local laws.

These requirements would make clear that providers must—from an accessibility standpoint—accommodate beneficiaries with disabilities and those without. We noted in the proposed rule that the phrase ''located in an area'' does not mean the provider's location must be, for instance, within a short drive or a mere 5-mile radius of the beneficiary's home. ''Area'' in this context would mean the location's immediate vicinity, such as the parking lot or a larger, multi-building complex in which the provider has its office. Also, nothing in the first bullet would prevent the provider from having security locks or security personnel between its office(s) and the building entrance. It instead references the beneficiary's ability to enter the building once access is granted (for instance, security staff signs in the beneficiary and directs the beneficiary to the provider's office).

Third, we proposed in new paragraph (3) to change ''prepared'' to ''prepared and able''. If the provider lacks the administrative or logistical ability to submit valid claims—even if it may be ''prepared'' to do so—we do not believe the provider can be considered operational for purposes of Medicare enrollment.

Fourth, and similar to proposed paragraph (2), proposed paragraph (4) would include the following additional requirements concerning the ''properly staffed, properly equipped . . . .'' criterion:

- Provider staff must be qualified (such as licensed or certified if required under State law) to perform their health care-related functions.
- Equipment must be functional, appropriate for the services and items the provider intends to furnish, and in sufficient quantity to provide these items and services.
- Appropriate medications for the services and items the provider intends to furnish and in sufficient quantity to provide these items and services.

We also believe that operationality should require more than proposed paragraphs (1) through (4), particularly with respect to administration, safety, and patient care. Hence, we proposed in new paragraph (5) that operationality requires the provider to have adequate written policies and records regarding its operations, such as, but not limited to, procedures for patient care, patient safety, medical and patient recordkeeping, and general administration.

We further stated in the proposed rule that the wide variety of provider types and scenarios might at times require us to consider information not addressed in our revised definition in order to determine the provider's operationality. Suppose a case arises where most of the definition's requirements are inapplicable to the provider, but this leaves insufficient remaining criteria for us to determine operational status. We believe we must have the ability to contemplate other information in this and other cases. We hence proposed an additional (though un-numerated) paragraph at the end of our revised definition stating that CMS may consider any information in determining whether the provider is operational.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Several commenters sought CMS confirmation that certain provider types, such as HHAs, would not be required to meet all the ''operational'' criteria due to those providers' particular characteristics. Another commenter requested that CMS not: (1) interpret ''open to the public'' to require a home health administrative office to operate as a patient-facing clinical site; (2) require an HHA to stock medications or equipment that it does not lawfully dispense, own, or routinely furnish; or (3) rely on an unlimited ''catch-all'' category (referenced previously) allowing CMS to consider ''any information'' without explaining how that data relates to ''operational'' regulatory requirements.

Response: Although we are unable in this rule to formally exclude specific provider types from various requirements in the ''operational'' definition, we recognize that certain provisions may not apply in all instances to all providers and suppliers—hence our ''as applicable'' reference in the proposed revised definition. We will keep this in mind—as we do with the current ''operational'' definition—when enforcing our revised definition. Regarding the ''catch-all'' category, this is necessary to account for situations not explicitly addressed within the ''operational'' definition.

Comment: Several commenters supported our proposed revised definition of ''operational.'' A commenter in particular agreed that providers should have adequate written policies and records regarding their operations, including patient care and patient safety.

Response: We appreciate the commenter's support.

Comment: Some commenters requested CMS to: (1) exempt State surveyed and accredited providers and suppliers from the ''operational'' requirement; or (2) rely on State survey or accreditation findings when determining operationality so as to avoid duplicity and inconsistent requirements. If CMS does neither, a few commenters stated that CMS should explain how: (1) the expanded definition will apply to institutional providers already subject to Federal and State oversight; and (2) overlapping State survey and operationality requirements will be reconciled before a denial or revocation occurs.

Response: We respectfully decline the commenters' first two requests. Again, provider enrollment requirements—such as § 424.510(d)(6)—are separate from State survey and accreditation requirements. The former must be met even if the provider is surveyed or accredited; this has been the case for decades. Insofar as the final two comments, we are respectfully unclear as to the guidance the commenter seeks. We can only reiterate that State survey, accreditation, and other State and Federal oversight requirements are separate from our consideration of whether a provider is operational.

Comment: Several commenters recommended that CMS issue guidance and examples regarding what does and does not constitute ''operational'' status under our revised definition.

Response: To the extent we deem necessary, we will release guidance on its expanded definition of ''operational.''

After reviewing the comments received, we are finalizing our proposed revised ''operational'' definition without modification. We are making one technical correction to our regulatory text, though. We mentioned previously that we are retaining the requirement that the provider have a ''qualified physical practice location.'' This has been a requirement for decades. Yet paragraph (1) of the proposed revised definition did not include the word ''physical'', even though it was intended. We are including it in paragraph (1) in our final regulatory text.

11. Signage (§ 424.510(f))

Sections 424.57(c)(7)(i)(D) and 410.33(g)(14)(ii) require DMEPOS suppliers and IDTFs, respectively, to maintain a permanent visible sign in plain view posting their normal hours of operation. The former adds that if the supplier's place of business is located within a building complex, the sign must be visible at the main entrance of the building (or the hours can be posted at the entrance of the supplier). We proposed in new § 424.510(f) to expand this requirement to include all providers and suppliers; § 424.510(f) would mirror the current language of § 424.57(c)(7)(i)(D). This would assist beneficiaries and site visit personnel in locating the provider's business, something that has occasionally proven difficult because the location contains no signage. To ensure consistency, we would also revise § 410.33(g)(14)(ii) to duplicate the language in proposed § 424.510(f).

Consistent with our proposed revisions to the definition of ''operational'', however, § 424.510(f) is not intended to supersede any other Medicare requirements regarding signage. Section 424.510(f) is strictly an enrollment requirement. In addition, we recognize that our proposed signage requirement may not be practicable in all circumstances. This could be due to, for instance, the type of provider involved, its particular business circumstances, etc. Thus, we proposed the following exceptions to the signage requirement:

- The provider shares office space with another provider (for example, physicians in a group practice sharing a common suite, though the group itself must have signage).
- The provider treats patients in the patients' homes.
- The provider treats patients in the provider's home and only uses the provider's address for administrative purposes.
- The provider performs telehealth services from home.

The following is a summary of the comments we received on this proposal and our responses.

Comment: A number of commenters opposed our proposed requirement, believing it would, in some cases, be burdensome and operationally infeasible for certain provider and supplier types; for example, providers located in large office buildings may be unable to maintain signage due to space limitations, building policies, etc. The commenters accordingly recommended several modifications to our proposal. These included but were not limited to: (1) treating the signage requirement as met if the provider is identifiable via publicly available means, such as a building directory or website; (2) permitting shared or centralized signage for providers in multi-tenant buildings, health system campuses, or similar facilities; (3) clarifying that a periodic signage lapse due to matters outside the provider's control (such as construction or natural disaster)—or minor signage

violations per a materiality standard—will not result in an adverse CMS finding; (4) limiting CMS enforcement to corrective action by allowing the provider time to remedy the issue (after CMS notification) before denying, revoking, or deactivating the provider; (5) exempting field-based and privacy-sensitive behavioral health sites from the signage requirement; and (6) adding more regulatory exceptions to the signage requirement, perhaps based on provider type and potentially including hospitals, HHAs, telehealth providers, and providers that furnish services in beneficiaries' homes.

Response: We appreciate these comments and respond as follows:

We respectfully disagree with the commenters' first and second recommendations. We do not believe a public directory or shared signage is an adequate substitute for individual, provider-specific signage; indeed, the former would completely undercut the need for the latter. We also must decline the commenters' third and fourth requests based on our earlier explanations that: (1) any degree of non-compliance still involves non-compliance; and (2) a mandatory pre-appeals cure period could reduce providers' willingness to maintain constant compliance, knowing that they can always correct the problem later. Regarding the fifth and sixth, we are unable to grant additional provider type exceptions in this final rule without further review of the issue. Nonetheless, we will monitor the implementation of § 424.510(f) and, if need be, consider future rulemaking to address.

Comment: Several commenters stated that CMS should deem § 424.510(f) as satisfied if the provider's signage complies with State survey, licensure, local, and other requirements.

Response: We respectfully disagree because Medicare enrollment requirements are—and have always been—separate and distinct from State and local requirements. Compliance with the latter does not mean automatic compliance with the former.

Comment: A few commenters questioned (1) how § 424.510(f) applies to institutional providers that are part of campuses or large medical complexes; (2) what type of signage is acceptable in such cases; and(3) what constitutes ''normal business hours'' and ''visible business signage''.

Response: CMS will, as applicable, issue public guidance on these topics as well as others concerning the signage requirement.

Comment: A few commenters stated that when enforcing § 424.510(f), CMS should account for situations such as (but not limited to) landlord restrictions, building types, local ordinances, or others than might prevent full compliance through no fault of the provider. A commenter requested that CMS explicitly state in the regulatory text that § 424.510(f) may not apply in all situations.

Response: We respectfully decline to add the final commenter's requested statement, for it could give the impression that CMS will grant exceptions in every case where the provider claims it cannot meet § 424.510(f) due to factors outside its control. This said, we recognize that atypical situations involving signage compliance may occur based on the facts involved. CMS will keep this in mind when applying§ 424.510(f)'s requirements.

Comment: A commenter supported our proposed exceptions to the signage requirement.

Response: We appreciate the commenter's support.

After reviewing the comments received, we are finalizing our proposed signage requirements without modification.

12. Retention and Furnishing of Documentation (§ 424.516)

We explained previously that under § 424.516(f)(1), providers and suppliers that furnish covered ordered, certified, referred, or prescribed Part A or B services, items or drugs must:

- Maintain the documentation described in § 424.516(f)(1)(ii) for 7 years from the date of service; and
- Upon CMS' or a Medicare contractor's request, provide access to that documentation.

The documentation described in § 424.516(f)(1)(ii) includes written and electronic documents (including the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item, or drug) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Part A or B services, items or drugs.

Section 424.516(f)(2) contains a similar documentation retention and submission requirement for physicians (or, when permitted, eligible professionals) who order, certify, refer, or prescribe Part A or B services, items or drugs. Section 424.516(a)(10), meanwhile, permits revocation if the provider or supplier fails to comply with the documentation and CMS access requirements in § 424.516(f).

In general, § 424.516(f) helps CMS determine, for instance, whether the service was reasonable and necessary, whether fraud, waste, or abuse is involved, and whether the provider is compliant with Medicare requirements.

We proposed to add new § 424.516(f)(3) clarifying that all documentation required to be retained and furnished under § 424.516(f) must be accurate, complete, and compliant with all CMS requirements. In our documentation reviews, we have seen: (1) patient charts missing medical director signatures; (2) hospice certifications signed before the face-to-face encounter; (3) certification end dates preceding the certification start dates; and (4) other types of inaccurate records. This makes it difficult for CMS and its contractors to verify the provider's compliance and the service's necessity; the program integrity benefits of § 424.516(f) are reduced if the documentation is inaccurate or non-adherent. We accordingly believe § 424.516(f)(3) is necessary.

We emphasize that our proposal is not intended to establish any new condition of payment. It would be restricted to the scope of documents addressed in § 424.516(f).

The following is a summary of the comments we received on this proposal and our responses.

Comment: A commenter supported our proposal but suggested that CMS—in potential § 424.535(a)(10) revocation cases—take into account situations where claims documentation has been lost due to natural disasters or other similar events. Another commenter requested that CMS: (1) confirm that records under § 424.516(f) may be retained and produced electronically; (2) specify accepted electronic formats and a secure transmission channel; and (3) provide a reasonable and defined production before utilizing § 424.535(a)(10).

Response: While we appreciate the commenters' support, recommendations, and requests, our proposal was limited to the need for documentation to be accurate and complete, rather than whether and how it could or should be furnished in the situations the commenters describe. Consequently, we respectfully believe these comments are outside the scope of this final rule.

Comment: A few commenters requested that CMS clarify that a provider will not be revoked under § 424.535(a)(10) for § 424.516(f)(3) documentation deficiencies that are immaterial (for example, the commenter stated, the error does not materially affect the ability to validate a claim), technical, or inadvertent.

Response: While we cannot make the blanket statement the commenters request, we acknowledge that not all

documentation errors are the same. As with all revocations, CMS will carefully evaluate the facts and circumstances of the case.

Comment: A commenter stated that when enforcing § 424.516(f)(3), CMS should recognize that some provider and supplier types, such as HHAs and hospices, furnish services in patients' homes.

Response: While we appreciate this comment, we again state that our proposal only referenced the need for the documentation to be accurate, complete, and compliant—a requirement that we respectfully do not believe should depend on the provider type involved or where or how services are furnished.

Comment: Several commenters stated that CMS should define ''accurate, complete, and compliant.''

Response: These terms will have plain meanings.

Comment: Several commenters stated that CMS should: (1) implement § 424.516(f)(3) using clear, uniform, and materiality-based standards; (2) clarify whether § 424.516(f)(3) would be limited to documentation already covered by § 424.516(f); and (3) confirm that § 424.516(f)(3) creates neither a new condition of payment nor new or duplicate clinical documentation or record-retention requirements regarding CoPs, claims, etc.

Response: While the first comment was unclear to us, we believe the commenter was requesting the implementation of factors—including a materiality standard—for § 424.535(a)(10) revocations that are based on § 424.516(f)(3) non-compliance. Assuming as such, we refer the commenter to our earlier statements regarding factors and materiality.

Section 424.516(f)(3), again, only applies to the § 424.516(f) documentation's accuracy, compliance, and completeness. It does not create other new requirements or conditions or expand the types of data that § 424.516(f) covers. Regarding the latter portion of the third comment, we cannot ascertain whether the commenters' reference to duplication effectively requests that we rescind § 424.516(f)(3) (and eliminate § 424.516(f) altogether) if other CMS provisions require the accurate submission of provider, physician, or practitioner documentation. If it does, we again remind stakeholders that enrollment requirements are separate from others and must be independently complied with.

After reviewing the comments received, we are finalizing proposed § 424.516(f)(3) without modification.

12. Corrective Action Plans (CAPs), Rebuttals, and Appeals

In certain situations, a provider or supplier may have an opportunity to correct a deficiency or contest a CMS finding regarding its enrollment by submitting, as applicable: (1) a CAP in response to a §§ 424.530(a)(1) or 424.535(a)(1) denial or revocation, respectively; (2) a rebuttal to a stay or deactivation of enrollment under §§ 424.541 or 424.546, respectively; or (3) an appeal of an initial determination under 42 CFR 498.3. We proposed several revisions to these processes.

a. CAPs (§ 405.809)

Sections 424.530(a)(1) and 424.535(a)(1) permit CMS to deny or revoke enrollment, respectively, if the provider is not compliant with the enrollment requirements in Title 42 or in the enrollment application applicable for its provider type. The provider may submit a CAP in response to this denial or revocation, which allows the provider to remedy the deficiency or deficiencies in question and achieve compliance. As has long been CMS practice, though, §§ 424.530(a)(1) and 424.535(a)(1) are the only denial or revocation reasons under §§ 424.530 and 424.535 for which the provider may submit a CAP. While § 405.809(a)(1) makes this clear with respect to § 424.535(a)(1), it is silent as to § 424.530(a)(1). To incorporate this CAP policy into regulation, we proposed to add § 424.530(a)(1) denials to § 405.809's purview. This would involve the following revisions:

- Section 405.809's title would change from ''Reinstatement of provider or supplier billing privileges following corrective action'' to ''Granting or reinstatement of provider or supplier billing privileges following corrective action.''
- In paragraph (a)(1), the language ''revocation for noncompliance under § 424.530(a)(1)'' would change to ''denial or revocation for non-compliance under § 424.530(a)(1) or § 424.535(a)(1)''.
- In paragraph (a)(2), ''revocation'' would change to ''denial or revocation''.
- In paragraph (b)(1), ''Reinstates'' would change to ''Approves or reinstates''.
- Paragraph (b)(1)(i) would be redesignated as paragraph (b)(1)(i)(B).
- Under new paragraph (b)(1)(i)(A), the effective date of the approval is based on the applicable timeframes described in §§ 424.520 and 424.521. This is consistent with existing practice.
- In paragraph (b)(1)(ii), ''reinstatement'' would change to ''approval or reinstatement''.
- In paragraph (b)(2), ''reinstate'' would change to ''approve or reinstate''.

b. Notification of Determinations

Section 498.3(b) lists several CMS or MAC provider enrollment decisions that are considered ''initial determinations''. These include, for example, enrollment denials, enrollment revocations, and inclusion of a provider on the preclusion list. The affected provider under § 498.5 may request a reconsideration of the initial determination, for which CMS or, if applicable, the MAC issues a reconsideration determination. Under §§ 498.20(a)(1) and 498.25(a)(1), CMS mails notice of the initial determination or reconsidered determination, respectively, to the provider. Furthermore, § 405.800 requires that denial and revocation notices (as well as notice regarding the addition of years to a reenrollment bar) be sent by certified mail. We proposed to revise §§ 405.800(a), (b)(1), and (c)(1), 498.20(a)(1) and 498.25(a)(1) to include email as an acceptable form of notice. We believe this would facilitate faster notice to the provider without the expense of paper mailing.

c. Appeals of Reactivation Effective Dates

Along with listing types of initial determinations, paragraph (d) of § 498.3 outlines administrative actions that are not initial determinations and thus not appealable under part 498. One type of provider enrollment finding that is not mentioned in either § 498.3(b) or (d) is the effective date of a reactivation under § 424.540(b). Under § 424.540(d)(2), a reactivation effective date is the date on which the Medicare contractor received the provider's reactivation submission that the Medicare contractor processed to approval. Due to lack of clarity among some stakeholders as to whether an assigned reactivation effective date may be appealed or rebutted, we proposed several regulatory changes.

First, we proposed to add new paragraph (3) to § 424.540(d) stating that a provider or supplier may rebut their assigned reactivation effective date via the general deactivation rebuttal procedures in § 424.546. As deactivations are not considered initial determinations—and to ensure consistent approaches—we do not believe reactivation effective dates should, either. Yet we also believe the provider should have an opportunity to be heard on the matter, and a rebuttal would provide that.

To accommodate reactivation effective date rebuttals within § 424.546,

we also proposed to revise the latter as follows:

- Change the title from ''Deactivation rebuttals'' to ''Rebuttals of deactivations and of reactivation effective dates''.
- In paragraph (a)(1), insert the following between ''under § 424.540,'' and ''the provider or supplier has 15 calendar days'': ''or is assigned a reactivation effective date by CMS or its contractor under § 424.540(d)(2),''.
- In paragraph (b)(2), insert the following between ''effective date,'' and ''and the reasons'': ''(or with the assigned reactivation effective date)''.
- In paragraph (b)(3), insert the following after ''deactivation'': ''or the reactivation effective date''.
- Delete existing paragraph (d) and replace with the following: ''Upon receipt of a timely and compliant deactivation (or reactivation effective date) rebuttal, CMS reviews the rebuttal to determine whether the imposition of the deactivation and/or the designated effective date (or the assigned reactivation effective date) are correct.''

In this vein, we would also revise § 424.545(b) to include assignments of reactivation effective dates as a ground for rebuttal.

The following is a summary of the comments we received on these proposals and our responses.

Comment: Several commenters supported our proposed use of electronic notifications.

Response: We appreciate the commenters' support.

Comment: Several commenters supported our proposed reactivation effective date rebuttal proposals, though a commenter stated that the effective date should be the date of submission, not the date of receipt by the Medicare contractor.

Response: We appreciate the commenters' support but are respectfully uncertain as to the submission and receipt dates the commenter refers to. If, as we suspect, the commenter is stating that the provider has 15 days to submit a rebuttal under § 424.546, this is correct. The use of ''receipt'' in § 424.546(d) simply means that CMS reviews the rebuttal upon receiving it. Paragraph (d) does not include or reference any effective date.

Comment: Several commenters supported our proposed revisions to § 405.809 regarding CAPs. However, they recommended that CAPs be permitted for additional denial and revocation reasons besides §§ 424.530(a)(1) and 424.535(a)(1).

Response: We appreciate the commenters' support and suggestions. However, we respectfully decline the commenters' request regarding CAP expansion for the same aforementioned reasons we do not have an across-the-board pre-revocation appeals or cure process.

Comment: A few commenters recommended that CMS either continue mailing denial and revocation notices or permit providers to opt into electronic-only notice. They expressed concern that an important notice delivered via a single electronic vehicle might not adequately reach the provider. Other commenters: (1) questioned how CMS will confirm email receipt; (2) recommended that emailed letters be sent to multiple individuals listed on the provider's application to help ensure the letter is received; and (3) sought provider protections for failed or untimely transmissions.

Response: While we intend to finalize our changes regarding electronic mail, we recognize the commenters' concerns. We will examine the possibility of emailing letters to multiple contacts and will take steps to ensure that emailed notices are sent timely. We will also attempt, as applicable, to furnish guidance regarding confirmation of the provider's receipt of the notice.

Comment: Several commenters stated that CMS should email denial and revocation letters on the same day they are dated.

Response: We will strive to do so.

Comment: A commenter stated that for reactivation effective-date disputes, CMS should: (1) specify the evidence and standard of review; (2) allow at least 30 calendar days for rebuttal; (3) provide a written decision; and (4) make additional review available for unresolved material factual disputes.

Response: We refer the commenter to CMS Publication 100–08, Chapter 10 for information regarding the first and third issues. Provider and supplier deactivation and stay rebuttals have always been 15 days, which we continue to believe is adequate time for submission. As rebuttals have never been considered initial determinations under § 498.3(b), there are no further administrative review rights once CMS' rebuttal decision has been made.

Comment: A few commenters requested that CMS: (1) implement delivery practices for notices that ensure providers receive the full response period contemplated by regulation and have a meaningful opportunity to respond within prescribed timeframes; and (2) clarify how notices are delivered when regulatory timeframes are measured in calendar days, since enrollment functions are generally performed during standard business hours and on weekdays.

Response: We respectfully are unsure as to the specific practices the commenters seek, the commenters' interpretation of ''meaningful opportunity'', which timeframes the commenters are referencing, or the clarification the commenters request. It appeared to us that these comments pertained to CMS' overall, existing enrollment notice delivery process as opposed to the specific email delivery proposal. Hence, we believe these comments go beyond—and are outside—the scope of this final rule.

Comment: A commenter stated that: (1) CMS should clearly coordinate CAP, rebuttal, reconsideration, and appeal procedures so that the use of one process does not waive or shorten another; and (2) CMS and MAC notices should identify all available options, deadlines, and consequences of concurrent review.

Response: We believe these comments go beyond the matter of reactivation effective date rebuttals to our overall, longstanding appeals and revocation processes. Thus, we believe they are outside the scope of this final rule.

After reviewing the comments received, we are finalizing these CAP, email, and rebuttal proposals without modification.

13. Fingerprinting (§ 424.518(c))

Section 424.518(c)(2)(ii)(A) states that 5 percent or greater individual owners of providers and suppliers in the ''high'' screening category must submit fingerprints for a national criminal background check. We proposed to revise this paragraph to clarify that individuals subject to fingerprinting must use the CMS-designated fingerprinting contractor for this task. We view this as a technical change because CMS already has a designated provider enrollment fingerprinting contractor that providers must use.

Comment: Several commenters supported our proposed revision to § 424.518(c)(2)(ii)(A).

Response: We appreciate the commenter's support.

Comment: A commenter recommended that CMS delay implementation of revised § 424.518(c)(2)(ii)(A) to give all parties time to prepare.

Response: While we appreciate the commenter's request, we reiterate that CMS already uses a designated fingerprinting contractor; consequently, there is no need to delay our proposed change.

Comment: A commenter stated that CMS should: (1) permit local police departments to perform fingerprinting to avoid bottlenecks to timely

fingerprinting, especially in rural and underserved areas; and (2) recognize good-faith compliance efforts when delays are caused by contractor scheduling limitations, processing timelines, and/or geographic access barriers.

Response: We appreciate these comments. For the first, we need consistency in our fingerprinting process, hence the need for a single source, though CMS works to avoid delays. Regarding the second, we are unclear as to whether the commenter is requesting explicit, regulatorily specified exemptions if delays are involved. If the commenter is, we respectfully cannot grant these when we have not reviewed the specific, unique facts of a particular case.

Comment: A commenter stated that: (1) CMS should consider alternative, comparable biometric or identity-verification methods if fingerprinting is not feasible; (2) providers should not face adverse enrollment actions because of contractor processing delays, system issues, limited access to fingerprinting locations, or other circumstances outside their reasonable control; (3) CMS should apply consistent procedures for documenting and addressing such circumstances before denial or revocation; (4) identify who is subject to fingerprinting, when fingerprinting is required, and how compliance must be demonstrated, including the availability and accessibility of CMS-designated fingerprinting contractors for individuals in rural or underserved areas; (5) provide accommodations for individuals unable to produce readable fingerprints because of disability, age, or occupational wear; and (6) clarify whether fingerprints obtained through other federally accepted or trusted identity-verification programs will be accepted.

Response: The first, second, third, and fifth comments—as well as most of the fourth comment—are outside the scope of this final rule because they appear to address the overall fingerprinting requirement under § 424.518(d) instead of our specific proposed revision.

CMS, as stated, uses a single, designated fingerprinting contractor. Applicable information can be found at *https://cmsfingerprinting.com/*. Regarding the sixth comment, all fingerprinting must be done via this contractor.

After reviewing the comments received, we are finalizing proposed revised § 424.518(c)(2)(ii)(A) without modification.

14. DMEPOS Accreditation (§ 424.58)

Consistent with §§ 424.57(c)(22) and 424.58, DMEPOS suppliers must be accredited by a CMS-approved accrediting organization (AO) to enroll and remained enrolled in Medicare. Section 424.58 details the general procedures and policies associated with DMEPOS accreditation. Many of these were added to § 424.58 in the CY 2026 HH PPS final rule (90 FR 55342) in an effort to strengthen CMS' oversight of the DMEPOS accreditation program in general and the DMEPOS AOs in particular. This included requirements regarding information and agreements that AOs must submit to CMS as part of their application/reapplication process. Three of these requirements are as follows:

- Per § 424.58(c)(1)(xxiii)(D), agreeing to notify CMS in writing of any decision to terminate, revoke, withdraw, or amend the accreditation status of a specific DMEPOS supplier within 3 business days of the date the AO took action.
- Per § 424.58(c)(1)(xxii), describing the AO's processes for—

++ Detecting and addressing DMEPOS supplier fraud, waste, and abuse (including identifying the AO's definitions of fraud, waste, and abuse); and

++ Reporting this activity to CMS and, as applicable, law enforcement.

- Per § 424.58(c)(1)(vii)(D), outlining the AO's policies and procedures for avoiding conflicts of interest and the appearance thereof involving individuals who conduct surveys or participate in accreditation decisions.

Upon further reflection since these three provisions were promulgated, we proposed the following changes thereto.

One revision would change the 3-business day period in § 424.58(c)(1)(xxiii)(D) to 5 calendar days. This would better align with § 424.58(e)(5)(i), which requires approved AOs to report the same information to CMS within 5 calendar days.

In addition, there currently is no timeframe in § 424.58 for reporting the fraud, waste, and abuse described § 424.58(c)(1)(xxii). We proposed in new § 424.58(c)(1)(xxiii)(N) that the AO must agree to notify CMS in writing (and, if applicable, law enforcement) of suspected fraud, waste, and abuse—consistent with the AO's CMS-approved definitions of those terms—within 3 calendar days of the date on which the AO determines that fraud, waste, or abuse may have occurred. (Current § 424.58(c)(1)(xxiii)(N) would be redesigned as new § 424.58(c)(1)(xxiii)(O)).

Notwithstanding the provisions of § 424.58(c)(1)(vii)(D) regarding conflicts of interest, none of them actually require the AO to report in its application/reapplication whether it has such conflicts. To help ensure that CMS makes fully informed AO approval decisions, we proposed to revise § 424.58(c)(1)(vii)(D)(*4*) to require the AO to also disclose to CMS all conflicts of interest (as described in § 424.58(c)(1)(vii)(D)(*3*) and (5)) it currently has and explain how and when it will terminate them.

The following is a summary of the comments we received on these proposals and our responses.

Comment: Several commenters stated that CMS should: (1) identify the types of conflicts of interest that must be reported to CMS and the vehicle for doing so; (2) specify the phrase ''suspected fraud, waste, and abuse'' and the reporting requirements associated therewith; and (3) explain how the AOs should contact law enforcement.

Response: CMS will issue separate guidance to the AOs on this matter.

Comment: A few commenters recommended that to account for holidays and weekends, CMS should change its: (1) proposed 3 calendar-day period in § 424.58(c)(1)(xxiii)(N) to, for example, 3 business days or 7 business days; and (2) proposed 5 calendar-day timeframe in § 424.58(c)(1)(xxiii)(D) to 5 business days.

Response: While we appreciate these suggestions, we believe the time periods we proposed are necessary given: (1) the risk that fraud, waste, and abuse can pose to the Trust Funds and beneficiaries; and (2) the importance of us receiving critical information from the AOs as soon as possible.

Comment: A commenter stated that proposed § 424.58(c)(1)(xxiii)(N) risks overwhelming the AOs and CMS with unsubstantiated fraud reports, hence diverting resources from the prevention of actual fraud. The commenter urged CMS to either to raise the reporting threshold or provide guardrails or guidance to avoid this.

Response: We respectfully disagree with the commenters' concern. We do not anticipate a mass of unsubstantiated reports arising from our proposal. Beyond this, we have an obligation to the American people to treat all potential fraud, waste, and abuse (even if it is only suspected and is awaiting investigation) with the utmost seriousness. Waiting to learn from the AO about DMEPOS fraud, waste, and abuse until after it happens reflects the aforementioned, insufficient ''pay and chase'' model. Immediately learning

when fraud, waste, and abuse is suspected will better enable us to be proactive in our program integrity activities.

Comment: A commenter requested that DMEPOS AOs have direct access to CMS enrollment data.

Response: We appreciate this request but believe it is outside the scope of this final rule.

After reviewing the comments received, we are finalizing our proposed DMEPOS accreditation revisions without modification.

15. Miscellaneous Comments

We received additional comments on our proposals. In general, these pertained to either our proposed enrollment provisions as a whole, multiple provisions regarding a single topic (such as revocations), or our existing provider enrollment process.

Comment: Several commenters supported our proposals to strengthen provider enrollment requirements and combat fraud. A commenter stated that these protections are especially important for vulnerable home health beneficiaries who may have limited ability to identify and report fraudulent or substandard care. The commenter suggested that CMS also consider whether HHAs should be required to document staff training as part of enrollment and ongoing compliance requirements.

Response: We thank the commenters' for their support. While we also appreciate the commenter's recommendation regarding documentation, we believe it is outside the scope of this final rule.

Comment: Many commenters opposed our enrollment proposals overall. They stated that the provisions could: (1) reduce and discourage provider participation; and (2) limit beneficiary health care access, especially in underserved areas. They recommended that CMS implement operational safeguards to avoid abrupt loss of access to care when a provider is revoked, denied, deactivated, etc. Some stated that CMS should clearly distinguish between fraudulent, intentional, or material noncompliance (as well as material risk) on the one hand, and technical, administrative, inadvertent, or promptly corrected noncompliance on the other—and to limit revocation and denial to the former. (An example commenters cited was failing to timely report changes in enrollment information (such as managing employees), which commenters did not believe should result in revocation.) Other commenters maintained that our proposals, taken together, would make Medicare enrollment substantially less predictable and reliable for providers acting in good faith. They stated that providers make significant investments in their facilities/practices, personnel, compliance, and patient care in the expectation that they will remain Medicare-enrolled absent clear evidence of fraud or intentional misconduct. Additional commenters maintained that the lack of factors, definitions, etc., in some of our new denial and revocation grounds make the latter arbitrary and capricious because they would give CMS unfettered revocation and denial discretion.

Response: We appreciate the concerns expressed. We do not expect provider participation or beneficiary access to be reduced given: (1) the limited number of revocations that traditionally occur; and (2) that previous promulgations of provider enrollment regulations (including those that added new denial and revocation grounds) did not lead to said reductions. Nonetheless, we constantly monitor potential access to care issues and will do with our new enrollment provisions.

As noted earlier, CMS carefully considers each potential denial and revocation situation and often utilizes measures such as deactivations and stays in lieu of revocations. Yet we cannot apply a materiality threshold to revocations or denials because: (1) non-compliance remains non-compliance regardless of the degree thereof; and (2) providers would have little incentive to remain consistently adherent to Medicare enrollment requirements if they knew that CMS only takes action if the non-compliance is material. Indeed, and most respectfully, providers should not assume that their mere avoidance of fraud and intentional misconduct exempts them from remaining compliant with all enrollment requirements.

We do not believe our new revocation and denial grounds would be arbitrary and capricious because, again, CMS will only take action when warranted and as specified in our regulations after a thorough and fair examination of the facts and circumstances of the case.

Comment: Commenters stated that Medicare enrollment enforcement (as well as our proposed enrollment provisions) must be targeted, evidence-based, and accompanied by meaningful procedural protections. Additional commenters stated that CMS should ensure that the consequence is proportionate to the conduct.

Response: We have always ensured that every potential denial or revocation case is meticulously assessed, and we only take action when justified. We do not routinely revoke providers and, as stated, often apply deactivations and stays to avoid the more significant consequences of a revocation and to ensure that the action is proportionate. Too, denied and revoked providers have robust due process rights under 42 CFR part 489, and denial and revocation letters explain the facts and legal basis behind the action.

Comment: Commenters stated that CMS's: (1) proposed denial and revocation reasons should be limited to provider and supplier types for which evidence exists of a program integrity problem; and (2) program integrity efforts should target higher-risk providers rather than burdening lower-risk ones.

Response: Several of our proposed grounds (for example, § 424.530(a)(20) and 424.535(a)(25)) are indeed limited to higher-risk provider and supplier types. The others address provider enrollment issues we have seen that are not limited to a few types of providers. While we appreciate the commenters' feedback, CMS cannot restrict its program integrity activities to higher-risk providers, for provider enrollment non-compliance—as well as fraud, waste, and abuse—can occur with any provider or supplier type.

Comment: Many commenters expressed concern that our enrollment provisions were proposed in the CY 2027 HH PPS proposed rule instead of a stand-alone enrollment rule. They stated that some provider and supplier types do not regularly review home health rules, believing that its provisions would not apply to them. Since many of our proposals apply to all providers and suppliers, they might not have seen important provisions. Hence, the commenters contended, CMS did not give adequate notice of its enrollment proposals, should withdraw them from the HH PPS proposed rule, and re-propose them in separate enrollment rule. Several commenters noted that CMS previously used stand-alone enrollment rulemaking (such as in 2003 and 2016) [54] to propose requirements applicable to all providers and suppliers. Other commenters stated that CMS should have at least proposed its provisions in the CY 2027 Physician

[54] Specifically: (1) ''Medicare Program; Requirements for Establishing and Maintaining Medicare Billing Privileges; Proposed Rule'' (68 FR 22064), published in the **Federal Register** on April 25, 2003; and (2) ''Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process; Proposed Rule'' (81 FR 10720), published in the **Federal Register** on March 1, 2016.

Fee Schedule [55] (91 FR 43842) proposed rule to ensure a wider audience.

Response: We respectfully disagree with the commenters for a number of reasons.

First, the CY 2027 HH PPS proposed rule's title explicitly listed ''Provider Enrollment'' as one of its topics. Thus, the proposed rule was a provider enrollment rule as well and not merely a proposed regarding home health or hospice payment. This ''Provider Enrollment'' reference, moreover, was not prefaced by ''Hospice'' or ''Home Health''. That is, it was broadly ''Provider Enrollment'' and not ''Home Health and Hospice Provider Enrollment'', making clear that the enrollment provisions were not limited to certain provider types.

Second, we proposed significant enrollment provisions applicable to all providers and suppliers in the CY 2022, CY 2024, and CY 2026 HH PPS proposed rules (86 FR 62240, 88 FR 77676, and 90 FR 55342, respectively). These included, for instance: (1) adding roughly 10 new retroactive revocation reasons; (2) expanding the maximum reapplication bar period from 3 years to 10 years; (3) adding in regulation new reasons for which we can return or reject an enrollment application or deactivate a provider's enrollment; (4) reducing the period of non-billing for which we can deactivate a provider from 12 consecutive months to 6 consecutive months; and (5) documentation request requirements. No commenters in those proposed rules indicated concern about a lack of adequate notice or requested that our provisions be removed and reproposed in an enrollment-only rule.

Third, the CY 2027 HH PPS proposed rule was especially appropriate for our provisions given: (1) the need to remedy as quickly as possible the serious program integrity issues the proposals address; and (2) the hospice-specific proposals in the rule.

Fourth, we received approximately 375 separate comment submissions on our proposed revisions, as many as we have ever received on any provider enrollment regulation, either as part of a payment rule or an enrollment-exclusive rule. This alone evidences that proper notice was given.

For these reasons, we respectfully decline to withdraw our enrollment provisions from the CY 2027 HH PPS proposed rule.

Comment: Many commenters stated that: (1) some of the information they believe is required under our proposals might be impossible to obtain or confirm; and (2) CMS should not deny or revoke enrollment based on information or conduct involving third parties (including independent contractors) that the provider could not reasonably have known or controlled.

Response: As explained previously: (1) we do not anticipate requesting affiliation data; (2) managing employees must be reported, and there has never been a ''due diligence'' standard for this requirement; and (3) for denial or revocation reasons based on the conduct of an owner, managing employee, managing organization, etc., we respectfully cannot base our decision on whether the provider knew of or could have controlled said conduct.

Comment: Commenters sought clarification on the following issues: (1) the effective date of any finalized enrollment provisions; (2) how CMS plans to implement its provisions and collect the required data; (3) whether CMS, PECOS, and the MACs will be able to accommodate and have the capacity to carry out these changes; and (4) whether our finalized enrollment provisions affect Programs of All-Inclusive Care for the Elderly providers (PACE).

Response: Our finalized enrollment provisions are effective on January 1, 2027, and we will be able to timely implement them. In addition, and except for our preclusion list revision, our changes do not apply to PACE providers that are not otherwise enrolled in Medicare.

Comment: A few commenters stated that enrollment actions against individual providers can affect an entire coordinated-care network, including physician-led Accountable Care Organizations (ACOs). They recommended that CMS establish a transition process that: (1) allows care to continue while an appeal is pending; (2) gives an ACO (or other health network) reasonable time to arrange alternative capacity; (3) avoids penalizing the network for disruptions outside its control; and (4) provides appropriate notice when an enrollment determination becomes final and disclosure is legally permissible.

Response: While we appreciate these comments, we are respectfully unclear as to: (1) the transition process, alternative capacity arrangements, penalties, and network disruptions the commenters are referencing; and (2) whether the stakeholders' comments pertain strictly to our proposals or to our larger provider enrollment process. If the commenters are requesting, in effect, a postponement in revocation enforcement until appeal rights are exhausted, we refer the commenters to our earlier statements regarding our inability to do so. We can reiterate, though, that: (1) CMS takes revocation action only when truly warranted and, for this reason, we do not expect our proposals to materially affect ACOs or other provider networks; and (2) providers are notified of any revocation or denial action.

Comment: Commenters stated that our proposed revocation reasons are overreaching. They maintained that CMS' program integrity efforts—both proposed and current—should instead be directed towards demonstrably fraudulent parties, high-risk providers, and intentional misconduct, not good-faith and historically compliant providers. Several commenters stated CMS should establish a risk-based system that rewards legitimate, compliant providers with fewer administrative requirements. Another commenter stated that Complex Rehab Technology suppliers should be exempt from our proposed denial and revocation reasons.

Response: We respectfully disagree with these comments. Rather than being overreaching, our proposed revocation reasons are principally targeted towards specific scenarios we have seen and are not intended to be widely utilized. Too, we again note the matter of non-compliance with enrollment requirements. Merely because a provider is not, for example, (1) screened at the ''high'' level under § 424.518, (2) in a traditionally high-risk geographic area, or (3) engaged in intentional misconduct does not mean we should ignore any non-compliance on that provider's part. We must ensure that all providers are compliant irrespective of their relative risk level or provider or supplier type.

Comment: A commenter stated that CMS should not finalize any of its expanded denial and revocation reasons until it publishes data regarding Administrative Law Judge (ALJ) reversal rates for enrollment denials and revocations—in particular, §§ 424.535(a)(1) and 424.535(a)(8)(ii) revocations. The commenter maintained, in essence, that denial and revocation reasons should not be added or broadened until CMS can ensure correct denial and revocation decisions as evidenced by low reversal rates for current grounds.

Response: We respectfully disagree. CMS must take quick action to address

[55] ''Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program'', published in the **Federal Register** on July 16, 2026.

program integrity vulnerabilities as they arise, without waiting for a particular ALJ affirmance threshold to be met. We can neither base our payment safeguard efforts on the latter nor avoid imposing a necessary denial or revocation solely because it might be overturned on appeal.

Comment: Commenters stated that providers should have the right to cure any deficiency (other than fraud or intentional misconduct) before a denial or revocation occurs.

Response: We respectfully direct the commenters to our previous statements regarding pre-denial and pre-revocation appeals processes.

Comment: A commenter stated that CMS should update MAC contracts to include defined timelines for review and approval or denial of Form CMS–855A changes.

Response: MACs are required to adhere to the application processing timeframes in CMS Publication 100–08, Chapter 10.

Comment: A commenter stated that CMS should use focused oversight—instead of new across-the-board requirements—to address the program integrity problems in Los Angeles County and elsewhere. The commenter suggested, for instance, revalidation of providers in the risk area, pre-claim review, and examining extreme utilization patterns and patient recertification rates.

Response: We sincerely appreciate these recommendations and note that CMS has indeed taken targeted steps to address Los Angeles County-type situations. However, program integrity is a national issue and, as earlier mentioned, we must be proactive in addressing enrollment non-compliance and potential payment safeguard risks—irrespective of the particular geographic location or the provider or supplier type involved. We cannot wait until misconduct occurs in a certain location before taking action.

Comment: Commenters expressed concern that a provider error on an enrollment application or in enrollment data reporting could keep them out of business for 10 years. They stated that revocation should not be used in response to minor provider errors. Other commenters added that CMS should use a more targeted, data analytics-driven approach to revocations rather than adopting a broader approach that—the commenter believed—can penalize providers for small errors. Other commenters suggested that CMS—in lieu of adding or expanding denial or revocation grounds—use other, more focused program integrity measures, such as (but not limited to) increased claims monitoring, Medicare Strike Force operations, civil money penalties, the False Claims Act, etc.

Response: We reaffirm that providers are not revoked or denied as a matter of practice but only when genuinely justified under the case's facts and circumstances and based on the applicable data; we consider this to be a ''targeted'' approach. Further, and to reiterate, CMS frequently applies deactivations and stays instead of revocations given our acknowledgement of the significance of a revocation.

CMS addresses payment safeguard threats via numerous vehicles. Yet this does not mean that CMS must forgo all others. Program integrity requires a comprehensive approach, and the provider enrollment process—including establishing new denial and revocation grounds directed at specific vulnerabilities—is a critical component thereof.

Comment: A few commenters requested that CMS explain to certified provider AOs the effects of retroactive revocations.

Response: Given that certain retroactive revocation grounds have existed for some time, we respectfully do not believe such guidance is necessary.

Comment: Several commenters stated that CMS should define the due diligence expected of providers in ascertaining an owner's or manager's criminal or adverse legal history.

Response: Sections 424.500 through 424.575 do not require providers to perform this activity.

Comment: A commenter stated that CMS should use super intelligence-assisted pre-payment claims analytics containing four minimum safeguards: (1) documented training data and known model limitations disclosed to plan sponsors and affected providers on request; (2) human review for every denial recommended previously a defined confidence threshold; (3) quarterly bias and drift monitoring with a public dashboard; and (4) evidentiary appeal rights for providers contesting model outputs. Other commenters suggested that CMS utilize real-time super intelligence fraud detection mechanisms in its enrollment activities, such as in detecting billing patterns.

Response: We appreciate these suggestions but believe they are outside the scope of this final rule.

Comment: A commenter stated that CMS should: (1) return to the 3-year DMEPOS reaccreditation cycle; and (2) implement section 427 of the Benefits Improvement and Protection Act of 2000.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: Several commenters maintained that good-faith providers should not be revoked if the matter was based on conflicting or unclear CMS or MAC guidance.

Response: We are respectfully uncertain as to which individual revocation grounds the commenters are referencing. While providers must abide by all CMS enrollment requirements at all times and it is ultimately the provider's responsibility to ensure it understands and follows CMS guidance, we again state that CMS carefully reviews the facts and circumstances of each potential revocation case.

Comment: A commenter requested clarity as to which enrollment provisions are applicable to which provider and supplier types.

Response: As we explained in the proposed rule and section V.C. of this final rule, the provisions apply to all provider and supplier types except as explicitly noted otherwise (for example, § 424.530(a)(20) applies to hospices, the DMEPOS accreditation provisions apply to DMEPOS suppliers, etc.)

Comment: A commenter stated that the proposed rule did not demonstrate significant fraud-risk associated with ambulatory surgical centers.

Response: We appreciate this comment but remind stakeholders that fraud, waste, and abuse can happen within every provider and supplier type. Indeed, even if a particular provider type might traditionally pose less payment safeguard risk than certain others, this does not mean it should be exempt from the same requirements that all providers must adhere to. Regardless of the provider type involved, CMS must halt fraud, waste, and abuse before it begins, not afterwards—and exempting certain providers from important program protections hampers such efforts.

Comment: A commenter supported our efforts to prevent fraudulent providers from circumventing their reenrollment bar and reenrolling in Medicare. This and another commenter requested that CMS define the situations under which a provider has the same ''identity'' to avoid unintended consequences of wrongly denied reenrollments.

Response: We appreciate the commenter's support. However, we believe the commenter's request is outside the scope of this final rule because we did not propose any changes to the ''different identity'' denial and revocation provisions in §§ 424.530(a)(12) and 424.535(a)(18).

Comment: A commenter requested CMS confirmation that co-location does not equate to an affiliation.

Response: We appreciate this comment but are unable to confirm or not confirm this matter without knowledge of the particular facts of the case.

Comment: Some commenters expressed concern about retroactive revocations based on a failure to timely report changes in enrollment. They stated that operational challenges beyond a good-faith provider's control could result in revocation. They requested that: (1) allow multiple concurrent change request submissions in PECOS: (2) enable providers to request an extension when a pending application prevents timely submission of additional updates, and (3) implement automated notifications for expiring licenses, insurance, accreditation, and other enrollment-related information.

Response: We stress again that CMS in every revocation and denial case carefully reviews the facts and circumstances and only takes action when warranted. However, we believe the commenters' three requests are outside the scope of this final rule.

Comment: Several commenters stated that with respect to institutional providers (such as hospitals), a CMS finding regarding geography, an affiliate, or an application filed for a different location does not meet the criteria of section 1866(b)(2) of the Act.

Response: As previously discussed, section 1866(b)(2) of Act is inapplicable to provider enrollment, which is governed by different statutory and regulatory provisions.

Comment: A commenter recommended that CMS: (1) issue guidance on pre-payment control frameworks that reduce the window between fraudulent billing and detection; (2) encourage providers to maintain documented pre-payment verification controls covering beneficiary eligibility confirmation, physician order authentication, and visit documentation validation; and (3) require that newly acquired HHAs maintain enhanced pre-payment review protocols during a defined transition period following ownership changes.

Response: We appreciate these suggestions but believe they are outside the scope of this final rule.

Comment: Given the impact of retroactive revocations, a commenter recommended that CMS: (1) provide written notice and a reasonable opportunity to cure certain application fee deficiencies before revocation; (2) clarify how providers may document timely application fee payment attempts; (3) evaluate the totality of the circumstances in § 424.535(a)(18) cases and require evidence of the provider's intent to circumvent an existing re-enrollment bar; and (4) for § 424.535(a)(20) cases, review the circumstances in their totality and be transparent as to how non-compliance is examined.

Response: We refer the commenter to our prior statements concerning cure opportunities. We believe the second, third, and fourth recommendations are outside the scope of this final rule since they involve revocation reasons and other matters we did not address or propose to revise.

Comment: Several commenters requested that CMS: (1) exempt fixed-site institutional providers (including hospitals), health complexes, provider-based departments, and on-campus locations from the purviews of §§ 424.530(a)(20) and 424.535(a)(24); and (2) exclude from § 424.530(a)(20) all co-location arrangements that predate the other provider's adverse action. Another commenter stated that facility-based, brick-and-mortar providers should be exempt from § 424.535(a)(24).

Response: While we thank the commenter for these requests, CMS does not—and, considering the wide variety of factual scenarios that occur, cannot—automatically exempt certain providers, locations, and arrangements from §§ 424.530(a)(20) and 424.535(a)(24). However, we again seek to assure providers that CMS recognizes all the concerns they have expressed regarding our enrollment provisions and will fully and thoroughly consider the circumstances of the case before denying or revoking enrollment.

Comment: Several commenters stated that CMS: (1) already has mechanisms for identifying and addressing fraud, waste and abuse; and (2) did not explain in the proposed rule the deficiencies in these existing authorities that prevent CMS from addressing fraudulent providers and suppliers. Existing program integrity mechanisms the commenters cited included (but were not limited to) risk-based screening, collaboration with the HHS–OIG and Department of Justice, and data analytics.

Response: In both the proposed rule and this final rule, we carefully explained the need and justification for each of our proposals—all of which are intended to eliminate program integrity gaps that cannot be addressed via current means.

Comment: Some commenters expressed concern that our proposals would discourage clinical and administrative staff from accepting employment with various providers out of fear that they or the provider may be revoked.

Response: We respectfully do not believe this will take place. We have previously added parties to the scopes of various denial and revocation grounds and are unaware of the scenario the commenter describes having occurred.

Comment: Several commenters stated that our proposed changes will flood CMS, the MACs, and the States with additional paperwork and enrollment transactions; they were especially concerned that this could increase MAC backlogs.

Response: We respectfully disagree, primarily because—as stated—clinical managing employees must currently be disclosed, and we do not anticipate requesting the submission of affiliation data under § 424.519.

Comment: Commenters stated that several of our proposals at least partly duplicate other, non-enrollment provisions to which providers must adhere. These include, for example, State survey requirements, accreditation standards, and State licensure. They maintained that CMS: (1) should avoid subjecting providers to duplicative requirements; (2) should not establish new enrollment requirements without assessing whether program integrity can be facilitated via other existing regulatory provisions; and (3) should consider these other requirements to which providers must adhere in determining whether to deny or revoke enrollment. Another commenter stated that CMS should treat DMEPOS supplier accreditation as a clear indicator of the supplier's legitimacy and compliance.

Response: We respectfully do not believe: (1) there is duplication between our main proposals and other, non-enrollment requirements; and (2) the issues that our proposals seek to address can be remedied via current authorities. Hence, our proposals are needed. We add that, as already noted, provider enrollment has its own, distinct set of requirements, and providers and suppliers—including DMEPOS suppliers—can still fail to meet said requirements or can otherwise pose risks even if they are State licensed, accredited, compliant with CoPs, etc.

Comment: A commenter suggested that CMS establish a CMS-compatible provider compliance data model that can, among other things: (1) technologically maintain a continuously updated provider compliance record; (2) enable automated monitoring; (3) alert an organization of upcoming deadlines,

requirements, or possible compliance issues (for example, a license is approaching expiration); and (4) provide digital evidence of compliance.

Response: We appreciate this recommendation but believe it is outside the scope of this final rule.

Comment: Several commenters stated that CMS should address the potential Medicaid consequences of these new authorities. They noted that § 455.416(c) requires States to deny or terminate the Medicaid enrollment of any provider revoked under Medicare and is currently included in the termination database under § 455.417. A commenter recommended that CMS clarify whether (and under what circumstances) our proposed revocation grounds would be considered ''for cause'' and thus require a Medicaid termination under § 455.416. Another commenter appeared to contend that § 455.416(c) raises due process concerns because the State must terminate enrollment without any independent State review of the case's underlying facts. An additional commenter requested that CMS clarify in the final rule that § 455.416(c) only applies to Medicare revocations based on fraud, gross clinical misconduct, or severe program abuse—not technical, geographic, or affiliate-based administrative revocations. Another commenter stated that CMS should: (1) issue guidance to State Medicaid agencies on how to handle Medicare revocations under our proposed provisions; and (2) recommend that States stay any corresponding Medicaid termination pending exhaustion of the provider's Medicare administrative appeal.

Response: We appreciate the commenters' feedback. CMS did not propose to interpret ''for cause'' or to clarify the scope or applicability of § 455.416(c). Therefore, we respectfully believe these comments are outside the scope of this final rule. We further do not foresee our proposals having a material overall effect on providers' Medicaid enrollments because we anticipate that only a limited number of them will be revoked thereunder.

While we will issue guidance to the States if deemed necessary, we do not have the authority to direct States to impose the stay the commenter recommends.

Comment: A commenter stated that CMS should collect and publish data on the use of our new authorities, including the number of actions taken, cited grounds, reversal rates, and any identified access concerns.

Response: CMS lists all currently revoked providers (as well as the revocation basis) at *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/revoked-medicare-providers-and-suppliers.* Revocations under our new authorities will be included. Although CMS does not publish enrollment-related appeals or beneficiary access data, we will, as previously mentioned, monitor the latter for potential issues, though we do not expect any to arise.

Comment: Commenters expressed concern that our proposed ''managing employee'' definition combined with several proposed expansions of existing denial and revocation reasons to include managing employees will increase the number of revocations.

Response: CMS cannot confirm whether this will or will not be so. We can merely repeat what we have stated throughout this final rule that we will carefully evaluate each potential revocation and denial case.

Comment: A commenter stated that providers: (1) are prohibited from employing or contracting with individuals who are OIG-excluded or SAM-debarred; and (2) agree to abide by all Medicare laws upon signing the Form CMS–855 application. While it was somewhat vague, it appears the commenter contended that this sufficiently guarantees that the provider does not have or associate with problematic parties and, if it does, CMS can revoke the provider. Consequently, there is no need for CMS' proposals that pertain to the conduct of the provider's owners, managing employees, etc.

Response: We respectfully disagree for two reasons. First, non-excluded and non-debarred owning, managing, and other parties can still present significant risks to the Medicare program. Second, certain persons and entities other than the provider are required to be reported on the application and carefully screened for said risks (for instance, reviewing a managing employee for felony convictions).

Comment: Commenters stated that denials and revocations based on an owning or managing party's actions should be restricted to situations where said party presents a material risk, and misconduct or program integrity concerns are involved. Another commenter requested that CMS define ''associated party'' as used in proposed revised § 424.530(a)(6) and (a)(7).

Response: We interpreted these comments as essentially requesting that CMS explicitly exempt providers from denial or revocation if: (1) the other party's conduct was not severe; or (2) the provider was not involved in it. Every case involving an owner's, manager's, or associate's activity is different, and CMS must weigh the facts and circumstances of each in determining whether to deny or revoke. We cannot exempt certain situations prior to this analysis. We also, again, emphasize that for these denials and revocations, the associate's behavior is the main consideration, not whether the provider was a party thereto.

As we are not finalizing proposed expanded § 424.530(a)(6) and (a)(7), we believe the commenter's request concerning the ''associated party'' term is moot.

Comment: Several commenters urged that CMS establish various exceptions from (and modifications to) our proposals for small providers.

Response: We respectfully direct the commenters to our prior statements regarding exceptions.

Comment: A commenter recommended that CMS: (1) work with MACs to establish clear and reasonable processing timeframes for provider enrollment and change of ownership requests, with transparent tracking of progress; and (2) require MACs to implement systems that prevent duplicate document requests and ensure that information already submitted is appropriately retained and applied to the pending file.

Response: We appreciate these suggestions but believe they are outside the scope of this final rule.

Comment: Several commenters stated that CMS should meet with stakeholders to develop provisions that promote program integrity without negatively impacting good-faith providers.

Response: CMS regularly communicates with provider organizations on enrollment matters, and we receive valuable suggestions. For reasons already mentioned, though, our proposals are very much needed to address material program integrity vulnerabilities.

Comment: A commenter stated that using data analytics would help CMS detect fraud in real-time and take prompt action instead of only being able to spot fraud months or years later. The commenter also suggested: (1) having beneficiaries more involved in detecting fraud; and (2) that CMS convene a task force to collaborate on modernizing home health technology infrastructure and on fraud, waste, and abuse measures. Another commenter recommended program integrity enhancements such as: (1) transmitting certain provider enrollment information (such as enrollment status) on crossover claims; (2) targeting pre-payment beneficiary confirmation for high-risk DMEPOS claims to verify medical need and receipt before payment is issued; (3) enhanced identity verification and

provider background checks; (4) real-time data sharing and analytics between CMS, MA plans, and supplemental insurers; (5) periodic risk-based revalidation; and (6) expansion of the preclusion list.

Response: While we believe these comments are outside the scope of this final rule, we sincerely appreciate the commenters' recommendations.

Comment: A commenter stated that with respect to SNFs, CMS should: (1) distinguish managerial control from clinical, professional, consulting, or advisory responsibilities; (2) provide examples of both reportable and non-reportable positions and arrangements; (3) clarify the relationship between managing employee and ADP disclosures; and (4) reconcile and update its SNF guidance and Form CMS–855A instructions (including explaining the: (i) difference between a managing employee and a clinical consultant ADP under section 1124(c) of the Act; and (ii) when and how each should be reported). Concerning this fourth request, the commenter stated that the SNF guidance advises SNFs to construe disclosure requirements broadly and to disclose when uncertain, while the proposed rule emphasizes that not every clinical employee is reportable. The commenter believed that CMS should reconcile these approaches so that SNFs do not unnecessarily over-report clinical staff.

Response: As we have indicated, the reporting of managing employees under § 424.502 and of parties (such as ADPs) under section 1124(c) of the Act are separate requirements with separate definitions and principles. The two are unrelated, and each must be met. This has been the case since the commencement of the SNF disclosure requirements in late 2024, and our proposed clarification in ''managing employee'' definition does not change this. Hence, we are uncertain as to the precise guidance or reconciliation the commenter seeks.

Comment: A commenter suggested that CMS establish an ''enrollment-only'' organizational supplier status whereby a supplier can enroll without obtaining Medicare billing privileges. The commenter stated that because other federal health care programs may require Medicare enrollment to participate, allowing suppliers to enroll via an abbreviated process could reduce provider and administrative burden while still permitting CMS to carefully screen the provider during the enrollment process.

Response: We thank the commenter for this recommendation but believe it is outside the scope of this final rule.

Comment: Commenters maintained that our proposals would force providers out of Medicare, which in turn could lead to lost employment for physicians, practitioners, administrative staff, etc.

Response: We respectfully disagree. Past provider enrollment rulemaking efforts have not resulted in material numbers of providers or provider staff departing the Medicare program, and we believe this will hold true following this final rule, too.

Comment: A commenter stated that to the extent CMS uses predictive models, risk scoring, or other automated analytics to identify high-risk enrollments or to support denial or revocation determinations, CMS should take several steps including (but not limited to): (1) ensuring transparency about the data and factors it used; (2) ensuring that the case is reviewed by a qualified human reviewer before any adverse determination; and (3) periodically auditing the model for accuracy and for disparate impact on small, rural, and safety-net participants. The commenter believed that revocation decisions should rest with CMS and not with a model; the commenter added that no provider should be revoked based on a score it can neither see nor challenge.

Response: While we cannot address the detailed operational aspects of our revocation and denial evaluations, we note that our decisions are made by individuals reviewing the case and not by predictive models or automated analytics.

Comment: A commenter requested clarification on six enrollment-related topics. The first is whether a nurse practitioner or physician assistant furnishing palliative care services under the home health benefit must: (i) be Medicare-enrolled; and (ii) reassign the right to bill Medicare to the HHA or another billing entity. The second is whether such services are considered included within the home health prospective payment system payment, separately billable professional services, or both depending on the service furnished and the billing practitioner. The third seeks guidance on enrollment form requirements, reassignment mechanics, practitioner affiliation with the agency, and the compliance implications when the agency contracts with an external palliative care practitioner or group. The fourth is whether HHAs are responsible for verifying PECOS enrollment for each nurse practitioner, physician assistant, physician, or other allowed practitioner involved in palliative care services. The fifth involves when verification in the prior sentence must occur, how often it must be repeated, what documentation must be retained, and whether claims will be denied if the palliative care practitioner is not properly enrolled, eligible to order and certify, or linked to the billing entity. The sixth seeks operational guidance and edits that HHAs can use prospectively to reduce preventable claim rejections and post-payment denials.

Response: We appreciate these comments but believe they are outside the scope of this final rule.

Comment: Several commenters stated that certain system issues with PECOS should be promptly resolved to help providers comply with CMS' new enrollments requirements.

Response: CMS will ensure that PECOS can effectively accommodate our finalized enrollment provisions.

Comment: A commenter stated that CMS in its provider enrollment activities should consider the approach reflected in the proposed Medicare Home Health Payment Integrity and Protection Act of 2026 (S. 5250), introduced by Senator Susan M. Collins on August 5, 2026.[56]

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter requested that CMS: (1) confirm that deactivation—not revocation—will be utilized in cases of infrequent billing and that CMS will notify the provider thereof; and (2) allow Bill for Denial claims to be considered active participation.

Response: We appreciate these requests but believe they are outside the scope of this final rule.

Comment: Several commenters stated that CMS should always consider potential access to care impact in its denial and revocation determinations, especially for rural and underserved areas. Others expressed broader concerns that our proposals will harm patient access.

Response: As previously stated, CMS considers the facts and circumstances in each denial and revocation case and consistently remains alert for any potential beneficiary access issues. Yet we are unaware of any material access to care problems arising from any of our prior enrollment rulemaking efforts, and we do not expect any to emerge from the present one.

Comment: Some commenters stated that a provider enrollment moratorium under § 424.570 impacts both fraudulent and legitimate providers and suppliers and is overly broad. These commenters

[56] *https://www.congress.gov/bill/119th-congress/senate-bill/5250/text.*

requested that CMS use a more targeted approach for combatting fraud and abuse—such as focusing on fraudulent actors—to minimize disruption to Medicare patients and bona fide providers.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter stated that CMS should deem a provider's documented attempt to report a change as timely compliance when PECOS limitations, contractor instructions, or a pending application prevent formal submission.

Response: As we have indicated regarding other commenters' requests for preliminary determinations, exemptions, etc., we are unable to pre-judge cases in this final rule. Every situation must be reviewed upon its unique facts and details.

Comment: A commenter stated that administrative or regulatory enrollment disruptions resulting from interactions among Federal healthcare programs, State healthcare programs, accreditation requirements, or payer credentialing systems should not be considered a ''termination'' or ''suspension'' for purposes of imposing derivative enrollment consequences on owners, managing employees, or managing organizations.

Response: We are respectfully uncertain as to the specific issue being raised. Our best interpretation is that the commenter believed § 424.530(a)(14)(i) should not apply to a provider if the owning or managing party's program or licensure termination or suspension involved any of the disruptions the commenter mentioned. Assuming this was the commenter's contention, we disagree. Again, we cannot exempt certain providers or owning or managing party actions from denial or revocation consideration before we thoroughly review the facts and circumstances involved.

Comment: A commenter urged CMS to enhance its and the MACs' resources to: (1) answer providers' enrollment questions; (2) process changes in enrollment data; and (3) respond to enrollment-related appeals.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: Several commenters stated that CMS should permit expedited review when: (1) a provider presents credible evidence that CMS has made a factual or legal error; (2) the revocation would materially disrupt beneficiary access; and (3) a small or rural provider is involved (with said appeals containing a binding decision deadline for an ALJ decision).

Response: If, as it appeared to us, the commenters are requesting expedited provider enrollment appeals in these two situations, we respectfully repeat our earlier statement that 42 CFR part 498 does not provide for such expedited appeals—or, for that matter, special appeal rights and decision deadlines for certain provider types.

Comment: A commenter stated that although section 1866(j) of the Act directs the Secretary to establish a process for enrolling providers and suppliers, it does not establish the grounds on which a provider may be revoked. Congress, the commenter contended, addressed that question in section 1866(a)(1) of the Act, which states that a provider with a provider agreement that meets certain criteria ''shall be qualified to participate [in Medicare] and shall be eligible for payments.'' Meanwhile, section 1866(b)(2) of the Act states that the Secretary may terminate or refuse to renew a provider agreement based on: (1) noncompliance with the provider agreement or applicable law; (2) failure to substantially meet the applicable provisions of section 1861; (3) an OIG exclusion; or (4) a felony conviction. The commenter maintained that because: (1) Congress only listed these four termination grounds in section 1866 of the Act; and (2) a provider enrollment termination has the same effect as an enrollment revocation, it follows—under the doctrine of *expressio unius*—that Congress only intended for enrollment to be revoked in one of the four section 1866(b)(2) of the Act situations. Accordingly, CMS cannot rely upon section 1866(j)—or, for that matter, sections 1102 and 1871 of the Act, because general rulemaking authority cannot be used to expand a statute—for a number of its proposed revocation grounds, such as § 424.535(a)(16) and (a)(24).

Response: We direct the commenter to our earlier responses that section 1866(b)(2) of the Act does not apply to provider enrollment.

Comment: A commenter stated that CMS should: (1) clarify how the proposed affiliation, ownership, associated-party, and management authorities will apply to value-based care and care coordination arrangements; (2) provide examples of arrangements that would not create enrollment risk; and (3) establish safe harbors or other protections for good-faith providers seeking to implement innovative care delivery models.

Response: We appreciate these comments. Our requirements would apply to value-based care and care coordination arrangements to the same extent as all other provider types and arrangements. Also, and consistent with our prior statements, we can neither pre-determine cases (such as whether a transaction presents risk) nor establish regulatory exceptions for certain provider types or health care models.

Comment: Commenters stated that CMS should delay (possibly in staged phases, with several commenters suggesting a 1-year postponement for all provisions) implementation of any finalized enrollment provisions to give stakeholders time to prepare. The commenters added that prior to implementation, CMS should: (1) issue detailed, explanatory public guidance to providers and the MACs; and (2) train provider staff on the new provisions. Another commenter stated that CMS should continue to solicit provider input on our provisions.

Response: We respectfully are unable to postpone implementation of our provisions in light of the need to take prompt action to address the program integrity vulnerabilities outlined in the rule. Although CMS will issue guidance to the MACs and, to the extent necessary, stakeholders, CMS does not train provider staff regarding enrollment requirements.

CMS welcomes additional stakeholder feedback regarding our new provisions.

Comment: Several commenters stated that our proposed enrollment provisions (including reporting requirements) would increase provider costs without improving patient care or program integrity.

Response: We respectfully disagree. We previously indicated why our affiliation and managing employee provisions would not add costs, and we believe that program integrity and patient care will be improved by the denial and removal of problematic providers from Medicare.

Comment: A commenter stated that the **Federal Register** notice for the proposed rule encouraged electronic comments, but the stated address ends in the placeholder docket identifier CMS–2026–XXXX, rather than a valid docket destination. The Administrative Procedure Act, the commenter maintained, requires a **Federal Register** notice that identifies the rulemaking proceeding and then requires the agency to give interested persons an opportunity to participate through written submissions. The commenter concluded that a notice that affirmatively directs stakeholders to an unusable electronic destination—while also encouraging that route—does not facilitate meaningful participation.

Response: We disagree. Ample notice of the rulemaking notice was given and providers had multiple ways to submit comments. The fact that we received roughly 375 comments on our enrollment provisions—including, we note, the provider's comments—indicates that meaningful participation was offered.

Comment: With respect § 424.547, a commenter stated that because deactivation of a certifying or ordering provider blocks HHA/hospice billing on affected claims, CMS must maintain accurate, up-to-date enrollment databases and ensure an efficient reactivation process, particularly for hospice physicians covering on-call or absences.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: Commenters were concerned about our proposals' possible impact on small, rural, and non-profit entities. They believed these providers may lack the resources to adhere to our provisions, meaning they may depart the Medicare program. They requested exemptions from certain provisions (or other modifications or special considerations) for such entities.

Response: While we appreciate the commenters' concerns, the concept of program integrity applies to all providers and suppliers—whether small, large, rural, etc. All enrolled parties must adhere to Medicare enrollment requirements, and we believe that granting exceptions based on size or location would be inconsistent with our obligation to ensure such compliance.

Comment: A commenter stated that in *FCC* v. *Fox Television Stations* (567 U.S. 239 (2012)), the Supreme Court held that: (1) due process requires agencies to give regulated entities fair notice of the conduct that is prohibited or required; and (2) a rule is constitutionally deficient when an ordinary person cannot tell what facts must be established. Since CMS declined to articulate various standards and terms, providers cannot ascertain what is required to remain compliant. The commenter stated that CMS, in effect, has not given providers fair notice. The commenter cited an example of a provider researching its owners, managers, and affiliates for adverse actions, finding none, and believing it is in compliance—but CMS nonetheless revokes the provider based on information it internally has and the provider does not. The commenter stated that a provider should not face consequences merely because CMS determines—based on nonpublic, inaccessible, delayed, or undefined information—that a relationship created an unarticulated risk.

Response: We respectfully disagree with the commenter because each of our denial and revocation grounds in §§ 424.530 and 424.535 identifies the basis for the action and the conduct or activity involved.

Comment: A commenter stated that CMS should resolve conflicting findings between State survey agencies and MACs before taking an adverse enrollment action.

Response: We again note that provider enrollment requirements are separate from the CoPs. Sections 424.500 through 424.575 are—and have always been—enforced outside of the State survey process, and the former requirements are neither dependent upon nor impacted by the latter.

Comment: A commenter questioned whether additional reviews under our proposals will increase processing times for enrollment applications and, if so, how CMS will minimize them.

Response: Based on our experience with past rulemaking efforts, we do not anticipate the present final rule causing processing delays. That said, and as always, we will monitor processing times and strive to ensure consistency across the MACs' enrollment processes.

Comment: A number of commenters stated that CMS should not impose denials and revocations under our new provisions without clear definitions, objective standards, and adequate provider education.

Response: We respectfully direct the commenters to our earlier discussions and responses regarding definitions, standards, and stakeholder guidance.

D. DME Benefit Expansion for Infusion Pumps and Drugs

1. Background

a. Home Infusion Therapy Benefit

In section 5012 of the 21st Century Cures Act (Pub. L. 114–255), Congress amended section 1861(s)(2) of the Act and added sections 1834(u) and 1861(iii) of the Act to establish a new Medicare home infusion therapy benefit effective January 1, 2021. This benefit covers certain professional services associated with the provision of home infusion therapy to a beneficiary who is under the care of a physician, nurse practitioner, or physician assistant. Home infusion therapy involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home through an external infusion pump. As indicated in a final rule we published in the **Federal Register** on November 8, 2019, titled ''Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements,'' the external infusion pump and other supplies, including home infusion drugs necessary for the effective use of the pump, are covered under the Part B DME benefit rather than the home infusion therapy benefit (84 FR 60612). Pursuant to section 1861(iii) of the Act, we published a final rule in the **Federal Register** on November 13, 2018, titled ''Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations'' (83 FR 56406) to define the scope of ''home infusion therapy,'' ''home,'' ''qualified home infusion therapy supplier,'' and ''home infusion drug'' at 42 CFR 486 Subpart I.

Section 486.525(a) implements the definition of ''home infusion therapy'' set forth at section 1861(iii)(1) of the Act, defining the term to include professional services, including nursing services, furnished in accordance with the plan of care described under 42 CFR 486.520, patient training and education (not otherwise paid for as DME), remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs furnished by a qualified home infusion therapy supplier in the individual's home. Section 486.505 implements the definition of ''home'' set forth at section 1861(iii)(3)(B) of the Act, defining the term as a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, critical access hospital (CAH), or skilled nursing facility (SNF) as defined in section 1861(e)(1), 1861(mm)(1), or 1819(a)(1) of the Act, respectively.

Section 486.505 implements the definition of ''qualified home infusion therapy supplier'' set forth at section 1861(iii)(3)(D)(i) of the Act, defining the term to mean a supplier of home infusion therapy that meets all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act: (1) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; (2) ensures the

safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; (3) is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act; and (4) meets such other requirements as the Secretary determines appropriate. A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet these requirements.

Section 486.505 implements the definition of ''home infusion drug'' set forth at section 1861(iii)(3)(C) of the Act, currently defining the term as a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME, excluding insulin pump systems and self-administered drugs or biologicals on a self-administered drug exclusion list.

b. Durable Medical Equipment Benefit

Under the Medicare Part B benefit for DME, a limited number of home infusion drugs (as defined under 42 CFR 486.505) are covered if it is determined that it is medically necessary to use an external infusion pump classified as DME for administration of the home infusion drug, and the home infusion drug being used with the pump is, itself, reasonable and necessary for the treatment of an illness or injury (84 FR 60612).

For an external infusion pump and associated supplies to be covered under the Part B DME benefit, the pump must, among other statutory and regulatory requirements, be ''appropriate for use in the home'' (see 42 CFR 414.202). This requirement means that the equipment must be capable of being safely and effectively used by the beneficiary or caregiver in the home without the assistance of a health care professional (84 FR 60628). As noted previously, section 1861(iii)(3)(C) of the Act limits the home infusion therapy benefit to drugs administered in the patient's home through a pump covered under the DME benefit as defined under section 1861(n) of the Act. Therefore, historically, external infusion pumps and associated home infusion drugs that do not meet the ''appropriate for use in the home'' requirement have not been eligible for coverage under the DME benefit and services associated with administering the home infusion have not been covered under the Part B home infusion therapy benefit.

2. Current Issues

Section 6222(a) of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75) amended section 1861(n) of the Act to expand the scope of the Medicare Part B benefit for DME to include certain external infusion pumps and associated home infusion drugs (as defined in section 1861(iii)(3)(C) of the Act) or other associated supplies that would not otherwise qualify as DME because the use of such an item would not meet the ''appropriate for use in the home'' requirement applied to the DME definition at 42 CFR 414.202. As stated in section V.D.1. of this final rule, CMS has historically interpreted the requirement that DMEPOS must be ''appropriate for use in the home'' to mean that the equipment must be capable of being safely and effectively used by the beneficiary or caregiver in the home without the assistance of a health care professional.

Effective for items furnished on or after April 1, 2027, section 6222(a) of the CAA, 2026, states an external infusion pump and associated home infusion drug (as defined in section 1861 (iii)(3)(C) of the Act) or other associated supplies that do not meet the ''appropriate for use in the home'' requirement applied to the definition of DME under 42 CFR 414.202 (or any successor to such regulation) must be treated as meeting such requirement if each of the following criteria is satisfied:

- The prescribing information approved by the FDA for the home infusion drug associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional;
- A qualified home infusion therapy supplier, as defined in section 1861(iii)(3)(D) of the Act, administers or supervises the administration of the drug or biological in a safe and effective manner in the patient's home, as defined in section 1861(iii)(3)(B) of the Act; and
- The FDA-approved prescribing information instructs that the home infusion drug be infused at least 12 times per year:

++ Intravenously or subcutaneously; or

++ At infusion rates that the Secretary determines would require the use of an external infusion pump.

Section 6222(a) of the CAA, 2026 does not define the term ''health care professional.'' In the proposed rule titled ''Calendar Year 2027 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the Expanded HH Value-Based Purchasing Model; Medicare Provider Enrollment, Durable Medical Equipment (DME), and DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Policies,'' which we published in the **Federal Register** on July 6, 2026, we proposed that the term ''health care professional'' would refer to any of the following clinicians, provided that such clinician is permitted to administer or supervise the administration of a home infusion drug in accordance with Federal and State law: physician (as defined in section 1861(r) of the Act); a clinical nurse specialist, nurse practitioner, or a physician assistant (as such terms are defined in section 1861(aa)(5) of the Act and regulations at 42 CFR 410.74 through 410.76); or a registered nurse otherwise licensed to practice nursing in the State in which the home infusion drug is administered (91 FR 41305). To ensure consistency across the Medicare program, we proposed to define physician, clinical nurse specialist, nurse practitioner, and physician assistant as such terms are defined under the Medicare home health benefit. Given that sections 1861(r) and (aa)(5) of the Act (as codified at 42 CFR 410.74 through 410.76) do not define ''registered nurse,'' we proposed to define ''registered nurse'' as a clinician licensed to practice nursing in the State in which the home infusion drug is administered (91 FR 41305).

Because of the risks associated with administering certain home infusion drugs in the home under the expanded DME benefit, we proposed limiting the definition of ''health care professional'' to these practitioners (91 FR 41305). We stated that we are aware of at least one drug, patisiran, that presents heightened safety risks and that may meet the new criteria and definition of home infusion drug under the revised definition of DME at section 1861(n) of the Act (91 FR 41305). In accordance with the prescribing information for the drug patisiran, adverse reactions during clinical trials included upper respiratory tract infections as well as infusion-related reaction symptoms including dizziness, headaches, chest pain, and other symptoms. Four serious adverse reactions of atrioventricular (AV) heart block (2.7 percent) occurred in patients treated with patisiran, including three cases of complete AV block. Warnings and precautions regarding infusion-related reactions under the highlights of prescribing information include the need to monitor for signs and symptoms of reactions during infusion, slow or interrupt the

infusion if clinically indicated, and discontinue the infusion if a serious or life-threatening infusion-related reaction occurs. Infusion-related reactions for other home infusion drugs that may be covered under the expansion of the DME benefit could be even more serious and require emergency medical assistance in certain situations. Based on our review, we stated that we believe that such safety concerns may be adequately monitored and mitigated if either a physician, clinical nurse specialist, nurse practitioner, physician assistant, or registered nurse administers or supervises the administration of the home infusion drug (91 FR 41305). We stated that we believe any of these clinicians, if available on hand, could address any emergency medical events that occur during the course of the infusion of the drug (91 FR 41305). We solicited comments on the proposal, including whether there are other clinicians that may be equally qualified to administer or supervise the infusions of the drugs in the home and also address any emergency medical events that occur during the course of the infusion of the drug (91 FR 41305).

We note that we did not propose that the term ''health care professional'' be defined to include a licensed practical nurse (LPN) or licensed vocational nurse (LVN) under the supervision of a registered nurse or physician (91 FR 41305). State law varies in terms of whether an LPN or LVN can perform certain emergency services such as delivering emergency medications. Thus, we stated that it is not clear that addressing the adverse effects associated with the administration of certain home infusion drugs would consistently fall under an LPN's or LVN's scope of practice (91 FR 41305). Additionally, as LPNs and LVNs practice under supervision without the same level of independent clinical authority as the professionals identified previously, we stated that we believe they are less suited to serve as a health care professional for administering complex home infusion drugs under the expanded Medicare DME benefit. In addition, we stated that we do not believe that supervising the administration of the drug in the home should be done remotely as this could violate state laws and compromise the safety of the home infusion therapy as a health care professional would not be present to perform any necessary emergency services (91 FR 41305). In order to be present and able to perform emergency services in the home setting if necessary for the safety and health of the beneficiary, we proposed that the health care professional be on site at the home to administer or directly supervise the administration of a home infusion drug covered under the expanded DME benefit (91 FR 41305). We solicited comments on the proposal (91 FR 41305).

As stated previously, section 6222(a) of the CAA, 2026 expands the DME benefit category to include external infusion pumps and associated home infusion drugs that the prescribing information instructs should be infused at least 12 times per year: (1) intravenously or subcutaneously (section 1861(n)(3)(A) of the Act); or (2) infused at infusion rates that the Secretary determines would require the use of an external infusion pump (section 1861(n)(3)(B) of the Act). Based on our review, we stated that there do not currently appear to be any home infusion drugs that must be infused at rates that would require the use of an external infusion pump that do not otherwise already fall under the criterion set forth under section 1861(n)(3)(A) of the Act (91 FR 41305). Therefore, we did not propose to include additional drugs under the scope of this DME benefit category expansion that do not already meet the criterion set forth under section 1861(n)(3)(A) of the Act (91 FR 41306). The criterion specified in section 1861(n)(3) of the Act is that the drug must be infused at least 12 times per year. Because of the way dosing information is typically framed in the prescribing information, we proposed that to meet this requirement, the drug must be infused at least once per month (91 FR 41306). We stated that we believe such clarification would be appropriate given that it is aligned with how home infusion drugs are typically framed in the prescribing information. Therefore, we proposed that home infusion drugs covered under this expanded DME benefit must be infused at least once a month (91 FR 41306). We solicited comments on the proposal (91 FR 41306).

We note that we did not propose a minimum or maximum number of times a drug must be infused to qualify as a ''home infusion drug'' (91 FR 41306). The duration of treatment is not always clear and is often patient-dependent. Prescribing information for infusion drugs will often call for infusions to continue indefinitely, until toxicity, or until adverse reactions preclude further treatment.

Finally, section 6222(b) of the CAA, 2026 requires the Secretary to ensure that patients are notified of the cost sharing for electing home infusion therapy compared to other applicable settings of care for the furnishing of infusion drugs under the Medicare program. We stated that we plan to implement this provision through subregulatory guidance (91 FR 41306).

3. Provisions of the Regulation

We proposed to revise the definition of DME under 42 CFR 414.202 to incorporate the amendments to section 1861(n) of the Act for implementation of section 6222(a) of the CAA, 2026, effective April 1, 2027 (91 FR 41306). Specifically, we proposed to provide that certain external infusion pumps, associated home infusion drugs, and related supplies will be treated as meeting the ''appropriate for use in the home'' requirement when the following three criteria under paragraphs (1) through (3) of section 1861(n) of the Act are satisfied (91 FR 41306):

- The prescribing information approved by the FDA for the home infusion drug (as defined in § 486.505) associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional. The health care professional must be a clinical nurse specialist (as defined in § 410.76), nurse practitioner (as defined in § 410.75), physician assistant (as defined in § 410.74), physician as defined in section 1861(r) of the Act, or a registered nurse otherwise licensed to practice nursing in the State in which the home infusion drug is administered. The health care professional must be on site at the home to administer or supervise the administration of the home infusion drug.
- A qualified home infusion therapy supplier (as defined in § 486.505) administers or supervises the administration of the home infusion drug in a safe and effective manner in the patient's home (as defined in § 486.505).
- The prescribing information instructs that the home infusion drug be infused at least 12 times per year (at least once a month), either intravenously or subcutaneously, or at infusion rates that the Secretary determines would require the use of an external infusion pump. We solicited comments on the proposal. We received comments on the proposed DME benefit expansion for infusion pumps and drugs from a range of stakeholders, including home infusion and specialty pharmacy organizations, health care providers and health systems, patient advocacy organizations, pharmaceutical manufacturers, DME suppliers, clinician organizations, device and technology stakeholders, and other health care

organizations. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported expanding Medicare coverage for certain external infusion pumps, associated home infusion drugs, and related supplies that would not otherwise meet the ''appropriate for use in the home'' requirement. Commenters stated that the expansion could improve access to home infusion and allow beneficiaries to receive clinically appropriate therapies in the home. Several commenters also expressed concern that the statutory expansion remains limited and may not substantially address the broader difference between home infusion coverage available to Medicare beneficiaries and individuals with commercial insurance.

Response: We thank the commenters for their support for expanding the DME benefit for certain external infusion pumps and associated home infusion drugs and supplies. Section 6222(a) of the CAA, 2026 amended section 1861(n) of the Act to provide that certain external infusion pumps and associated home infusion drugs or other associated supplies that would not otherwise meet the ''appropriate for use in the home'' requirement are treated as meeting that requirement when the statutory criteria are satisfied. We are finalizing the expansion consistent with section 6222(a) of the CAA, 2026 and as proposed. To the extent comments requested expansion beyond the therapies that satisfy the statutory criteria, those requests are beyond the scope of this rulemaking and, where they would require modification of the statutory criteria, would require legislative action.

Comment: The majority of commenters supported the proposed requirement that the health care professional be physically present in the home to administer or supervise administration of the home infusion drug, emphasizing patient safety and the need for clinical support when administering therapies that may result in serious infusion reactions or require emergency intervention. A commenter recommended that CMS permit supervision through real-time audio and video technology when clinically appropriate and consistent with FDA approved prescribing information, rather than requiring physical presence in every circumstance.

Response: We thank the commenters for their comments. We continue to believe that requiring the health care professional to be physically present in the home is appropriate for the therapies covered under this expanded DME benefit. As discussed in the proposed rule, certain drugs that may qualify under this provision may present safety risks that require the health care professional to be available in the home to address an adverse event or provide emergency services. Accordingly, we are finalizing the physical presence requirement as proposed. Administration or supervision for purposes of this provision may not be furnished remotely.

Comment: Several commenters supported CMS's proposal to limit the health care professionals who may administer or supervise the administration of home infusion drugs to physicians, clinical nurse specialists, nurse practitioners, physician assistants, and registered nurses, stating that the designated health care professionals have the appropriate clinical training and authority to administer or supervise home infusion drugs. Some commenters also supported excluding licensed practical nurses and licensed vocational nurses because their scope of practice and authority may vary by State.

Several other commenters recommended that CMS not limit the definition to the specific professional categories identified in the proposed rule. Concerns were raised that a fixed list of professional types could restrict access to home infusion, particularly in rural and underserved areas. These commenters recommended allowing appropriately licensed health care professionals to administer or supervise administration when authorized under applicable State scope of practice and licensure requirements. The commenters also emphasized competency, appropriate training, and authority under State law rather than professional title alone.

A commenter recommended that CMS not categorically exclude pharmacists where State law authorizes them to administer parenteral medications and to recognize the role pharmacists may play in infusion therapy. A commenter also requested that CMS clarify that home infusion drugs are administered by health care professionals, while qualified home infusion therapy suppliers remain the entities authorized to furnish and bill for home infusion therapy services.

Response: We thank the commenters for their comments regarding the definition of health care professional. In the CY 2027 HH PPS proposed rule (91 FR 41305), we proposed, that to be covered under the expanded DME benefit, the prescribing information approved by the FDA for the home infusion drug (as defined in § 486.505) associated with the pump must instruct that the drug should be administered by or under the supervision of one of the following health care professionals: a clinical nurse specialist (as defined in § 410.76), nurse practitioner (as defined § 410.75), physician assistant (as defined in § 410.74), physician as defined in section 1861(r) of the Act, or a registered nurse otherwise licensed to practice nursing in the State in which the home infusion drug is administered because of the risks associated with administering certain home infusion drugs in the home. We excluded LPNs and LVNs from this definition for two related reasons: (1) State law varies as to whether LPNs and LVNs may independently perform certain tasks associated with home infusion drug administration, such as responding to adverse drug events; and (2) because LPNs and LVNs typically practice under supervision rather than with independent clinical authority, we were concerned that they would be less suited, as a category, to administer complex home infusion drugs.

After further review and consideration of the public comments, we continue to believe that it is important for a health care professional administering or supervising the administration of a home infusion drug to have the clinical authority necessary to safely administer or supervise the administration of the drug and respond to adverse events or other medical events that may occur during the infusion.

However, both concerns are more accurately and more precisely addressed by the independent clinical authority that a State has conferred on a given professional to administer or supervise the administration of the home infusion drug, rather than by a categorical exclusion based on license title. State scope-of-practice determinations already reflect a judgment about which activities a licensed professional—including an LPN or LVN—may perform independently versus only under supervision and categorical exclusions may not adequately account for differences in these state rules and regulations. We also agree with commenters concerned about beneficiary access to the expanded benefit in areas where there may be a shortage of registered nurses and other specific types of health care professionals named in the proposed rule, especially in rural areas, and believe that not limiting the definition of health care professional to the specific categories identified in the proposed rule may prevent certain

situations where patients in rural or underserved areas cannot access home infusion therapy simply because their available clinician does not fall within a specifically named profession type. We believe this approach appropriately addresses the safety concerns identified in the proposed rule while also addressing potential beneficiary access concerns.

After consideration of the public comments, we are not finalizing the proposed limitations on the definition of a health care professional and are revising 42 CFR 414.202(2)(i)(A) to state that the administration or supervision of the home infusion drug must be within the scope of the health care professional's practice as specified by applicable Federal and State laws, regulations, and licensure requirements. This would enable any health care professional to provide these services if it is within their scope of practice, in order to more accurately reflect the clinical authority States have already conferred and to address potential access problems in rural areas. Regarding the comment requesting that we clarify that home infusion drugs are administered by a health care professional, we note that the proposed 42 CFR 414.202(2)(i), consistent with section 6222(a)(1) of the CAA, 2026, requires that the FDA-approved prescribing information for the home infusion drug instruct that the drug be administered by or under the supervision of a health care professional. Separately, 42 CFR 414.202 (2)(ii), consistent with section 6222(a)(2) of the CAA, 2026, requires that a qualified home infusion therapy supplier administer or supervise the administration of the home infusion drug in a safe and effective manner in the patient's home. These requirements address different aspects of the provision. Paragraph (2)(i) addresses the health care professional who may administer or supervise the administration of the drug, while paragraph (2)(ii) addresses the role of the qualified home infusion therapy supplier in furnishing home infusion therapy services.

We also believe that the qualified home infusion therapy supplier will employ, contract with, or coordinate with the health care professional who administers or supervises the administration of the home infusion drug. Section 1861(iii)(3)(D)(i) of the Act permits a qualified home infusion therapy supplier to subcontract with a pharmacy, physician, provider of services, or supplier to meet the applicable qualified home infusion therapy supplier requirements. The qualified home infusion therapy supplier remains responsible for furnishing and billing for the home infusion therapy services in accordance with the applicable requirements. For these reasons, and due to the scope-of-practice standard in 42 CFR 414.202(2)(i)(A), we believe we have appropriately addressed the commenter's concerns.

Comment: Commenters expressed differing views regarding CMS's proposal to interpret the statutory requirement that the prescribing information instruct that the home infusion drug be infused at least 12 times per year to mean at least once per month. Several commenters supported the proposed interpretation, stating that it would provide a reasonable and administratively workable standard for applying the statutory frequency criterion. Some commenters also supported not establishing a separate minimum or maximum number of infusions.

Several other commenters recommended that CMS apply the statutory language of at least 12 times per year without specifying an infusion during every calendar month. These comments stated that annual and monthly frequency requirements are not necessarily equivalent because dosing schedules may vary based on the drug, treatment phase, clinical response, and other clinical circumstances. A comment provided an example of a therapy administered through treatment cycles that result in more than 12 infusions annually without an infusion occurring during every calendar month. Comments also stated that the ''at least once a month'' criterion is not what is provided in the statute and that CMS has arbitrarily read additional requirements into the statute that Congress did not include.

Several commenters also raised concerns regarding loading periods, temporary treatment interruptions, illness, travel, scheduling issues, provider shortages, and individualized dosing adjustments. The comments requested flexibility so that these circumstances would not unnecessarily affect access to the benefit.

Other comments sought broader relief from the annual frequency criterion of 12 infusions, stating that the statutory frequency threshold limits the range of therapies that may qualify for the expanded benefit.

Response: We thank the commenters for expressing their thoughts and concerns regarding the frequency criterion. Section 6222(a) of the CAA, 2026 amended section 1861(n) of the Act to require, among other applicable criteria, that the prescribing information instruct that the home infusion drug be infused at least 12 times per year. In the proposed rule, we proposed to interpret this statutory requirement to mean that the drug must be infused at least once per month based on how dosing information for home infusion drugs is typically described in prescribing information.

We agree that the statutory requirement of at least 12 infusions per year does not necessarily require an infusion during every calendar month. A dosing schedule may provide for 12 or more infusions per year while also including treatment cycles or periods during which an infusion does not occur.

After consideration of the public comments expressing concern about our deviation from the statutory language, we are not finalizing our proposed interpretation that at least 12 times per year means at least once per month. We are not including the parenthetical ''at least once a month'' in paragraph (2)(iii) of the definition of DME in 42 CFR 414.202, and we are finalizing the regulatory text consistent with the statutory requirement of ''at least 12 times per year.''

We clarify that this criterion is not based on how often an individual beneficiary receives an infusion, but rather what the applicable prescribing information instructs regarding the frequency of infusion. However, we disagree with comments requesting that CMS waive, reduce, or establish exceptions to the requirement that the prescribing information instruct that the drug be infused at least 12 times per year. Congress expressly established the 12 times per year criterion in section 1861(n)(3) of the Act. We do not have authority through this rulemaking to eliminate or modify that statutory requirement. A change to that requirement would require a change in the statute.

Comment: Commenters expressed concern that Medicare beneficiaries may face higher cost sharing when receiving infusion therapy in the home and recommend that beneficiaries receive clear information regarding expected costs before electing home infusion.

Response: Section 6222(b) of the CAA, 2026 requires the Secretary to ensure that beneficiaries are notified of the cost sharing for electing home infusion therapy compared with other applicable settings of care. We agree that beneficiaries should be appropriately notified of cost sharing implications, and CMS plans to implement this statutory requirement through subregulatory guidance.

Comment: Commenters from home infusion and specialty pharmacy organizations, health care providers, pharmaceutical manufacturers, patient advocacy organizations, DME suppliers, and device and technology stakeholders provided feedback regarding implementation of the expanded DME benefit. Several commenters addressed reasonable and necessary determinations for external infusion pumps, drugs, and associated supplies, pump necessity including a comment that specifically mentioned, titration and dose ramp up periods, and infusion monitoring technology. Several commenters also addressed implementation of the Medicare home infusion therapy services benefit, including payment categories, HCPCS coding, Medicare Administrative Contractor (MAC) coordination, supplier enrollment and billing, subcontracting and supplier arrangements, claims processing, operational guidance, and implementation timing.

Response: The provisions of this rule address the scope of the DME benefit under section1861(n) of the Act, as amended by section 6222(a) of the CAA, 2026. Reasonable and necessary determinations under section 1862(a)(1)(A) of the Act and issues concerning home infusion therapy payment, coding, supplier arrangements, billing, claims processing, and other operational matters are outside the scope of these provisions. Reasonable and necessary determinations for pumps, drugs, and supplies will be addressed by the DME MACs through the applicable coverage process. CMS is also working to address other implementation issues following publication of this final rule and in advance of the effective date, as appropriate. Additionally, we encourage suppliers to provide beneficiaries with a voluntary advance notice (for example, a voluntary Advance Beneficiary Notice of Non-coverage) when the mode of administration of a drug changes from an external infusion pump to another mode (for example, IV drip) and the requirements set forth under section 1861(n)(3) of the Act are not met, so that beneficiaries understand the potential impact of such a change on Medicare coverage and payment. We believe this notice will support beneficiary understanding about their financial responsibility and informed decision-making.

After consideration of the public comments, we are finalizing modifications to the definition of DME under 42 CFR 414.202 to incorporate the amendments to section 1861(n) of the Act by section 6222(a) of the CAA, 2026, effective April 1, 2027. Specifically, we are finalizing that certain external infusion pumps, associated home infusion drugs, and related supplies will be treated as meeting the ''appropriate for use in the home'' requirement when the following criteria under paragraphs (1) through (3) of section 1861(n) of the Act are satisfied:

- The prescribing information approved by the FDA for the home infusion drug (as defined in § 486.505) associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional. The health care professional must be on site at the home to administer or supervise the administration of the home infusion drug, and the administration or supervision must be within the health care professional's scope of practice as specified by applicable Federal and State laws, regulations, and licensure requirements.
- A qualified home infusion therapy supplier (as defined in § 486.505) administers or supervises the administration of the home infusion drug in a safe and effective manner in the patient's home (as defined in § 486.505).
- The prescribing information instructs that the home infusion drug be infused at least 12 times per year either intravenously or subcutaneously, or at infusion rates that the Secretary determines would require the use of an external infusion pump.

E. DMEPOS Competitive Bidding Program—Country of Origin

In the CY 2027 HH PPS proposed rule, CMS discussed requiring Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) contract suppliers to report the country of origin for the lead items furnished during the DMEPOS CBP contract's period of performance. Under section 1847(b)(3)(A) of the Act and 42 CFR 414.422(a), CMS specifies the terms and conditions of DMEPOS CBP contracts.

During an active round of the DMEPOS CBP, contract suppliers are required, as a term of their contracts, to use a reporting form, known as Form C, to provide product information (manufacturer name, model name, and model number) for the lead item they furnish. The information provided in the form is included in the Medicare Supplier Directory on the *Medicare.gov* website with the products the supplier plans to provide during the next 6-month period. Contract suppliers are also required to maintain the accuracy of their product information for the lead item they furnish using Form C. Form C includes an attestation that all the reported information is accurate and up to date. This attestation needs to be completed to fulfill a Form C submission requirement.

We will request that the information collection be revised to include the country of origin for each lead item they report on a new ''country of origin'' field on Form C. As done historically with the other product information reported on Form C by a contract supplier, the reported country of origin information would also be populated on the Medicare Supplier Directory for the contract supplier during the contract period of performance. This information would allow beneficiaries and interested parties to have access to the information on the country from which the DMEPOS item originated, if interested.

Contract suppliers would identify the country of origin based on the markings on the product for the lead item, or where an exemption to marking applies, obtain documentation from the manufacturer or distributor. Under U.S. Customs and Border Protections rules (19 CFR 134.11, 134.46), imported goods must be properly marked to indicate the country of origin (for example): ''Made in [Country]''), unless an exemption applies (for example, an item that is incapable of being marked, like a catheter), as explained at 19 CFR 134.32.

To correctly identify the country of origin for a product in the absence of a marking or to verify a marking, contract suppliers may need to obtain documentation from the manufacturer or distributor indicating the country of origin for its product, which could include one or a combination of the following: manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification.

The details for this update to Form C will be included under OMB Control Number 0938–1408 (CMS–10744).

We received public comments on these revisions. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the increased transparency that the discussed change would provide to beneficiaries, stating that transparency regarding product sourcing helps beneficiaries make informed decisions.

Response: CMS appreciates commenters' support and agrees that transparency regarding a product's

country of origin helps beneficiaries make informed decisions about their DMEPOS suppliers and the DMEPOS they purchase. CMS views this requirement as a complement to the manufacturer and model information that contract suppliers have historically provided and is available in the Medicare Supplier Directory during an active round of the DMEPOS CBP.

Comments: Several commenters opposed the proposal. Commenters discussed that the country of origin offers limited value to beneficiaries because suppliers already report the manufacturer and model information beneficiaries actually care about; that manual entry of information via Form C will create unnecessary burden for contract suppliers; that responsibility for verifying manufacturer information should not shift to home health agencies; and that it is questionable whether beneficiaries would actually inquire about the country of origin.

Response: Manufacturer and model information does not indicate where a product is made, so country of origin remains a distinct, complementary data point that supports beneficiaries who wish to consider the country of origin when selecting a supplier and the DMEPOS they want to purchase. CMS acknowledges concerns about the burden of manual Form C entry and will explore options, including a bulk data entry method, to streamline reporting. CMS did not intend, and does not intend, to shift verification responsibility to home health agencies as the reporting obligation applies to contract suppliers, which are best positioned to confirm country of origin information. Finally, even if not all beneficiaries actively seek country of origin information, making it available increases transparency and supports informed decision-making for those who do.

Comments: Commenters raised several concerns: some stated that the discussed change does not explain how country of origin information will be used and asked for clarification on whether it will inform future policy or enforcement actions; some noted that the discussed change does not identify enforcement actions, and another commenter expressed concern that country of origin reporting alone would not be enough to address concerns related to ownership structures, supply chain security, or other policy objectives. Commenters also discussed that the competitive bidding program's cost-driven structure could let unvetted foreign manufacturers supply substandard or non-compliant products, risking beneficiary safety. Commenters expressed concern that reporting only on the lead item would give beneficiaries an incomplete understanding of the country of origin, since non-lead items can fall under the same HCPCS code as a lead item yet may have a different country of origin; beneficiaries unfamiliar with country of origin distinctions may incorrectly assume all products under a HCPCS code share the lead item's origin.

Response: CMS clarifies that the primary purpose of this discussed change is to increase beneficiary-facing transparency about a product's country of origin, not to establish a new enforcement mechanism. CMS may use aggregate country of origin data to inform future policy considerations, such as identifying whether reliance on limited number of countries for certain DMEPOS items creates supplier chain vulnerabilities, in later rulemaking. CMS acknowledges that country of origin reporting alone will not fully address broader ownership structure or supply chain security objectives and will continue to explore complementary policy approaches. Regarding beneficiary safety, existing supplier standards and product quality standards remain in effect regardless of a product's country of origin, and this discussed change does not change the bid evaluation or supplier qualification criteria that bidders must meet to be awarded a DMEPOS CBP contract. CMS acknowledges that beneficiaries may assume all items under a HCPCS code share the lead item's country of origin and, therefore, intends to provide education clarifying that the lead item's country of origin does not necessarily apply to non-lead items furnished under the same HCPCS code. Regarding the availability and reliability of country of origin data, CMS notes that under U.S. Customs and Border Protection rules, imported goods must generally be marked ''Made in [Country]'' unless an exemption applies as provided at 19 CFR 134.32. Where a marking is absent or requires verification, contract suppliers may need to obtain documentation from the manufacturer or distributor identifying the product's country of origin, which could include manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification, individually or in combination.

Comments: Commenters offered several recommendations. Commenters suggested that CMS should include more than just the lead item's country of origin, with several recommending that the Medicare Supplier Directory display the country of origin for all products, not only the lead item. Additionally, commenters recommended CMS specify a clear definition of the ''country of origin'' field, use uniform definitions and reliable documentation standards, and permit suppliers to rely on documentation provided by manufacturers or distributors. Commenters also recommended that CMS require prospective reporting of country of origin, displayed in advance and updated promptly whenever products change, with a couple of these commenters also recommending a correction or audit process for information changes. Furthermore, commenters recommended educational materials. These recommendations included beneficiary education explaining what country of origin information means and the distinction between lead and non-lead items, as well as providing educational materials before the bidding window opens. Another commenter requested that CMS display manufacturer, model, and interoperability information alongside country of origin. A commenter suggested CMS allow bulk data entry to reduce burden associated with the discussed changes. Finally, a commenter recommended that, rather than country of origin reporting, CMS focus on stronger supplier vetting, manufacturer quality standards, and product approval safeguards.

Response: We appreciate these recommendations. The Medicare Supplier Directory will display the country of origin information, but CMS believes requiring contract suppliers to report on both lead items and non-lead items is too burdensome. However, we can expand the policy later, if needed. CMS agrees that a clear, uniform definition of ''country of origin'' and reliable documentation standards will improve consistent reporting. CMS believes the proposed rule provided guidance to contract suppliers on identifying country of origin and the types of documentation that may be used, as follows: ''Contract suppliers would identify the country of origin based on the markings on the product for the lead item, or where an exemption to marking applies, obtain documentation from the manufacturer or distributor.'' Under U.S. Customs and Border Protection's rules (19 CFR 134.11 and 134.46), imported goods must be properly marked with: ''Made in [Country],'' unless an exemption applies (for example, an item that is incapable of being marked, like a catheter), as

explained at 19 CFR 134.32. To correctly identify the country of origin for a product in the absence of a marking or to verify a marking, contract suppliers may need to obtain documentation from the manufacturer or distributor indicating the country of origin for its product, which could include one or a combination of the following: manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification. CMS agrees that timely, prospective reporting improves usefulness for beneficiaries and will provide guidance on the expected timeframe for updates following a product change, and will consider establishing a correction process suppliers can use to promptly amend inaccurate entries. CMS agrees that education supports successful implementation and plans to provide materials explaining country of origin information and the lead/non-lead item distinction in advance of the next competitive bidding contract period of performance, which is expected to start no sooner than January 1, 2028. CMS will display manufacturer, model, and country of origin information on the Medicare Supplier Directory to give beneficiaries a more complete product view. CMS notes that the comments about interoperability information are out of scope. Finally, CMS agrees that supplier vetting and product quality standards are important complements to transparency measures, and country of origin reporting is not intended to replace, but instead strengthen, existing vetting and quality requirements under the DMEPOS CBP.

After considering all comments, we will proceed with the information collection revision through the standard PRA process.

F. Revising Covered Document Review Date (CDRD) Evaluation and Notification for the DMEPOS CBP—Technical Corrections to 42 CFR 414.414(d)

In the CY 2026 HH PPS final rule (90 FR 55554 and 55555), we finalized revisions to § 414.414(d) to reflect changes to the required financial documents. As part of those revisions, the provisions governing the covered document review date (CDRD), previously located at § 414.414(d)(2), were redesignated as § 414.414(d)(3). We also intended to revise § 414.414(d)(3)(ii)(B) so that it would align with the CDRD changes that were finalized in the CY 2026 Home Health final rule. The regulation text was updated correctly with the required financial documents at § 414.414(d)(1) and (2), but the CDRD regulation text was inadvertently omitted from the Code of Federal Regulations at § 414.414(d)(3).

In this CY 2027 HH PPS final rule, we are making the technical corrections to § 414.414(d), by adding the CDRD regulation text that was inadvertently omitted when § 414.414(d)(2) was redesignated as § 414.414(d)(3) and updating § 414.414(d)(3)(ii)(B) in accordance with the CY 2026 HH PPS final rule.

VI. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide a notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

B. Information Collection Requirements (ICRs)

In the CY 2027 HH PPS proposed rule, we solicited public comment on each of the issues for the following sections of this document that contain information collection requirements (ICRs). Failure to submit HH QRP data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year would result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points.

1. ICRs for HH QRP

As discussed in section III of this final rule, we proposed to revise the HH QRP OASIS data submission deadlines beginning with the CY 2027 HH QRP. CMS also proposed to revise the HH QRP OASIS and HHCAHPS Annual Payment Update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). CMS proposed some revisions to regulatory text in support of rule proposals or to improve digital transfer of information during the reconsiderations process. Finally, we solicited public comments on one Request for Information (RFI) on future measure concepts for the HH QRP.

The net effect of the proposals is no changes to expected burden associated with OASIS data collection.

We received public comment on our OASIS submission proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters raised issues related to burden related to some proposals. Related to the OASIS submission proposal, commenters had concerns about operational and staffing challenges, administrative burden, and data validation, especially for small or rural HHAs that may struggle with staffing challenges and operational issues. A few commenters expressed concerns that providers continue to experience staffing shortages and turnover of HH staff. Some commenters that supported the proposal noted the current clinical and administrative burden around implementing OASIS all-payer submissions and changing payment requirements. Several commenters encouraged CMS to establish a phased implementation or grace period to meet submission requirements, to provide flexibility for the first several data submission cycles. A few other commenters cited recent implementation of the HOPE tool to stress the benefits of a phased implementation.

Response: We appreciate the commenters' concerns about operational and staffing challenges, especially for small or rural HHAs. We do not believe that the proposal adds burden for HHA staff by changing the data submission deadline; rather, it shifts the existing workflow from 4.5 months after each quarterly data collection period to the 15th day of the second month after the end of the calendar quarter. Since workflows are in place for the necessary processes, we do not believe a phased implementation approach is necessary.

Comment: Related to the OASIS and HHCAHPS APU proposals, commenters

also raised concerns of burden. Commenters who supported the APU calendar updates with concerns commonly raised the issue of burden associated moving to a new APU calendar. They noted that to ensure an effective transition would require investments in quality assurance resources, data analytics, clinical education, software systems, and compliance oversight.

Response: We thank commenters for outlining potential burden issues related to the APU update proposals. We will provide clear guidance around the implementation of this policy that should limit costs associated with the transition and implementation of calendar year APU reporting. We also do not anticipate changes in scoring methodologies associated with this transition to calendar year reporting of APU calculations.

2. ICRs for the Expanded HHVBP Model

We did not propose any changes to the expanded HHVBP Model in the CY 2027 HH PPS proposed rule.

3. ICRs for DMEPOS Requirements for Identical Replacement Items

The proposed clarification neither imposes new information collection requirements nor eliminates existing ones. Rather, it further explains and reinforces the intent of this section when the item furnished is a replacement item. The PRA package for Medicare Fee-for-Service Prepayment Review of Medical Records is CMS–10417 and approved under OMB control number 0938–0969. In section V.B. of this final rule, we clarify that a new face-to-face encounter and related documentation are not required to support payment for replacement durable medical equipment, prosthetic, orthotic and supply (DMEPOS) items. Under existing Medicare requirements, suppliers and providers are already obligated to maintain documentation sufficient to demonstrate compliance with coverage requirements under 42 CFR 410.38 at the time the item is furnished. This rule clarifies that CMS does not consider an additional comprehensive beneficiary examination necessary to ''gather subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered'' when the item being furnished is a replacement item. If a claim for a replacement DMEPOS item is subject to audit, the provider must nevertheless submit documentation from the original face-to-face encounter to demonstrate that medical necessity, billing and coverage requirements have been satisfied. Accordingly, the intent of 42 CFR 410.38, which requires a face-to-face encounter for certain DMEPOS items, would continue to apply when the item is initially furnished; however, the requirement would not need to be repeated solely for replacement items. Therefore, we assume this clarification would have a negligible monetary impact.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

4. ICRs for Provider Enrollment

For those enrollment provisions not addressed in this section VI.B.4. of this final rule, we do not believe that any of them would impose an information collection burden on interested parties. Provisions that are addressed as follows either will impose such a burden or will not but require further explanation.

a. Signage

Section 424.510(f) would require all providers and suppliers (regardless of type) to maintain a permanent visible sign in plain view and post their hours of operation. While we believe the vast majority of providers and suppliers already maintain such signage, some do not. For purposes of this ICR statement, we project that: (1) roughly 200,000 providers will need to obtain or revise their signage under § 424.510(f); (2) it would take each provider an average of 5 hours to do so; and (3) this activity—at least for currently enrolled providers—would mostly occur in the first year following § 424.510(f)'s effective date. (The 200,000 figure includes providers and suppliers already enrolled in Medicare and those that may be newly enrolling over the next 3 years.) We believe the supplier's office staff would acquire the signage. Per data from the U.S. Bureau of Labor Statistics' (BLS') May 2025 National Occupational Employment and Wage Statistics for all wage estimates (*https://www.bls.gov/oes/tables.htm*), the mean hourly wage for the ''Office and Administrative Support Workers, All Other'' category (43–9199) is $23.40; with fringe benefits and overheard, the figure is $46.80. This results in a total burden over the first three of this requirement of 1 million hours and $46,800,000. The annual cost over the three-year period would be $15,600,000.

This burden estimate will be submitted for OMB review and approval as part of new information collection request—that is, a request for a new OMB control number. Stakeholders will be able to furnish public comment on this estimate during the PRA process.

b. Clarification of ''Managing Employee'' Definition

All providers and suppliers must report their managing employees (and any changes in their managing employees) to CMS. This reporting requirement falls within the overall OMB-approved ICR burden for the following forms:

- Form CMS–855A (Medicare Enrollment Application for Institutional Providers; OMB Control No. 0938–0685).[57]
- Form CMS–855B (Medicare Enrollment Application—Clinics/Group Practices and Certain Other Suppliers; OMB Control No. 0938–1377).[58]
- Form CMS–855I (Medicare Enrollment Application—Physicians and Non-Physician Practitioners; Clinics/Group Practices and Certain Other Suppliers; OMB Control No. 0938–1355).[59]
- Form CMS–855S (Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers; OMB Control No. 0938–1056).[60]

We proposed to revise the definition of ''managing employee'' in § 424.502 to identify certain individuals who fall within this definition. As explained in section V.C. of this final rule, these persons have always qualified as managing employees and thus must be reported. We are simply identifying them in § 424.502 to reiterate this point.

c. Documentation

(1) ''Operational''

Paragraph (5) of our revised definition of ''operational'' in § 424.502 would require, in part, that the provider or supplier have adequate written policies and records regarding its operations. We do not believe this would impose an additional information collection burden on providers and suppliers. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), providers and suppliers typically maintain such policies and records as a usual and customary business practice. Therefore, we have not assigned any burden to this requirement.

(2) Section 424.516(f)

Section 424.516(f) requires providers and suppliers to maintain certain types

[57] OMB control number 0938–0685 expires September 30, 2027.

[58] OMB control number 0938–1377 expires September 30, 2027.

[59] OMB control number 0938–1355 is currently pending OMB reapproval.

[60] OMB control number 0938–1056 expires September 30, 2029.

of documentation. We proposed to revise this paragraph to make clear that said documentation must be accurate, complete, and consistent with CMS requirements. We do not believe this would impose an additional information collection burden on providers and suppliers. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), providers and suppliers typically maintain such policies and records as a usual and customary business practice. Therefore, we have not assigned any burden to this requirement.

d. Private Equity Companies (PECs) and Real Estate Investment Trusts (REITs)

The Form CMS–855A enrollment application for certified providers and certain certified suppliers (Medicare Enrollment Application for Institutional Providers OMB Control No. 0938–0685) requires providers and suppliers to report whether any party listed on the application is a PEC or a REIT. We announced in the proposed rule our intention to expand this requirement to the following Medicare provider and supplier enrollment forms:

- Form CMS–855B (Medicare Enrollment Application—Clinics/Group Practices and Certain Other Suppliers; OMB Control No. 0938–1377).
- Form CMS–855S (Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers; OMB Control No. 0938–1056).
- Form CMS–20134 (Medicare Diabetes Prevention Program (MDPP) Suppliers).

Although this announcement would not, in and of itself, impose an information collection burden, the revisions of the Forms CMS–855B and CMS–855S, to collect PEC and REIT data would do so. The Forms CMS–855B and CMS–855S burdens will be addressed in the information collection requests that CMS will submit to the Office of Management and Budget to request revisions to these two forms. However, the Form CMS–20134 is exempt under section 3021 of the Affordable Care Act.

e. Disclosure of Affiliations

As discussed in section V.C. of this final rule, we proposed to revise our affiliation provisions in §§ 424.502 and 424.519. We solicited comments from interested parties as to whether any additional ICR burden would ensue from these changes. As we explained in section V.C. of this final rule, though, we do not foresee an ICR burden associated with said revisions, for we do not anticipate requesting providers and suppliers to disclose the data referenced in § 424.519.

f. Reactivation Effective Dates

We proposed to permit providers that have been assigned an effective date for their reactivation to submit a rebuttal if they disagree with said date. We believe the rebuttal and the associated burden would be incurred after an administrative action. In accordance with the implementing regulations for the PRA (5 CFR 1320.4(a)(2) and (c)), the burden associated with any information collected subsequent to the administrative action is exempt from the requirements of the PRA (that is, the rebuttal submitted subsequent to the assignment of the reactivation effective date).

g. Comments Received

The vast majority of the comments we received regarding the burden associated with our provider enrollment provisions overlapped between information collection requirements and other burdens normally addressed in the RIA. With the exception of the following comment, which was largely limited to information collection requirements, the burden comments and our responses will be addressed in the RIA section.

Comment: Several commenters expressed concern that CMS did not assess costs for its revised ''managing employee'' definition. A few stated, as noted in section V.C. of this final rule, that this revision expands the types of reportable managing employees, further asserting that CMS admits as much in its use of terms such as ''added'' and ''expand upon'' in the proposed rule. This, they believed, contradicts CMS' statements that the revised definition imposes no additional costs because these persons have always had to be reported. They maintained that this: (1) is a procedural error and reflects ''internally inconsistent'' decision-making that is arbitrary and capricious; (2) denies the public a meaningful opportunity to comment on the proposal; and (3) fails to consider any benefits that might stem from the revised definition when weighed against what the commenter believes are the associated costs. Another commenter stated that if providers are not currently reporting clinical managing employees, the burden of doing so now is real and should be reported—even if CMS believe no burden exists because these persons should always have been reported.

Response: As we explained in section V.C. of this final rule (to which we refer readers for a more robust discussion), we continue to maintain that the clinical personnel in question always fell within the ''managing employee'' definition and must be disclosed. Our use of terminology such as ''added'' and ''expand upon'' simply referenced the formal listing of these persons in the revised definition as a reminder of this. It is not an expansion of the definition, and we made this point clear in the proposed rule. Accordingly, the revision is neither arbitrary nor capricious and does not represent inconsistent decision making.

Our position that the proposal merely clarified that such individuals have always qualified as managing employees is why we did not include a burden estimate. That said, the revised ''managing employee'' definition in the present final rule would seemingly increase compliance with a requirement that already exists. Although the resulting costs (and benefits) would be attributable to this final rule, quantification is extremely challenging and infeasible given that the scope of each provider's or supplier's individual reporting circumstances will likely vary widely.

We add that the public had a meaningful opportunity to comment on the proposed revised definition, as evidenced by the significant number of comments we received on this proposal. Insofar as benefits, we explained the reason and need for our revision in the proposed and final rules.

Comment: A commenter stated that: (1) the expanded definition of ''operational'' would require practices to develop and maintain written policies addressing patient care, patient safety, recordkeeping, and administration; and (2) the signage requirement at proposed § 424.510(f) would require practices to install and maintain compliant signage at each applicable location. The commenter disagreed that these and other requirements would not impose a burden. If the CMS believes that providers are already complying with the aforementioned ''written policies'' and signage requirements, the commenter believed there would be no reason to include them in regulation.

Response: While we have added a burden estimate for the signage requirement, we believe that providers—as part of their ordinary course of business—already maintain the written policies in (1). Insofar as the commenter's last statement, it is customary for CMS to promulgate provider enrollment regulatory requirements even if provider already performs this function as part of its day-to-day operations. For instance, when we established the documentation

retention requirements in § 424.516(f) in 2010, we stated that the burden associated with maintaining documentation and furnishing it upon request is a usual and customary business practice and thereby exempt from the PRA under 5 CFR 1320.3(b)(2).[61]

After reviewing the comments received (some of which, again, are addressed in the RIA section of this final rule), we are finalizing the aforementioned projections.

5. ICRs for Country of Origin

When ready, the following changes will be submitted to OMB for approval under control number 0938–1408 (CMS–10744) using the standard, non-rule related PRA process (which includes the publication of 60- and 30-day **Federal Register** notices) to facilitate the change.

As discussed in section V.E. of this final rule, we plan to revise Form C (Semi-Annual Report) to collect the country of origin information for the lead items furnished during the DMEPOS CBP contract's period of performance. Because contract suppliers are required to submit Form C once every 6 months during January and July throughout the DMEPOS Competitive Bidding Program contract's period of performance, contract suppliers will be required to report this information twice a year. A DMEPOS CBP contract supplier will continue to be required as a term of its contract to maintain the accuracy of its product information (manufacturer name, model name, and model number) for the lead item it furnishes on Form C, and they will now be required to also maintain the accuracy of the country of origin for each product it reports in a newly added ''country of origin'' field on Form C. Form C will continue to require an attestation that all the reported information is accurate and up to date.

Contract suppliers should be able to identify the country of origin based on the markings on the product for the lead item. For example, under U.S. Customs and Border Protections rules, (19 CFR 134.11 and 134.46) imported goods must be properly marked with: ''Made in [Country],'' unless an exemption applies (for example an item that is incapable of being marked, such as a catheter), as explained at 19 CFR 134.32. To correctly identify the country of origin for a product in the absence of a marking or to verify a marking, contract suppliers may need to refer to readily available documentation from the manufacturer or distributor indicating the country of origin for its product, which could include a combination of the following: manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification.

Since the publication of the proposed rule, CMS has published on the Competitive Bidding Implementation Contractor website the number of contracts to be awarded to suppliers for each product category included in Round 2028 based on the methodology established at 42 CFR 414.414(h)(3)(i) and, therefore, we have updated the burden estimates accordingly. These numbers total 43 contracts. While these figures are expected to reflect the number of contracts awarded for the applicable competition, CMS may award additional contracts to meet the small supplier participation target and to ensure beneficiary demand is met. To account for these potential additional contract awards, CMS estimates that approximately 50 contracts will be awarded for Round 2028. We also estimate that each contract supplier's annual time burden will be 0.2 hours (1 contract supplier/year × 0.1 hr/response × 2 responses/year) at a cost of $21.95 (0.2 hr × $109.74/hr (adjusted by 100 percent for fringe benefits and other indirect costs for an Administrative Services Manager, BLS Occupation Code: 11–3012)). Given that we anticipate that 50 contracts will be awarded for Round 2028, we estimate that the aggregate annual time burden will be 10 hours (50 contract suppliers/year × 0.1 hr/response × 2 responses/year) at a cost of $1,097.40 (10 hr × $109.74/hr) (See Table 22).

TABLE 22: DMEPOS CBP COUNTRY OF ORIGIN ANNUAL BURDEN ESTIMATES

Collection	Respondents	Annual Responses (per respondent)	Total Annual Responses	Time per Response	Total Annual Time (non-aggregate)	Labor Rate ($/hr)	Total Annual Cost ($) (aggregate)
CMS-10744 (OMB 0938-1408)	50 Contract Supplier	2	100	6 min (0.1 hr)	12 min (0.2 hr)	109.74	1,097

We received public comments on these revisions. The following is a summary of the comments we received and our responses.

Comment: Commenters reported that requiring DMEPOS CBP contract suppliers to provide the country of origin for the lead items furnished during the DMEPOS CBP contract's period of performance on Form C is unnecessarily burdensome if they are required to manually enter this information as there are many products from various manufacturers that fall under the lead item for each product category being competitively bid in Round 2028.

Response: We believe that the country of origin information will allow beneficiaries and interested parties to learn where the DMEPOS item originated, if interested. We anticipate a minimal burden for DMEPOS contract suppliers as we believe they will be familiar with the DMEPOS they provide as, per the U.S. Customs and Border Protection rules (19 CFR 134.11 and 134.46), imported goods must generally be marked ''Made in [Country]'' unless an exemption applies as provided at 19 CFR 134.32. Where a marking is absent or requires verification, contract suppliers may need to obtain documentation from the manufacturer or distributor identifying the product's country of origin, which could include manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification, individually or in combination. The time needed to identify the country of origin in these instances is accounted for in the burden estimate. We also anticipate providing a drop-down list from which DMEPOS

[61] ''Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements'' (75 FR 24437).

contract suppliers would select the country of origin for the lead item in each product category included on their DMEPOS CBP contract. This mechanism would eliminate manual entry and help ensure consistency and accuracy across submissions.

Comment: Commenters noted that country of origin information would be difficult to capture, and that penalties for inaccuracies or missing information could exacerbate supply chain issues and costs.

Response: Our burden estimate assumes suppliers can obtain country of origin data through these existing marking requirements and manufacturer or distributor relationships, and we are not imposing monetary penalties tied to this data collection.

After considering all comments, we will proceed with the information collection revision through the standard PRA process.

VII. Regulatory Impact Analysis

A. Statement of Need

1. HH PPS

Section 1895(b)(1) of the Act requires the Secretary to establish an HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) the computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amount be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standard prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality and links the quality data submission to the annual applicable percentage increase.

Sections 1895(b)(2) and 1895(b)(3)(A) of the Act, as amended by sections 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, required the Secretary to implement a 30-day unit of payment, for 30-day periods beginning on and after January 1, 2020. Section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the BBA of 2018, requires the Secretary to annually determine the impact of differences between assumed behavior changes, as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, section 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. The HH PPS wage index utilizes the wage adjustment factors used by the Secretary for purposes of sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act for hospital wage adjustments.

2. HH QRP

Section 1895(b)(3)(B)(v) of the Act authorizes the HH QRP, which requires HHAs to submit data in accordance with the requirements specified by CMS. Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points.

3. Expanded HHVBP Model

In the CY 2022 HH PPS final rule (86 FR 62292 through 62336) and codified at 42 CFR part 484, subpart F, we finalized our policy to expand the HHVBP Model to all Medicare certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. CY 2022 was a pre-implementation year. CY 2023 was the first performance year in which HHAs individual performance on the applicable measures affected their Medicare payments in CY 2025. We did not propose any expanded HHVBP Model-specific changes in the proposed rule.

4. DMEPOS Encounter Requirements for Identical Replacement Items

In this final rule, we clarify that a new face-to-face encounter and related documentation, as described in 42 CFR 410.38, is not necessary to support the payment of replacement DMEPOS items.

5. Provider Enrollment

Consistent with section 1866(j) of the Act, we finalizing a number of Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include but are not limited to: (1) adding and modifying grounds for denying or revoking a provider's or supplier's Medicare enrollment; and (2) expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers, which we believe would assist in protecting the Trust Funds and Medicare beneficiaries.

6. DMEPOS Coverage of External Infusion Pumps

With section 6222 of the Consolidated Appropriations Act, 2026, Congress modified section 1861(n) of the Act to expand the scope of the DME benefit to enable coverage for home infusion of drugs that: (1) must be administered by or under the supervision of a health care professional; (2) are administered by a qualified home infusion therapy supplier; and (3) have prescribing information that requires infusion at least 12 times per year. This regulatory action implements the changes made by section 6222 of the CAA, 2026 to the definition of DME.

7. DMEPOS Competitive Bidding—Country of Origin

For the DMEPOS CBP, we plan to request a revision to the information collection under OMB Control Number 0938–1408 (CMS–10744) to collect from DMEPOS Competitive Bidding contract suppliers the country of origin for the lead items furnished during the DMEPOS CBP contract's period of performance.

The reported country of origin information would be populated on the Medicare Supplier Directory for the contract supplier during the contract period of performance so beneficiaries and interested parties may learn where the DMEPOS item originated, if interested.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96 354); section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis that presents the cost and benefit of the rulemaking to the best of our ability.

C. Detailed Economic Analysis

1. Effects of the Changes for the CY 2027 HH PPS

This rule finalizes updates to the Medicare payments under the HH PPS for CY 2027. The net transfer impact related to the changes in payments under the HH PPS for CY 2027 is estimated to be $415 million (2.4 percent) above the updated projected CY 2026 baseline of $17.399 billion, leading to total projected spending of approximately $17.8 billion for 2027. The $415 million increase in estimated payments for CY 2027 reflects the effects of the final CY 2027 home health payment update percentage of 2.1 percent ($365 million increase), and an estimated 0.3 percent increase that reflects the updated FDL ($50 million increase).

We use the latest data and analysis available. However, we do not adjust for future changes in such variables as number of visits or case-mix. This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, based primarily on Medicare claims data for periods that ended on or before December 31, 2025. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly legislated general Medicare program funding changes made by the Congress or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that overall changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 23 represents how HHA revenues are likely to be affected by the finalized policy changes for CY 2027. For this analysis, we used an analytic file with linked CY 2025 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2025. The first column of table 23 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the recalibration of the case-mix weights offset by the case-mix weight budget neutrality factor. The fourth column shows the payment effects of updating the CY 2027 wage index (that is, the FY 2027 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023 (FY 2023 cost report data)) with a 5-percent cap on wage index decreases. The aggregate impact of the changes in the fourth column is zero percent, due to the wage index budget neutrality factor. The fifth column shows the payment effects of the final CY 2027 home health payment update percentage. The sixth column shows the payment effects of the final FDL. The seventh column shows the payment effects of the final temporary adjustment on all payments. The aggregate impact of the final temporary adjustment reflected in the seventh column equals zero percent because both the CY 2026 and CY 2027 payment rates include a 3.0 percent temporary adjustment. The last column shows the combined effects of all the finalized provisions.

Overall, it is projected that aggregate payments in CY 2027 would increase by 2.4 percent, which reflects the final 2.1 percent increase to the home health payment update percentage and the 0.3 percent increase from the updated FDL. As illustrated in table 23, the combined effects of all changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than

others due to the distributional impact of the CY 2027 wage index, the percentage of total HH PPS payments that were subject to the LUPA or paid as outlier payments, and the degree of Medicare utilization.

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TABLE 23: CY 2027 HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY

	Number of Agencies	CY 2027 Case-Mix Weights Recalibration Neutrality Factor	CY 2027 Updated Wage Index (with 5% cap)	CY 2027 Final HH Payment Update Percentage	CY 2027 Fixed-Dollar Loss (FDL) Update	Temporary Adjustment	Total
All Agencies	**10,082**	**0.0%**	**0.0%**	**2.1%**	**0.3%**	**0.0%**	**2.4%**
Facility Type and Control							
Free-Standing/Other Vol/NP	653	-0.1%	0.4%	2.1%	0.4%	0.0%	2.8%
Free-Standing/Other Proprietary	8,598	0.0%	-0.1%	2.1%	0.3%	0.0%	2.3%
Free-Standing/Other Government	91	0.1%	1.6%	2.1%	0.5%	0.0%	4.3%
Facility-Based Vol/NP	363	0.0%	0.3%	2.1%	0.5%	0.0%	2.9%
Facility-Based Proprietary	20	0.3%	0.7%	2.1%	0.4%	0.0%	3.5%
Facility-Based Government	154	0.0%	1.2%	2.1%	0.5%	0.0%	3.8%
Subtotal: Freestanding	9,358	0.0%	0.0%	2.1%	0.3%	0.0%	2.4%
Subtotal: Facility-based	537	0.0%	0.5%	2.1%	0.5%	0.0%	3.1%
Subtotal: Vol/NP	1,017	-0.1%	0.4%	2.1%	0.4%	0.0%	2.8%
Subtotal: Proprietary	8,638	0.0%	-0.1%	2.1%	0.3%	0.0%	2.3%
Subtotal: Government	245	0.0%	1.3%	2.1%	0.5%	0.0%	3.9%
Facility Type and Control: Rural							
Free-Standing/Other Vol/NP	157	-0.1%	1.5%	2.1%	0.4%	0.0%	3.9%
Free-Standing/Other Proprietary	889	-0.1%	0.0%	2.1%	0.2%	0.0%	2.2%
Free-Standing/Other Government	56	0.4%	0.8%	2.1%	0.5%	0.0%	3.8%
Facility-Based Vol/NP	141	0.0%	0.1%	2.1%	0.5%	0.0%	2.7%
Facility-Based Proprietary	8	0.3%	-0.4%	2.1%	0.5%	0.0%	2.5%
Facility-Based Government	110	0.1%	1.7%	2.1%	0.6%	0.0%	4.5%
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	496	-0.1%	0.3%	2.1%	0.4%	0.0%	2.7%
Free-Standing/Other Proprietary	7,709	0.0%	-0.1%	2.1%	0.3%	0.0%	2.3%
Free-Standing/Other Government	35	-0.1%	2.0%	2.1%	0.5%	0.0%	4.5%
Facility-Based Vol/NP	222	0.0%	0.4%	2.1%	0.5%	0.0%	3.0%
Facility-Based Proprietary	12	0.3%	1.3%	2.1%	0.3%	0.0%	4.0%
Facility-Based Government	44	-0.1%	0.8%	2.1%	0.4%	0.0%	3.2%
Facility Location: Urban or Rural							
Rural	1,389	-0.1%	0.3%	2.1%	0.3%	0.0%	2.6%
Urban	8,693	0.0%	0.0%	2.1%	0.3%	0.0%	2.4%
Facility Location: Region of the Country (Census Region)							
New England	303	-0.1%	0.6%	2.1%	0.3%	0.0%	2.9%
Mid Atlantic	361	-0.1%	1.2%	2.1%	0.4%	0.0%	3.6%

East North Central	1,327	-0.1%	-0.5%	2.1%	0.3%	0.0%	1.8%
West North Central	536	-0.2%	0.3%	2.1%	0.4%	0.0%	2.6%
South Atlantic	1,569	-0.1%	-0.4%	2.1%	0.3%	0.0%	1.9%
East South Central	355	-0.2%	-0.5%	2.1%	0.2%	0.0%	1.6%
West South Central	1,938	0.0%	-0.7%	2.1%	0.3%	0.0%	1.7%
Mountain	725	0.1%	-0.5%	2.1%	0.4%	0.0%	2.1%
Pacific	2,924	0.2%	0.4%	2.1%	0.3%	0.0%	3.0%
Outlying	44	0.3%	0.9%	2.1%	0.3%	0.0%	3.6%
Facility Size (Number of 30-day Periods)							
< 100 periods	2,412	0.6%	-0.1%	2.1%	0.4%	0.0%	3.0%
100 to 249	1,611	0.4%	-0.1%	2.1%	0.4%	0.0%	2.8%
250 to 499	1,812	0.3%	-0.1%	2.1%	0.4%	0.0%	2.7%
500 to 999	1,923	0.2%	0.0%	2.1%	0.3%	0.0%	2.6%
1,000 or More	2,324	-0.1%	0.0%	2.1%	0.3%	0.0%	2.3%

Source: CY 2025 Medicare claims data for periods with matched OASIS records ending in CY 2025 (as of July 14, 2026).

Notes: The "Temporary Adjustment" column includes the value of zero because both the CY 2026 and CY 2027 payment rates already include a 3% temporary adjustment. The “CY 2027 Updated Wage Index (with 5% cap)” column reflects a 5-percent cap on wage index decreases. The "Fixed Dollar Loss (FDL) Update" column reflects a change in the FDL from 0.37 to 0.29. Due to missing Provider of Services file information (from which home health agency characteristics are obtained), some subcategories in the impact tables have fewer agencies represented than the overall total (of 10,082): totals involving facility type (only) add up to 9,895 and totals involving control type add up to 9,900.

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central-Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
Pacific=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

We received public comments on our estimated impact analysis. The following is a summary of the comments we received and our responses.

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Comment: Several commenters welcomed CMS's projected 2.4 percent aggregate increase of $420 million in CY 2027 Medicare home health payments, however, these commenters asserted that this national figure masks significant variation and shouldn't be treated as a proxy for any individual HHA's revenue change. A commenter stated that CMS's impact analysis focuses on aggregating national spending and assumes stable future utilization patterns despite individual HHAs often experiencing significantly different results due to wage index changes, case mix distribution, rural service patterns, low utilization payment adjustments, outlier utilization, and local workforce conditions. A commenter stated that these projections are a meaningful stabilizing step, but that they should not be read as evidence that current payment is excessive, as home health providers continue to face sustained labor shortages, wage and benefit inflation, transportation costs, technology and compliance obligations, and increasing patient complexity. Another commenter recommended that CMS provide additional state-level and rural-specific impact analyses to allow stakeholders to better evaluate how payment policies affect provider sustainability and beneficiary access across different geographic regions.

Response: We appreciate the commenters' concerns that the aggregate impacts may not be representative of the impacts that individual providers may face. However, we believe that our impact analysis is reflective of how HHAs are impacted by the provisions of this final rule in that we provide impacts by type of facility, urban/rural, regions and other areas of the country, and facility size. Although we acknowledge that individual providers may experience different results based on differences in such as changes in wage index or case-mix changes, LUPA payments and/or outlier payments, we believe that the information provided in table 23 is sufficient for providers to evaluate how the finalized policies will impact providers. This impact analysis is not designed to predict the exact financial result for every individual HHA. As one commenter pointed out, payment effects naturally vary by wage index area, case-mix distribution, rural location, LUPA frequency, and outlier use; however, we account for that variation through the design of the payment system itself, not through the impact analysis. We agree that a positive or stable aggregate projection doesn't by itself show that payment levels are excessive, nor does it capture agency-level cost pressures such as wage and benefit inflation, transportation costs, technology and compliance investments, and rising patient complexity. The impact analysis is not intended to answer that broader question. It estimates the effect of this rule's specific policy changes relative to current law. We separately monitor industry financial conditions, access to care, and cost trends through other channels, including the home health market basket update, MedPAC's annual reports to Congress, and ongoing engagement with industry stakeholders. The impact analysis of this final rule represents the projected effects of the changes in home health payments from CY 2026 to CY 2027 using the most recent complete data available at the time of rulemaking, in the case of the proposed rule, we used an analytic file with linked CY 2025 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2025 as of March 15, 2026. For the final rule, we used an analytic file with linked CY 2025 OASIS assessments and CY 2025 home health claims data as of July 14, 2026. Although certain events may limit the scope or accuracy of our impact analysis, because such an analysis is susceptible to forecasting errors due to other changes in the forecasted impact time-period. The nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs including the impacts to individual HHAs. We thank the commenters for their recommendations to include different types of impact analyses including, provider level impacts, state level impacts and rural specific impact analysis. We will continue to monitor the impacts of the policies finalized in this rule and may include such analysis in future rulemaking as appropriate.

2. Effects of the Changes for the HH QRP for CY 2027

Failure to submit HH QRP data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. For the CY 2023 program year, 820 of the 11,549 active Medicare-certified HHAs, or approximately 7.1 percent, did not receive the full annual percentage increase because they did not meet assessment submission requirements. The 820 HHAs that did not satisfy the reporting requirements of the HH QRP for the CY 2023 program year represent $149 million in home health claims payment dollars during the reporting period out of a total $16.4 billion for all HHAs.

We proposed to revise the HH QRP data submission deadlines beginning with the CY 2027 HH QRP. We also proposed to revise the HH QRP OASIS and HHCAHPs annual payment update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). We proposed revisions to regulatory text in support of rule proposals to improve digital transfer of information during the reconsiderations process. Finally, we solicited public comments on one Request for Information (RFI) on future measure concepts for the HH QRP. The net effect of these proposals is no change in burden for OASIS data collection.

Comment: Though we believe our proposals have no additional burden, commenters raised issues related to burden related to some proposals. Related to the OASIS submission proposal, commenters had concerns about operational and staffing challenges, administrative burden, and data validation, especially for small or rural HHAs that may struggle with staffing challenges and operational issues. A few commenters expressed concerns that providers continue to experience staffing shortages and turnover of HH staff. Some commenters that supported the proposal noted the current clinical and administrative burden around implementing OASIS all payer submissions and changing payment requirements. Several commenters encouraged CMS to establish a phased implementation or grace period to meet submission requirements, to provide flexibility for the first several data submission cycles. A few other commenters cited recent implementation of the HOPE tool to stress the benefits of a phased implementation.

Response: We appreciate the commenters' concerns about operational and staffing challenges, especially for small or rural HHAs. We do not believe that the proposal adds burden for HHA staff by changing the data submission deadline; rather, it shifts the existing workflow from 4.5 months after each quarterly data collection period to the 15th day of the second month after the end of the calendar quarter. Since workflows are in place for the necessary processes, we do not believe a phased implementation approach is necessary.

Comment: Related to the OASIS and HHCAHPS APU proposals, commenters also raised concerns of burden. Commenters who supported the APU calendar updates with concerns commonly raised the issue of burden associated moving to a new APU calendar. They noted that to ensure an effective transition would require investments in quality assurance resources, data analytics, clinical education, software systems, and compliance oversight.

Response: We thank commenters for outlining potential burden issues related to the APU update proposals. We will provide guidance around the implementation of this proposal that we believe will limit costs associated with the transition and implementation of calendar year APU reporting. We also do not anticipate changes in scoring methodologies associated with this transition to calendar year reporting of APU calculations.

3. Effects of the Expanded HHVBP Model

In the CY 2022 HH PPS final rule (88 FR 77676), we estimated that the expanded HHVBP Model would generate a total projected 5-year gross FFS savings of $3,376,000,000. Given that we did not propose any expanded HHVBP Model-specific changes in the proposed rule, these estimates are unchanged.

4. DMEPOS Encounter Requirements for Identical Replacement Items

This proposed provision would clarify that a face-to-face encounter and related documentation, as described in 42 CFR 410.38, is not necessary to support the payment of replacement DMEPOS items. The fiscal impact of this clarification cannot be estimated as this rule only identifies whether a face-to-face encounter is required for payment for replacement of DMEPOS items. Given the volume of Medicare beneficiaries and associated claims for payment, we do not audit all claim submissions for compliance with Medicare conditions of payment—including the face-to-face encounter. In addition, for those claims audited, it is one of many Medicare coverage requirements, and therefore delineating its compliance rate is not operationally feasible. This situation can only be identified upon medical record review, and replacements were not the sole focus of a medical review audit. Rather, varied medical review decision-making and the need for this clarification was identified anecdotally. As such, we cannot reliably forecast any cost for this limited subset of claims for replacement items.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

5. Provider Enrollment

As previously noted, we proposed a number of provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. This RIA addresses provisions that: (1) we believe will have a financial impact; and (2) will not, in our view, have such an impact but which require explanation. For those provisions not listed in this section VII.C.5. of this final rule, we do not foresee a financial impact.

a. Revocation Effective Dates

Existing § 424.535(g)(1) states that except as described in § 424.535(g)(2) and (3), a revocation becomes effective 30 days after CMS or its contractor mails notice of its determination to the provider or supplier (hereafter occasionally and collectively ''providers''). Under current § 424.535(g)(2)(i) through (xv), there are grounds for which CMS can revoke a provider's enrollment retroactively to the date the provider's non-compliance commenced. Retroactive revocation allows CMS to collect monies that have been paid to the provider since the beginning of its non-compliance. We explained in section V.C. of this final rule that we proposed to make the effective dates of all of our revocation reasons in § 424.535 retroactive. Existing revocation grounds that are currently applied prospectively but would become retroactive are listed as follows (along with their proposed retroactive effective dates):

- *§ 424.535(a)(1) (Noncompliance with enrollment requirements):* The date the non-compliance began (per CMS' or the CMS contractor's determination).
- *§ 424.535(a)(5)(b)(ii) (Noncompliance with enrollment requirements):* The date the Medicare enrollment requirement was not satisfied.
- *§ 424.535(a)(6) (Application fee noncompliance):* The date on which CMS or its contractor determines that the provider should be revoked under paragraph (a)(6).
- *§ 424.535(a)(7):* The date on which the conduct resulting the revocation occurred.
- *§ 424.535(a)(10)(i) (Document retention):* The date on which CMS or the CMS contractor determines that the provider has not complied with this retention requirement.
- *§ 424.535(a)(10)(ii) (Document access to CMS):* The day after the date by which the provider was required to furnish access.
- *§ 424.535(a)(11) (Capitalization):* The day after the date by which the provider was required to furnish the requested documentation.
- *§ 424.535(a)(14) (Abusive prescribing):* The date of the last prescription in the applicable pattern or practice.
- *§ 424.535(a)(15) (False Claims Act judgments):* The date of the judgment.
- *§ 424.535(a)(17) (Referral of debt to Treasury):* The date on which CMS referred the debt to the Department of Treasury.
- *§ 424.535(a)(18) (Revoked under different name or identifier):* The effective date of the provider's current enrollment.
- *§ 424.535(a)(19) (Undue risk):* The date on which CMS or its contractor determines that the provider should be revoked under paragraph (a)(19).
- *§ 424.535(a)(20) (Billing from non-compliant location):* The earliest date on the claims for the non-compliant location that are triggering the revocation.
- *§ 424.535(a)(21) (Abusive ordering, certifying, etc.):* The date of the last order, certification, referral, or prescription in the applicable pattern or practice.
- *§ 424.535(a)(22) (Patient harm):* The date of the prior action resulting in the revocation.
- *§ 424.535(a)(23) (Condition or standard noncompliance):* Under § 424.535(g)(xv)(D), the current paragraph (a)(23) revocation effective date for all standard or condition violations other than those listed in § 424.535(g)(xv)(A) through (C) is prospective; that is, it is 30 days after the date that CMS or the CMS contractor mails the revocation letter to the provider or supplier. We proposed to make these (a)(23) prospective effective dates retroactive back to the date of the violation or non-compliance (per CMS' or the CMS contractor's determination).

Table 24 contains several data categories. The first identifies those new retroactive revocation grounds for which we are able to calculate savings to the Medicare program. The second is the average annual number of revocations that occur for each of these revocation grounds. The third is the average length of time between when the non-compliance begins in these situations and 30 days after the revocation letter is sent to the provider in question. For instance, suppose a provider undergoes a change in its billing agency's address effective May 1

but fails to report it to CMS within 90 days. The provider is revoked under § 424.535(a)(9). The revocation letter is mailed to the provider on August 15, meaning the effective date under existing § 424.535(g)(1) is September 15. The period between the date of non-compliance and the effective date under current paragraph (g)(1) is thus 45 days (that is, the period between July 31 (the day after the 90-day reporting deadline) and September 15). Under our proposal, though, the provider would be ineligible for payments for services furnished during this 45-day period because its revocation would now be retroactive back to the date of non-compliance (July 31).

The last two categories address the savings that would accrue to Medicare from the proposed retroactive grounds listed in the first column. Based on internal CMS data, we calculated in the fourth column of table 24 the average amount of actual payments made to the providers in each of the table's proposed retroactive revocation reasons during the time period in the table's third column. To illustrate, table 24 indicates that 17 providers per year are revoked under § 424.535(a)(22), with the third column identifying a 95-day period. The fourth column reflects the average annual payments each of these 17 providers receive during their respective 95-day periods (or $20,586).

The fifth column estimates the total savings for each of our proposed retroactive revocation reasons—specifically, we multiplied the figures in the second column by those in the fourth. Using our § 424.535(a)(22) example, the total annual savings figure is $349,962 (or 17 × $20,586).

We used this same approach when calculating projected savings for the new retroactive revocation grounds we finalized in the CY 2026 HH PPS final rule (90 FR 55342).

TABLE 24: RETROACTIVE REVOCATION GROUNDS

New Retro Revocation Basis Under § 424.535	Number of Revocations Per Year	Estimated Length of Time (in Days) Between When the Non-Compliance Occurs and 30 Days After the Revocation Letter is Sent	Average Payments Made to the Revoked Provider During Estimated Non-Compliance Time Period ($)	Estimated Total Annual Savings (Number of Revocations x Average Payments) ($)
(a)(1)	10	90	225,896	2,258,960
(a)(5)(ii)	20	45	1,955,854	39,117,080
(a)(10)	19	65	187,087	3,554,653
(a)(13)(i) (for DEA certificate revocations and suspensions)	9	90	18,743	168,687
(a)(14)	1	100	4,721	4,721
(a)(17)	6	730 (2 years)	892	5,352
(a)(19)	255	30	143,153	36,504,015
(a)(22)	17	95	20,586	349,962
TOTALS & AVERAGES	**337**	**156**	**N/A**	**81,963,430**

Accordingly, we project annual savings of $81,963,430 stemming from our retroactive revocation proposals.

b. Expanded and New Revocation Reasons

As discussed in section V.B. of this final rule, we proposed the following expanded and new revocation grounds:

- We would expand existing § 424.535(a)(4) to permit revocation if the provider submits false or misleading information on or associated with any provider enrollment-related CMS or Medicare form (including forms created by and/or submitted to CMS contractors). Section 424.535(a)(4) would no longer be limited to false or misleading information on the enrollment application.
- Revised § 424.535(a)(16) would include a new revocation ground permitting enrollment if the provider—or any owner, managing employee, managing organization, officer, or director thereof—was convicted of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.
- New § 424.535(a)(24) would permit revocation if CMS determines that the provider's enrollment presents a high risk of fraud, waste, or abuse due to the provider's location within a limited geographic area that has an excessive number of providers and suppliers.
- New § 424.535(a)(25) would permit revocation if CMS determines that the HHA, hospice, or DMEPOS supplier did not comply with the provisions and requirements of, as applicable, § 424.550(b) or § 424.551.

As we cannot predict the number of instances in which we would utilize these new and expanded grounds, we are unable to establish a savings estimate.

c. Preclusion List

The preclusion list is a compilation of providers that are prohibited from receiving Medicare Advantage or Part D payments. One ground for which a provider can be placed on the preclusion list if it has a felony conviction with the past 10 years. We proposed to expand this to include felony convictions of the provider's owner, managing employee/organization, or corporate officer/director. As with our proposed revocation provisions, though, we are unable to establish a savings estimate for this expansion. This is because we cannot predict the number of instances where we would place a provider on the preclusion based on an owner's, managing employee's, etc., felony conviction.

d. Hospice Reactivations

Section 424.540(b)(3)(i) states that an HHA whose Medicare billing privileges are deactivated under § 424.540 must obtain an initial State survey or accreditation before its Medicare billing privileges can be reactivated. We proposed to expand § 424.540(b)(3)(i) to include hospices.

An average of roughly 226 hospices each year seek to reactivate their enrollments. Although hospice surveys and accreditation costs vary widely, we project—solely for purposes of this estimate—that the average cost would be $6,000. This results in an annual cost of our proposed § 424.540(b)(3)(i) expansion of $1,356,000. We welcomed comments on this projection.

e. Conclusion

We do not believe our proposals would negatively impact access to care,

including in rural areas. We have promulgated numerous denial and revocation provisions in prior CMS provider enrollment regulations with no such impact, and we do not anticipate that our new denial and revocation grounds (and expansions of existing ones) would result in large numbers of denial and revocations.

We solicited comment from interested parties regarding any additional costs that may arise from our proposed enrollment provisions.

The following is a summary of the comments we received on our RIA burden projections and our responses.

Comment: A number of commenters stated that CMS underestimated the burden of its proposed provider enrollment provisions. They maintained that providers would need to expend additional resources to, for example: (1) gather and report information, such as affiliations and managing employees, which may only be attainable from outside parties; (2) review and consistently monitor personnel and affiliates for adverse history; (3) revise policies and systems; (4) train personnel; (5) involve compliance and legal staff; and (6) retain documentation demonstrating reasonable efforts to comply. They stated that CMS should withdraw its proposed provider enrollment provisions and conduct a revised burden analysis of the cumulative administrative and financial burden imposed across all provider sectors. This should include separate cost analyses: (1) for each of the foregoing activities as well as others that providers will incur; and (2) broken down by provider type (including, a commenter requested, physician practices, along with a separate RFA for these suppliers) and not simply limited to HHAs and hospices. A commenter stated that the SNF Guidance regarding the reporting of data required under section 1124(c) of the Act [62] is indicative of some of the costs that providers will incur under our proposals.

Response: We appreciate these comments. We addressed several of these matters in the preambles to the CY 2027 HH PPS proposed rule and section V.C. of this final rule. We discuss them again here and at somewhat greater length.

First, we reiterate our statement in the preamble and ICR sections of this final rule regarding the revised ''managing employee'' definition. The revision merely clarifies that such individuals have always qualified as managing employees, which is why we did not include a burden estimate. It would also seemingly increase compliance with a requirement that already exists. While the resulting costs (and benefits) would be attributable to this final rule, quantification is extremely challenging and infeasible because, as stated in the ICR section, the scope of each provider's or supplier's individual reporting circumstances will likely vary widely.

Second, we do not anticipate requesting disclosure of the affiliation data in § 424.519. No reporting burden is thus implicated.

Third, and outside of an explicit reporting requirement, §§ 424.500 through 424.575 have never required providers and suppliers to: (1) perform research to determine whether an associated party (for example, an owner or managing employee) has a criminal conviction, suspension, etc.; or (2) regularly monitor their staff for such actions. Any decision to conduct these functions is the provider's own. Indeed, CMS has promulgated numerous enrollment provisions over the past two decades that added or expanded grounds for which we can deny or revoke enrollment based on certain associates' actions. We did not include research costs in our burden estimates for those rules, but in those cases commenters did not request us to do so. Moreover, any burden estimate would be infeasible because we have no means of knowing which and how many providers would engage in this research.

Fourth, cost estimates for staff training, compliance guide updates, consulting, etc., are challenging to quantify for a variety of reasons, including because they have not been part of previous analyses of provider enrollment regulations. Also of note is that these are not requirements for enrolling and maintaining enrollment in Medicare. We believe that in the provider enrollment realm, these activities are done—if they are done at all—on the provider's own volition. As such, we cannot know or even roughly estimate: (1) how many providers have compliance guides and, for those that do, what, if any, revisions would be necessary and to what degree; (2) the degree to which staff training would be necessary and the number of impacted personnel or providers; and (3) which providers would need to consult with outside parties.

It is true that in the November 16, 2023, final rule wherein we implemented requirements for SNFs to report certain data on their associated parties, the ICR wage burden included (but was not limited to) the BLS hourly rate for attorneys; we believed that SNFs would consult with legal counsel when preparing data for disclosure. However, this was limited to the specific data reporting requirement. In this same vein, the SNF Guidance that the final previous commenter referenced addressed activities involving the research and disclosure of the affiliation data. The present final rule does not require research or new information disclosures.

Fifth, CMS does not break down costs by provider type in its provider enrollment rulemaking except if the requirement: (1) is specific to a particular provider type (such as DMEPOS accreditation); or (2) involves the completion of Form CMS–855 applications by different categories of providers (for instance, certified providers that complete the Form CMS–855A). Even in the latter case, though, the Form CMS–855 estimate is per application type, not provider type. The fact is that for enrollment provisions pertaining to all or most provider and supplier types, CMS has no means of sub-dividing, individually assessing, and predicting the costs and impacts for each of the more than 35 provider and supplier types that enroll in Medicare—effectively, 35 separate RIAs and RFAs—which is why we have not previously done so and have instead utilized an overall estimate.

In sum, we believe that our ICR and RIA estimates reflect an accurate and fair assessment of the burdens associated with our proposals. Most respectfully, we further add that stakeholder disagreement with CMS' assessment that no burden exists does not mean that CMS failed to consider the possible burden, for we indeed did.

Comment: A commenter asked CMS to include a small, solo, and rural provider impact analysis in the RIA and RFA sections that outlines the effect of retroactive revocations and the 15-day reduced claims submission period for revoked providers.

Response: We outlined the retroactive revocation impact in the RIA—specifically, $82 million in transfers from revoked providers and suppliers to the federal requirement. However, we have no way to estimate how much of this will involve small or rural providers because we cannot predict how many of these revoked providers will fall into that category. Insofar as the reduction of the § 424.535(h) claims submission timeframe from 45 days to 15 days, we do not anticipate a burden because only the timeframe is changing, not the requirement that the pre-revocation claims be submitted within a fixed period after revocation.

[62] *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos.*

Comment: A commenter stated that the use of a CMS-designated fingerprinting contractor will increase costs for providers and should be calculated in the RIA.

Response: CMS has utilized a fingerprinting contractor for several years. It is not a new requirement, and our revision to § 424.518(d) merely reflects existing practice. Hence, there is no burden change.

Comment: A commenter recommended that CMS state the burden estimate separately for simple and complex enrollments rather than as a single average.

Response: While we appreciate this comment, there is no means of formally classifying in rulemaking a particular enrollment as ''simple'', ''complex'', or something else.

Comment: A commenter stated that our proposed enrollment provisions should be assessed for their population-level, not merely provider-level, effects. The commenter cited the potential impact on the local care ecosystem, with cascading effects on hospital readmission rates, unmet skilled nursing needs, and caregiver strain that are measurable at the population level. The commenter stated that a legal epidemiology framework counsels CMS to pair any expansion of enrollment authority with a published, stratified impact analysis—by geography (such as rural/urban status), county, agency size, and the dual-eligible share of the patient panel—before finalization. The commenter recommended that this be included in the final rule. Another commenter stated that the RIA did not consider the unintended cascading consequences across Medicare enrollments.

Response: We have no means of estimating the impact of our provider enrollment proposals by county, provider size, percentage of dual-eligible population, etc. We cannot predict, for example: (1) the counties in which providers may be revoked or the patient populations of those providers; or (2) the locations and sizes of hospices that will be deactivated, seek to reactivate their billing privileges, and then undergo a State survey or accreditation.

We also explained in the proposed rule that we do not anticipate beneficiary access issues arising from our proposals, in part because (1) revocations will be few; (2) there are well over 2 million enrolled providers and suppliers; and (3) we have not seen beneficiary access problems—nor, for that matter, the cascading effects the commenters cite—arise from any of our prior enrollment rulemaking efforts.

Comment: A commenter requested that CMS perform an impact analysis specific to non-profit and community-based providers.

Response: We are unable to perform a separate, sub-categorized analysis for non-profit and community-based providers because—consistent with our response to the previous comment—we cannot gauge, for instance, what percentage of providers revoked under a particular new revocation ground will be non-profit or community-based.

Comment: A commenter stated that the RFA should address the rule's enrollment—enrollment enforcement provisions, including addressing and implementing alternatives such as: (1) prospective effective dates; and (2) exceptions from §§ 424.530(a)(22) and 424.535(a)(25) for certain CIMOs (for example, those involving joint ventures);

Response: We addressed prospective effective dates in the ''Alternatives Considered'' section of the proposed rule and explained why we believed that making all of our revocation reasons retroactive was necessary. As for §§ 424.530(a)(22) and 424.535(a)(25), we did not consider exceptions to their applicability and, respectfully, were not required to. Indeed, in response to comments received, we address in the preamble to this final rule the bases for our declination to establish said exemptions.

Comment: A commenter stated that CMS should identify the program integrity benefit attributable to each proposal, rather than relying on aggregate savings from retroactive revocations.

Response: We refer the commenter to the preambles to the proposed rule and this final rule, wherein we explain the program integrity reasons for our proposals and what we believe they will help achieve—specifically, the benefits they will furnish.

Comment: A commenter stated that CMS should publish an analysis outlining anticipated revocation and denial rates by the dual-eligible share of each affected provider's patient panel. Another commenter requested estimates on the number of providers that would be placed on the preclusion list based on our revised ''preclusion list'' definition.

Response: As we explained in the proposed rule, we cannot predict the number of denials and revocations that would occur under our new provisions because they are new; we have no historical data upon which to base a projection. The same is true for our revisions to the ''preclusion'' list definition in §§ 422.2 and 423.100; we are unable to estimate how many providers would be placed on the preclusion list as a result.

Comment: A commenter believed that CMS understated the burden of its hospice reactivation survey requirement. The commenter stated that in addition to direct survey or accreditation fees, hospices may incur significant consultant expenses, staff preparation time, and policy and documentation review costs.

Response: The burden we calculated is consistent with the basic formula we used for our DMEPOS reaccreditation provisions in the CY 2026 HH PPS proposed rule.

Comment: A commenter stated that CMS should perform a proposal-specific assessment of the affected universe, estimated frequency of action, compliance and monitoring costs, implementation burden, and beneficiary access implications. Several other commenters stated that CMS must assess the impact on a provision-by-provision basis. Additional commenters contended that the RIA contained little analysis regarding the impact and burden of our proposals on providers.

Response: We disagree. We considered the possible impact of each provision we proposed. We made clear in the proposed rule's ICR and RIA sections that for those provisions not addressed at further length in those sections, we did not anticipate a burden. There were some provisions that we felt would not impose a burden but that we believed required additional explanation in the ICR and RIA sections, which we provided. For the remaining provisions, we outlined the applicable burden. Every provision was therefore reviewed for possible effect.

Comment: A commenter noted CMS's conclusion in the proposed rule's RIA that the proposed denial and revocation grounds will not significantly affect providers, suppliers, or beneficiaries because revocations are infrequent, only a small share of providers are revoked, and CMS expects to use the authorities only when appropriate. The commenter contended that this does not take into account: (1) our newly proposed grounds; (2) expanded affiliation disclosures; (3) the revision to our ''managing employee'' definition; (4) the extension of reapplication bars; and (5) revised § 424.535(i).

Response: We indeed took into account these items (other than revised § 424.535(i), which we are not finalizing), and we maintain our position that there will not be a significant impact on providers, suppliers, and beneficiaries for the reasons we cited. We also refer the

commenter to section V.C. of this final rule for further discussion on this issue.

Comment: A commenter suggested that CMS solicit data on (1) the number of existing shared location arrangements; (2) the prevalence of shared vendors and management relationships; and (3) the operational cost of identifying historic affiliations and newly reportable personnel.

Response: While we appreciate these suggestions, we respectfully do not believe solicitation of this information is necessary—especially the second and third elements because, again, we do not anticipate asking providers to furnish the data referenced in § 424.519, and the clinical personnel referenced in the revised ''managing employee'' definition must already be reported.

Comment: A commenter contended that because the proposed impact analysis addressed only home health and related entities, CMS should: (1) publish an RFA targeted towards their effect on small physician practices; and (2) seek public comment on that analysis before finalizing any of the enrollment provisions. If applicable, CMS should state the basis for any certification that these provisions will not have a significant economic impact on a substantial number of small entities, specifically physician practices.

Response: The provider enrollment RIA took into account all provider and supplier types, not simply HHAs. Also—and similar to our previous statements regarding the inability to establish separate cost estimates for each provider type—we respectfully cannot craft an RFA targeted towards only a specific provider type given the need to address all potentially impacted providers and suppliers.

We do not believe our provider enrollment provisions will have a significant economic impact on a substantial number of small businesses, including physician practices. We previously mentioned that: (1) the reporting of clinical managing employees is already required; (2) we do not plan to request the disclosure of affiliation data under § 424.519; and (3) revocations under our proposed provisions will be comparatively few in number. Given that there are well over 2 million enrolled providers and suppliers, the impact of these provisions on the entire provider universe will thus be very small—even when accounting for the potential (though uncalculatable) effects of our reapplication bar expansion and new denial grounds, which we also believe will impact few providers and suppliers.

Comment: A commenter expressed concern that CMS: (1) assessed beneficiary access according to the number of providers that would remain enrolled; and (2) accordingly concluded that beneficiary access would not be impaired. The commenter believed that access is often localized and specialty specific. Even if 2 million providers remain enrolled, the commenter maintained, a patient that is receiving care from a provider that is later revoked could lose that care, especially if that provider is the only one in a rural area.

Response: While we appreciate the commenter's concern, we believe that—for purposes of our provider enrollment provisions—beneficiary access must be gauged on a national, overall level. This is how we have addressed patient care impact in past provider enrollment regulations, and we believe is the best means of evaluating the provisions' true effect on beneficiaries. Moreover, even in the event that a beneficiary can no longer see a revoked physician, our experience is that they have been able to obtain care elsewhere considering, again, the millions of existing providers.

Comment: A few commenters stated that our provider enrollment proposals are inconsistent with Presidential Executive Order 14192 (''Unleashing Prosperity Through Deregulation,'' (90 FR 9065), which direct agencies to reduce burdens.

Response: We refer stakeholders to section IX.J. of this final rule for a discussion of the rule's interaction with this order.

After reviewing the public comments, we are finalizing our p provider enrollment RIA, though the signage requirement burden in the ICR statement will be included in the accounting statement.

6. DMEPOS Coverage of External Infusion Pumps

This final rule expands the scope of the Medicare Part B benefit for DME by revising the interpretation of the ''appropriate for use in the home'' requirement in the definition of DME at 42 CFR 414.202 for certain drugs or biologicals infused in the home that fulfill specific requirements outlined in the statute. Since drugs or biologicals administered through an external infusion pump that is classified as DME can be covered under the Medicare Part B benefit as supplies necessary for the effective use of the external infusion pump, expanding the scope of the DME benefit has the effect of expanding coverage to drugs or biologicals that were not previously covered through home infusion. At this time, we expect that there is only one drug that did not previously meet the requirements for coverage through home infusion but does meet the requirements as modified by section 6222 of the Consolidated Appropriations Act, 2026, and will be used by a sufficient number of Medicare beneficiaries to warrant consideration: patisiran. While there may be other drugs that meet the basic requirements for coverage, we believe that use through home infusion would be negligible. In addition, it is possible that pharmaceutical makers may introduce new drugs or biologicals, or reformulate existing products, that will qualify for coverage under this expanded scope, but we cannot predict or estimate what impact this may have.

This expanded scope mirrors changes that had been proposed in 2020 rulemaking, ''Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)'' (85 FR 70358). At that time, we had estimated Medicare savings of roughly $3 million per year. Since then, claims data show that significantly fewer beneficiaries have been receiving patisiran infusions. Claims data for 2025 show that only 69 beneficiaries received patisiran infusions. As we noted in the previous proposed rule, the primary impact of this expanded scope relates to the difference in beneficiary cost sharing between infusion therapy received in an outpatient clinic setting and home infusion therapy: cost sharing for each outpatient infusion is the normal 20 percent Part B coinsurance limited to the Part A deductible ($1,736 in 2026), while cost sharing for home infusion therapy is not limited.

Claims data show that the annual cost of patisiran for each beneficiary receiving it in 2025 was approximately $313,000. Based on the typical infusion every three weeks, these patients likely received 17 infusions each year. When received in an outpatient setting, the capped cost sharing would apply, so each beneficiary would pay $1,736 per infusion or approximately $29,500 for the year. If, instead, patisiran was received as home infusion, cost sharing for the patisiran alone would be approximately $3,700 per infusion, or $62,900 per year. There would also be additional charges for home infusion (for example, home infusion services, pump rental, other supplies) that exceed the charges for outpatient infusion, and CMS believes these would cost Medicare approximately $7,000 per beneficiary per year, and the beneficiary approximately $2,000 in cost sharing (additional charges for outpatient infusion would cost Medicare approximately $4,000). Taken together,

a beneficiary that receives patisiran through home infusion instead of outpatient infusion would save Medicare approximately $31,000 per year because of the higher cost sharing (the beneficiary would pay an additional $34,000) offset by the higher total cost of home infusion (additional $3,000 net cost to Medicare).

Given this substantial cost sharing difference, we believe it is unlikely that beneficiaries would consider home infusion for patisiran unless they are either enrolled in Medicaid or have purchased Medicare supplement insurance (Medigap). While CMS does not directly track how many beneficiaries have enrolled in private Medigap plans, a recent report from the Kaiser Family Foundation (''Key Facts About Medigap Enrollment and Premiums for Medicare Beneficiaries,'' 2024. Retrieved from *https://www.kff.org/medicare/key-facts-about-medigap-enrollment-and-premiums-for-medicare-beneficiaries/*) suggests that approximately 40 percent of original Medicare beneficiaries have Medigap plans. CMS data show that approximately 17 percent of Medicare beneficiaries are also enrolled in Medicaid. CMS has no practical way of knowing, specifically, whether beneficiaries receiving infusion therapy are more or less likely than the overall Medicare population to have non-Medicare insurance that limits the impact of Medicare cost sharing. For purposes of estimating regulatory impact, we assume that approximately one-third of beneficiaries receiving patisiran would not consider home infusion because of the higher cost sharing. Of the remainder, we estimate that approximately 50 percent may not switch to home infusion, either because they prefer to receive it in an outpatient setting or because, in consultation with their medical providers, they have concluded that home infusion is not appropriate for them. Therefore, we estimate that roughly one-third of beneficiaries receiving patisiran would switch to home infusion therapy, although there is substantial uncertainty associated with this estimate. Based on this estimate of the number who might switch, and the savings to Medicare of $31,000 per beneficiary who switches, we estimate initial aggregate savings to the Medicare program would be approximately $800 thousand per year.

We note that many Medicare beneficiaries have chosen to receive their Medicare benefits through Part C (Medicare Advantage). The differences in cost sharing discussed here apply strictly to those who have chosen original Medicare (Parts A and B). Medicare Advantage plans set their own cost sharing policies, and we have no way to estimate whether and how these changes in coverage for home infusion therapy would lead Medicare Advantage plans to change their policies and the cost sharing beneficiaries may face in different settings.

We also note that, by definition, infusion drugs that were not previously covered by Part B in the home infusion setting would have been covered by Part D. However, the drugs that are covered by this new benefit require infusion under the supervision of a medical professional, and the service charges related to such supervised infusion, together with rental of the infusion equipment, would not have previously been payable under Part B or Part D. Therefore, we do not believe that a significant number of beneficiaries would be switching from Part D coverage to this new benefit under Part B, given the significant out of pocket payments that would have been required.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters provider feedback regarding the potential impacts of the expanded DME benefit expansion for infusion pumps and drugs. Specifically, commenters raised concern that the higher cost sharing related to home infusion would impact Medicaid and Medicare Supplement Insurance (Medigap) carriers, and we did not adequately explore these impacts.

Response: We appreciate the comments regarding the potential impacts of the expanded DME benefit. As discussed in this section, the impact of the expanded benefit will depend on the number of drugs that qualify for coverage and the number of beneficiaries who elect to receive infusion therapy in the home. We have described in detail the cost sharing implications for a drug that we believe will be covered under this benefit, and we recognize that there may be others covered under this benefit. However, we do not know at this time which other drugs may be covered now or in the future, what the cost of these drugs would be, and how many beneficiaries would avail themselves of the opportunity to receive the drugs through home infusion. Therefore, we cannot specifically identify what the impact may be to Medicaid or Medigap carriers.

7. DMEPOS Competitive Bidding—Country of Origin

As explained earlier, for the DMEPOS CBP, we will request to revise the collection currently approved under OMB Control Number 0938–1408 (CMS–10744) to collect from DMEPOS Competitive Bidding contract suppliers the country of origin for the lead items furnished during the DMEPOS CBP contract's period of performance.

Specifically, contract suppliers under a DMEPOS CBP contract will continue to be required as a term of their contracts to maintain the accuracy of the product information (manufacturer name, model name, and model number) for the lead item the supplier furnishes on Form C, and would now be required to also include the country of origin for each product it reports on a new ''country of origin'' field on Form C. Contract suppliers are required to submit Form C once every 6 months during January and July throughout the DMEPOS Competitive Bidding Program Contract's period of performance, and Form C includes an attestation that all the reported information is accurate and up to date. This attestation would need to be completed to fulfill a Form C submission requirement. The details for this update to Form C would be included in advance of the required reporting through an updated CMS–1074.

As done historically with the product information reported on Form C by a contract supplier, the reported country of origin information would be populated on the Medicare Supplier Directory for the contract supplier during the contract period of performance. This information would allow beneficiaries and interested parties to learn the country from which the DMEPOS item originated, if interested.

Contract suppliers should be able to identify the country of origin based on the markings on the product for the lead item. Under US Customs and Border Protections rules (19 CFR 134.11, 134.46), imported goods must be properly marked with: ''Made in [Country],'' unless an exemption applies (for example, an item that is incapable of being marked, like a catheter), as explained at 19 CFR 134.32. To correctly identify the country of origin for a product in the absence of a marking or to verify a marking, contract suppliers may need to refer to available documentation from the manufacturer or distributor indicating the country of origin for its product, which could include a combination of the following: manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification.

We did not receive public comments on the regulatory impact analysis of this provision, and therefore, we are finalizing this section as proposed.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of commenters will be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach used in estimating the number of entities reviewing this proposed rule. We did not receive any public comments specific to our solicitation.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule. Therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

We sought comments on this assumption. We did not receive any public comments specific to our solicitation.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $119.10 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 4.61 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $549.05 (4.61 hours × $549.05). Therefore, we estimate that the total cost of reviewing this regulation is $360,726 ($549.05 × 657) [657 is the number of estimated reviewers, which is based on the total number of unique commenters from this year's proposed rule].

E. Alternatives Considered

1. HH PPS

In section II.C.1.e. of this final rule, we describe that to achieve budget neutrality as required by law, we calculated an illustrative permanent adjustment by determining what the 30-day base payment amount should have been in CYs 2020, 2021, 2022, 2023, 2024, and 2025 in order to achieve the same estimated aggregate expenditures as obtained from the simulated 60-day episodes as required by statute. We proposed not implementing a permanent adjustment to the CY 2027 30-day base payment rate. One alternative to not proposing a permanent adjustment included proposing a −1.024 percent permanent adjustment for CY 2027 if we could show that the observed behavior changes in CY 2025 claims could be directly attributed to the implementation of the PDGM as we discussed in the CY 2026 final rule (90 FR 55366 through 55367). However, we continue to believe that implementing a permanent adjustment would not be appropriate because our analysis suggests that the majority of the behavior change related to the implementation of the PDGM occurred in CYs 2020 through 2022 and that the behavior change observed in CYs 2023 through 2025 is related to factors other than the implementation of the PDGM.

We proposed implementing a temporary adjustment to continue reconciling retrospective overpayments from CYs 2020, 2021, 2022, 2023, 2024 and 2025, as discussed in section II.C.1.f. of this final rule. Section 1895(b)(3)(D)(iii) of the Act gives CMS the authority to make a temporary adjustment in a time and manner appropriate through notice and comment rulemaking.

We considered not proposing implementing a temporary adjustment. However, due to the growing temporary adjustment amount calculated from CYs 2020 through 2025, to delay the implementation of a temporary adjustment would lead to many more years of reductions to the payment rate to reach budget neutrality. Another alternative would be to apply a temporary adjustment factor to the CY 2027 payment rate that would recoup the full calculated temporary adjustment dollar amount, to date, of $4.9 billion. However, we believe that applying a temporary adjustment factor accounting for the temporary adjustment dollar amount of $4.9 billion to the CY 2027 payment rate may adversely affect HHAs given the magnitude of this adjustment to the payment rate in a single year. Although we are not establishing a timeframe to recoup the calculated temporary adjustment dollar amount of $4.9 billion (to date), we believe it is prudent to continue implementing an adjustment to account for some of this amount to slow its continued growth. Postponing any collection of this large dollar amount would lead to an extended duration of temporary adjustments or larger reductions to the payment rates in future years to reach budget neutrality sooner.

Therefore, we believe it is best to finalize implementing a temporary adjustment decrease of 3.0 percent to the CY 2027 base payment rate.

2. HH QRP

With regard to the proposal to revise the HH QRP assessment data submission deadline from 4.5 months to no later than the 15th day of the second month after the end of each quarter, we considered keeping the deadline unchanged. We determined that the revised timeframe is a reasonable amount of time for HHAs to submit data and make any necessary corrections, and that the benefits of this shortened timeframe include making the data timelier and more actionable which increases the value of publicly reported data both for consumers and their families and for HHAs to use in their quality improvement activities.

With regard to the proposal to revise the HH QRP OASIS and HHCAHPs annual payment update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31), we believe this update will provide clarity to HH payment updates and facilitate the alignment of the HH QRP pay-for-reporting policies with other HH payment policies without adding burden to providers.

3. Provider Enrollment

There were two principal alternatives we considered. First, we considered retaining the existing prospective effective dates for some of our revocation grounds. However, as explained in section V.C. of this final rule, we do not believe that providers are entitled to payment for services and items furnished while non-compliant. Second, and in a similar vein, we contemplated adding no more than a few denial grounds as bases for a reapplication bar. Yet because of the concerning provider conduct behind some denials, we believe we must have the discretion to bar such providers from repeatedly attempting to enter Medicare by submitting multiple applications.

4. DMEPOS Competitive Bidding—Country of Origin

We considered having all DMEPOS suppliers submit the country of information for their product at the time they submit a bid for the DMEPOS CBP, instead of first submitting it on day one of their DMEPOS CBP contract, if awarded. However, this would have

presented two issues. First, because the purpose is to make the country of origin available to beneficiaries and interested parties on the Supplier Directory, it would be unnecessary to require all bidders to submit this information at the time they submit a bid when only a subset of bidders will ultimately receive a DMEPOS CBP contract (and have its information available on the Supplier Directory). Secondly, we believe it would be unnecessary to require this information at the time of bid submission, approximately 1 year before contracts are awarded, as it would not be used in the bid evaluation process. As a result, we believe it is most appropriate that only contract suppliers be required on a routine basis to submit accurate and up-to-date country of origin information for its products on Form C.

F. Accounting Statement and Table

Consistent with OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf*) in table 25, we have prepared an accounting statement showing the classification of the impacts associated with the provisions of this final rule.

TABLE 25: ACCOUNTING STATEMENT

HH PPS (FROM CY 2026 TO CY 2027)		
Category	**Primary Estimate**	
Annualized Monetized Transfers	$415 million	
From Whom To Whom	Federal Government To Medicare HHAs	
PROVIDER ENROLLMENT PROVISIONS (CY 2027)		
Transfers		
Category	**Primary Estimate**	
Annualized Monetized Transfers from New Retroactive Revocation Reasons	-$82 million	
From Whom To Whom	Federal Government To Medicare Providers and Suppliers	
Category	**Primary Estimate**	
Annualized Monetized Transfers for Reactivating Hospices	$1.4 million	
From Whom to Whom	Hospices to State Survey Agencies or Accrediting Organizations	
Costs		
Category	**Primary Estimate**	**Discount Rate**
Signage Requirement Costs for Providers and Suppliers	$13.9 million	3%
	$12.4 million	7%
DMEPOS COVERAGE OF EXTERNAL INFUSION PUMPS (CYs 2027-2031)		
Category	**Primary Estimate**	**Discount Rate**
Annualized Monetized Transfers	-$1.9 million	3%
	-$2.1 million	7%
From Whom To Whom	Federal Government To Beneficiaries	
Category	**Primary Estimate**	**Discount Rate**
Annualized Monetized Transfers	$1.22 million	3%
	$1.34 million	7%
From Whom To Whom	From Beneficiaries To DME and Home Infusion Suppliers	

G. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. In addition, HHAs are small entities, as that is the term used in the RFA. Individuals and States are not included in the definition of a small entity.

The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business economy. We utilized the NAICS U.S. industry title ''Home Health Care Services'' and corresponding NAICS code 621610 in determining impacts for small entities. The NAICS code 621610 has a size standard of 19 million [63] and approximately 96 percent of HHAs are considered small entities. We estimate that almost all home infusion therapy suppliers are, similarly, small entities. Table 26 shows the number of firms, revenue, and average revenue per firm for the home health care services category (NAICS 621610). Table 27 shows the number of nonemployer establishments, total, and average revenue per nonemployer establishment.

[63] *https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023.xlsx.*

TABLE 26: NUMBER OF FIRMS, REVENUE, AND AVERAGE REVENUE PER FIRM OF HOME HEALTH CARE SERVICES FOR NAICS CODE 621610

NAICS	NAICS Description	Enterprise Size ($1,000)	Number of Firms	Receipts ($1,000)	Average Receipts Per Firm ($1,000)
621610	Home Health Care Services	<100	6,361	232,967	$37
621610	Home Health Care Services	100-499	7,099	1,869,713	$263
621610	Home Health Care Services	500-999	3,866	2,829,374	$732
621610	Home Health Care Services	1,000-2,499	5,218	8,370,496	$1,604
621610	Home Health Care Services	2,500-4,999	2,560	8,833,076	$3,450
621610	Home Health Care Services	5,000-7,499	885	5,275,636	$5,961
621610	Home Health Care Services	7,500-9,999	450	3,789,016	$8,420
621610	Home Health Care Services	10,000-14,999	466	5,256,982	$11,281
621610	Home Health Care Services	15,000-19,999	235	3,621,448	$15,410
621610	Home Health Care Services	>20,000	1,058	73,271,709	$69,255
621610	Home Health Care Services	Total	28,198	113,350,417	$4,020

Source: Data obtained from United States Census Bureau table "us_6digitnaics_rcptsize_2022" (SOURCE: 2022 SUSB Annual Data Tables by Establishment Industry) Release Date: 4/10/2025: *https://www2.census.gov/programs-surveys/susb/tables/2022/us_6digitnaics_rcptsize_2022.xlsx.*

Notes: The 'Average Receipts Per Firm' column is calculated as the Receipts ($1,000)/Number of firms. The 'Total' row represents all the home health care services firms under NAICS 621610. Overall receipts (revenue) for the 28,198 firms (NAICS 621610) are approximately $113 billion.

TABLE 27: NUMBER, TOTAL, AND AVERAGE REVENUE OF NONEMPLOYER ESTABLISHMENTS OF HOME HEALTH CARE SERVICES BY NAICS CODE 621610

NAICS	NAICS Description	Establishments With Sales, Value of Shipments, or Revenue Size of Establishments Code	Number of Nonemployer Establishments	Total Nonemployer Sales, Value of Shipments, Or Revenue ($1,000)	Average Revenue Per Nonemployer Establishment ($1,000)
621610	Home Health Care Services	All Establishments	412,098	9,525,542	**$23.115**

Source: Data obtained from United States Census Bureau table title "All Sectors: Nonemployer Statistics by Legal Form of Organization and Receipts Size Class for the U.S., States, and Selected Geographies: 2023" (SOURCE: U.S. Census Bureau, 2023 Economic Surveys) Release Date: 05/15/2025: https://data.census.gov/table?q=NONEMP2023.NS2300NONEMP&codeset=naics~62161

Notes: Estimated average revenue is calculated as Total Nonemployer Sales, Value of Shipments, or Revenue ($1,000)/Number of Nonemployer Establishments. For the total, this is the average estimated impact across all number of firms.

The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHA visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that the payment policies in this final rule will have a significant positive economic impact on a substantial number of small entities.

Specifically, we estimate that the net impact of the payment policies in this final rule will be a positive 2.4 percent impact in the aggregate for CY 2027 or approximately $415 million. As discussed in the preamble, the net increase in CY 2027 is mostly driven by the impact of the final CY 2027 home health payment update percentage and the updated FDL. Table 23 details the total percentage payment increase by number of 30-day periods and impact by facility type, size, and location. As shown in table 23, when examining the distribution of projected payment impacts across individual agency groups, a substantial share of HHAs are projected to receive a payment increase of 3 percent or more. For example, agencies in the Mid-Atlantic (360 agencies, 3.6 percent), Pacific (2,880 agencies, 3.0 percent), and outlying (44 agencies, 3.6 percent) census regions alone account for approximately 3,284 agencies. This represents roughly 33 percent of all 10,082 HHAs which are each projected to receive a total payment impact of at least 3.0 percent. Additional groups projected to receive impacts of 3 percent or more include free-standing/other government (91 agencies, 4.3 percent), facility-based proprietary (20 agencies, 3.5 percent), facility-based government (154 agencies, 3.8 percent), and several rural and urban facility subcategories. Collectively, these groups confirm that more than 5 percent of HHAs are projected to experience a payment impact of 3 percent or more. We estimate that smaller HHAs (those with less than 100 periods of care and thereby lower overall revenues) would receive a 3.0 percent payment impact in CY 2027. Also, we estimate that larger

HHAs (those with more than 1,000 periods of care and thereby higher overall revenues) would receive a 2.3 percent payment impact in CY 2027. We estimate that HHAs located in the Mid-Atlantic and outlying regions would receive the largest impact reflecting a 3.6 percent payment impact. The East South Central and West South Central region would receive the lowest impact reflecting a 1.6 and 1.7 percent increase respectively.

In summary, the payment policies in this final rule will increase Medicare payments to HHAs, with small agencies receiving a slightly larger percentage increase than large ones. We solicited comments on this RFA analysis on small entities and did not receive any public comments.

Regarding options for regulatory relief, we note that section 1895(b)(3)(D)(i) of the Act requires CMS to annually determine the impact of differences between the assumed behavior changes finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56455) and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Additionally, section 1895(b)(3)(D)(ii) and (iii) of the Act requires us to make permanent and temporary adjustments to the payment rate to offset for such increases or decreases in estimated aggregate expenditures through notice and comment rulemaking. While our analysis of claims suggests that the majority of the behavior change related to the implementation of the PDGM occurred in CYs 2020 through 2022 and that the behavior change observed in CYs 2023 through 2025 is related to factors other than the implementation of the PDGM, we determined that it was not necessary to implement a permanent adjustment because we do not consider behavior changes directly attributed to the implementation of PDGM. We include the calculations described in section II.C.1.f. of this final rule to illustrate the impact of differences between the assumed behavior changes and actual behavior changes if such behaviors were attributable to the implementation of the PDGM. We note that the law requires us to annually calculate the impact of differences between the assumed behavior changes and actual behavior changes through 2026 claims. We will also continue to reprice claims, per the finalized methodology, and make any additional adjustments at a time and manner deemed appropriate in future rulemaking.

As discussed previously in the Alternatives Considered section of this final rule, we explored alternatives to the proposed 3.0 percent temporary adjustment including proposing a temporary adjustment factor to the CY 2027 payment rate that would recoup the full calculated temporary adjustment dollar amount, to date, of $4.9 billion. However, we believe that applying a temporary adjustment factor accounting for the temporary adjustment dollar amount of $4.9 billion to the CY 2027 payment rate may adversely affect HHAs given the magnitude of this adjustment to the payment rate in a single year. We solicited comments on the overall HH PPS RFA analysis and did not receive public comments.

This rule does not affect health care enterprises operated by small government entities such as counties or towns with populations 50,000 or less. HHS generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. The RFA threshold analysis, therefore, indicates that there is not a significant economic impact on a substantial number of small entities. Furthermore, the regulation review costs mentioned previously, is de minimis and will not impose any additional burden on these small businesses. The statement of need for the various proposed policies in this rule is discussed in section VII.A. of this final rule. Additionally, the alternatives considered for the various proposed policies in this rule are discussed in section VII.E. of the final rule. We considered potential alternatives for the policies proposed in this rule, including routine technical rate-setting updates and temporary adjustment. The home health payment update percentage is established annually in accordance with existing statutory requirements of section 1895(b) of the Act. We maintain that limiting the application of the permanent adjustment to analysis of data from CYs 2020 through 2022 continues to be the most accurate application of the law. The data continues to show minimal changes that could be attributed to the PDGM implementation after CY 2022 by a large proportion of home health providers. We also continue to acknowledge the difficulty in attributing any behavior change occurring from CYs 2023 through 2025 directly to the PDGM implementation and its effects on expenditures from the other changes occurring in those years. After completing the analysis required by law, we determined that it was not necessary to apply a permanent adjustment. For the temporary adjustment, we explored alternatives to delay, reduce, or increase the temporary adjustments; however, this would delay progress on the BBA of 2018 requirement and may adversely affect HHAs if reductions to the payment rate are too high in a single year. The proposed policy is expected to increase revenue for small HHAs. Therefore, the Secretary has determined that this final HH PPS rule would have a significant positive economic impact on a substantial number of small entities.

We also mention that regarding our provider enrollment provisions, we identified several alternatives we considered in subsection VII.E.3. of this final rule. Moreover, we are not finalizing our proposed expansions of the denial and revocation grounds at §§ 424.530(a)(6), 424.530(a)(7), and 424.535(i), and have reiterated that we do not anticipate: (1) requesting the submission of the affiliation data in § 424.519; and (2) significant numbers of revocations arising from our proposals. We have therefore attempted to limit any impact on small businesses to the maximum extent possible.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA of 1995 UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100

million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately $193 million. This final rule will not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than $193 million in any 1 year.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under these criteria of Executive Order 13132 and have determined that it would not impose substantial direct costs on State or local governments.

J. Unleashing Prosperity Through Deregulation

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations. This final rule is expected to constitute a regulatory action under Executive Order 14192. The rule is estimated to result in annualized costs of approximately $2.3 million, calculated using a 7 percent discount rate and expressed in 2024 dollars over a perpetual time horizon.

K. Conclusion

In conclusion, we estimate that the provisions in this final rule will result in an estimated net increase in home health payments of 2.4 percent for CY 2027 ($415 million). The $415 million increase in estimated payments for CY 2027 reflects the effects of the final CY 2027 home health payment update percentage increase of 2.1 percent ($365 million increase), and an estimated 0.3 percent increase that reflects the effects of an updated FDL ($50 million).

L. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

VIII. Waiver of Delay in Effective Date

The Congressional Review Act (CRA) (Pub. L. 104–121, Title II) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines (5 U.S.C. 801(a)(3) and 808(2)).

We believe that further notice and public procedure are unnecessary, and that it would be impracticable and contrary to the public interest to delay the effective date of the CY 2027 HH PPS final rule for the following reasons.

If the effective date of this final rule is delayed by 60 days, the finalized HH PPS updated policies (including the HH Quality Reporting Program (HH QRP)) would not be effective as of the beginning of the payment year, and CMS would be compelled to continue to use obsolete reimbursement rates, which would disadvantage HHAs. We note that our waiver of the delayed effective date only applies to the policies that are adopted in this final rule. The DMEPOS replacement item, provider enrollment, expanded DME definition for infusion therapies and DMEPOS competitive bidding provisions will take effect as specified in the **DATES** section of this final rule.

In accordance with section 1895(b)(1)(B) of the Act, CMS annually updates the unadjusted national, standardized prospective payment rate on a calendar year basis. We typically issue the HH PPS final rule by November 1 of each year to both comply with the statutory requirement under section 1895(b)(1)(B) of the Act to annually update these payment amounts on a calendar year basis and ensure 60-days' notice so that the payment policies for these systems are effective on January 1, the first day of the calendar year to which the policies are intended to apply. The HH QRP is intended to align with the HH PPS.

In this final rule, we update Medicare home health payment rates and revise other policies that relate to the HH PPS for CY 2027. We find that, in order to comply with the statutory requirement to annually update these payment rates, we must ensure that the rule is effective no later than 1 full year after the effective date of the previous year's update (that is, January 1 of each year). Moreover, it is in the public interest to waive the 60-day delay of the effective date, so that HHAs are appropriately reimbursed starting at the beginning of the calendar year. Therefore, we find good cause exists to waive the 60-day delay in the effective date for this final rule.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 28, 2026.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Incorporation by reference, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

§ 405.400 [Amended]

■ 2. Section 405.400 is amended in the definition of ''opt-out period'' by removing the phrase ''the date the affidavit is signed'' and adding in its place the phrase ''the date the first submitted affidavit is signed''.

§ 405.450 [Amended]

■ 3. Section 405.450 is amended in paragraph (a) by removing the phrase ''renew opt-out'' and adding in its place the phrase ''cancel automatic renewal''.

§ 405.800 [Amended]

■ 4. Section 405.800 is amended by removing the term ''certified mail'' and adding in its place the phrase ''certified mail or email'' in paragraphs (a), (b)(1), and (c)(1).

■ 5. Section 405.809 is amended as follows:

■ a. Revising the section heading and paragraph (a)(1);

■ b. In paragraph (a)(2), removing the term ''revocation'' and adding in its place the phrase ''denial or revocation'';

■ c. In paragraph (b)(1) introductory text, removing the term ''Reinstates'' and adding in its place the phrase ''Approves or reinstates'';

■ d. Revising paragraph (b)(1)(i);

■ e. In paragraph (b)(1)(ii), removing the term ''reinstatement'' and adding in its place the phrase ''approval or reinstatement'';

■ f. In paragraph (b)(2), removing the term ''reinstate'' and adding in its place the phrase ''approve or reinstate''.

The revisions are as follows:

§ 405.809 Granting or reinstatement of provider or supplier billing privileges following corrective action.

(a)(1) May only submit a corrective action plan for a denial or revocation for non-compliance under §§ 424.530(a)(1) or 424.535(a)(1) of this chapter; and

* * * * *

(b) * * *

(1) * * *

(i) The effective date of the—

(A) Approval is based on the applicable timeframes described in §§ 424.520 and 424.521; and

(B) Reinstatement is based on the date the provider or supplier is in compliance with all Medicare requirements.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 6. Section 410.33 is amended by revising paragraph (g)(14)(ii) to read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * * *

(g) * * *

(14) * * *

(ii) Maintain a permanent visible sign in plain view and posts hours of operation. If the IDTF's place of business is located within a building complex, the sign must be visible at the main entrance of the building or the hours can be posted at the entrance of the IDTF.

* * * * *

■ 7. Section 410.38 is amended by adding paragraph (d)(2)(iii) to read as follows:

§ 410.38 Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS): Scope and conditions.

* * * * *

(d) * * *

(2) * * *

(iii)(A) For purposes of § 410.38(d), replacement item means an item identified by the same Healthcare Common Procedure Coding System (HCPCS) code as the original item, that has been—

(*1*) In continuous use by the same beneficiary and is at the end of its reasonable useful lifetime; or

(*2*) Lost, stolen, or irreparably damaged.

(B) Items ordered as replacement items do not require a new face-to-face encounter. All other requirements specified in § 410.38 continue to apply.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 8. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 9. Section 414.202 is amended by revising the definition of ''Durable medical equipment'' to read as follows:

§ 414.202 Definitions.

* * * * *

Durable medical equipment means:

(1) Equipment, furnished by a supplier or a home health agency that meets the following conditions:

(i) Can withstand repeated use.

(ii) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(iii) Is primarily and customarily used to serve a medical purpose.

(iv) Generally is not useful to an individual in the absence of an illness or injury.

(v) Is appropriate for use in the home except as provided in paragraph (2) of this definition.

(2) On or after April 1, 2027, an external infusion pump that meets all conditions in paragraphs (1)(i) through (iv) of this definition provided that the following criteria are satisfied:

(i) The prescribing information approved by the FDA for the home infusion drug (as defined in § 486.505) associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional.

(A) The administration or supervision of the home infusion drug must be within the scope of the health care professional's practice as specified by applicable Federal and State laws, regulations, and licensure requirements.

(B) The health care professional must be on site at the home to administer or supervise the administration of the home infusion drug.

(ii) A qualified home infusion therapy supplier (as defined in § 486.505) administers or supervises the administration of the home infusion drug in a safe and effective manner in the patient's home (as defined in § 486.505).

(iii) The prescribing information instructs that the home infusion drug be infused at least 12 times per year—

(A) Either intravenously or subcutaneously; or

(B) At infusion rates that the Secretary determines would require the use of an external infusion pump.

* * * * *

■ 10. Section 414.414 is amended by revising paragraph (d)(3) to read as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(d) * * *

(3) *Process for reviewing covered documents.*

(i) *Submission of covered documents for CMS review.* To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the

later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) *CMS feedback to a supplier with missing covered documents.*

(A) *For Round 1 bids.* CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to review the submitted covered documents and notify bidders of any covered documents that are missing or provide confirmation that all covered documents were received by the close of the bid window.

(iii) *Submission of missing covered documents.* Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 11. The authority continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 12. Section 422.2 is amended by revising paragraph (3) introductory text for the definition of ''Preclusion list'' to read as follows:

§ 422.2 Definitions.

* * * * *

Preclusion list * * *

(3) The individual or entity—or any owner, managing employee, managing organization, officer, or director thereof (as those terms are defined in § 424.502)—regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph (3) are—

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 13. The authority citation continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 14. Section 423.100 is amended by revising paragraph (3) introductory text for the definition of ''Preclusion list'' to read as follows:

§ 423.100 Definitions.

* * * * *

Preclusion list * * *

(3) The prescriber—or any owner, managing employee, managing organization, officer, or director thereof (as those terms are defined in § 424.502)—regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph (3) are—

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 15. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 16. Section 424.58 is amended by—
■ a. Revising paragraph (c)(1)(vii)(D)(*4*);
■ b. In paragraph (c)(1)(xxiii)(D), removing the phrase ''3 business days'' and adding in its place the phrase ''5 calendar days'';
■ c. Redesignating paragraph (c)(1)(xxiii)(N) as paragraph (c)(1)(xxiii)(O); and
■ d. Adding new paragraph (c)(1)(xxiii)(N).

The revision and addition read as follows:

§ 424.58 Accreditation.

* * * * *

(c) * * *

(1) * * *

(vii) * * *

(D) * * *

(4) For notifying CMS when a conflict of interest is discovered. This includes disclosing to CMS all conflicts of interest (as described and defined in § 424.58(c)(1)(vii)(D)(*3*) and (*5*)) it currently has and explaining how and when it will terminate them.

* * * * *

(xxiii) * * *

(N) Agrees to notify CMS in writing (and, if applicable, law enforcement) of suspected fraud, waste, or abuse—consistent with the accrediting organization's CMS-approved definitions of those terms per paragraph (c)(1)(xxii) of this section—within 3 calendar days of the date on which the accrediting organization determines that fraud, waste, or abuse may have occurred.

* * * * *

■ 17. Section 424.502 is amended by—
■ a. In the definition of ''Affiliation''—
■ i. Republishing the introductory text;
■ ii. Revising paragraph (3); and
■ iii. Adding new paragraph (6);
■ b. In the definition of ''Final adverse action'';
■ i. Republishing the introductory text; and
■ ii. Adding new paragraph (6);
■ c. Revising paragraph (1) of the definition of ''Managing employee''; and
■ d. Revising the definition of ''Operational''

The additions and revisions are as follows:

§ 424.502 Definitions.

* * * * *

Affiliation means, for purposes of applying § 424.519, any of the following:

* * * * *

(3) An interest in which an individual or entity—or any of its owning or managing employees or organizations—exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of this paragraph (3), sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W–2 employee of the organization.

* * * * *

(6) Any marketing, business, fulfillment, financial, or managerial relationship, whether direct or indirect (including, for example, common use of the same organization to perform these services).

* * * * *

Final adverse action means one or more of the following actions—

* * * * *

(6) *Misdemeanor conviction.* A conviction of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years preceding enrollment, revalidation or reenrollment.

* * * * *

Managing employee means—

(1) A general manager, business manager, administrator, director, or other individual that exercises

operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W–2 employee of the provider or supplier. For purposes of this definition, this includes not only a hospice or skilled nursing facility administrator and a hospice or skilled nursing facility medical director but also any of the following:

(i) Medical directors other than skilled nursing facility and hospice medical directors.

(ii) Clinical directors.

(iii) Departmental heads (for example, a hospital's chief of cardiology).

(iv) Supervising physicians (not simply those at independent diagnostic testing facilities).

(v) Nursing directors.

(vi) Alternate administrators.

(vii) All other clinical personnel not listed in paragraphs (1)(i) through (vi) of this definition who meet the ''managing employee'' definition.

* * * * *

Operational means (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered) the provider or supplier meets all of following requirements:

(1) Has a qualified physical practice location.

(2) Is open to the public for the purpose of providing health care related services, which includes, but is not limited to, all of the following:

(i) The provider's or supplier's location is fully accessible to all patients and lacks safety hazards. For purposes of this paragraph (2)(i), accessible means—

(A) The provider or supplier is located in an area and a building that patients can enter with reasonable ease; and

(B) The location is compliant with all federal Americans with Disabilities Act regulations and all applicable and equivalent state and local laws.

(ii) The provider's or supplier's hours of business are sufficient to regularly serve patients.

(iii) Medicare beneficiaries can contact and locate the provider's or supplier's location based on publicly available information (for example, the internet).

(3) Is prepared and able to submit valid Medicare claims.

(4) Is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered,) to furnish these items or services. This includes, but is not limited to, the following:

(i) Provider or supplier staff must be qualified (such as licensed or certified if required under state law) to perform their health care-related functions.

(ii) Equipment must be functional, appropriate for the services and items the provider or supplier intends to furnish, and in sufficient quantity to provide these items and services.

(iii) Appropriate medications for the services and items the provider or supplier intends to furnish and in sufficient quantity to provide these items and services.

(5) Has adequate written policies and records regarding its operations, such as, but not limited to, procedures for patient care, patient safety, medical and patient recordkeeping, and general administration.

* * * * *

■ 18. Section 424.510 is amended by adding paragraph (f) to read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

* * * * *

(f) *Signage.* (1) The provider or supplier must maintain a permanent visible sign in plain view and post hours of operation. If the provider's or supplier's place of business is located within a building complex, the sign must be visible at the main entrance of the building or the hours can be posted at the entrance of the provider or supplier.

(2) The requirement in paragraph (f)(1) of this section does not apply if the provider or supplier—

(i) Shares office space with another provider or supplier (for example, physicians in a group practice sharing a common suite, though the group itself must have signage);

(ii) Treats patients in the patients' homes;

(iii) Treats patients in the provider's or supplier's home and only uses the provider's or supplier's address for administrative purposes.

(iv) Performs telehealth services from home.

* * * * *

■ 19. Section 424.516 is amended by adding paragraph (f)(3) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(f) * * *

(3) All documentation required to be retained and furnished under this paragraph (f) must be accurate, complete, and compliant with all CMS requirements.

* * * * *

■ 20. Section 424.518 is amended by revising paragraph (c)(2)(ii)(A) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers

* * * * *

(c) * * *

(2) * * *

(ii)(A) Using the CMS-designated fingerprinting contractor, requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier; and

* * * * *

§ 424.519 [Amended]

■ 21. Section 424.519 is amended in paragraph (b) by removing the phrase ''has or, within the previous 5 years, had'' and adding in its place the phrase ''has or has had''.

■ 22. Section 424.530 is amended by—

■ a. Revising paragraph (a)(4); (13); (14); and (16);

■ b. Adding paragraphs (a)(19) through (22);

■ c. Revising paragraph (f) introductory text;

■ d. Removing paragraphs (f)(2)(i) through (iv); and

■ e. Redesignating paragraphs (f)(3)(i) and (ii) as revised paragraphs (f)(2)(i) and (ii).

The revisions and additions read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(4) *False or misleading information.* The provider or supplier submits false or misleading information on or associated with any CMS or Medicare provider enrollment-related form. (Offenders may be referred to the Office of Inspector General for investigation and possible criminal, civil, or administrative sanctions.) This includes but is not limited to:

(i) Enrollment-related forms created by or submitted or both to CMS contractors;

(ii) Documentation furnished as part of the completion or submission of the CMS or Medicare enrollment-related form.

(iii) Form CMS–588 (Electronic Funds Transfer (EFT) Authorization Agreement; O.M.B Control Number 0938–0626).

(iv) Documents required to demonstrate compliance with HHA capitalization requirements in § 489.28.

(v) Opt-out affidavits under 42 CFR part 405, subpart D.

(vi) Letters from a provider demonstrating that a particular provider official qualifies as an authorized or delegated official under § 424.502.

(vii) Any other required or requested enrollment-related documentation.

* * * * *

(13) *Affiliation that poses undue risk.* CMS determines that the provider or supplier—or any of its owning or managing employees or organizations—has or has had an affiliation under § 424.519 that poses an undue risk of fraud, waste, or abuse to the Medicare program.

* * *

(14) *Other program termination or suspension.* (i) The provider or supplier—or any owner, managing employee, or managing organization thereof—is currently terminated or suspended (or otherwise barred) from participation in a State Medicaid program or any other federal health care program, or the provider's or supplier's license is currently revoked or suspended (or voluntarily surrendered in lieu of further action) in a State other than that in which the provider or supplier is enrolling. In determining whether a denial under this paragraph (a)(14) is appropriate, CMS considers the following factors:

(A) The reason(s) for the termination, suspension, revocation, or surrender.

(B) Whether, as applicable, the provider or supplier—or owner, managing employee, or managing organization thereof—

(*1*) Is currently terminated or suspended (or otherwise barred) from more than one program (for example, more than one State's Medicaid program);

(*2*) Has been subject to any other sanctions during its participation in other programs or by any other State licensing boards; or

(*3*), Has had any other final adverse actions (as that term is defined in § 424.502) imposed against it.

(C) Any other information that CMS deems relevant to its determination.

(ii) CMS may apply paragraph (a)(14)(i) of this section to the provider or supplier under any of the provider's or supplier's—or owner's, managing employee's, or managing organization's—current or former names, numerical identifiers or business identities, and regardless of whether any appeals are pending.

* * * * *

(16) *Misdemeanor conviction.* The provider or supplier—or any owner, managing employee, managing organization, officer, or director thereof—was convicted of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

* * * * *

(19) *Same suite.* The provider's or supplier's practice location is in the same suite or office as another provider or supplier whose Medicare enrollment has been revoked or denied under § 424.535 or § 424.530.

(20) *Hospice medical director or administrator.* A hospice's enrollment may be denied if any of the following apply:

(i) The hospice's medical director is either of the following:

(A) The medical director of multiple other hospices.

(B) Practices at such a distance (for example, in a different state) from the enrolling hospice that the medical director cannot realistically perform all medical director functions required under 42 CFR part 418.

(ii) The hospice's administrator is either of the following:

(A) The administrator of multiple other hospices.

(B) Located at such a distance from the enrolling hospice that the administrator cannot realistically perform all administrator functions required under 42 CFR part 418.

(iii) The hospice's medical director does not have an active physician medical license in the State in which they are practicing.

(21) *Misuse of identity.* The provider or supplier is attempting to enroll under another party's identity.

(22) *Change in majority ownership non-compliance.* CMS determines that the HHA, hospice, or DMEPOS supplier has failed to comply with the provisions and requirements of, as applicable, § 424.550(b) or § 424.551.

* * * * *

(f) *Reapplication bar.* CMS may prohibit a prospective provider or supplier from enrolling in Medicare for up to 10 years if their enrollment application is denied for any reason under § 424.530.

* * * * *

■ 23. Section 424.535 is amended by—

■ a. Revising paragraph (a)(4);

■ b. Revising paragraph (a)(8)(ii) introductory text;

■ c. Removing paragraphs (a)(8)(ii)(A) through (D) and (a)(8)(iii);

■ d. Revising paragraph (a)(16);

■ e. Revising paragraph (a)(19);

■ f. Adding paragraphs (a)(24) and (25).

■ g. Revising paragraphs (g)(1) and (2);

■ h. Removing paragraph (g)(3);

■ i. Revising paragraphs (h)(1)(i) and (ii).

The revisions and additions read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(4) *False or misleading information.* The provider or supplier submits false or misleading information on or associated with any CMS or Medicare provider enrollment-related form. (Offenders may be referred to the Office of Inspector General for investigation and possible criminal, civil, or administrative sanctions.) This includes but is not limited to—

(i) Forms created by and/or submitted to CMS contractors.

(ii) Documentation furnished as part of the completion or submission of the CMS or Medicare enrollment-related form.

(iii) Form CMS–588 (Electronic Funds Transfer (EFT) Authorization Agreement; OMB Control Number 0938–0626), which must be submitted with the enrollment application.

(iv) Documents required to demonstrate compliance with HHA capitalization requirements in § 489.28.

(v) Opt-out affidavits under 42 CFR part 405, subpart D.

(vi) Letters from a provider demonstrating that a particular provider official qualifies as an authorized or delegated official under § 424.502.

(vii) Any other required or requested enrollment-related documentation.

* * * * *

(8) * * *

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.

* * * * *

(16) *Misdemeanor conviction.* The provider or supplier—or any owner, managing employee, managing organization, officer, or director thereof—was convicted of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

* * * * *

(19) *Affiliation that poses undue risk.* CMS determines that the provider or supplier—or any of its owning or managing employees or organizations—has or has had an affiliation under § 424.519 that poses an undue risk of

fraud, waste, or abuse to the Medicare program.

* * * * *

(24) *High-risk based on excess providers in area.* CMS determines that the provider's or supplier's enrollment presents a high risk of fraud, waste, or abuse due to the provider's or supplier's location within a limited geographic area that has an excessive number of providers and suppliers.

(25) *Change in majority ownership non-compliance.* CMS determines that the HHA, hospice, or DMEPOS supplier did not comply with the provisions and requirements of, as applicable, § 424.550(b) or § 424.551.

* * * * *

(g)(1) Except as described in paragraph (g)(2) of this section, the effective dates of the revocations identified in this section are as follows:

(i) For revocations under paragraph (a)(1) of this section:

(A) If the revocation is based on non-compliance with the enrollment requirements in Title 42 or in the enrollment application applicable to the provider or supplier type, the date the non-compliance began (per CMS' or the CMS contractor's determination).

(B) If the revocation is based on a State license revocation, suspension, or surrender in lieu of further disciplinary action, the date of the license revocation, suspension, or surrender.

(C) For revocations based on termination of a provider agreement under part 489 of this chapter, and as applicable to the type of provider involved, the later of—

(*1*) The date of the provider agreement termination; or

(*2*) The date that CMS establishes under § 489.55.

(ii) For revocations under paragraph (a)(2) of this section, the date of the exclusion or debarment.

(iii) For revocations under paragraph (a)(3) of this section, the date of the felony conviction.

(iv) For revocations under paragraph (a)(4) of this section, and as applicable to the situation, the date the certification statement was signed or the false or misleading information was submitted.

(v)(A) For revocations under paragraph (a)(5)(i) of this section, the date on which the provider's or supplier's practice location was no longer operational (per CMS' or the CMS contractor's determination).

(B) For revocations under paragraph (a)(5)(ii) of this section, the date the Medicare enrollment requirement was not satisfied.

(vi) For revocations under paragraph (a)(6) of this section, the date on which CMS or its contractor determines that the provider or supplier should be revoked under paragraph (a)(6).

(vii) For revocations under paragraph (a)(7) of this section, the date on which the conduct resulting in the revocation occurred.

(viii)(A) For revocations under paragraph (a)(8)(i) of this section, the earliest date of service on the claim or claims that is or are triggering the revocation.

(B) For revocations under paragraph (a)(8)(ii) of this section, the last date of service on the claims in the applicable pattern or practice.

(ix) For revocations under paragraph (a)(9) of this section, the day following the date by which the provider or supplier was required to report the applicable change, addition, or deletion.

(x)(A) For revocations under paragraph (a)(10) of this section based on a failure to retain documentation, the date on which CMS or the CMS contractor determines that the provider or supplier has not complied with this retention requirement.

(B) For revocations under paragraph (a)(10) of this section based on a failure to provide access to the documentation, the day after the date by which the provider or supplier was required to furnish access.

(xi) For revocations under paragraph (a)(11) of this section, the day after the date by which the HHA was required to submit the requested documentation.

(xii) For revocations under paragraph (a)(12) of this section, the date of the termination, revocation, or bar.

(xiii)(A) For revocations under paragraph (a)(13)(i) of this section, the date of the certificate revocation, suspension, or surrender.

(B) For revocations under paragraph (a)(13)(ii) of this section, the date of the revocation or suspension of the ability to prescribe.

(xiv) For revocations under paragraph (a)(14) of this section, the date of the last prescription in the applicable pattern or practice.

(xv) For revocations under paragraph (a)(15) of this section, the date of the judgment.

(xvi) For revocations under paragraph (a)(16) of this section, the date of the conviction.

(xvii) For revocations under paragraph (a)(17) of this section, the date on which CMS referred the debt to the Department of Treasury.

(xviii) For revocations under paragraph (a)(18) of this section, the effective date of the provider's or supplier's current enrollment.

(xix) For revocations under paragraph (a)(19) of this section, the date on which CMS or its contractor determines that the provider or supplier should be revoked under this paragraph.

(xx) For revocations under paragraph (a)(20) of this section, the earliest date on the claims for the non-compliant location that are triggering the revocation.

(xxi) For revocations under paragraph (a)(21) of this section, the date of the last order, certification, referral, or prescription in the applicable pattern or practice.

(xxii) For revocations under paragraph (a)(22) of this section, the date of the prior action resulting in the revocation.

(xxiii)(A) For revocations under paragraph (a)(23) of this section—

(*1*) If the standard or condition violation involves the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's Federal or State license, certification, accreditation, or MDPP recognition, the effective date is the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

(*2*) If the standard or condition violation involves a non-operational practice location, the effective date is the date the non-operational status began (per CMS' or the CMS contractor's determination).

(*3*) If the standard violation involves a felony conviction of an individual or entity described in § 424.67(b)(6)(i), the effective date is the date of the felony conviction.

(B) For all other revocations under paragraph (a)(23) of this section based on a condition or standard violation, the effective date is the date of non-compliance with the condition or standard.

(xxiv) For revocations under paragraph (a)(24) of this section, the date on which CMS or its contractor determines that the provider or supplier should be revoked under paragraph (a)(24).

(xxv) For revocations under paragraph (a)(25) of this section, the date on which CMS or its contractor determines that the provider or supplier should be revoked under paragraph (a)(25).

(xxvi) For revocations under paragraph (i) of this section, the effective date of the revocation (or date of the denial) that triggered the revocation(s) of the other enrollment(s).

(2) [To be added]

* * * * *

(h)(1)(i) Except for HHAs as described in paragraph (h)(1)(ii) of this section, a revoked provider or supplier must,

within 15 calendar days of the date of the revocation letter, submit all claims for items and services furnished before the effective date of the revocation.

(ii) A revoked HHA must, within 15 calendar days of the date of the revocation letter, submit all claims for items and services furnished before the later of the following:

* * * * *

■ 24. Section 424.540 is amended by—

■ a. In paragraph (b)(3)(i), removing the term ''HHA'' and adding in its place the phrase ''HHA or hospice''; and

■ b. Adding paragraph (d)(3).

The addition reads as follows:

§ 424.540 Deactivation of Medicare billing privileges.

* * * * *

(d) * * *

(3) A provider or supplier may rebut their assigned reactivation effective date via the procedures in § 424.546.

* * * * *

■ 25. Section 424.545 is amended by revising paragraph (b) to read as follows:

§ 424.545 Provider and supplier appeal rights.

* * * * *

(b) A provider or supplier whose billing privileges are deactivated or has been assigned a reactivation effective date may file a rebuttal in accordance with § 424.546 of this chapter.

* * * * *

■ 26. Section 424.546 would be amended as follows:

■ a. Revising the section heading, and paragraphs (a)(1) and (b)(2);

■ b. In paragraph (b)(3), removing the term ''deactivation'' and adding in its place the phrase ''deactivation or reactivation effective date''; and

■ c. Revising paragraph (d).

The revisions read as follows:

§ 424.546 Rebuttals of deactivations and of reactivation effective dates.

(a)(1) If a provider or supplier receives written notice from CMS or its contractor that the provider's or supplier's billing privileges are to be or have been deactivated under § 424.540 or is assigned a reactivation effective date by CMS or its contractor under § 424.540(d)(2), the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to CMS as permitted under § 424.545(b).

* * * * *

(b) * * *

(2) Specify the facts or issues about which the provider or supplier disagrees with the deactivation's imposition and/or the effective date (or with the assigned reactivation effective date), and the reasons for disagreement.

* * * * *

(d) Upon receipt of a timely and compliant deactivation (or reactivation effective date) rebuttal, CMS reviews the rebuttal to determine whether the imposition of the deactivation or the designated effective date (or the assigned reactivation effective date) or both are correct.

* * * * *

■ 27. Section 424.570 is amended as follows:

■ a. Revising paragraphs (a)(1)(i) and(1)(iii)(C);

■ b. Redesignating paragraph (a)(1)(iv) as paragraph (a)(1)(iv)(A).

■ c. Adding paragraph (a)(1)(iv)(B).

The revisions and addition read as follows:

§ 424.570 Moratoria on newly enrolling Medicare providers and suppliers.

(a) * * *

(1) * * *

(i) CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area. Solely for purposes of this section, the term ''new'' means any of the following application types:

(A) Initial enrollment applications.

(B) Change of ownership applications that require an initial enrollment per § 424.570(a)(1)(iii)(C).

(C) Enrollment applications from revoked providers or suppliers whose reenrollment bars under § 424.535(c) have expired and are seeking to enroll again in the Medicare program.

(D) Reactivation applications.

(E) Enrollment applications from voluntarily terminated providers/suppliers seeking to enroll again in the Medicare program.

* * * * *

(iii) * * *

(C) Changes in ownership (except changes in ownership that require an initial enrollment, such as, but not limited to, an HHA, hospice, or DMEPOS supplier change in majority ownership under § § 424.550(b) or § 424.551).

(iv)(A) A temporary moratorium does not apply to any enrollment application that has been received by the Medicare contractor prior to the date the moratorium is imposed.

(B) The date the moratorium is imposed is the moratorium's effective date, which is the date on which the moratorium notice is filed for public inspection at the Office of the Federal Register (OFR).

* * * * *

PART 484—HOME HEALTH SERVICES

■ 28. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

■ 29. Section 484.245 is amended by—

■ a. In paragraph (b)(2)(ii)(A), removing the parenthetical phrase ''(July 1 through June 30)'' and adding in its place the parenthetical phrase ''(January 1 through December 31)'';

■ b. In paragraph (d)(1)(i), removing the phrase ''a letter of noncompliance'' and adding in its place the phrase ''receive notification of non-compliance'';

■ c. In paragraph (d)(2) introductory text, removing the hyperlink ''*HHAPureConsiderations@cms.hhs.gov*'' and adding in its place the hyperlink ''*HHAPUReconsiderations@cms.hhs.gov*'';

■ d. In paragraph (d)(2)(v), removing the phrase ''non-compliance letter'' and adding in its place the phrase ''non-compliance notification''; and

■ e. Revising paragraph (d)(4)(i);

The revision reads as follows:

§ 484.245 Requirements under the Home Health Quality Reporting Program (HH QRP).

* * * * *

(d) * * *

(4)(i) CMS notifies the HHA of its final decision regarding any reconsideration request through a CMS designated data submission system.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 30. The authority for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

§ 498.3 [Amended]

■ 31. Section 498.3 is amended in paragraph (b)(19) by removing the term ''renew opt-out'' and add in its place the phrase ''cancel automatic renewal''.

§ 498.20 [Amended]

■ 32. Section 498.20 is amended in paragraph (a)(1) by removing the term ''mails'' and add in its place the phrase ''mails or emails''.

§ 498.25 [Amended]

■ 33. Section 498.25 is amended by revising paragraph (a)(1) to remove the term ''mails'' and add in its place the phrase ''mails or emails''.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–22750 Filed 11–4–26; 5:00 pm]

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 423 and 429

Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 423 and 429

[CMS–4215–F]

RIN 0938–AV90

Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This rule finalizes and codifies the Medicare Drug Price Negotiation Program (''Negotiation Program'') and establishes certain new policies for the Negotiation Program and the Medicare Prescription Drug Benefit Program (''Part D Program'') as required by the Inflation Reduction Act of 2022. This final rule also finalizes a proposed policy for specific fixed combination drugs that are new formulations.

DATES:

Effective date: These regulations are effective on December 5, 2026.

Applicability date: These regulations are applicable to the Negotiation Program beginning with respect to initial price applicability year 2029 and to Part D Program coverage beginning January 1, 2029.

FOR FURTHER INFORMATION CONTACT: Elisabeth Daniel, *IRARebateandNegotiation@cms.hhs.gov,* or (667) 290–8793, for issues related to the Medicare Drug Price Negotiation Program.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This final rule finalizes and codifies policies related to the implementation of certain provisions of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022) and amendments made by the ''Working Families Tax Cut'' legislation (Pub. L. 119–21, July 4, 2025).

This final rule also finalizes and codifies policies for the Medicare Drug Price Negotiation Program at part 429 consistent with sections 1191 through 1198 of the Social Security Act (hereinafter ''the Act'') as well as policies for the Medicare Prescription Drug Benefit Program at part 423 consistent with section 11001(b) of the IRA, which made certain amendments to the Act, including with respect to Medicare Part D.

2. Summary of the Provisions

We are codifying policies established in final guidance for the Negotiation Program [1] in regulatory text. Specifically, we are codifying, with limited modification, the policies set forth in guidance for the Medicare Drug Price Negotiation Program by adding the new part 429 to title 42, Chapter IV of the Code of Federal Regulations and modifying policies for the Medicare Prescription Drug Benefit Program at part 423.

In addition, we are codifying new policies for the Medicare Drug Price Negotiation Program as follows:

- Finalizing § 429.125(b)(4)(ii) regarding treatment of specific fixed combination drugs in our determinations of qualifying single source drugs. In this section, we are establishing a policy for specific fixed combination drugs that we determine are new formulations of existing drugs. Under this policy, if CMS determines that products with the same New Drug Application (NDA)/Biologics License Application (BLA) holder differ in active moiety(ies), active ingredient(s), or antigen component(s) due to the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s), then CMS will identify the potential qualifying single source drug using all dosage forms and strengths of the shared active moiety(ies), active ingredient(s), or antigen component(s) that are offered by the same NDA/BLA holder.
- Finalizing § 429.125(c)(3)(i), to clarify how CMS will identify the day from which to measure the 7- and 11-year time since approval and licensure periods for drugs that formerly qualified for the Orphan Drug Exclusion.
- Finalizing § 429.130, to codify the process and schedule according to which CMS reviews information to determine if the manufacturer of a generic drug or biosimilar that is approved or licensed, respectively, is engaged in Bona Fide Marketing (as defined in § 429.20) of that generic drug or biosimilar.
- Finalizing § 429.210(c), to provide additional details related to the Primary Manufacturer transfer of responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity.
- Finalizing § 429.415(a)(2) and § 429.510(d)(2)(ii), to explain how CMS will calculate the 30-day equivalent supply for a selected drug or therapeutic alternative, respectively, payable under Part B that is typically administered one time (for example, some vaccines, gene therapies, and cancer therapies).
- Finalizing § 429.440 with modifications, to explain how CMS will implement the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030. We are modifying our proposed stepwise approach, at § 429.440(b)(4), for calculating a selected drug's ceiling in the event that certain ceiling amounts are below the Temporary Floor for Small Biotech Drugs.
- Finalizing §§ 429.605 and 429.610 with modifications, to clarify when off-label use would be considered for renegotiation eligibility and selection by aligning the renegotiation eligibility and selection policies for off-label use with the initial offer development process.

Unless otherwise specified, CMS finalizes that the provisions herein would apply with respect to all initial price applicability years beginning with initial price applicability year 2029, including, for example, with respect to the selection of drugs and the negotiation or renegotiation of MFPs for initial price applicability year 2029 that will take place during calendar year 2027. In this final rule, unless otherwise specified, references hereinafter to ''the Negotiation Program Guidance'' are to the most recent program guidance published by CMS, which is the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of sections 1191–1198 of the Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 that was published on September 30, 2025. In this final rule, unless otherwise specified, references hereinafter to ''the revised guidance for initial price applicability year 2026'' are to the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2026 that was published by CMS on June 30, 2023. Additionally, in this final rule, unless otherwise specified, references

[1] The most recent final guidance published for the Negotiation Program is the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028, available at: *https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.*

hereinafter to ''the final guidance for initial price applicability year 2027'' are to the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 that was published by CMS on October 2, 2024.

Given that the identification and selection of drugs for negotiation and renegotiation occurs more than 2 years before the first application of the MFP (that is, before the start of the selected drug's first initial price applicability year), the processes for drugs that were selected for negotiation for initial price applicability years 2026, 2027, and 2028 and for renegotiation for initial price applicability year 2028 will be at varying stages of implementation when this rule is finalized. Consistent with the program instruction requirement at sections 11001(c) and 11002(c) of the IRA, the program guidance issued by CMS for initial price applicability years 2026, 2027, and 2028 remains applicable and is not superseded by this final rule with respect to such years. In other words, because sections 11001(c) and 11002(c) of the IRA require CMS to implement the Negotiation Program for initial price applicability years 2026, 2027, and 2028 through program instruction and other forms of program guidance, the requirements for a selected drug that was included on the list of selected drugs with respect to initial price applicability year 2026, 2027, or 2028 are set forth with respect to such years in the applicable program guidance. Revisions to the implementation of policy for 2026, 2027, and 2028 with respect to drugs selected for initial price applicability years 2026, 2027, and 2028 would be addressed by CMS through publication of revised guidance. In accordance with the expiration of the statutory program instruction requirement at the end of 2028, CMS finalizes that the provisions herein, as applicable, will apply starting in 2029 with respect to the drugs selected for initial price applicability years of 2026, 2027, or 2028.

Finally, CMS reminds interested parties that the exclusion for small biotech drugs from what is otherwise a negotiation-eligible drug under section 1192(d)(2) of the Act ended in initial price applicability year 2028 and is, therefore, not codified in this final rule. However, the definition of an eligible small biotech drug for purposes of the calculation of the Temporary Floor for Small Biotech Drugs on the maximum fair price for small biotech drugs under section 1194(d) of the Act is included in this final rule (as described in more detail in section II.E.2. of this final rule).

3. Summary of Costs and Benefits

We are finalizing new policies for the Negotiation Program as follows: a policy for specific fixed combination drugs that are new formulations; clarification for drugs that formerly qualified for the orphan drug exclusion; revisions regarding process and schedule of CMS review of information in making the determination for Bona Fide Marketing; additional details related to the Primary Manufacturer transfer of responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity; calculation of the 30-day equivalent supply for a selected drug that is typically administered one time; implementation of the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030; and clarification of off-label use in consideration for renegotiation eligibility and selection. In summary, the effects of the IRA are to reduce government expenditures for Part B, to increase expenditures for Part D through 2030, and to decrease Part D expenditures beginning in 2031. For a detailed discussion of the economic impacts, see section VI. of this final rule.

B. Background

Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169), signed into law on August 16, 2022, establish the Medicare Drug Price Negotiation Program (hereinafter the ''Negotiation Program'') to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products. Specifically, in accordance with section 1191(c)(3) of the Act, MFP means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year. The requirements for this program are described in sections 1191 through 1198 of the Act, as added by sections 11001 and 11002 of the IRA and as amended by section 71203 of the ''Working Families Tax Cut'' legislation (Pub. L. 119–21).

Under the IRA, with respect to each initial price applicability year, CMS shall: (1) publish a list of selected drugs in accordance with section 1192 of the Act; (2) enter into agreements with manufacturers of selected drugs in accordance with section 1193 of the Act; (3) negotiate MFPs for such selected drugs in accordance with section 1194 of the Act; (4) publish MFPs for selected drugs in accordance with section 1195 of the Act; (5) carry out administrative duties and compliance monitoring in accordance with section 1196 of the Act; and (6) impose civil monetary penalties (CMPs) in accordance with section 1197 of the Act. With respect to initial price applicability year 2028 and subsequent years, in accordance with section 1194(f) of the Act, CMS shall also: (1) determine renegotiation-eligible drugs; (2) determine whether to select drugs for renegotiation; and (3) renegotiate the MFP for any drug selected for renegotiation. To the extent applicable, any references in this final rule to the ''MFP'' include a renegotiated MFP. Section 1198 of the Act establishes certain limitations on administrative and judicial review relevant to the Negotiation Program.

Additionally, on July 4, 2025, the ''Working Families Tax Cut'' legislation was signed into law. Section 71203(a)(2) of the ''Working Families Tax Cut'' legislation amended section 1192(e)(3)(A) of the Act to modify the requirements for a drug to qualify for the Orphan Drug Exclusion. Section 71203(a)(3) of the ''Working Families Tax Cut'' legislation also added new section 1192(e)(4) of the Act, which describes the treatment of former orphan drugs.

For the first year of the Negotiation Program, the Secretary of the U.S. Department of Health and Human Services (''the Secretary'') selected 10 high expenditure, single source drugs covered under Part D for negotiation. The negotiated MFPs for these drugs took effect in initial price applicability year 2026.[2] The Secretary selected an additional 15 drugs covered under Part D for negotiation for initial price applicability year 2027,[3] and 15 drugs covered under Part D or payable under Part B or both for initial price applicability year 2028.[4] The Secretary will select up to 20 drugs covered under Part D or payable under Part B or both for initial price applicability year 2029 and subsequent initial price applicability years. Beginning with initial price applicability year 2028, the Secretary could also select drugs from initial price applicability year 2026 and

[2] See: *https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.*

[3] See: *https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf.*

[4] See: *https://www.cms.gov/files/zip/selected-drug-list-negotiated-prices-also-known-maximum-fair-prices-statutezip.zip.*

subsequent initial price applicability years for renegotiation. The Secretary selected one drug for renegotiation for initial price applicability year 2028.[5]

For initial price applicability years 2026 through 2028 of the Negotiation Program, sections 11001(c) and 11002(c) of the IRA direct CMS to implement the Negotiation Program through program instruction and other forms of program guidance. CMS issued initial or draft versions of program guidance for each initial price applicability year 2026,[6] 2027,[7] and 2028 [8] and requested public comment on each version. CMS then issued a revised or final version of the guidance for each of these program years.[9] [10] [11] In the final rule, we proposed to codify these requirements at parts 423 and 429 to title 42, chapter IV of the Code of Federal Regulations (CFR) to implement sections 11001 and 11002 of the IRA. The effective date of the finalized provisions is discussed in section I.A.5. of this final rule.

Consistent with the program instruction requirement of sections 11001(c) and 11002(c) of the IRA, CMS will issue program guidance related to manufacturer effectuation of the MFP for 2028, including with respect to drugs payable under Part B. CMS intends to codify requirements related to MFP effectuation for 2029 and subsequent years in future rulemaking. CMS stated in the Negotiation Program Guidance its intent to codify MFP effectuation policies for 2029 and subsequent years after guidance for 2028 has been finalized.

C. Publication of the Proposed Rule and General, Out-of-Scope, and Within Scope Public Comments

1. Publication of the Proposed Rule

In response to the Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program proposed rule (91 FR 36236 through 36368) (''proposed rule''), we received approximately 11,330 timely comment letters containing a variety of feedback and recommendations on the proposed rule and the information collection requests (ICRs) contained within the proposed rule.

2. General Comments

We received general comments on the Negotiation Program proposed rule. The following is a summary of the general comments we received and our responses.

Comment: Many commenters expressed general support for the Negotiation Program and the proposed policies.

Response: We thank commenters for their support.

Comment: Some commenters expressed general opposition to the Negotiation Program and the proposed policies.

Response: We appreciate the commenters for sharing their concern.

Comment: Some commenters noted that codifying policies of the Negotiation Program in regulation should not be an opportunity for CMS to expand the program requirements. A commenter urged CMS to assess whether proposed policies are consistent with statute, supported by reasoned decision making, and responsive to stakeholder comments as it implements the Negotiation Program.

Response: We appreciate this input and note that we have pursued implementation in accordance with the statutory requirements of the Negotiation Program. We appreciate the comments received from interested parties on the proposed rule. We read and responded to all significant comments received timely.

Comment: Many commenters expressed concern about the impact of the Negotiation Program on innovation and drug development, as well as concern about creating uncertainty in the pharmaceutical market. A few commenters recommended CMS continue to be transparent as it implements the Negotiation Program, and one of these commenters noted that CMS should adopt clear standards, consistent definitions, and predictable procedures across the Negotiation Program. A couple of commenters recommended CMS monitor and report on the impact of the Negotiation Program on patient access to prescription drugs.

Response: We thank these commenters for their input. Although the U.S. prescription drug market is the largest in the world—with a track record of fostering innovation—patients in the United States generally pay more for prescription drugs than anywhere else.[12] We believe the Negotiation Program will make prescription drugs more affordable for people with Medicare and the Medicare program—without restricting innovation and new product research and development.[13] [14] We also expect the Negotiation Program to encourage drug manufacturers to create business models to stay competitive, fostering the development of new treatments. Only drugs that have been approved by the Food and Drug Administration (FDA) for at least 7 years and only biological products that have been licensed by the FDA for at least 11 years are eligible for selection as part of the Negotiation Program, unless they are otherwise excluded in accordance with statute. With the implementation of the Negotiation Program, we believe prescription drugs will be more affordable, allowing more patients to purchase those prescription drugs and adhere to their medications. As a result, prescription drug sales likely will continue to grow and drug manufacturers will reap the rewards of more patients being able to afford their medications.

3. Out of Scope Comments

Many comments, including those related to implementation of policies and processes of maximum fair price (MFP) effectuation, such as operations of the Medicare Transaction Facilitator (''MTF''), were out of scope for purposes of this rulemaking.

4. Within Scope Comments

Summaries of the public comments within the scope of the proposed rule and our responses to those public comments are provided in the various sections of this final rule under the appropriate heading. Commenters included drug manufacturers and their trade associations, patient advocacy organizations, thought leaders, pharmacies and their trade associations, health plans, pharmacy benefit managers and their trade association,

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[5] See: *https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2028.pdf.*

[6] See: *https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf.*

[7] See: *https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

[8] See: *https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.*

[9] See: *https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.*

[10] See: *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

[11] See: *https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.*

[12] Assistant Secretary for Planning and Evaluation, ''International Prescription Drug Price Comparisons: Estimates Using 2022 Data,'' February 2024, see: *https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf.*

[13] Conti, Rena M., Richard G. Frank, and David M. Cutler, ''The Myth of the Free Market for Pharmaceuticals,'' *The New England Journal of Medicine,* vol. 390, no. 16, April 20, 2024.

[14] *Novo Nordisk et al.* v. *Becerra et al.,* brief amicus curiae of economists and scholars of health policy, Feb. 2, 2024, *https://litigationtracker.law.georgetown.edu/wp-content/uploads/2023/10/Novo-Nordisk_2024.02.02_Amicus-Brief-Economists-and-Health-Policy-Scholars.pdf.*

and individuals. A summary of the major issues and our responses follow.

D. Waiver of Delay in Effective Date

The Congressional Review Act (CRA) generally requires that the effective date of a major rule be 60 days after the rule is published in the **Federal Register**. 5 U.S.C. 801(a)(3)(A)(ii). The CRA allows an agency to issue a rule that would otherwise be subject to a 60-day delayed effective date requirement with an effective date at such time as the Federal agency promulgating the rule determines in circumstances where notice and public procedure are impractical, unnecessary, or contrary to the public interest (5 U.S.C. 808(2)).

CMS is waiving the 60-day delay in the effective date for this rule to allow it to meet the statutory deadline of February 1 for publication of the selected drug list (as required by sections 1192(a) and 1191(b)(3) of the Act), and avoid an infeasible scenario where CMS must wait until 60 days after the date the rule is published in the **Federal Register** to close the collection of Initial Delay Requests from Biosimilar Manufacturers (CMS–10844, OMB 0938–1452, Expiration 11/30/2028) as we are finalizing in § 429.110. To meet the statutory deadline of February 1 for publication of the selected drug list (as required by sections 1192(a) and 1191(b)(3) of the Act), based on experience from initial price applicability years 2026, 2027, and 2028, CMS needs a minimum of approximately seven weeks to conduct the review process for Initial Delay Requests, as specified in section 1192(f) of the Act. The volume of Initial Delay Requests we receive varies by year, as well as the scope and complexity of review, since each application presents unique drug-specific considerations. Collecting and reviewing Initial Delay Requests in January 2027 without a waiver of the 60-day delay in the effective date would be infeasible for CMS to make determinations with respect to such requests, as CMS would have insufficient time to: (1) review such request(s); (2) request additional information and documents from the Biosimilar Manufacturer necessary to make determinations (if applicable); (3) allow a Biosimilar Manufacturer time to produce and submit to CMS the requested information (consistent with section 1192(f)(1)(B)(ii)(II) of the Act); and (4) review the additional information and documents submitted by Biosimilar Manufacturers to determine whether the selection of a negotiation-eligible drug that includes the reference product for the Biosimilar should be delayed, before the statutory deadline of February 1 for publication of the selected drug list (as required by sections 1192(a) and 1191(b)(3) of the Act).

Review of an Initial Delay Request may require CMS to consider a substantial volume of technical information, and potentially request additional information from the Biosimilar Manufacturer, in order to make a determination. For example, in reviewing an Initial Delay Request pursuant to section 1192(f) of the Act, CMS must, among other actions, determine whether there is a high likelihood that the Biosimilar Manufacturer's Biosimilar will be licensed and marketed under section 351(k) of the Public Health Service Act before the date that is 2 years after the selected drug publication date with respect to such initial price applicability year for which a reference drug would be included on the selected drug list absent a successful Initial Delay Request (the High Likelihood Deadline). CMS must also, among other actions, determine that the Biosimilar Manufacturer and the Reference Manufacturer have not entered into an agreement that (1) requires or incentivizes the Biosimilar Manufacturer to submit an Initial Delay Request or (2) directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time.

As part of the Initial Delay Request, the Biosimilar Manufacturer must submit all agreements related to the Biosimilar filed with the Federal Trade Commission (FTC) or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and to the extent available, the manufacturing schedule for the Biosimilar submitted to FDA during its review of the application for licensure and the Biosimilar Manufacturer's disclosures pertaining to the marketing of the Biosimilar (for example, in filings with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation distributed to the shareholders of privately held companies) about capital investment, revenue expectations, and other actions typically taken by a manufacturer in the normal course of business in the year (or the 2 years, as applicable) before marketing of a Biosimilar.

In this example, CMS must review the aforementioned materials to determine whether there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline and whether there are any agreements between the Biosimilar Manufacturer and Reference Manufacturer that would require the denial of the Initial Delay Request. If CMS began reviewing Initial Delay Requests in January 2027, CMS would have insufficient time for the following actions before the February 1 statutory publication deadline for the selected drug list. First, CMS must review the applicable agreements filed with the FTC or the Assistant Attorney General, any manufacturing schedule for the Biosimilar submitted to the FDA, and applicable disclosures pertaining to the marketing of the Biosimilar. Second, CMS may need to submit follow up requests to Biosimilar Manufacturers where, for example, the information and documents provided are insufficient for determining whether any agreement(s) violate the statutory requirements for granting the Initial Delay Requests, or where the information and documents provided do not establish clear and convincing evidence as required by statute that the Biosimilar will be marketed before the High Likelihood Deadline. Third, CMS would need to provide the Biosimilar Manufacturer with adequate time to produce and submit to CMS additional information and documents regarding the agreements and marketing of the Biosimilar before the High Likelihood Deadline. Fourth, CMS must review this additional information and documents provided by the Biosimilar Manufacturer to determine if the agreements violate the statutory requirements for granting the Initial Delay Request, and whether there is clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline. These determinations must be made before the February 1 statutory publication deadline for the selected drug list.

In this example, CMS believes that completing these actions as part of the review of Initial Delay Requests to determine whether the selection of a negotiation-eligible drug should be delayed by one year before the February 1 statutory publication deadline for the selected drug list would be infeasible if CMS began reviewing Initial Delay Requests in January 2027.

In recognition of these timing requirements, such requests must be due by a date specified by CMS, which would be no later than the end of December of the calendar year prior to the selected drug publication date. A 60-day delay for completion of data collection, after the date of publication

in the **Federal Register**, would be in direct conflict with this provision.

Specifically, a 60-day delay in effective date following publication in the **Federal Register** would mean these actions would not begin until the effective date in early January 2027. This would prevent CMS from reviewing, following up, and granting Initial Delay Requests, if applicable, in accordance with section 1192(f) of the Act by the selected drug publication date for initial price applicability year 2029. Further, a 60-day delay would be inconsistent with our regulation as codified in § 429.110(f).

If CMS were to begin reviewing Initial Delay Requests 60 days after the publication of this Final Rule in the **Federal Register**, CMS would have a period of less than one month to review such requests, which is approximately half the minimum time that CMS believes is necessary, before the February 1 deadline for publication of the selected drug list (as required by sections 1192(a) and 1191(b)(3) of the Act). As explained in the preceeding example, such a timeline is insufficient for CMS to review the Initial Delay Request and request follow ups, if necessary, allow Biosimilar Manufacturer(s) time to compile and submit additional information and documents, and for CMS to review such additional information and documents. Allowing CMS to request additional information and documents from the Biosimilar Manufacturer, if applicable (consistent with section 1192(f)(1)(B)(ii)(II) of the Act), and providing sufficient time for a manufacturer to respond to such requests, are key parts of the Initial Delay Request process, and could not be reasonably completed before the statutory deadline if CMS did not waive the 60-day delay in effective date. Therefore, this delay would interfere with the timely implementation of this statutorily authorized program. CMS finds good cause to waive the 60-day delay in effective date of the final rule, otherwise CMS will not be able to complete the Initial Delay Request process before the February 1, 2027 deadline for publication of the selected drug list (as required by sections 1192(a) and 1191(b)(3) of the Act).

E. Severability of Provisions

Finally, CMS is clarifying and emphasizing its intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, CMS finalizes provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal.

II. Proposed Requirements for the Medicare Drug Price Negotiation Program and Analysis of and Responses to Public Comments

A. General Provisions

1. Basis and Scope (§ 429.10)

In proposed § 429.10, we proposed that part 429 implements sections 1191 through 1198 of the Act and sections 11001 and 11002 of the IRA, which set forth the requirements of the Medicare Drug Price Negotiation Program. The Medicare Drug Price Negotiation Program requires the Secretary to negotiate and renegotiate, for applicable periods, Medicare prices for certain high expenditure, single source drugs and biological products.

Additionally, in proposed § 429.10(c), we proposed that, were any provision of part 429 to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provision would be severable from part 429 and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances. While the provisions in part 429 are intended to present a comprehensive approach to implementing the Medicare Drug Price Negotiation Program, we intend that each of them is a distinct, severable provision, as proposed. Through this rulemaking, the policies contained herein are intended to operate independently of each other, even if each serves the same general purpose or policy goal. For example, we intend that the policies related to requests for a biosimilar delay (proposed § 429.110) are distinct and severable from the policies related to the identification of qualifying single source drugs (proposed § 429.125). As another example, we intend that the policy for additional price exchange opportunities for purposes of providing additional flexibility to extend and consider offers and counteroffers (proposed § 429.530) is distinct and severable from the policies for CMS and Primary Manufacturers (as defined in proposed § 429.20) to submit written initial offers and statutory written counteroffers, respectively, for purposes of determining an agreed-upon MFP (proposed § 429.520(a) and 429.525(a), respectively). Even where one provision makes reference to a second provision, § 429.10(c) clarifies the intent of the agency is that the two provisions would be severable if one provision were to be invalidated in whole or in part. For example, we would still be able to adjust the preliminary price based on section 1194(e)(1) factors (as defined in proposed § 429.20) as described in § 429.510(f) even if the provision for Primary Manufacturers to submit market data and revenue and sales volume data for the selected drug in the United States is deemed invalid (proposed § 429.505(b)(2)(v)).

We did not receive public comments on our proposals in this section.

Final Decision: We are finalizing § 429.10 as proposed.

2. Definitions (§ 429.20)

In the proposed rule, we proposed to codify the definitions of terms consistent with the meanings given in sections 1191 through 1198 of the Act or established in the Negotiation Program Guidance, as applicable, as well as new definitions based on policies detailed in this final rule.

a. Additional Delay Request

We proposed to define ''Additional Delay Request'' as a request to delay the inclusion on the selected drug list of a reference drug for which an initial delay request has been granted for a second initial price applicability year consistent with proposed § 429.110 and section 1192(f)(1)(B)(i)(II) of the Act.

b. Applicable Program Agreement

We proposed to define ''applicable program agreement'' as an agreement under the Manufacturer Discount Program as specified in section 1860D–14C of the Act or a rebate agreement described in section 1927(b) of the Act.

c. Authorized Generic Drug

We proposed to define ''authorized generic drug'' in accordance with the definition of such term at section 1192(e)(2)(B) of the Act. Section 1192(e)(2)(B)(i) of the Act defines an ''authorized generic drug'' that is a drug as a drug as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic (FD&C) Act. Section 1192(e)(2)(B)(ii) of the Act defines an authorized generic drug that is a biological product as a product that has been licensed under section 351(a) of the Public Health Service (PHS) Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling, packaging (other than

repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark than the reference product.

d. Authorized Representative

We proposed to define ''authorized representative'' as an individual that has the authority or capacity to legally bind the Primary Manufacturer to the terms and conditions of the Negotiation Program Agreement and meets one of the following criteria:

- Chief Executive Officer of the Primary Manufacturer.
- Chief Financial Officer of the Primary Manufacturer.
- An individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer of the Primary Manufacturer.
- An individual that has been granted delegation of signature authority on behalf of one of the individuals specified in paragraphs (1) through (3) of this proposed definition.

We solicited comment on this proposed definition and potential alternative formulations, including whether to adopt a broader definition to account for other contexts within the Negotiation Program, such as an individual making a submission to CMS on behalf of an entity other than a Primary Manufacturer.

e. Average Manufacturer Price (AMP)

We proposed to define ''average manufacturer price (AMP)'' as having the meaning given such term in section 1927(k)(1) of the Act.

f. Average Non-Federal Average Manufacturer Price (non-FAMP)

We proposed to define ''average non-Federal Average Manufacturer Price (non-FAMP)'' as having the meaning set forth in section 1194(c)(6) of the Act.

g. Average Sales Price (ASP)

We proposed to define ''average sales price (ASP)'' as the manufacturer's price for a quarter for a drug represented by a particular 11-digit National Drug Code (NDC–11) determined under § 414.804 and as reported in section 1927(b)(3) of the Act.

h. Billing Unit

We proposed to define ''billing unit'' as the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a Healthcare Common Procedure Coding System code), as established by CMS.

i. Biologics Licenses Application (BLA)

We proposed to define ''Biologics License Application (BLA)'' as an application submitted under section 351 of the PHS Act.

j. Biosimilar Biological Product or Biosimilar

We proposed to define ''biosimilar biological product'' or ''biosimilar'' as having the meaning given such term in section 1847A(c)(6) of the Act. For purposes of these regulations, we use the terms ''biosimilar biological product'' and ''biosimilar'' interchangeably when describing the requirements of sections 11001 and 11002 of the IRA. Specifically, section 1192(f)(5) of the Act, as added by section 11002 of the IRA, uses the meaning given to ''biosimilar biological product'' from section 1847A(c)(6) of the Act. We proposed to use the term ''biosimilar'' throughout part 429 unless otherwise specified, such as related to the ''Biosimilar'' included in a Biosimilar Delay Request under section 11002 of the IRA in proposed § 429.20.

k. Biosimilar Delay Request

We proposed to define ''Biosimilar Delay Request'' as either an Initial Delay Request or an Additional Delay Request.

l. Biosimilar Manufacturer

We proposed to define ''Biosimilar Manufacturer'' as one of the following:

- The BLA holder for the Biosimilar.
- If a BLA has been submitted to the U.S. Food and Drug Administration (FDA) for review but the Biosimilar has not been licensed, the sponsor of the BLA submitted for review by the FDA.
- If the Biosimilar has not been licensed and the BLA has not been submitted to the FDA, the organization planning to be the sponsor when the BLA is submitted for review by the FDA.

We believe that this approach is appropriate because: (1) it clearly identifies one manufacturer that may submit a Biosimilar Delay Request for a given Biosimilar, avoiding the possibility that we would receive two such requests naming the same Biosimilar for the same initial price applicability year; and (2) the status of the application for licensure for the Biosimilar is material to CMS' consideration of a request for a Biosimilar Delay Request, as described in section II.B.3. of this final rule.

m. BLA Holder

We proposed to define ''BLA holder'' as the entity that is the holder of the license(s) permitting marketing of a biological product in accordance with section 351 of the PHS Act.

n. Bona Fide Marketing

We proposed to define ''Bona Fide Marketing'' as having the meaning set forth in proposed § 429.130(a). Further discussion of CMS' review of one or more manufacturers of an approved generic drug or licensed biosimilar engaging in Bona Fide Marketing is included in section II.B.6.d. of this final rule.

o. Combined Part B and Part D Amount

We proposed to define ''combined Part B and Part D amount'' as an amount equal to the weighted average of the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amount as determined by CMS under proposed § 429.420(s).

p. CPI–U

We proposed to define ''CPI–U'' as the monthly Consumer Price Index for All Urban Consumers (United States city average) index level for all items from the Bureau of Labor Statistics.

q. Direct and Indirect Remuneration (DIR)

We proposed to define ''Direct and Indirect Remuneration (DIR)'' as having the meaning set forth in 42 CFR 423.308.

r. Drug Covered Under Part D

We proposed to define ''drug covered under Part D'' as a covered part D drug as defined in section 1860D–2(e) of the Act. We acknowledge that section 1860D–2(e) of the Act defines the term ''covered part D drug'' rather than ''drug covered under Part D''. For purposes of this rule, we use the term ''drug covered under Part D'' for simplicity and intend this term to be synonymous with the statutory term ''covered part D drug''.

s. Drug Payable Under Part B

We proposed to define ''drug payable under Part B'' as a drug or biological product for which payment may be made under part B of Title XVIII of the Act.

t. Estimated Remuneration at Point-of-Sale Amounts (ERPOSA)

We proposed to define ''estimated renumeration at point-of-sale amounts (ERPOSA)'' as the estimated amount of rebates or other price concessions that the Part D plan sponsor is required to apply, or has elected to apply, to the negotiated price as a reduction in the drug price made available to the beneficiary at the point of sale.

u. Extended-Monopoly Drug

We proposed to define ''extended-monopoly drug'' as having the meaning set forth in section 1194(c)(4) of the Act.

v. FDA-Approved Indication

We proposed to define ''FDA-approved indication'' as the information included in drug labeling per 21 CFR 201.57(c)(2) or FDA regulation(s) as applicable.

w. Fixed Combination Drug

We proposed to define ''fixed combination drug'' as having the meaning set forth in 21 CFR 300.50.

x. Generic Drug

We proposed to define ''generic drug'' as a drug approved in an Abbreviated New Drug Application (ANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (''FD&C Act'').

y. Healthcare Common Procedure Coding System (HCPCS) Code

We proposed to define ''Healthcare Common Procedure Coding System (HCPCS) code'' as a billing and payment code, as established by CMS for payment under Part B, used to describe a drug or biological and for which CMS may publish a payment amount.

z. High Likelihood Deadline

We proposed to define ''High Likelihood Deadline'' as the date that is 2 years after the statutorily defined selected drug publication date for the initial price applicability year for which the reference drug would be included on the selected drug list absent a successful Initial Delay Request. This period of time is consistent with time periods specified in sections 1192(f)(1)(A) and (2)(B)(i)(I) of the Act.

aa. Initial Delay Period

We proposed to define ''Initial Delay Period'' as the time period between: (1) the selected drug publication date for the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request, as proposed in § 429.110(g); and (2) the selected drug publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request as set forth in section 1192(f)(2) of the Act.

ab. Initial Delay Request

We proposed to define ''Initial Delay Request'' as a request to delay the inclusion of a reference drug on the selected drug list by one initial price applicability year consistent with proposed § 429.110(c) and section 1192(f)(1)(B)(i)(I) of the Act.

ac. Initial Price Applicability Year

We proposed to define ''initial price applicability year'' as having the meaning set forth in section 1191(b)(1) of the Act.

ad. Knowingly

We proposed to define ''knowingly'' as having the meaning set forth in 42 CFR 1003.110.

ae. Long-Monopoly Drug

We proposed to define ''long-monopoly drug'' as having the meaning set forth in section 1194(c)(5) of the Act.

af. Manufacturer

We proposed to define ''manufacturer'' as having the meaning set forth in section 1191(c)(1) of the Act.

ag. Manufacturer Discount Program

We proposed to define ''Manufacturer Discount Program'' to mean the Medicare Part D Manufacturer Discount Program established under section 1860D–14C of the Act.

ah. Maximum Fair Price (MFP)

We proposed to define ''maximum fair price (MFP)'' as having the meaning set forth in section 1191(c)(3) of the Act.

ai. Medicare Drug Price Negotiation Program (or Negotiation Program)

We proposed to define ''Medicare Drug Price Negotiation Program (or Negotiation Program)'' as the program created by sections 11001 and 11002 of the Inflation Reduction Act and codified in sections 1191 through 1198 of the Act and as amended.

aj. Medicare Drug Price Negotiation Program Agreement (or Negotiation Program Agreement)

We proposed to define ''Medicare Drug Price Negotiation Program Agreement (or Negotiation Program Agreement)'' as the agreement between a Primary Manufacturer and CMS as set forth in proposed § 429.200 of this chapter and section 1193(a) of the Act.

ak. NDA Holder

We proposed to define ''NDA holder'' as the entity that is the holder of the approval(s) to market a drug product in accordance with section 505(c) of the FD&C Act.

al. Negotiation-Eligible Drug

We proposed to define ''negotiation-eligible drug'' as having the meaning set forth in section 1192(d) of the Act. We refer readers to proposed § 429.115 (and related discussion in section II.B.4. of this final rule) for CMS' proposals for identifying drugs that meet this statutory definition.

am. Negotiation Period

We proposed to define ''negotiation period'' as having the meaning set forth in section 1191(b)(4) of the Act.

an. Net Part D Plan Payment and Beneficiary Liability

We proposed to define ''Net Part D Plan Payment and Beneficiary Liability'' as, for purposes of the Medicare Drug Price Negotiation Program, the total gross covered prescription drug cost for a selected drug covered under Part D net of direct and indirect remuneration (DIR) and Manufacturer Discount Program payments and excluding prescription drug event (PDE) records for which a compound code indicates the PDE record is for a compounded drug.

ao. New Drug Application (NDA)

We proposed to define ''New Drug Application (NDA)'' as an application submitted under section 505(b) of the FD&C Act.

ap. Off-Label Use

We proposed to define ''off-label use'' as the use for a condition for a selected drug or therapeutic alternative that is not an FDA-approved indication but is included in evidence-based clinical practice guidelines and is a medically accepted indication payable under Part B or covered under Part D or both, taking into consideration major drug compendia, authoritative medical literature, and accepted standards of medical practice, or some combination thereof.

aq. Orphan Drug Designation

We proposed to define ''orphan drug designation'' as the meaning set forth in 21 CFR 316.3(b)(11).

ar. Outcomes

We proposed to define ''outcomes'' as the impact of an intervention, which may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life.

as. Part B Data

We proposed to define ''Part B data'' as having the meaning of Original Medicare (OM) Part B claims data and Medicare Advantage (MA) encounter data for Part B items or services.

at. Partnership

We proposed to define ''partnership'' as having the meaning set forth in section 1192(f)(1)(C)(ii) of the Act.

au. Personally Identifiable Information (PII)

We proposed to define ''personally identifiable information (PII)'' as having the meaning set forth at 2 CFR 200.1.

av. Plasma-Derived Product

We proposed to define ''plasma-derived product'' as having the meaning set forth in section 1192(e)(3)(C) of the Act.

aw. Preliminary Price

We proposed to define ''preliminary price'' as the numerical dollar amount used by CMS in developing an initial offer in accordance with § 429.510(e) by adjusting the starting point of a selected drug based on section 1194(e)(2) factors.

ax. Price Applicability Period

We proposed to define ''price applicability period'' as having the meaning set forth in section 1191(b)(2) of the Act.

ay. Primary Manufacturer

We proposed to define ''Primary Manufacturer'' as the manufacturer identified by CMS as the NDA holder or the BLA holder for the selected drug.

az. Private Label Distributor

We proposed to define ''private label distributor'' as having the meaning set forth in 21 CFR 207.1.

ba. Protected Health Information (PHI)

We proposed to define ''protected health information (PHI)'' as having the meaning set forth at 45 CFR 160.103.

bb. Qualifying Single Source Drug

We proposed to define ''qualifying single source drug'' as having the meaning set forth in section 1192(e) of the Act. We refer readers to proposed § 429.125 (and related discussion in section II.B.6. of this final rule) for CMS' proposals for identifying drugs that meet this statutory definition.

bc. Rare Disease or Condition

Section 1192(e)(3)(A) of the Act describes ''rare disease or condition'' as having the definition used for such term in section 526(a)(2) of the FD&C Act. Therefore, we proposed to define ''rare disease or condition'' as having the meaning set forth in section 526(a)(2) of the FD&C Act.

bd. Reference Drug

We proposed to define ''Reference Drug'' as a negotiation-eligible drug that includes the reference product for the biosimilar as described in section 1192(f)(1)(B) of the Act.

be. Reference Manufacturer

We proposed to define ''Reference Manufacturer'' as the Primary Manufacturer of the Reference Drug that is named in a Biosimilar Delay Request.

bf. Reference Product

We proposed to define ''Reference Product'' as having the meaning set forth in section 1191(c)(4) of the Act.

bg. Relabeler

We proposed to define ''relabeler'' as having the meaning set forth in 21 CFR 207.1.

bh. Renegotiation-Eligible Drug

We proposed to define ''renegotiation-eligible drug'' as having the meaning set forth in section 1194(f)(2) of the Act.

bi. Repackager

We proposed to define ''repackager'' as having the meaning given the term ''repacker'' set forth in 21 CFR 207.1.

bj. Request To Terminate

We proposed to define ''Request to Terminate'' as a written request submitted by a Primary Manufacturer to CMS, that CMS determines meets the conditions described in § 429.205(b)(1), to request termination of its applicable program agreements in the context of a Primary Manufacturer's decision not to enter into or to terminate a Negotiation Program Agreement.

bk. Secondary Manufacturer

We proposed to define ''Secondary Manufacturer'' as a manufacturer of a drug product included in the selected drug, that is not the Primary Manufacturer for the selected drug, and that either: (1) is listed as a manufacturer in an NDA or BLA for the selected drug; or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer but is not listed on an NDA or BLA of the selected drug. A Secondary Manufacturer includes any manufacturer of any authorized generic drug(s) and any repackager or relabeler of the selected drug that meet either of these criteria.

bl. Second Delay Period

We proposed to define ''Second Delay Period'' as the time period between (1) the publication date of the selected drug list for initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request and (2) the publication date of the selected drug list for initial price applicability year that is 2 years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request as set forth in section 1192(f)(2) of the Act.

bm. Section 1194(e)(1) Factors

We proposed to define ''section 1194(e)(1) factors'' as the factors described in section 1194(e)(1) of the Act.

bn. Section 1194(e)(2) Factors

We proposed to define ''section 1194(e)(2) factors'' as the factors described in section 1194(e)(2) of the Act.

bo. Selected Drug

We proposed to define ''selected drug'' as having the meaning set forth in section 1192(c) of the Act. We refer readers to proposed § 429.105 (and related discussion in section II.B.2. of this final rule) for CMS' proposals for identifying drugs that meet this statutory definition.

bp. Selected Drug Publication Date

We proposed to define ''selected drug publication date'' as having the meaning set forth in section 1191(b)(3) of the Act.

bq. Self-Administered Drug

We proposed to define ''self-administered drug'' to mean, a drug or biological that is identified by the U.S. Department of Health and Human Services Office of Inspector General (OIG) as a self-administered drug pursuant to section 1847A(g)(1) of the Act.

br. Sequestration Payment Adjustment

We proposed to define ''sequestration payment adjustment'' to mean, when applicable, the amount that is applied to a Part B claim to determine the Medicare payment amount—after determining coinsurance, deductible, merit-based incentive payment adjustments, and any applicable Medicare Secondary Payment adjustments.

bs. Small Biotech Drug

We proposed to define ''Small Biotech Drug'' as meaning a drug that is determined by CMS under the proposed § 429.440(b)(2), in accordance with section 1192(d)(2) of the Act, as eligible for the Temporary Floor for Small Biotech Drugs.

bt. Specified Manufacturer

We proposed to define ''Specified Manufacturer'' as having the meaning set forth in section 1860D–14C(g)(4)(B)(ii) of the Act, as determined by CMS for the purposes of the Manufacturer Discount Program in accordance with §§ 423.2716, 423.2720, and 423.2724.

bu. Starting Point

We proposed to define ''starting point'' as the numerical dollar amount used by CMS in developing an initial offer in accordance with proposed § 429.510(d) that is then adjusted by CMS based on section 1194(e)(2) factors to determine the preliminary price, per the process described in proposed § 429.510(e).

bv. Temporary Floor for Small Biotech Drugs

We proposed to define ''Temporary Floor for Small Biotech Drugs'' as having the meaning set forth in § 429.440(b)(3). We refer readers to proposed § 429.440(b)(1) and (2) (and related discussion in section II.E.9.b. of this final rule) for CMS' proposals for the process for a Primary Manufacturer to request consideration and CMS' determination of eligibility for the Temporary Floor for Small Biotech Drugs.

bw. Therapeutic Advance

We proposed to define ''therapeutic advance'' as a demonstrated improvement in one or more outcomes or other clinical considerations for each identified condition of a selected drug as compared to its therapeutic alternative(s). For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS would consider the extent to which the drug represents a therapeutic advance at the time of consideration based on all available information at such time of consideration.

bx. Therapeutic Alternative

We proposed to define ''therapeutic alternative'' as a pharmaceutical product or group of pharmaceutical products other than the selected drug that may be used to treat the same condition or disease state as the selected drug.

by. Total Allowed Charges

We proposed to define ''total allowed charges'' as the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service paid for under part B of Title XVIII of the Act, without a sequestration payment adjustment applied.

bz. Total Expenditures

We proposed to define ''total expenditures'' as having the meaning set forth in section 1191(c)(5) of the Act. We refer readers to § 429.120 and section II.B.5. of this final rule for CMS' proposals for calculating total expenditures under Part D and total expenditures under Part B that meet this statutory definition.

ca. Total Expenditures Measurement Period

Sections 1192(d)(1)(A) and (d)(1)(B) of the Act require that CMS calculate total expenditures under Part D and Part B, respectively, using data from the most recent 12-month period for which data are available prior to the selected drug publication date with respect to an initial price applicability year, but ending no later than October 31 of the year prior to the year of such drug publication date. To describe this 12-month period, we proposed to define ''total expenditures measurement period'' as the 12-month period ending on October 31 of the year prior to the year of the selected drug publication date with respect to an initial price applicability year.

cb. Total Gross Covered Prescription Drug Costs

Section 1191(c)(5) of the Act specifies that the term ''total gross covered prescription drugs costs'' is defined at section 1860D–15(b)(3) of the Act. The term ''total gross covered prescription drug costs'' does not appear at section 1860D–15(b)(3) of the Act, but section 1860D–15(b)(3) of the Act does define the term ''gross covered prescription drug costs,'' and § 423.308 codifies this term. We therefore proposed to define ''total gross covered prescription drug costs'' as having the meaning given the term ''gross covered prescription drug costs'' set forth at 42 CFR 423.308.

cc. Unit

We proposed to define ''unit'' as having the meaning set forth in section 1191(c)(6) of the Act.

cd. Unmet Medical Need

We proposed to define ''unmet medical need'' as a circumstance in which the relevant disease or condition is one for which no other treatment options exist, or existing treatments do not adequately address the disease or condition. For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS will consider the extent to which the drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration.

ce. Wholesale Acquisition Cost (WAC) Unit Price

We proposed to define ''Wholesale Acquisition Cost (WAC) unit price'' as the manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC–11 level.

We received public comments on our proposed definitions. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested that for the definition of ''off-label use'', CMS clarify that ''authoritative medical literature, and/or accepted standards of medical practice'' should be relevant to the Medicare population when it considers off-label use for the purpose of determining therapeutic alternatives. The commenter stated that clinical guidelines outside the United States would not be relevant and including such international guidelines could increase the administrative burden on the agency.

Response: We appreciate this commenter's suggestion to limit evidence related to off-label use to the Medicare population, and the commenter's statement that using clinical guidelines outside the United States would be irrelevant and increase administrative burden. As discussed in section II.F.3.d.1. of the proposed rule (91 FR 36292), we will consider information from studies with different study populations but intend to prioritize research and real-world evidence relating to Medicare populations, including individuals with disabilities, patients with end-stage renal disease, and Medicare-aged populations. Clinical practice guidelines developed outside the United States will not be categorically excluded from consideration or deemed irrelevant to the Medicare population solely on the basis of their country of origin. Rather, the relevance of any clinical practice guideline will be assessed, in part, based on the extent to which the guideline and its recommendations are reasonably applicable to the care delivery setting in which they are

intended to be implemented and the Medicare population. We refer the commenter to § 429.505 for additional information on how we evaluate evidence.

Comment: A commenter supported the broad definition of ''outcomes'' which includes aspects of a patient's life.

Response: We appreciate the commenter's support.

Comment: A commenter recommended that CMS clarify that research and development costs, as described under definitions relating to research and development costs in Appendix A of the Negotiation Program Guidance, should be applied in the rule. This commenter supported the exclusion of acquisition costs from consideration of research and development costs.

Response: We thank this commenter for their suggestion. Because the term ''Research and Development (R&D) Costs and Recoupment'' is defined in the information collections for Identification and Selection of Renegotiation-Eligible Drugs ICR Form (CMS–10844, OMB 0938–1443) and the Negotiation Data Elements ICR Form (CMS–10849, OMB 0938–1452), consistent with the general directive established in this final rule that data submissions must be reported to CMS in the form and manner specified by CMS, CMS declines to add a definition of ''Research and Development (R&D) Costs and Recoupment'' to § 429.20.

Comment: A commenter suggested that the definition of ''starting point'' should state the methodology for developing the starting point, rather than defining the term by referencing § 429.510.

Response: We appreciate this commenters' input. We believe the current definition of ''starting point'' appropriately indicates that the term refers to the numerical dollar amount used by CMS in developing an initial offer and that such dollar amount is determined per § 429.510(d) and then adjusted by CMS based on section 1194(e)(2) factors to determine the preliminary price, per the process described in proposed § 429.510(e). We do not believe repeating the process of determining the starting point outlined in § 429.510(d) is necessary.

Comment: A commenter recommended that CMS broaden the definition of ''unmet medical need'' to include public health needs and health outcomes important to patients, such as improvement in the safety profile of a drug, prevention of disease progression, improvement in quality of life, reduction in time off from work, and improvement in caregiver outcomes. The commenter also requested that CMS specify and publicly report the submitted data that CMS considers to be evidence an unmet medical need; and provide the public and Primary Manufacturers with detailed evidence on the factors considered in determining if a product meets or does not meet an unmet medical need and how this factor impacted the resulting MFP. A commenter suggested that ''unmet medical need'' be considered at the time of the launch of the product.

Response: Consistent with our response to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, we note that the definition of ''unmet medical need'' is adopted from section 60.3.3.1 of the Negotiation Program Guidance, which was developed after consideration of public comments submitted for the revised guidance for initial price applicability year 2026 and with reference to section 1194(e)(2)(D) of the Act and FDA's ''Guidance for Industry Expedited Programs for Serious Conditions—Drugs and Biologics.'' Many of the considerations commenters raised, such as patient quality of life, are considered as part of other factors listed at section 1194(e)(2) of the Act. We will evaluate the extent to which a selected drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration, which aligns with CMS' approach to identifying indications for a selected drug, reviewing manufacturer costs and data, selecting a therapeutic alternative(s), and considering other negotiation factors.

Comment: A commenter recommended that CMS revise the definition of ''therapeutic advance'' to include representation of significant impact among a socially or economically vulnerable population, which is not evident among non-vulnerable populations; or patient-focused improvements in the symptoms or health outcomes associated with a disease (for example, reduction of symptoms, delayed progression of illness, ability to perform daily functions, improvements in adherence, quality of life); or improvements on a validated clinical outcome assessment for the disease state.

Response: We appreciate this commenter's suggestions. Consistent with the Negotiation Program Guidance, we will determine whether a selected drug represents a therapeutic advance by examining improvements in outcomes for the selected drug compared to its therapeutic alternative(s) per the definition in this section of the final rule. We note that many of the other factors mentioned are considered during the development of the initial offer as outlined in § 429.510.

Comment: A commenter stated that CMS' proposed rule did not provide sufficient context regarding the potential expansion for the definition of ''authorized representative''. The commenter stated that, absent other entities, submissions or program contexts CMS has in mind, they cannot reasonably comment on whether an expanded definition is necessary or operable. The commenter recommended that CMS not finalize as proposed and instead identify the specific circumstances CMS intends the definition to cover in future rulemaking.

Response: We appreciate this commenter's suggestions. After further consideration of the intended application of the definition of ''Authorized Representative'' across Negotiation Program requirements and information collections, we believe that the proposed definition of ''Authorized Representative'', which was intended to be a general term, is more restrictive than intended given that it is limited to only individuals with the authority or capacity to legally bind a Primary Manufacturer and could be read as limited to use only in the context of the signing of a Negotiation Program Agreement. This may create issues for Biosimilar Manufacturers attempting to certify submissions in response to the Biosimilar Delay ICR Form (CMS–10844, OMB 0938–1443) or for Primary Manufacturers attempting to certify submissions such as the Negotiation Data Elements ICR Form (CMS–10849, OMB 0938–1452). Accordingly, we are making a clarifying change to the proposed definition of Authorized Representative by revising the defined term to ''Authorized Representative *of the Primary Manufacturer*'' and striking the reference ''*to the terms and conditions of the Negotiation Program Agreement*''. Additionally, we have added a definition of ''*Authorized Representative of the Biosimilar Manufacturer*'' under § 429.20 to provide specification on who may sign a Biosimilar Delay Request on behalf of a Biosimilar Manufacturer.

Comment: A few commenters opposed the definitions of ''Primary Manufacturer'' and ''Secondary Manufacturer'', stating that such definitions do not align with statute and may result in a Primary Manufacturer being held responsible, for example, for violations by or noncompliance of a Secondary Manufacturer.

Response: As discussed in CMS' response in Negotiation Program Guidance and the final guidance for initial price applicability year 2027, given that section 1193(a)(1) of the Act instructs CMS to negotiate with ''the manufacturer'' to arrive at the MFP for a given selected drug to which ''the manufacturer'' would provide access in accordance with the statute, and given that the term ''the manufacturer'' appears repeatedly throughout the statutory provisions establishing the Negotiation Program, the best statutory interpretation is to interpret the term ''manufacturer'' as a single entity for the negotiation process, responsible for negotiation of a single MFP for a given selected drug. Thus, in accordance with section 1193(a)(1) of the Act and other statutory references to ''the manufacturer,'' CMS will enter into a Negotiation Program Agreement with ''the manufacturer'' of a selected drug, where ''the manufacturer'' is the NDA/BLA holder. We adopted the designations and definitions of ''Primary Manufacturer'' and ''Secondary Manufacturer,'' respectively, to establish a process to negotiate the maximum fair price with ''the manufacturer'' to align with the meaning of the statutory language and establish responsibilities and requirements of the Primary Manufacturer related to data collection and submission and MFP availability for the selected drug manufactured, marketed, controlled, or sold by the Secondary Manufacturer(s).

Final Decision: After consideration of public comments received, we are finalizing § 429.20 with modifications. We are making clarifying modifications to the term ''Authorized representative''. We are adding ''of the Primary Manufacturer'' to the term and removing ''to the terms and conditions of the Negotiation Program Agreement'' from the definition. We also are adding a definition for ''Authorized Representative of a Biosimilar Manufacturer''. The term as finalized in this rule is defined as ''an individual that has the authority or capacity to legally bind the Biosimilar Manufacturer and meets one of the following criteria:

- Chief Executive Officer of the Biosimilar Manufacturer
- Chief Financial Officer of the Biosimilar Manufacturer
- An individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer of the Biosimilar Manufacturer
- An individual that has been granted delegation of signature authority on behalf of one of the individuals specified in paragraphs (1) through (3) of this definition''.

We are making additional non-substantive, technical modifications to other definitions. To the term, ''Combined Part B and Part D amount'', we are correcting a typographical error to a citation to ''§ 429.430''; to the term, ''FDA-approved indication'', we are adding ''other'' before ''FDA regulations as applicable''; to the term ''Initial Delay Period,'' we are replacing ''as proposed'' in paragraph (1) with ''as described'' to reflect that this a final regulation; to the term ''therapeutic advance'' at section II.A.2.bw. of the proposed rule, we are adding ''.'' after ''at such time of consideration''; to the term ''therapeutic alternative'' at proposed § 429.20, we are removing erroneous text ''For the purpose of developing the initial offer CMS considers therapeutic advance as of the date specified in § 429.505(d)(2)'', we are replacing ''unmet medical need'' with ''therapeutic advance'', and we are replacing ''addresses an unmet medical need'' with ''represents a therapeutic advance; to the term ''self-administered drug'', we are adding ''product'' after ''biological''; and to the definition of ''unmet medical need'', we are changing ''would'' to ''will''.

3. Limitation on Review (§ 429.30)

Section 1198 of the Act establishes that there shall be no administrative or judicial review of any of the following: (1) the determination of a unit, with respect to a drug or biological product, pursuant to section 1191(c)(6) of the Act; (2) the selection of drugs under section 1192(b) of the Act, the determination of negotiation-eligible drugs under section 1192(d) of the Act, the determination of qualifying single source drugs under section 1192(e) of the Act, and the application of the Biosimilar Delay under section 1192(f) of the Act; (3) the determination of a MFP under subsection (b) or (f) of section 1194 of the Act; and (4) the determination of renegotiation-eligible drugs under section 1194(f)(2) of the Act and the selection of renegotiation-eligible drugs under section 1194(f)(3) of the Act. CMS proposed to codify these limitations on review in proposed § 429.30.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed concern that the limitations on administrative and judicial review of precluded sections specified in section 1198 of the Act increase the need for CMS to act with restraint in finalizing its proposed policies related to those sections. Specifically, these commenters noted that such limitations increase the need for establishing objective regulatory standards and for ensuring methodological consistency with regards to certain policies precluded from administrative and judicial review.

Response: We appreciate these comments and reiterate that section 1198 of the Act establishes that there shall be no administrative or judicial review of the determinations described in that section. We believe the policies set forth and described in this final rule are consistent with the law and accomplish the aim of establishing objective regulatory standards and ensuring methodological consistency.

Final Decision: After consideration of public comments, we are finalizing § 429.30 as proposed.

B. Identification of Selected Drugs (§§ 429.100 through 429.135)

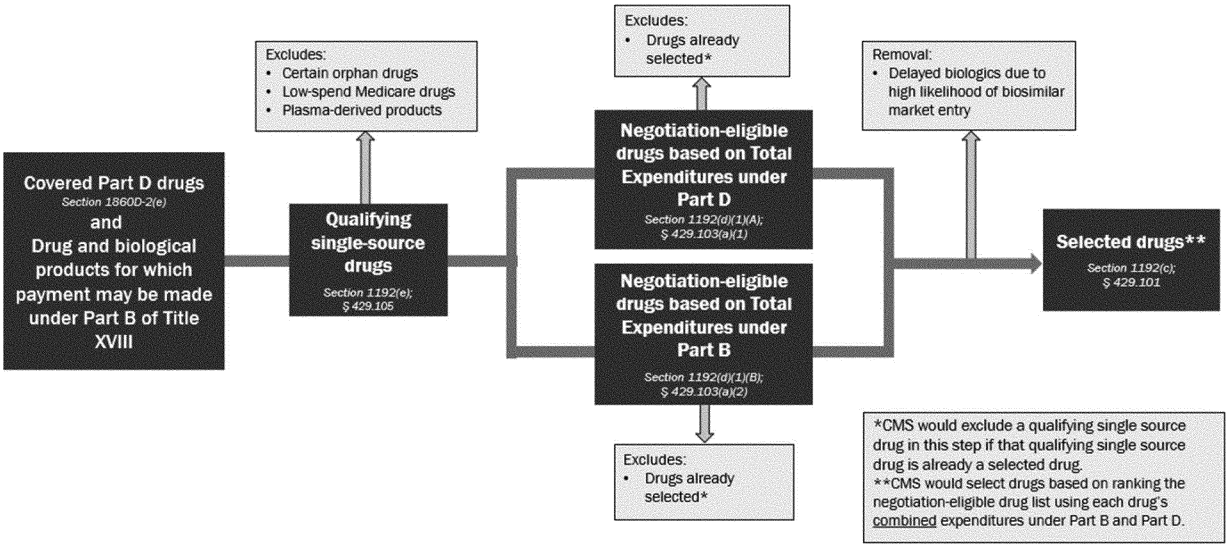
Section 1192 of the Act establishes the requirements governing the publication of the list of selected drugs for an initial price applicability year, the identification of selected drugs, ranking of negotiation-eligible drugs, and the identification of qualifying single source drugs. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example with respect to initial price applicability year 2028, section 30 of the Negotiation Program Guidance. With respect to initial price applicability years beginning with initial price applicability year 2029, we proposed to codify these steps in an order reflecting the sequence of the statutory provisions which these sections are implementing, with proposed revisions as noted in this section, in proposed §§ 429.100 through 429.135.

Beginning with respect to initial price applicability year 2029 and in accordance with section 1192 of the Act, we proposed in §§ 429.100 through 429.135 to codify the policies for identification of selected drugs described in sections 30 and 40.2 of the Negotiation Program Guidance, subject to proposed modifications as noted herein. As a matter of program operations, we would first identify qualifying single source drugs with respect to each initial price applicability year. As a part of this identification process, CMS would exclude certain drugs as proposed in § 429.125(e). Next, we would identify negotiation-eligible drugs using total expenditures under Part B or Part D of Title XVIII of the Act, as applicable and calculated as set forth in proposed § 429.120, to identify qualifying single source drugs that are

Part B high spend drugs, Part D high spend drugs, or both, as proposed in § 429.115. (In these steps, we would also exclude drugs that are already selected drugs in accordance with section 1192(d)(3) of the Act.) As proposed in § 429.105(a), we would rank these negotiation-eligible drugs for an initial price applicability year according to the total expenditures for such drugs. In accordance with section 1192(a) of the Act and subject to section 1192(f) of the Act (which permits the delay in the selection and negotiation of biological products for biosimilar market entry when certain requirements are met consistent with proposed § 429.110, hereinafter ''Biosimilar Delay''), we proposed at § 429.105(c) to select up to 20 negotiation-eligible drugs with the highest total expenditures under Part B and Part D of Title XVIII of the Act for negotiation for initial price applicability year 2029 and each initial price applicability year thereafter, and publish the list of selected drugs as proposed at § 429.100. As discussed in detail in section II.G.3. of this final rule, we may also select a drug or drugs for renegotiation based on criteria proposed in § 429.610.

Finally, as proposed in § 429.100, we would publish the list of drugs selected for negotiation, including the list of drugs selected for renegotiation, if any, not later than the selected drug publication date. We also proposed to publish a list of the up to 30 top negotiation-eligible drugs (including the up to 20 selected drugs) ranked by combined total expenditures under Part B and Part D. Detailed descriptions of these proposals for initial price applicability year 2029 and each initial price applicability year thereafter is included later in this section. Figure 1 provides a visual depiction of this proposed process.

FIGURE 1: DIAGRAM OF PROPOSED PROCESS FOR SELECTING DRUGS FOR NEGOTIATION FOR INITIAL PRICE APPLICABILITY YEARS BEGINNING WITH INITIAL PRICE APPLICABILITY YEAR 2029



1. Publication of the Selected Drug List (§ 429.100)

Section 1192(a)(4) of the Act requires that, not later than the selected drug publication date with respect to the initial price applicability year, in accordance with section 1192(b) of the Act, the Secretary shall select and publish a list of, with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs, as described in section 1192(d)(1) of the Act, with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year). Proposed § 429.20 defines the term ''selected drug publication date'' to have the meaning set forth in section 1191(b)(3) of the Act, which provides that the term ''selected drug publication date'' means, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 30.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

We proposed at § 429.100(a) to codify the requirement at section 1192(c)(1) of the Act that each drug included on the selected drug list [15] for an initial price applicability year is a selected drug with respect to such initial price applicability year and each subsequent year unless and until CMS makes a determination in accordance with proposed § 429.135(a) that such drug will be deselected (as described in further detail in section II.B.6.d. of this final rule). We proposed at § 429.100(b) to codify the requirement that CMS publish the selected drug list and the drugs selected for renegotiation, if any, for each initial price applicability year beginning with initial price applicability year 2029, no later than the selected drug publication date with respect to the initial price applicability year. For example, for initial price applicability year 2029, we would publish this information no later than February 1, 2027. As proposed in § 429.100(b)(1), the selected drug list would include the 20 (or all, if such number is less than 20) drugs payable under Part B, covered under Part D, or both, selected for negotiation for the initial price applicability year as determined in § 429.105(c) and discussed in section II.B.2 of this final

[15] CMS would publish one list with respect to each initial price applicability year. The list would include the selected drug list of the drugs selected for negotiation for the initial price applicability year, as well as drugs selected for renegotiation, if any.

rule. As proposed in § 429.100(b)(2), we would also publish the list of drugs selected for renegotiation, if any, as set forth in proposed § 429.610.

For each selected drug, we proposed at § 429.100(b)(3)(i) to add to the MFP file no later than the selected drug publication date the active moiety, active ingredient, antigen component, or, in the case of a potential qualifying single source drug identified under the general fixed combination drug policy proposed at § 429.125(b)(4), the distinct combination of active moieties, active ingredients, or antigen components,[16] as applicable, identified as set forth in proposed § 429.125(b). For a potential qualifying single source drug identified under proposed § 429.125(b)(4)(i), we proposed to publish the shared active moiety/active ingredient identified under proposed § 429.125(b)(4)(i), plus any additional active moiety/active ingredient included in new formulations of such potential qualifying single source drug. We proposed at § 429.100(b)(4)(i) to take the same approach for each drug selected for renegotiation, if any, except we would publish the active moiety/active ingredient previously identified for the initial price applicability year for which the drug was originally selected for negotiation. We proposed at § 429.100(b)(3)(ii) and (b)(4)(ii) to add to the MFP file no later than the selected drug publication date the NDC–11s identified in accordance with § 429.100(c)(1) and the corresponding NDC–9s and HCPCS codes, as applicable, for the selected drug and the drug selected for renegotiation, if any. For drugs selected for renegotiation, the NDC–11s (and corresponding NDC–9s and HCPCS codes) added to the MFP file would also reflect information previously submitted by the Primary Manufacturer, including submissions in accordance with proposed § 429.100. At § 429.100(c), we proposed the process we would use to identify the list of NDC–11s described in the prior sentences for each selected drug and each drug selected for renegotiation, if any. As proposed at § 429.100(f), the agency's list of NDC–11s would be used in the administration of the Negotiation Program, including to identify the NDC–11s of the selected drug that are subject to the negotiation process set forth in proposed subpart F and the renegotiation process set forth in proposed subpart G (as applicable), identify the NDC–11s of the selected drug to which the MFP (if one is agreed to by CMS and the Primary Manufacturer) applies for the price applicability period, to calculate the ceiling set forth in proposed § 429.410 for drugs selected for negotiation, to calculate the ceiling set forth in proposed § 429.620(b) for drugs selected for renegotiation, and to calculate how to apply the MFP, if one is agreed to by CMS and the Primary Manufacturer, and to the extent data are available to support such calculations, across dosage forms and strengths set forth in proposed § 429.700 for selected drugs and proposed § 429.600(b)(2) for drugs selected for renegotiation.

To identify the list of NDC–11s of the selected drug, including for a drug selected for renegotiation, set forth at proposed § 429.100(c), we proposed at § 429.100(c)(1) to first identify NDC–11s associated with the NDA(s)/BLA(s) of the selected drug. We would compile all NDC–11s belonging to the selected drug associated with HCPCS codes that appear on NDC–HCPCS code crosswalks published by CMS [17] for the most recent quarter in the total expenditures measurement period (as such term is defined in proposed § 429.20), and all NDC–11s belonging to the selected drug that had Part D PDE utilization in the total expenditures measurement period. We would also identify any additional NDC–11s associated with the NDA(s)/BLA(s) of the selected drug as found in recent updates of the NDC Structured Product Labeling (SPL) Data Elements file (NSDE) file or the NDC Directory (including its NDC Excluded Drugs Database file). In section 30.4 of the Negotiation Program Guidance, we stated that we will remove any NDC–11s for which CMS has evidence suggesting a lack of coverage under Part D and Part B. Based on lessons learned from policy implementation in initial price applicability years 2026 through 2028, we proposed to remove such requirement for initial price applicability year 2029 and subsequent years. Starting with a more comprehensive list of NDC–11s holds utility for CMS and Primary Manufacturers, as it reduces the number of NDC–11s that a Primary Manufacturer must identify as missing from the list, as required in proposed § 429.100(d)(1). We would publish the selected drug list, as well as the list of drugs selected for renegotiation, in a form and manner of CMS' choosing, which may be on the CMS website.

We proposed at § 429.100(c)(2) to transmit the list of NDC–11s identified at proposed § 429.100(c)(1) to the Primary Manufacturer. As proposed at § 429.100(c)(3), we may revise our list of NDC–11s of each selected drug, including without limitation using information submitted by the Primary Manufacturer in accordance with proposed § 429.100.

In accordance with a Primary Manufacturer's responsibility under section 1193(a)(4)(B) of the Act and under the Negotiation Program Agreement (set forth in proposed § 429.200 and described in section II.C.1. of this final rule), we proposed in § 429.100(d) that a Primary Manufacturer must review the list of NDC–11s provided by CMS at proposed § 429.100(c) and provide information on each NDC–11 on the list of NDC–11s that make up a selected drug as a part of their data submission. More specifically, we proposed at § 429.100(d) that a Primary Manufacturer must review the list of NDC–11s and provide proposed revisions to the list, as needed, by adding any NDC–11s associated with the NDA(s)/BLA(s) of the selected drug that do not appear on the agency's list of NDC–11s of the selected drug, including any missing NDC–11s of a Secondary Manufacturer. A Primary Manufacturer must also provide identifying information for any NDC–11 that appears on the list of NDC–11s, including any NDC–11s added by the Primary Manufacturer, on whether NDC–11(s): are for products distributed by or under the name of a private label distributor; are not manufactured, marketed, controlled or sold by the Primary Manufacturer or a Secondary Manufacturer; represent a sample package; represent an inner package or an outer package; and whether an NDC–11 has been discontinued. As described in proposed § 429.100(c)(3), we may revise the list of NDC–11s that make up the selected drug based on this information submitted by the Primary Manufacturer.

In accordance with a Primary Manufacturer's responsibility under section 1193(a)(5) of the Act and under the Negotiation Program Agreement (set forth in proposed § 429.200), we proposed in § 429.100(e) that a Primary Manufacturer has an ongoing obligation

[16] For simplicity, we hereinafter use the term ''active moiety/active ingredient'' to refer to the active moiety, active ingredient, antigen component, or, in the case of a potential qualifying single source drug identified under the general fixed combination drug policy proposed at § 429.125(b)(4), the distinct combination of active moieties, active ingredients, or antigen components, that we proposed to identify as specified at proposed § 429.125(b)(1) through (b)(4). In limited cases, we refer to active moieties, active ingredients, and antigen components in the plural (that is, ''active moieties/active ingredients/antigen components'' or ''active moiety(ies)/active ingredient(s)/antigen component(s)) when we believe such terminology provides greater clarity to the discussion.

[17] See: *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

to report, at least 30 calendar days prior to the change taking effect, any changes to the information provided in § 429.100(d) to ensure the list of NDC–11s of the selected drug identified in accordance with proposed § 429.100(c) remains complete and accurate. For example, under proposed § 429.100(e), a Primary Manufacturer must report to CMS any new NDC–11s of the selected drug at least 30 days prior to their first marketed date by or on behalf of the Primary Manufacturer or any Secondary Manufacturer(s) of such selected drug. Failure to provide timely reporting of changes to the list of NDC–11s of the selected drug as described in proposed § 429.100(e) may be considered a violation of the Negotiation Program Agreement under section 1193(a)(5) of the Act and proposed § 429.200(b).

Since the Negotiation Program's inception, interested parties have recommended greater transparency into the process for selecting drugs. In response to these recommendations and in accordance with policy established in the Negotiation Program Guidance, we published a list of the 50 top negotiation-eligible drugs for initial price applicability year 2028 (including the 15 selected drugs for initial price applicability year 2028).[18] To harmonize the request from interested parties for greater transparency into the process for selecting drugs with CMS operations, for initial price applicability year 2029 and subsequent years, we proposed to publish a list of the up to 30 top negotiation-eligible drugs (including the up to 20 selected drugs) ranked by combined total expenditures under Part B and Part D, as determined under proposed § 429.105(a), and information on the NDC–9s, NDC–11s, and HCPCS codes for these negotiation-eligible drugs, as applicable and to the extent feasible. The purpose of publishing a list of negotiation-eligible drugs beyond selected drugs was, and remains, to promote transparency in the drug selection process. The conditions that determine which drugs meet the statutory requirements for a drug to become a qualifying single source drug, negotiation-eligible drug, or selected drug for a given initial price applicability year are not static. Such list was not, and is not, intended to predict or replicate the selected drug list for future initial price applicability years. The honed focus on the up to 30 top drugs would continue to provide transparency into the drug selection process. We believe the prior policy of publishing negotiation-eligible drugs with rankings lower than 30 (that is, #31 through #50) provided less meaningful transparency into the drug selection process for a given initial price applicability year, as identifying such drugs provides little insight into the criteria and conditions that were material to the identification of the selected drug list for that initial price applicability year. Finally, consistent with prior policy, we proposed that the list of top drugs based on combined total expenditures would reflect the removal of negotiation-eligible drugs that qualify for the Biosimilar Delay.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported CMS' proposal to publish a list of the up to 30 top negotiation-eligible drugs (including the up to 20 selected drugs) ranked by combined total expenditures under Part B and Part D, stating that the list will improve public understanding of the drug selection process and help predict drugs that may be selected in the future, which would inform activities such as formulary planning and manufacturer preparations. A commenter supported reducing the published list of negotiation-eligible drugs to up to 30 negotiation-eligible drugs as a way to continue supporting transparency in the selection process while appropriately not overstating the predictive value of any single year's rankings. Some commenters supported CMS' efforts to provide transparency but urged CMS to return to the policy set forth in the Negotiation Program Guidance to publish a list of the up to 50 top negotiation-eligible drugs. These commenters stated that a more comprehensive list is critical for manufacturers to understand CMS' expenditure methodology and anticipate whether and when their products are likely to be selected, as well as for purchasers, researchers, and policymakers to better understand how the selection methodology operates, evaluate trends in Medicare drug spending, and identify drugs approaching the selection threshold. A commenter stated that, although the narrower list may offer sufficient transparency into the current initial price applicability year, visibility into drugs ranked #31 through #50 remains valuable to manufacturers assessing potential eligibility in the subsequent initial price applicability year. This commenter also stated that visibility into drugs ranked #31 through #50 is particularly important given CMS' inclusion of Medicare Advantage expenditures in the calculation of total expenditures under Part B: since MA expenditures are not included in CMS' published Part B spend data, anticipation of potential selection is challenging for manufacturers without the list of up to 50 top negotiation-eligible drugs. A commenter urged CMS to publish a list of drugs that were not considered qualifying single source drugs because they qualified for the orphan drug exclusion or the plasma-derived product exclusion and that, absent the exclusion, would have ranked among the 50 top negotiation-eligible drugs. A commenter recommended that CMS identify any drug falling within the top 20 drugs in total expenditures on a net basis but that is not a selected drug because it does not fall within the top 20 drugs in total expenditures on the gross basis used for selection.

Response: We thank the commenters for their support and suggestions. We agree with the commenter who stated that the list of up to 30 top drugs offers sufficient transparency into the current initial price applicability year and affirm that the purpose of the list of top negotiation-eligible drugs was, and is, to promote transparency into the drug selection process for the initial price applicability year for which the list of top negotiation-eligible drugs is published. As we stated in the proposed rule (91 FR 36245 through 36246), the conditions that determine which drugs meet the statutory requirements for a drug to become a qualifying single source drug, negotiation-eligible drug, or selected drug for a given initial price applicability year are not static, and such list was not, and is not, intended to predict or replicate the selected drug list for future initial price applicability years. We recognize that the Part B Spending Dashboard [19] does not include Part B data for beneficiaries enrolled in MA. However, the absence of MA data from the Dashboard does not, in itself, provide a sufficient basis for publishing a list of up to 50 drugs with the highest Part B expenditures. As we have previously stated, such a list is not intended to predict or otherwise indicate which drugs may ultimately be selected for negotiation for future initial price applicability years.

We therefore disagree with the premise that an expanded list of up to 50 top negotiation-eligible drugs would provide greater benefit to interested parties as compared to the list of up to 30 top negotiation-eligible drugs, since

[18] See: *https://www.cms.gov/files/document/factsheet-medicare-top-50-negotiation-eligible-drug-list-ipay-2028.pdf.*

[19] See: *https://data.cms.gov/tools/medicare-part-b-drug-spending-dashboard.*

neither version of such list can or should be used to help manufacturers, researchers, or insurers predict drugs that may be selected in the future. We decline the suggestions to publish additional information such as the drugs that qualified for the orphan drug exclusion or plasma-derived product exclusion or information about drugs ranked using total expenditures on a net basis; such requests would be operationally infeasible due to the time constraints required to meet statutory deadlines and the complexity of the preparation that must be undertaken in advance of the selected drug publication date, and, in the case of the request for information about total expenditures on a net basis, irrelevant to the methodology CMS is statutorily required to use for purposes of drug selection.

Comment: A few commenters recommended that CMS take steps to increase transparency around the selected drug list. These commenters provided specific recommendations, including that CMS should publish a preliminary ''watch list'' prior to the selected drug publication date; provide advance notice to manufacturers of each drug appearing on the list of up to 30 top negotiation-eligible drugs; explain the methodology and data underlying the published rankings; and disclose material assumptions used to aggregate spending across dosage forms and strengths.

Response: We appreciate the suggestions. We believe that the publication of the selected drug list and the list of up to 30 top negotiation-eligible drugs provides sufficient transparency into the drug selection process. We believe that publishing a ''watch list'' or providing manufacturers with advance notice that their drug will be on the list of up to 30 top negotiation-eligible drugs prior to the selected drug publication date is operationally infeasible due to the time constraints required to meet statutory deadlines and the complexity of the preparation that must be undertaken in advance of the publication of the selected drug list by the selected drug publication date. We therefore decline to adopt these recommendations. In response to the recommendations that CMS explain the methodology and data underlying the published rankings and disclose material assumptions used to aggregate spending across dosage forms and strengths, we direct readers to §§ 429.120 and 429.125, respectively, which provide details on these processes.

Comment: A commenter supported CMS' proposal in § 429.100(e) to require Primary Manufacturers to notify CMS at least 30 calendar days prior to introducing new NDC–11s, stating that this requirement is essential for program oversight.

Response: We agree and thank this commenter for their support.

Final Decision: After consideration of public comments, we are finalizing § 429.100 as proposed.

2. Selection of Drugs for Negotiation (§ 429.105)

Section 1192(b)(1)(A) of the Act requires that, in carrying out section 1192(a) of the Act, the Secretary shall, with respect to an initial price applicability year, rank negotiation-eligible drugs, as described in section 1192(d)(1) of the Act, according to the total expenditures for such drugs under parts B and D of Title XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest. Section 1192(b)(1)(B) of the Act requires that the Secretary select from such ranked drugs with respect to such initial price applicability year the negotiation-eligible drugs with the highest such rankings. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 30.3 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

We proposed at § 429.105 to select 20 (or all, if such number is less than 20) negotiation-eligible drugs for negotiation for each initial price applicability year.

First, with respect to an initial price applicability year, we proposed at § 429.105(a) to rank the list of negotiation-eligible drugs identified at proposed § 429.115 by combined total expenditures under both Part B and Part D in descending order: the negotiation-eligible drug with the highest total expenditures under Part B and Part D would be listed first, and the negotiation-eligible drug with the lowest total expenditures under Part B and Part D would be listed last (the proposed methodology for the calculation of total expenditures under Part B and total expenditures under Part D is described in proposed § 429.120 and section II.B.5. of this final rule). If a negotiation-eligible drug appears on both the Part D high-spend drug list and Part B high-spend drug list (set forth in proposed § 429.115(a)(1) and (a)(2), respectively, and described in section II.B.4. of this final rule), it would receive only one ranking for purposes of selection, according to its combined total expenditures under both Part B and Part D. If a negotiation-eligible drug appears on only one high-spend list, CMS would still combine total expenditures under both Part B and Part D.

Second, with respect to an initial price applicability year, we proposed at § 429.105(b) to remove any biological products that qualify for delayed selection under section 1192(f) of the Act, as proposed at § 429.110 and described in section II.B.3. of this final rule.

Finally, we proposed at § 429.105(c) to select for negotiation the 20 (or all, if such number is less than 20) highest ranked negotiation-eligible drugs remaining on the ranked list for the initial price applicability year. In guidance for initial price applicability years 2026, 2027 and 2028, including, for example, section 30.3 of the Negotiation Program Guidance, we established that for initial price applicability years 2026, 2027, and 2028, in the event that two or more negotiation-eligible drugs had the same total expenditures to the dollar, and such total expenditures were the 10th or 15th highest among negotiation-eligible drugs, as applicable for the initial price applicability year, we will rank those negotiation-eligible drugs based on which drug had the earlier approval or licensure date, as applicable, associated with the earliest-approved FDA application belonging to the NDA/BLA holder and containing the drug's active moiety/active ingredient, and select based on that ranking until there were 10 or 15 (as applicable) selected drugs (or until all drugs were selected, if the number of negotiation-eligible drugs was less than 10 or 15, as applicable). In the proposed rule, we proposed to modify this methodology. We proposed that to determine whether two or more negotiation-eligible drugs have the same total expenditures, and such total expenditures are the 20th highest among negotiation-eligible drugs (or the highest, if the number is less than 20), we would evaluate such total expenditures to the cent, rather than to the dollar as under prior policy. We believe that determining total expenditures to the cent, rather than the dollar, is more precise for purposes of determining the selected drug list. For such drugs with the same combined total expenditures under Part B and Part D to the cent, we would continue to rank those negotiation-eligible drugs

based on which drug has the earliest-approved FDA application belonging to the NDA/BLA holder and containing the drug's active moiety/active ingredient, and select based on that ranking until there are 20 selected drugs (or until all drugs are selected, if the number of negotiation-eligible drugs is less than 20).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters supported CMS' proposal to evaluate total expenditures to the cent, rather than to the dollar as under prior policy, when determining whether two or more negotiation-eligible drugs have the same total expenditures, and such total expenditures are the 20th highest among negotiation-eligible drugs (or the highest, if the number is less than 20). These commenters stated that the proposal is a practical regulatory improvement that improves accuracy in drug selection.

Response: We thank these commenters for their support.

Comment: A commenter stated that as the Negotiation Program expands and drug selection decisions impact an increasing number of supply chain entities, interested parties will require greater certainty regarding how CMS identifies and ranks negotiation-eligible drugs. This commenter recommended that CMS clearly define all datasets, variables, calculations, decision rules, and criteria used to determine eligibility, ranking, and selection, including how CMS will identify and evaluate drugs with the same total expenditures to the cent, but the commenter did not specify which aspects of these processes require further details in their view. This commenter also recommended that CMS evaluate the potential market effects of ranking negotiation-eligible drugs with the same total expenditures based on which drug has the earliest-approved FDA application, asserting that this methodology could inadvertently disadvantage products that have experienced follow-on competition from generics or biosimilars.

Response: We appreciate this commenter's input. We believe this final rule provides robust details regarding how we identify qualifying single source drugs (§ 429.125), calculate total expenditures (§ 429.120), rank and identify negotiation-eligible drugs (§ 429.115), and identify selected drugs (§ 429.105). For example, § 429.120(a) sets forth that we will use gross covered prescription drug costs for PDE records that meet the criteria described in § 429.120(a)(1) through (a)(5) to calculate total expenditures under Part D; likewise, § 429.120(b) sets forth that we will use total allowed charges on OM Part B claims that meet the criteria in § 429.120(b)(1)(i) through (b)(1)(vi), in addition to total allowed charges that would have been applicable under OM Part B for each MA encounter data record for Part B services that meet the criteria described in § 429.120(b)(2)(i) through (b)(2)(ix). To provide another example, § 429.125(b) describes the public sources—which include, but are not limited to RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file—that we use to identify the active moiety/active ingredient in a potential qualifying single source drug.

While we appreciate the recommendation to evaluate the potential market effects of ranking negotiation-eligible drugs with the same total expenditures to the cent based on which drug has the earliest-approved FDA application, we disagree with the premise that this methodology could disadvantage products with generic or biosimilar competition because a potential qualifying single source drug would not be a qualifying single source drug that could become a negotiation-eligible drug or selected drug if CMS determines that a generic drug is approved or a biosimilar is licensed for the potential qualifying single source drug, and such generic drug or biosimilar is subject to Bona Fide Marketing.

Final Decision: After consideration of public comments, we are finalizing § 429.105 as proposed.

3. Request for a Biosimilar Delay (§ 429.110)

a. Overview of the Requirements for a Delay in the Selection and Negotiation of Certain Biological Products With High Likelihood of Biosimilar Market Entry

Section 1192(b)(1)(C) of the Act requires the Secretary to remove from the ranked list of negotiation-eligible drugs (described at proposed a § 429.105 and section II.B.2. of this final rule) any negotiation-eligible drug for which the inclusion on the selected drug list is delayed in accordance with section 1192(f) of the Act. Specifically, section 1192(f)(1)(B) of the Act allows the manufacturer of a biosimilar biological product (defined at proposed § 429.20 as the ''Biosimilar Manufacturer'' of a Biosimilar) to submit a request, prior to the selected drug publication date for an initial price applicability year, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (defined at proposed § 429.20 as a ''Reference Drug'') on the selected drug list for such given initial price applicability year (which we refer to as a ''Biosimilar Delay'').

Section 1192(f) of the Act provides for two potential requests for a Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year (''Initial Delay Request'' as defined in proposed § 429.20) under section 1192(f)(1)(B)(i)(I) of the Act; and (2) a request to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year (''Additional Delay Request'') under section 1192(f)(1)(B)(i)(II) of the Act. Together, CMS refers to an Initial Delay Request and an Additional Delay Request as ''Biosimilar Delay Requests'' as defined in proposed § 429.20. Proposed § 429.110(b) through (f) address the requirements for a Biosimilar Manufacturer to submit a Biosimilar Delay Request and for CMS to determine if the inclusion of the Reference Drug on the selected drug list should be delayed due to such Biosimilar Delay Request. As set forth in proposed § 429.110(a), for purposes of the provisions at proposed § 429.110 and in our discussion of this section herein, all references to ''marketed'' or ''marketing'' mean Bona Fide Marketing as defined in proposed § 429.20 and set forth at proposed § 429.130(a). We discuss Bona Fide Marketing further in section II.B.6.d. of this final rule.

Biosimilar Manufacturers that believe that the Reference Drug of their Biosimilar may be a selected drug for an initial price applicability year may submit an Initial Delay Request for the first year and an Additional Delay request for the second year, and CMS would disregard that request if the Reference Drug would not, in fact, be a selected drug for an initial price applicability year. Biosimilar Manufacturers are encouraged to consult publicly available data on expenditures for drugs payable under Part B and/or covered under Part D, including data published by CMS, including but not limited to data on the Medicare Part B Drug Spending Dashboard [20] and the Medicare Part D

[20] Available at: *https://data.cms.gov/tools/medicare-part-b-drug-spending-dashboard*. Of note, this dashboard excludes MA data for Part B beneficiaries.

Drug Spending Dashboard,[21] which may allow them to determine the likelihood that a given drug may be a selected drug.

As discussed in further detail in section IV. of this final rule, we also proposed revisions to a currently approved information collection for a manufacturer to submit an Initial Delay Request, titled the Negotiation Program Drug Selection for Initial Price Applicability Year 20XX under section 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS–10844, OMB 0938–1443) (hereinafter, the ''Drug Selection ICR''), for a 60-day public comment period concurrently with the proposed rule. A form and manner for submitting a Biosimilar Delay Request, consistent with proposed § 429.110(f), would be specified in the ICR for an initial price applicability year for an Initial Delay Request or an Additional Delay Request. As discussed in further detail in the accompanying 60-day package, we included questions specific to an Initial Delay Request only within the ICR because CMS did not grant an Initial Delay Request for initial price applicability year 2028 and thus we are not including questions pertaining to submitting an Additional Delay Request for initial price applicability year 2029. We will expand the collection to include questions pertaining to an Additional Delay Request when necessary for an upcoming initial price applicability year when there is a Biosimilar Manufacturer that would be eligible to submit an Additional Delay Request after the granting of an Initial Delay Request. Information submitted in a Biosimilar Delay Request that is trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(3) and (4)).

For an Initial Delay Request, if we determine that an otherwise negotiation-eligible drug should be delayed from selection because of the requirements proposed in § 429.110(c), but the Biosimilar is not licensed and marketed based on the requirements proposed in § 429.110(h) during the Initial Delay Period (which we proposed to define in § 429.20 as the time period between: (1) the selected drug publication date for the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request; and (2) the selected drug publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request), the Biosimilar Manufacturer would have the opportunity to submit an Additional Delay Request consistent with proposed § 429.110(e). If the Biosimilar Manufacturer fails to submit an Additional Delay Request or submits an Additional Delay Request that we determine does not meet all the requirements proposed in § 429.110(e), as proposed in § 429.110(h)(1)(ii), the Reference Drug would be included on the selected drug list for the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request. However, we would not include the Reference Drug on such list if another biosimilar of the Reference Drug is marketed before the publication date of the list.

If the Biosimilar named in a successful Additional Delay Request is not licensed and marketed during the Second Delay Period (which we proposed to define in § 429.20 as the time period between: (1) the publication date of the selected drug list for initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request; and (2) the publication date of the selected drug list for initial price applicability year that is 2 years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request), as proposed in § 429.110(h)(2), the Reference Drug would be included on the selected drug list for the initial price applicability year that is 2 years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request(s). However, if another biosimilar of the Reference Drug is marketed prior to the publication date of such list, we would not include the Reference Drug on the selected drug list.

Additionally, as proposed in § 429.110(i)(1), if CMS delayed the selection and negotiation of a Reference Drug for 1 or 2 years, but the Biosimilar was not licensed and marketed, and the Reference Manufacturer agrees to an MFP for the Reference Drug, the Reference Manufacturer would owe a rebate to the Federal Supplementary Medical Insurance Trust Fund for drugs payable under Part B or the Medicare Prescription Drug Account for drugs covered under Part D for the years that the manufacturer would have provided access to the MFP for the Reference Drug but for the successful Biosimilar Delay Requests. Consistent with section 1192(f)(4) of the Act and as described in section II.B.3.c. of this final rule, and in proposed § 429.110(i) of the proposed rule includes the proposed requirements for the calculation of the rebate.

Consistent with section 1198(2) of the Act and proposed § 429.30, there would be no administrative or judicial review of CMS' determinations under section 1192(f) of the Act and in proposed § 429.110 regarding a Biosimilar Delay Request.

b. Requirements for Granting a Biosimilar Delay Request (§ 429.110(c) Through (f))

Section 1192(f)(1)(B)(ii)(I) of the Act requires that the request for the delay be made by the Biosimilar Manufacturer and cannot be initiated by a separate party, such as CMS or the Reference Manufacturer. The Biosimilar Manufacturer, as defined in proposed § 429.20, that is specifically eligible to submit the request is the BLA holder for the Biosimilar or, if the Biosimilar has not yet been licensed, the sponsor of the BLA submitted for review by the FDA. Also included in the definition of ''Biosimilar Manufacturer'' at proposed § 429.20, if neither the Biosimilar has been licensed nor the BLA has been submitted to FDA, the Biosimilar Manufacturer eligible to submit the request is the organization planning to be the sponsor of the BLA submitted for review by FDA. This approach, which is consistent with the policies for implementation as described in sections 30.3.1 through 30.3.1.5 of Negotiation Program Guidance, is appropriate because: (1) it clearly identifies one manufacturer that may submit a Biosimilar Delay Request for a given Biosimilar, avoiding the possibility that CMS would receive two such requests naming the same Biosimilar for the same initial price applicability year; and (2) the status of the application for licensure for the Biosimilar is material to CMS' consideration of a Biosimilar Delay Request, as described in proposed § 429.110. For both an Initial Delay Request and an Additional Delay Request, certain requirements must be met for CMS to grant such requests. These requirements are included in proposed § 429.110(c) for an Initial Delay Request and proposed

[21] Available at: *https://data.cms.gov/tools/medicare-part-d-drug-spending-dashboard.*

§ 429.110(e) for an Additional Delay Request.

Section 1192(f)(1)(B)(ii)(I) and (II) of the Act requires the Biosimilar Manufacturer to make the request prior to the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer is requesting a Biosimilar Delay. As such, we proposed at § 429.110(f) that a Biosimilar Manufacturer may submit to CMS a request for a Biosimilar Delay at the time and in a form and manner specified by CMS. Consistent with the process and timeline for previous initial price applicability years, CMS intends to collect requests via the CMS Health Plan Management System (CMS HPMS) and provide for a 30-day submission period as discussed in the Drug Selection ICR. We will not consider late or incomplete submissions. Upon receipt of a complete Biosimilar Delay Request, CMS will consider whether the requirements are met, as applicable, in proposed 429.110(c) for an Initial Delay Request or proposed § 429.110(e) for an Additional Delay Request.

With respect to Initial Delay Requests, we would first determine if the proposed requirements under proposed § 429.110(c)(1) have been met. Section 1192(f)(1)(A) of the Act and proposed § 429.110(c)(1)(i) require that the Reference Drug would be an extended-monopoly drug, as defined in section 1194(c)(4) of the Act and proposed § 429.20, included on the selected drug list for the initial price applicability year, absent the Biosimilar Delay. For Initial Delay Requests, this means that the Reference Drug must have received its initial BLA licensure at least 12 years, but fewer than 16 years, prior to the start of the relevant initial price applicability year. Section 1194(c)(4)(B)(ii) of the Act specifies that selected drugs for which a manufacturer had an agreement under the Negotiation Program for an initial price applicability year prior to 2030 are excluded from the definition of extended-monopoly drugs (definition proposed at § 429.20). Importantly, however, an Initial Delay Request must be submitted by a Biosimilar Manufacturer before the selected drug publication date for an initial price applicability year and before the Reference Manufacturer would have entered into an agreement under the Negotiation Program. Therefore, we continue to believe the exception to the definition of ''extended-monopoly drug'' in section 1194(c)(4)(B)(ii) of the Act would not apply at the time that a delay would be requested for initial price applicability year 2029. Accordingly, we believe the Biosimilar Delay Request process under section 1192(f) of the Act is applicable for future initial price applicability years. As such, Biosimilar Manufacturers may submit an Initial Delay Request for initial price applicability year 2029, provided that the Reference Drug named in the request would have been licensed for at least 12 years but fewer than 16 years prior to the start of the initial price applicability year beginning on January 1, 2029.

Additionally, to qualify for an Initial Delay Request, section 1192(f) of the Act requires the following (as proposed in § 429.110(c)):

- In accordance with section 1192(f)(1)(A) of the Act and as described in proposed § 429.110(c)(1)(ii), the Reference Drug must include the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has been approved or accepted for review by FDA. We note that to grant a Biosimilar Delay Request, the licensure application for the Biosimilar does not need to include all of the dosage forms, strengths, and indications for which the Reference Drug has received approval. With respect to the reference product, the Initial Delay Request may list the brand name and/or the name of the reference product's active ingredient.
- In accordance with section 1192(f)(2)(D)(iii) of the Act and as described in proposed § 429.110(c)(1)(iii), a Biosimilar Delay Request would not be granted if more than 1 year has elapsed since the licensure of the Biosimilar and marketing of the Biosimilar has not commenced.
- In accordance with section 1192(f)(2)(D)(iv) of the Act and as described in proposed § 429.110(c)(1)(iv)(A), the Biosimilar Manufacturer must not be the same as the Reference Manufacturer and must not be treated as being the same under section 1192(f)(1)(C) of the Act. For the purposes of this determination, all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC), or in a partnership, shall be treated as one manufacturer in accordance with section 1192(f)(1)(C) of the Act. For the purposes of this determination, ''partnership'' (as proposed at § 429.20) is defined at section 1192(f)(1)(C)(ii) of the Act as a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the Reference Manufacturer and the Biosimilar Manufacturer.
- In accordance with section 1192(f)(2)(D)(iv) of the Act and as described in proposed § 429.110(c)(1)(iv)(B), the Biosimilar Manufacturer and the Reference Manufacturer must not have entered into an agreement that—

++ Requires or incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay Request; or

++ Directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time.

We would consider any agreement between the Biosimilar Manufacturer and the Reference Manufacturer that directly or indirectly restricts the quantity of the Biosimilar that the Biosimilar Manufacturer may sell during any period of time on or after the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer is requesting a Biosimilar Delay, as failing to meet this requirement.

Once we determine the requirements proposed in § 429.110(c)(1) are met, we would then determine if there is a high likelihood, as required in section 1192(f)(1)(A) of the Act and as proposed in § 429.110(c)(2), that the Biosimilar will be licensed and marketed before the date that is 2 years after the statutorily defined selected drug publication date for the initial price applicability year for which the Reference Drug would be included on the selected drug list absent a successful Initial Delay Request (''High Likelihood Deadline,'' as defined in proposed § 429.20). For example, the High Likelihood Deadline for an Initial Delay Request for initial price applicability year 2029 would be February 1, 2029. Specifically, in accordance with section 1192(f)(3) of the Act and consistent with implementation of the policies in section 30.3.1.3 of Negotiation Program Guidance Program, we proposed in § 429.110(d) that there is a high likelihood the Biosimilar will be licensed and marketed before the High Likelihood Deadline if each of the following criteria are met:

- An application for licensure under section 351(k) of the PHS Act for the Biosimilar has been accepted for review or approved by FDA.
- CMS has identified clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline.

We proposed at § 429.110(d)(1) that CMS will specify the due date by which the application for licensure must be accepted for review or approved by the FDA, which will be a date before the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer requests a Biosimilar Delay in order to permit

sufficient time for CMS to review the information and finalize the selected drug list prior to publishing the selected drug list for the initial price applicability year. This would enable CMS to use the most recent possible data to make this determination, while still allowing for sufficient time for such requests to inform the selected drug list prior to the selected drug publication date as required by section 1192(a) of the Act. If the Biosimilar's application for licensure has not been accepted for review by the specified date, including in the case where the Biosimilar Manufacturer submitted an application for licensure that has not been accepted for review by FDA or for which a filing determination is pending, we would deny the Initial Delay Request. Additionally, CMS would consider an application for licensure under section 351(k) of the PHS Act that has been accepted for review and received a complete response letter from the FDA to meet the section 1192(f)(3)(A) requirement that an application for licensure under section 351(k) for the biosimilar biological product has been accepted for review by FDA.

To demonstrate clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline, we proposed at § 429.110(d)(2) that the Biosimilar Delay Request must include information to demonstrate both: (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed; and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. These requirements address the two primary contributing factors to delays in marketing of biosimilars approved in the United States to date, and so we believe that evidence showing that a Biosimilar meets these two requirements is sufficient to establish clear and convincing evidence that the Biosimilar will be marketed.

First, regarding the proposal at § 429.110(d)(2)(i) that the Biosimilar Delay Request must clearly demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline: we will only consider patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar. For example, if a Biosimilar Manufacturer has obtained licensure with biosimilar labeling that omits a patent-protected indication or other patent-protected information, then such patents that cover the omitted indication or the omitted information will not be considered to be ''applicable to the Biosimilar''. Specifically, we proposed at § 429.110(d)(2)(i)(A) through (D) that the Biosimilar Manufacturer must demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline through any of four pathways specified. The first option the Biosimilar Manufacturer may demonstrate is that there will be no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar. The second option the Biosimilar Manufacturer may demonstrate is that one or more court decisions or decisions by the United States Patent and Trademark Office (USPTO)'s Patent Trial and Appeal Board (PTAB) establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patents relating to the reference product included in the Reference Drug that a patent holder asserted was applicable to the Biosimilar. The third option the Biosimilar Manufacturer may demonstrate is that neither a court nor PTAB has adversely ruled against the Biosimilar Manufacturer's patent assertion(s) pertaining to unexpired patent(s) relating to the reference product included in the Reference Drug applicable to the Biosimilar, and the Biosimilar Manufacturer has publicly announced a precise launch date for the Biosimilar that is both a calendar date before the High Likelihood Deadline and is not contingent on the outcome of pending litigation. Finally, the fourth option the Biosimilar Manufacturer may demonstrate is that the Biosimilar Manufacturer has a signed agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before the High Likelihood Deadline, without improper constraints on the Biosimilar Manufacturer. In accordance with the parameters set forth in section 1192(f)(2)(D)(iv) of the Act and proposed § 429.110(c)(1)(iv) of this section, an improper constraint includes, but is not limited to: circumstances in which the Biosimilar Manufacturer is the same as the Reference Manufacturer or is treated as being the same pursuant to section 1192(f)(1)(C) of the Act; an instance in which the Biosimilar Manufacturer has entered into an agreement with the Reference Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay Request; and an instance in which a Biosimilar Manufacturer has entered into an agreement with the Reference Manufacturer that directly or indirectly restricts the quantity of the Biosimilar sold in the United States on or after the selected drug publication date of the initial price applicability year for which the Biosimilar Manufacturer is requesting a Biosimilar Delay.

Second, regarding the proposal at § 429.110(d)(2)(ii) that the Biosimilar Delay Request must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline, to assess this requirement, we proposed to consider the Biosimilar Manufacturer's progress against the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug as evidenced by both: (1) disclosures about capital investment, revenue expectations, and actions consistent with the normal course of business for marketing of a biosimilar biological product before the High Likelihood Deadline; and (2) a manufacturing schedule that is consistent with the public-facing statements and demonstrates readiness to meet revenue expectations. We proposed these criteria because we believe they are indicative of operational readiness and should be available in the elements that CMS must consider in making this determination as required by section 1192(f)(1)(B)(ii) of the Act.

In accordance with sections 1192(f)(3)(B), CMS must use information from items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act submitted to CMS by the Biosimilar Manufacturer requesting the Biosimilar Delay to identify if there is clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline. Consistent with these statutory requirements and the policies implementing section 30.3.1.3 of the Negotiation Program Guidance, we proposed at § 429.110(f)(1)(i) through (iii) the information we would review for such ''clear and convincing evidence,'' which must include—

- All agreements related to the Biosimilar filed with the Federal Trade Commission (FTC) or the Assistant Attorney General under subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003;
- To the extent available, the manufacturing schedule for the Biosimilar submitted to FDA during its review of the application for licensure under section 351(k) of the PHS Act for the Biosimilar; and
- To the extent available, the Biosimilar Manufacturer's disclosures

pertaining to the marketing of the Biosimilar (for example, in filings with the Securities and Exchange Commission (SEC) required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation distributed to the shareholders of privately held companies) about capital investment, revenue expectations, and other actions typically taken by a manufacturer in the normal course of business in the year (or the 2 years, as applicable) before marketing of a Biosimilar.

To illustrate what information specifically that CMS might identify within such documentation to potentially demonstrate that the Biosimilar has a high likelihood of being marketed before the High Likelihood Deadline, we provide three examples of ''clear and convincing evidence'' that might be included in the documentation required at section 1192(f)(3)(B) of the Act and proposed in § 429.110(f)(1)(i) through (iii). These examples are illustrative but alone may not always constitute ''clear and convincing evidence'' of a high likelihood of being marketed. First, we provide two examples of evidence that could potentially demonstrate that a patent (or patents) related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed: (1) the listing of a signed agreement between the Biosimilar and Reference Drug Manufacturers under ''Legal Proceedings'' or another section, as appropriate, in a Form 10–K, along with a copy of the agreement if required to be filed with the Federal Trade Commission (FTC) or the Assistant Attorney General under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and (2) the lack of any adverse actions from a court or PTAB under ''Legal Proceedings'' or another section, as appropriate, in a Form 10–K pertaining to a Biosimilar Manufacturer's patent assertion(s) of an unexpired patent or patent(s) relating to the reference product included in the Reference Drug applicable to the Biosimilar, and the Biosimilar Manufacturer publicly announced a precise launch date for the Biosimilar by a calendar date prior to the High Likelihood Deadline within the operational preparations and/or other steps to market and/or produce the Biosimilar under ''Management's Discussion and Analysis (MD&A)'' or another section, as appropriate, in a Form 10–K. Second, we provide one example of evidence that could potentially demonstrate that the Biosimilar Manufacturer is operationally ready: information regarding the operational preparations and/or other steps to market and/or produce the Biosimilar under ''MD&A'' or another section, as appropriate, in a Form 10–K. These distinct examples are intended to be for illustrative purposes only and do not supersede the requirements of the originating authorities for the required documentation (for example, the Securities Exchange Act of 1934 governing disclosure requirements). Consistent with section 1192(f)(1)(B)(ii)(III)(bb) of the Act, comparable documentation that is distributed to the shareholders of privately held companies could be provided in lieu of any examples of disclosures required under the Securities Exchange Act of 1934 for publicly traded companies. These examples are not exhaustive of the information that might be included in the documentation required at section 1192(f)(3)(B) of the Act and in a submission for a request for an Initial Delay Request necessary to demonstrate ''clear and convincing evidence''.

Finally, consistent with section 1192(f)(1)(B)(ii)(II) of the Act and at proposed § 429.110(f)(2), we may request additional information from the Biosimilar Manufacturer as necessary to make a determination with respect to the Initial Delay Request after reviewing an Initial Delay Request. Any such written request would specify the additional information required, a form and manner in which the Biosimilar Manufacturer must provide the additional information, and the deadline for providing such information.

As proposed at § 429.110(g)(1), we would provide in writing a notice of determination, on or after the selected drug publication date for the initial price applicability year by a specific date to be set forth by CMS, to the Biosimilar Manufacturer that requested the Initial Delay Request regarding whether the request was successful or unsuccessful. If unsuccessful, we would specify the reason for the unsuccessful request. Such reasons provided may include: (1) failure to submit all elements of the Biosimilar Delay Request by the applicable deadline (CMS–10844, OMB 0938–1443); (2) failure to meet another statutory requirement for granting a request (other than the high likelihood requirement), including in the case that the Reference Drug would not have been a selected drug for the initial price applicability year absent the Initial Delay Request; or (3) failure to demonstrate a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline. We also proposed at § 429.110(g)(1)(i)(B) to notify each Reference Manufacturer named in a successful Biosimilar Delay Request. We proposed that such notification would be in writing and would identify the Reference Drug that would have been a selected drug in the initial price applicability year, absent the successful Initial Delay Request. Reference Manufacturers named in unsuccessful Initial Delay Requests would not be notified. We will publish the number of Reference Drugs that would have been selected drugs for the initial price applicability year, absent successful Initial Delay Requests, as part of publishing the selected drug list as proposed in § 429.100 and described in section II.B.1. of this final rule (see proposed § 429.110(g)(2)).

Section 1192(f)(2)(B) of the Act requires CMS to determine whether each Biosimilar named in a successful Initial Delay Request is licensed and marketed during the Initial Delay Period. CMS proposed at § 429.110(h)(1) that we would determine whether each Biosimilar named in a successful Initial Delay Request was licensed and marketed during the Initial Delay Period. If we determine that the Biosimilar is not licensed and marketed during the Initial Delay Period, we proposed at § 429.110(h)(1)(i) that the Biosimilar Manufacturer will have the opportunity to submit an Additional Delay Request. In proposed § 429.110(g)(3), for successful Initial Delay Requests submitted with respect to the initial price applicability year, we proposed to notify a Biosimilar Manufacturer if CMS has determined that the Biosimilar named in the Biosimilar Manufacturer's successful Initial Delay Request is licensed and marketed during the Initial Delay Period by a date to be specified by CMS in technical guidance, which will be no later than the end of October of the calendar year of the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer submitted the successful Initial Delay Request. For example, if CMS determined that a Biosimilar Manufacturer's Initial Delay Request was successful for initial price applicability year 2029, CMS would provide this notification to the Biosimilar Manufacturer no later than the end of October 2027.

If the Biosimilar Manufacturer chooses to submit an Additional Delay Request, sections 1192(f)(2)(B)(i)(I) and (iii) of the Act include requirements for an Additional Delay Request. We proposed these requirements in

§ 429.110(e), along with the corresponding documentation requirements in § 429.110(f). Consistent with section 1192(f)(2) of the Act, to first be eligible for an Additional Delay Request, we would need to determine that the Biosimilar listed in the Additional Delay Request was identified in a successfully granted Initial Delay Request (consistent with proposed § 429.110(c)) and the licensure and marketing under section 351(k) of the PHS Act has not commenced between the publication date of the selected drug list for the initial price applicability year for which the Initial Delay Request was granted and the date that is 1 year following that publication date. We proposed these requirements at § 429.110(e)(1)(i) and (ii). Additionally, as a threshold requirement, we would determine that the requirements proposed at § 429.110(c)(1)(ii) through (iv) for an Initial Delay Request, in accordance with sections 1192(f)(1) and (2) of the Act, remain met for purposes of the Additional Delay Request (see proposed § 429.110(e)(1)(iii)). Further, in accordance with section 1192(f)(2)(D)(ii) of the Act and as described in proposed § 429.110(e)(1)(iv), a Biosimilar named in the Biosimilar Manufacturer's successful Initial Delay Request is not eligible for an Additional Delay Request if the status of the Reference Drug would change to a long-monopoly drug (as defined in proposed § 429.20), with respect to the initial price applicability year for which the Biosimilar Manufacturer is submitting an Additional Delay Request. If the requirements proposed in § 429.110(e)(1)(i) through (iv) are met, we would then reevaluate and determine whether the requirements in proposed § 429.110(d) regarding whether there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline continue to be met as proposed in § 429.110(e)(2). Finally, in accordance with section 1192(f)(2)(B)(i)(II) of the Act and as described in proposed § 429.110(e)(3), we must determine, on the basis of clear and convincing evidence, that the Biosimilar Manufacturer has made a significant amount of progress towards both licensure and marketing of the Biosimilar since the Biosimilar Manufacturer's submission of the successful Initial Delay Request. In accordance with section 1192(f)(2)(B)(i)(II) of the Act, CMS is required to use information from the following items when assessing whether there is clear and convincing evidence that the Biosimilar Manufacturer has made a significant amount of progress towards licensure and marketing of the Biosimilar since the Biosimilar Manufacturer's submission of the successful Initial Delay Request for the Biosimilar: (1) all agreements related to the Biosimilar filed with the FTC or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (as described in section 1192(f)(1)(B)(ii)(I)(bb) of the Act); and (2) additional information and documents that CMS may request after CMS has reviewed the information required for submission of the Additional Delay Request necessary to make a determination about an Additional Delay Request (as described in section 1192(f)(1)(B)(ii)(II) of the Act).

Consistent with implementation of policies in section 30.3.1.4 of the Negotiation Program Guidance, recognizing that approximately 1 year has passed since submission of the successful Initial Delay Request, we would consider whether the Biosimilar Manufacturer demonstrates that the Biosimilar will be licensed and marketed before the High Likelihood Deadline. Specifically, we proposed at § 429.110(e)(3) that the determination of whether a significant amount of progress has been made by the Biosimilar Manufacturer towards licensure and marketing of the Biosimilar since the successful Initial Delay Request submission for such Biosimilar will be based on a holistic review of the documentation submitted with the Additional Delay Request (as described in proposed § 429.110(f)(1), including any follow-up documentation requests from CMS to the manufacturer described in proposed § 429.110(f)(2)). Within the request we would consider if the Biosimilar Manufacturer can demonstrate affirmative progress towards being operationally ready to market the Biosimilar, meaning that we would consider the Biosimilar Manufacturer's progress on the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug since the successful Initial Delay Request submission for the Biosimilar evidenced in any updates or supplements to the documents specified in section 1192(f)(1)(B)(ii)(III) of the Act and as described in proposed § 429.110(f)(1). Additionally, we would consider if the manufacturing schedule (as provided in § 429.110(f)(1)(ii)) is consistent with the public-facing statements (that may be identified within the information provided in the materials set forth at proposed § 429.110(f)(1)(iii)) and demonstrates readiness to meet revenue expectations.

After completing our review of an Additional Delay Request, similar to the process for notification after an Initial Delay Request, we would notify the Biosimilar Manufacturer that submitted the Additional Delay Request regarding CMS' determination of whether the Additional Delay Request was successful or unsuccessful (see proposed § 429.110(g)(1)(i)(A)). We also proposed to notify the Reference Manufacturer of a successful Additional Delay Request (see proposed § 429.110(g)(1)(i)(B)) and would publish the number of Reference Drugs that would have been selected drugs for the initial price applicability year if they had not been determined eligible by CMS for a Biosimilar Delay Request for that initial price applicability year (see proposed § 429.110(g)(2)).

c. Review for Failure of the Biosimilar To Be Licensed and Marketed; Rebate Owed for Failure of a Biosimilar To Be Licensed and Marketed (§ 429.110(h) and (i))

As discussed previously, CMS proposed at § 429.110(h)(1) that we would determine whether each Biosimilar named in a successful Initial Delay Request was licensed and marketed during the Initial Delay Period. If we determine that the Biosimilar is not licensed and marketed during the Initial Delay Period, we proposed at § 429.110(h)(1)(i) that the Biosimilar Manufacturer will have the opportunity to submit an Additional Delay Request. In proposed § 429.110(h)(1)(ii), we proposed that if the Biosimilar Manufacturer chooses not to submit an Additional Delay Request, or submits an Additional Delay Request that CMS determines does not meet all requirements in proposed § 429.110(e), CMS would include the Reference Drug on the selected drug list for the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request (for example, the selected drug list for initial price applicability year 2030 for successful Initial Delay Requests for initial price applicability year 2029), unless a different biosimilar biological product is marketed before the publication of the selected drug list for the applicable initial price applicability year, in which case CMS could also determine, in accordance with section 1192(c) of the Act and described in section II.B.6.d. of this final

rule, that the Reference Drug no longer meets the criteria to be a selected drug and will be excluded from such applicable list of drugs selected for an initial price applicability year. Further, in accordance with section 1192(f)(2)(C) of the Act and as described in proposed § 429.110(h)(2), CMS must determine whether each Biosimilar named in a successful Additional Delay Request is licensed and marketed during the Second Delay Period. We proposed at § 429.110(h)(2)(i) that if CMS determines that the Biosimilar is not licensed and marketed during the Second Delay Period, unless a different biosimilar biological product is marketed, CMS would include the Reference Drug on the selected drug list for the initial price applicability year that is 2 years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request.

In accordance with sections 1192(f)(2)(B)(ii), 1192(f)(2)(C), and 1192(f)(4)(A) of the Act and as described in proposed § 429.110(i)(1), if—(1) CMS delayed the selection and negotiation of a Reference Drug for 1 or 2 years; (2) CMS determined that the Biosimilar was not licensed and marketed; and (3) the manufacturer of the Reference Drug agrees to an MFP for the Reference Drug, the Reference Manufacturer is required to pay a rebate for the years that the manufacturer would have provided access to the MFP for the Reference Drug but for the delay. In accordance with section 1192(f)(4)(B) of the Act, we specify in proposed § 429.110(i)(4) that the rebate owed by the Reference Manufacturer, for the year for which an Initial Delay Request and, if applicable, an Additional Delay Request was granted will be calculated as follows:

- In accordance with section 1192(f)(4)(B)(i) of the Act and as described in proposed § 429.110(i)(4)(ii), in the case of a Reference Drug that is a drug covered under Part D, 75 percent of the difference between the AMP, with respect to each of the calendar quarters of the price applicability period, and the MFP negotiated for the Reference Drug multiplied by the number of units dispensed under Part D for the Reference Drug in each calendar quarter of the price applicability period that would have applied but for the delay.
- In accordance with section 1192(f)(4)(B)(ii) of the Act and as described in proposed § 429.110(i)(4)(iii), in the case of a Reference Drug payable under Part B, 80 percent of the difference between the payment amount under section 1847A(b) of the Act, with respect to each of the calendar quarters of the price applicability period, and the MFP negotiated for the Reference Drug, multiplied by the number of units of the billing and payment code of the Reference Drug administered or furnished under Part B (excluding units that are packaged into the payment amount for an item or service and are not separately payable under Part B) for each calendar quarter of the price applicability period that would have applied but for the delay.
- As described in proposed § 429.110(i)(4)(iv), in the case of a Reference Drug that is a drug covered under Part D and payable under Part B, the rebate amount will be calculated by summing the rebate amount for the units payable under Part B as specified in proposed § 429.110(i)(4)(iii) and the rebate amount for units covered under Part D as specified in proposed § 429.110(i)(4)(ii).

For the year for which an Additional Delay Request was granted, we will adjust the MFP as described in section 1195(b)(1)(A) of the Act to account for changes in the CPI–U. Additionally, before applying a rebate as described in proposed § 429.110(i)(5), we will determine if the Reference Drug transitioned to a long monopoly drug, at the time of its inclusion on the selected drug list for the initial price applicability year. For drugs payable under Part B and covered under Part D, we would calculate the rebate for the units payable under Part B following the Part B formula and we would calculate the rebate for the units covered under Part D following the Part D formula.

In the case of a Reference Drug that CMS determines transitioned to a long-monopoly drug during the delay, in accordance with section 1192(f)(4)(C) of the Act and as described in proposed § 429.110(i)(5) through (6), the rebate calculation will substitute the MFP negotiated for the Reference Drug with the following amount. The amount will be equal to 65 percent of the average non-FAMP (consistent with proposed § 429.20 and defined in 38 U.S.C. 8126(h)(5)) for 2021 (or the first full year following market entry if there is no non-FAMP for 2021) increased by the percentage increase in the CPI–U from September 2021 (or December of such first full year following the market entry) to September of the year prior to the selected drug publication date for the initial price applicability year that would have applied but for the Initial Delay Request. For example, if inclusion of the Reference Drug on the selected drug list is delayed until initial price applicability year 2030 due to a successful Initial Delay Request, and the Reference Drug transitions to a long-monopoly drug, the rebate calculation will use September of the year prior to the selected drug publication date for initial price applicability year 2029 (September 2026) for the purposes of adjusting for inflation the average non-FAMP for 2021. As described in proposed § 429.110(i)(6), the rebate calculation will substitute the MFP negotiated for the Reference Drug with the amount that is further adjusted by the annual percentage increase in the CPI–U for the 12-month period ending with July of the calendar year that is 2 years before the initial price applicability year for which the Additional Delay Request was granted.

In accordance with section 1192(f)(4)(B) of the Act and as described in proposed § 429.110(i)(4)(i), we intend to apply the MFP to the rebate calculation for all the previous initial applicability years where the Reference Drug would have been on the selected drug list if not for the successful Biosimilar Delay Request. For example, if the Reference Drug would have been on the list for initial price applicability years 2029 and 2030 but for the approval of an Initial Delay Request and an Additional Delay Request, and CMS determines the Biosimilar was not licensed and marketed, we will use the MFP agreed to for initial price applicability year 2031 to calculate the rebate amount for initial price applicability years 2029 and 2030.

In accordance with section 1192(f)(4)(D) of the Act and as described in proposed § 429.110(i)(3), the rebates paid for drugs payable under Part B would be deposited in the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act. The rebates paid for drugs covered under Part D would be deposited in the Medicare Prescription Drug Account established under section 1860D–16 of the Act, which is within the Federal Supplementary Medical Insurance Trust Fund. Under proposed § 429.110(i)(2), we would specify a form and manner for the administration of rebates, including the timing and mechanism for notifying manufacturers when a rebate is owed and the process for payment, in future rulemaking.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters suggested that CMS expand the Initial Delay Request submission window beyond 30 days so that Biosimilar Manufacturers have sufficient time to respond. A commenter recommended that CMS publish the opening and

closing dates of the submission window not less than 90 days before the window opens so that sponsors can sequence regulatory submissions around it. A commenter requested that CMS provide advance notice of a Reference Drug's potential or actual selection so that Biosimilar Manufacturers have reasonable advance notice to prepare a request for delay. A commenter requested CMS publish the number of Initial Delay Requests and Additional Delay Requests received and the number of requests granted, as well as a list of all Reference Drugs for the requests that were submitted.

Response: We thank the commenters for their suggestions. Consistent with our response to similar comments in the final guidance for initial price applicability year 2027 and the Negotiation Program Guidance, this final rule describes the timing for the submission of a request for a biosimilar delay in accordance with section 1192(f) of the Act (the ''Biosimilar Delay'') and is based on a set timeline in the statute and operational constraints related to the drug selection process. CMS must make a full determination and may not immediately delay the selection of a Reference Drug whilst making a complete determination of the requirements specified in section 1192(f) of the Act to determine the outcome of a request to delay the inclusion of a Reference Drug by one initial price applicability year (an ''Initial Delay Request''). Further, the deadline for an Initial Delay Request will be set as close to the selected drug publication date as is administratively feasible. We adopted this timeline under the authority granted in section 1192(f)(1)(B)(ii) of the Act to set the time, form, and manner of Biosimilar Delay requests, and have exercised this authority to establish a timeline (which is described in section II.B.3. of this final rule) that allows CMS to carefully review the Initial Delay Request documentation and, if applicable, to request follow-up information from the manufacturer of a biosimilar (the ''Biosimilar Manufacturer'') on its Initial Delay Request. The timeline ensures that we will have adequate time to review follow-up data and make a well-informed determination. These timing and operational constraints do not allow for any additional notice or to extend the submission period beyond 30 days.

In response to commenters' requests to publish data used to make determinations regarding the Reference Drug and to publish the list of all Reference Drugs for submitted Initial Delay Requests, we reiterate the response provided to similar comments in the Negotiation Program Guidance and the revised guidance for initial price applicability year 2026. Specifically, the submission of an Initial Delay Request does not guarantee that a Reference Drug would be a selected drug absent the Initial Delay Request, nor does it guarantee that the Initial Delay Request will be granted even if the Reference Drug would be a selected drug absent the Biosimilar Delay. CMS, therefore, will not publish a list of Biosimilar Manufacturers submitting an Initial Delay Request or CMS' determinations. However, as described in section II.B.3. of this final rule, we will notify each Biosimilar Manufacturer that submits an Initial Delay Request of CMS' determination regarding such request on or after the selected drug publication date for the initial price applicability year as described in § 429.110(g)(1)(i)(A). We will also notify each Reference Manufacturer named in a successful Initial Delay Request, as described in § 429.110(g)(1)(i)(B). Further, as described in § 429.110(g)(2), we will publish the number of Reference Drugs that would have been selected drugs for the initial price applicability year, absent successful Initial Delay Requests, as part of publishing the selected drug list set forth in § 429.100.

Comment: A couple of commenters asked CMS to allow submissions of requests as close as reasonably possible to the selected drug publication date for the initial price applicability year to ensure that decisions are informed by the most recent developments. A commenter requested that CMS maintain the end of December submission due date for the Initial Delay Request. A few commenters suggested that CMS accept supplemental late-breaking information that may impact CMS' determination. A commenter suggested CMS permit Biosimilar Manufacturers to submit amendments to address potential errors or omissions during CMS' consideration process. A couple of commenters requested that CMS create a dispute resolution or appeal process for CMS' determination that a Biosimilar does not qualify for the Biosimilar Delay.

Response: We thank commenters for this feedback. Consistent with our response to the comments immediately prior, and our response to similar comments in the Negotiation Program Guidance, the timing for submission of a request for a biosimilar delay is based upon the statute and operational constraints related to the drug selection process. We decline at this time to create a dispute resolution process for the Biosimilar Delay. The statutory deadlines for the Negotiation Program do not provide enough time to establish a dispute resolution process before the selected drug publication date. Additionally, we believe that the submission period allows manufacturers to provide the relevant data to support their application for the Biosimilar Delay and, following the close of the submission period, for CMS to request additional information or to address an error or omission as applicable, and we decline to use a dispute resolution process for a manufacturer to supplement a submission.

Comment: A commenter suggested CMS provide notice to the Reference Manufacturer of an Initial Delay Request or an Additional Delay Request, before a determination of whether the Initial Delay Request or Additional Delay Request will be granted. A couple of commenters suggested that CMS provide notice to Reference Manufacturers of unsuccessful Initial Delay Request or Additional Delay Request submissions. In the event that an Initial Delay Request or Additional Delay Request is not granted, a couple of commenters recommended that CMS provide the Biosimilar Manufacturer that requested the Initial Delay Request or Additional Delay Request rationale for why the Initial Delay Request or an Additional Delay Request was not granted.

Response: We thank this commenter for their input. Information regarding the timing for CMS to notify each Reference Manufacturer named in a successful Biosimilar Delay Request is discussed in section II.B.3.b. of the proposed rule (91 FR 36250) and in § 429.110(g)(1)(i)(B). Additionally, on this same page of the proposed rule, CMS stated we would not notify Reference Manufacturers named in unsuccessful Initial Delay Requests as an unsuccessful Initial Delay Request does not impact selection. Accordingly, notifying the Reference Manufacturer of an unsuccessful Initial Delay Request would generate more administrative burden for CMS and as such, we decline to adopt this suggestion in the final rule. As finalized at § 429.110(g)(1), we will provide a written notice to the Biosimilar Manufacturer regarding whether the request was successful or unsuccessful. If unsuccessful, we will specify the reason for the unsuccessful request.

Comment: A commenter requested that CMS clarify the date by which a Biologics License Application filed under section 351(k) of the PHS Act (hereinafter referred to as 351(k) application) must be accepted for review by the FDA to qualify for a

Biosimilar Delay, and suggested that CMS permit a Biosimilar Manufacturer to update its Initial Delay Request with changes to the 351(k) BLA filing status on any date on or before the January 31st prior to the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer requests a Biosimilar Delay. A commenter requested that CMS permit Biosimilar Manufacturers who have not yet filed 351(k) applications to submit Initial Delay Requests. A commenter supported CMS' proposal to identify a date by which the Biosimilar Manufacturer's BLA must be accepted for review by the FDA to be considered for the Initial Delay Requests. A few commenters requested that CMS permit Biosimilar Manufacturers who have filed 351(k) applications but have not yet had the application accepted by the FDA for review, to submit Initial Delay Requests, subject to acceptance of the application. A commenter recommended that Biosimilar Manufacturers be able to submit information accompanying the Initial Delay Request that indicates it is likely that the 351(k) application will be approved by the publication of the selected drug list for the applicable initial price applicability year. A commenter recommended that CMS permit Biosimilar Manufacturers to submit information as part of the Initial Delay Request demonstrating that the FDA is likely to approve the 351(k) application. A few commenters argued that CMS' proposed approach to determining the high likelihood standard is closer to requiring certainty of launch than high likelihood of launch within the biosimilar delay window, which is not aligned with statute. A commenter stated that CMS' proposal to determine whether there is a high likelihood that a Biosimilar will be licensed and marketed within the statutory timeframe by January of the calendar year of the selected drug publication date for the initial price applicability year for which the Reference Drug would be selected absent the Initial Delay Request is not the best reading of the statute but did not provide an alternative interpretation for consideration.

Response: We thank commenters for their feedback. Consistent with our response to similar comments in the final guidance for initial price applicability year 2027 and the revised guidance for initial price applicability year 2026, we believe that section II.B.3. of the proposed rule aligns with the statutory language and do not find reason to allow for additional circumstances that would meet the licensure component of high likelihood determination. As stated in section 1192(f)(3)(A) of the Act, the Secretary must find that the BLA has been accepted for review or approved by the FDA. We also state that in section II.B.3. of the proposed rule that the Biosimilar Manufacturer must be operationally ready, and that the finding is made reasonably in advance of the selected drug publication date to allow CMS to finalize the selected drug list. As such, commenters' suggestions are either inconsistent with the statute requiring the BLA to have been accepted for review or approved by the FDA, or infeasible due to the timing required to release the selected drug list.

As stated in § 429.110(d)(1), we will specify the due date by which the application for licensure must be accepted for review or approved by the FDA, which will be a date before the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer requests a Biosimilar Delay, in order to permit CMS to review the information and finalize the selected drug list for the initial price applicability year. As discussed in the Negotiation Program proposed rule (91 FR 36249), this would enable CMS to use the most recent possible data to make a determination on the Initial Delay Request and before publication of the selected drug list for the initial price applicability year. Accordingly, we decline to specify a date by which a 351(k) application must be accepted by the FDA to qualify for a Delay in this forum.

As discussed in the Negotiation Program proposed rule (91 FR 36248), we believe that the best interpretation of section 1192(f)(1)(A) of the Act requires that the 351(k) application has been approved or accepted for review by the FDA by January 15 of the selection year. Additionally, as discussed in the Negotiation Program proposed rule (91 FR 36250), in accordance with section 1192(f)(3)(B) of the Act, we must use information from items described in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act submitted to us by the Biosimilar Manufacturer requesting the Biosimilar Delay to identify if there is clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline. We believe the requirements detailed in that section are the best read of the statute for ascertaining that there is clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline. The statute requires clear and convincing evidence, and contrary to commenters' arguments, the requirements detailed in the section are intended to comply with this evidentiary standard. Commenters' alternative proposals did not satisfy this evidentiary standard, and as such, we decline to modify our proposed approach at this time.

Comment: A few commenters stated that CMS should request all information under its authority in section 1192(f)(1)(B)(ii)(II) of the Act that a Biosimilar Manufacturer deems relevant to determination of a high likelihood of marketing and offered suggestions on the types of supportive evidence that CMS should consider when evaluating whether a Biosimilar Manufacturer is likely to meet the High Likelihood Deadline. A couple of commenters stated that much of the information relevant to marketing of a Biosimilar is commercially sensitive and therefore may not be reflected in the types of information set forth in § 429.110(f)(1) and therefore requested that CMS permit Biosimilar Manufacturers to submit confidential business information as part of the Initial Delay Request process. A commenter requested that CMS establish protection for treatment of confidential commercial or financial information in the regulatory text, as well as the preamble.

Response: We thank commenters for their feedback. In response to commenters' suggestions to use any evidence as acceptable evidence under section 1192(f)(1)(B)(ii)(II) of the Act, we note that this provision applies only after we have first reviewed the information submitted in accordance with sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act and determine that additional information is needed from the Biosimilar Manufacturer. As discussed in the Negotiation Program proposed rule (91 FR 36247), we note that we will protect from disclosure information submitted in a Biosimilar Delay Request that is a trade secret or confidential commercial or financial information if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(3), (4)). We decline at this time to amend the regulatory text regarding confidential information.

Comment: A few commenters recommended that CMS strike references to a precise launch date, stating that identifying a clearly specified launch date is not always possible, and that CMS should instead rely on other public facing statements from manufacturers indicating that they will be able to launch within the 2-year window. A commenter suggested that a Biosimilar Manufacturer should be

determined to have high likelihood of marketing the Biosimilar if either option is indicated: lack of agreements with the FTC or the Department of Justice (DOJ) prohibiting marketing of the drug; or public facing investor disclosures or manufacturing schedules indicating that marketing is set to commence within the 2-year timeframe. A couple of commenters recommended that CMS accept a ''Notice of First Commercial Marketing'', provided to the Reference Manufacturer by the Biosimilar Manufacturer at least 180 days prior to marketing of the Biosimilar, as documentation of meeting the high likelihood standard. A few commenters recommended CMS consider relevant court orders and litigation developments; litigation status and legal status; evidence of manufacturing and commercial readiness; public statements indicating readiness to launch to investors or the SEC accompanied by attestations from executives of the Biosimilar Manufacturer; other information submitted by interested parties. A commenter stated that the circumstances indicating high likelihood that CMS proposed should not represent the exclusive circumstances under which a high likelihood determination could be made. A couple of commenters supported CMS' proposal to consider disclosure about capital investment, revenue expectations, and actions consistent with the normal course of business and manufacturing schedules as part of Initial Delay Request evaluation.

Response: We thank commenters for their feedback. We appreciate commenters' concerns regarding the current items a Biosimilar Manufacturer can use to demonstrate clear and convincing evidence that that Biosimilar will be marketed before the High Likelihood Deadline. As stated previously in the Negotiation Program Guidance, CMS remains bound by the statutory constraints that the Biosimilar Manufacturer must provide ''clear and convincing evidence,'' to be found in the documentation specific in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act.[22] As discussed previously, we recognize that representatives of a manufacturer have fiduciary obligations as company representatives and legal disclosure requirements under the Securities Act of 1934 for a public traded company. We again decline to specify that statements of a fiduciary alone that the Biosimilar will be marketed and/or that there are no patent barriers demonstrate ''clear and convincing'' evidence that there is a high likelihood the Biosimilar will be marketed by the High Likelihood Deadline. We do not believe that this information alone is ''clear and convincing.'' Additionally, we disagree with commenters' suggestions that the statute permits CMS to consider an attestation as evidence separate from the specified documentation in the statute. We also disagree with the alternatives suggested by commenters for demonstrating clear and convincing evidence that the Biosimilar will be marketed by the High Likelihood Deadline because they do not account for the often complex and serial nature of patent litigation between reference product and biosimilar manufacturers prior to market entry of a biosimilar and/or whether there are patents related to the Reference Drug that could prevent the Biosimilar from being marketed before the High Likelihood Deadline.

As stated previously in the Negotiation Program Guidance, we identified examples of the type of information we may consider to be ''clear and convincing evidence'' in the documentation submitted by the Biosimilar Manufacturer including the documentation specified in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act to evaluate if the Biosimilar has a high likelihood of being marketed by the High Likelihood Deadline. As described at § 429.110(d)(2), the Biosimilar Delay Request must include information to demonstrate both: (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed; and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar. Regarding the proposal at § 429.110(d)(2)(i) that the Biosimilar Delay Request must clearly demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline, we proposed at § 429.110(d)(2)(i)(A) through (D) that the Biosimilar Manufacturer must demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline through any of four pathways specified. The first option the Biosimilar Manufacturer may demonstrate is that there will be no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar. The second option the Biosimilar Manufacturer may demonstrate is that one or more court decisions or decisions by the USPTO's PTAB establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patents relating to the reference product included in the Reference Drug that a patent holder asserted was applicable to the Biosimilar. The third option the Biosimilar Manufacturer may demonstrate is that neither a court nor PTAB has adversely ruled against the Biosimilar Manufacturer's patent assertion(s) pertaining to unexpired patent(s) relating to the reference product included in the Reference Drug applicable to the Biosimilar, and the Biosimilar Manufacturer has publicly announced a precise launch date for the Biosimilar that is both a calendar date before the High Likelihood Deadline and is not contingent on the outcome of pending litigation. Finally, the fourth option the Biosimilar Manufacturer may demonstrate is that the Biosimilar Manufacturer has a signed agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before the High Likelihood Deadline, without improper constraints on the Biosimilar Manufacturer.

Regarding the proposal at § 429.110(d)(2)(ii) that the Biosimilar Delay Request must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline, to assess this requirement, we propose to consider the Biosimilar Manufacturer's progress against the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug as evidenced by both: (1) disclosures about capital investment, revenue expectations, and actions consistent with the normal course of business for marketing of a biosimilar biological product before the High Likelihood Deadline; and (2) a manufacturing schedule that is consistent with the public-facing

[22] Which includes: all agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; the manufacturing schedule for the Biosimilar submitted to FDA during its review of the application for licensure under section 351(k) of the PHS Act for the Biosimilar; and the Biosimilar Manufacturer's disclosures pertaining to the marketing of the Biosimilar (for example, in filings with the SEC required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation distributed to the shareholders of privately held companies) about capital investment, revenue expectations, and other actions typically taken by a manufacturer in the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product.

statements and demonstrates readiness to meet revenue expectations. As discussed in the proposed rule (91 FR 36250), we proposed these criteria because we believe they are indicative of operational readiness and should be available in the elements that we must consider in making this determination as required by section 1192(f)(1)(B)(ii) of the Act. These examples are illustrative but alone may not always constitute ''clear and convincing evidence'' of a high likelihood of marketing.

Comment: A few commenters recommended that CMS consider the totality of circumstances when considering whether to grant an Initial Delay Request. A commenter recommended that CMS consider the following additional criteria when evaluating the high likelihood standard: the Biosimilar Manufacturer has not stated that it will not market the product prior to the end of the relevant period; the Biosimilar Manufacturer has not withdrawn its BLA; the Biosimilar Manufacturer is not in arrears for fees under section 744H of the FD&C Act; no manufacturing facility has ''official action indicated'' as a status; there are no clinical trial protocol amendments that would delay enrollment completion and marketing beyond the pause period. A commenter recommended that CMS consult with FDA on whether a Biosimilar is likely to meet the high likelihood threshold. A commenter requested additional transparency on how CMS evaluates the high likelihood standard.

Response: We thank commenters for their feedback. As previously stated in this section, we remain bound by the statutory constraints that the Biosimilar Manufacturer must provide ''clear and convincing evidence,'' to be found in the documentation specific in sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the Act. The information suggested by commenters does not provide clear and convincing evidence that the patents relevant to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline, or that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline. As discussed previously, we will consider the totality of the circumstances in making a determination of whether there is a high likelihood that a Biosimilar will be licensed and marketed by the High Likelihood Deadline given the information and acceptable documentation provided as part of the Initial Delay Request. Additionally, we will not take the absence of negative information as suggested by commenters within the specified acceptable documentation as clear and convincing evidence of high likelihood that a Biosimilar will be licensed and marketed before the High Likelihood Deadline. We direct readers to the Negotiation Program proposed rule (91 FR 36249 and 36250) for more information on how CMS determines whether there is a high likelihood that a Biosimilar will be licensed and marketed before the High Likelihood Deadline as discussed in section 1192(f)(3)(B) of the Act. In the Negotiation Program proposed rule (91 FR 36250), we discussed examples of the circumstances under which the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline, though clarified that the examples are not exhaustive of the information that might be included in the documentation required at section 1192(f)(3)(B) of the Act in a submission for a request for an Initial Delay Request necessary to determine ''clear and convincing evidence'' that the Biosimilar will be marketed before the High Likelihood Deadline. Finally, we believe we will have sufficient information submitted by the Biosimilar Manufacturer as part of the Initial Delay Request or Additional Delay Request to determine that there is clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline and declines at this time to implement a structural consultation with FDA regarding High Likelihood.

Comment: A few commenters requested that CMS remove or clarify the proposed requirement that Biosimilar Manufacturers not have pending litigation regarding patent infringement. A commenter recommended that CMS revise the standard to ''neither a court or PTAB has ruled that the Biosimilar Manufacturer has infringed on a patent'' and clarify that resolution of patent litigation be taken as clear and convincing evidence of that the Biosimilar will be marketed before the High Likelihood Deadline. A commenter supported the proposal to disqualify Initial Delay Request applications that indicate an agreement between the Reference Manufacturer and the Biosimilar Manufacturer exists to require the Biosimilar Manufacturer to submit a Biosimilar Delay Request, delay market entry, or restrict quantity sold. The commenter requested that CMS clarify what types of agreements between the biosimilar manufacturer and reference manufacturer are disqualifying and recommended clarifying that quantity limits and improper constraints restrict output, timing, or ability to compete, such as volume caps, deferring entry, or encourage substitution for an authorized biosimilar are disqualifying. The commenter requested that CMS clarify that settlements between the Biosimilar Manufacturer and the Reference Manufacturer not be automatically disqualifying, just because litigation is involved.

Response: We thank commenters for these suggestions. We refer readers to the Negotiation Program proposed rule (91 FR 36249) and proposed § 429.110(d)(2). We state that the Biosimilar Delay Request must include information to demonstrate both: (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline; and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline. These requirements address the two primary contributing factors to delays in marketing of biosimilars approved in the United States to date, and so we believe that evidence showing that a Biosimilar meets these two requirements is sufficient to establish clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline. In response to the commenter requesting that resolution of patent litigation be taken as sufficient clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline, we note that other barriers may be present that could prevent the Biosimilar Manufacturer from being operationally ready by the High Likelihood deadline. Accordingly, we decline at this time to remove the requirement that Biosimilar Manufacturers not have pending litigation regarding patent infringement and decline at this time to revise the standard by which High Likelihood is determined.

Consistent with our response to similar comments in the Negotiation Program Guidance, the final guidance for initial price applicability year 2027, and the revised guidance for initial price applicability year 2026, we reiterate that section 1192(f)(2)(D)(iv) of the Act excludes certain Biosimilar Manufacturers from the Biosimilar Delay if CMS determines that the Biosimilar Manufacturer is the same as the Reference Manufacturer or that the Biosimilar Manufacturer has entered into any agreement with the Reference

Manufacturer that requires or incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay, or that restricts the quantity (either directly or indirectly) of the Biosimilar that may be sold in the United States over a specified period of time. We confirm that the existence of an agreement alone between a Biosimilar Manufacturer and a Reference Manufacturer does not disqualify the Biosimilar from being eligible for a delay. CMS will consider all information available at the time of the Biosimilar Manufacturer discloses the existence of an agreement between the Biosimilar Manufacturer and Reference Manufacturer to determine whether the agreement requires or incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay Request or restricts the quantity (either directly or indirectly) of the Biosimilar that may be sold in the United States over a specified time consistent with the statute. At this time, we decline to provide specific details on what types of agreements would be considered disqualifying and refers readers to the characteristics of such agreements as described in section 1192(f)(2)(D)(iv) of the Act. We decline to provide specific details at this time to avoid inadvertently providing an inflexible or exhaustive list of agreements that could unintentionally leave out certain agreements that, as required by statute, would require denying the Biosimilar Delay Request.

Comment: A few commenters opposed the October deadline by which CMS proposes to require Biosimilar Manufacturers to demonstrate licensing and marketing during the Initial Delay Period or Second Delay Period, and recommended CMS evaluate at the end of the year instead. A couple of commenters recommended that CMS provide an initial determination of whether licensing and marketing have occurred in October, accompanied by a public notice, before making a final determination at the end of the year. A commenter suggested requiring ongoing updates from the Biosimilar Manufacturer regarding launch dates. A couple of commenters requested that CMS provide additional transparency on how a Biosimilar Manufacturer can demonstrate that it has made a significant amount of progress toward both licensure and marketing of the Biosimilar since the submission of the Initial Delay Request and provide additional clarity on timing of when a determination of licensure and marketing would be made.

Response: We appreciate these comments. In the Negotiation Program proposed rule (91 FR 36251), and in proposed § 429.110(g)(3), we proposed to notify a Biosimilar Manufacturer if CMS has determined that the Biosimilar named in the Biosimilar Manufacturer's successful Initial Delay Request is licensed and marketed during the Initial Delay Period by a date specified by CMS in technical guidance, which will be no later than the end of October of the calendar year of the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer submitted the successful Initial Delay Request. For successful Initial Delay Requests submitted with respect to initial price applicability year 2029 for example, we will notify a Biosimilar Manufacturer if CMS has determined that the Biosimilar named in the Biosimilar Manufacturer's successful Initial Delay Request is licensed and marketed during the Initial Delay Period in fall 2027. Consistent with our response to similar comments in the final guidance for initial price applicability year 2027, and in accordance with section 1192(f)(2)(B) of the Act, in specifying the end of October date, we considered the time needed for a Biosimilar Manufacturer to submit an Additional Delay Request and for CMS to review such a request prior to publication of the selected drug list for the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request. We will specify the notification date based on the comments received and operational considerations to allow for sufficient notice prior to the publication of the selected drug list for the initial price applicability year. Accordingly, we believe that a date no later than the end of November is an appropriate deadline by which to determine if a Biosimilar has been licensed or marketed. If a Biosimilar Manufacturer fails to demonstrate that the Biosimilar has been licensed or marketed by the end of November deadline following an Additional Delay Request, there are no additional steps that the Biosimilar Manufacturer may take. As such, we believe that a deadline for the Biosimilar Manufacturer to demonstrate licensure and marketing following an Additional Delay Request that is later than the deadline, for the Initial Request is appropriate.

In response to commenters requesting additional transparency on how CMS determines the Biosimilar Manufacturer has made a significant amount of progress towards licensure and marketing of the Biosimilar since the Biosimilar Manufacturer's submission of the successful Initial Delay Request, as described in the Negotiation Program proposed rule (91 FR 36251) and in accordance with section 1192(f)(2)(B)(i)(II) of the Act, CMS is required to use information from the following items when assessing whether there is clear and convincing evidence that the Biosimilar Manufacturer has made a significant amount of progress toward licensure and marketing of the Biosimilar since the Biosimilar Manufacturer's submission of the successful Initial Delay Request for the Biosimilar: (1) all agreements related to the Biosimilar filed with the FTC or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (as described in section 1192(f)(1)(B)(ii)(I)(bb) of the Act); and (2) additional information and documents that CMS may request after CMS has reviewed the information required for submission of the Additional Delay Request necessary to make a determination about an Additional Delay Request (as described in section 1192(f)(1)(B)(ii)(II) of the Act).

Specifically, we proposed at § 429.110(e)(3) that the determination of whether a significant amount of progress has been made by the Biosimilar Manufacturer towards licensure and marketing of the Biosimilar since the successful Initial Delay Request submission for such Biosimilar will be based on a holistic review of the documentation submitted with the Additional Delay Request (as described in § 429.110(f)(1), including any follow-up documentation requests from CMS to the manufacturer described in § 429.110(f)(2)). Within the request we would consider if the Biosimilar Manufacturer can demonstrate affirmative progress towards being operationally ready to market the Biosimilar, meaning that we would consider the Biosimilar Manufacturer's progress on the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug since the successful Initial Delay Request submission for the Biosimilar evidenced in any updates or supplements to the documents specified in section 1192(f)(1)(B)(ii)(III) of the Act and as described in § 429.110(f)(1). Additionally, we would consider if the manufacturing schedule (as provided in § 429.110(f)(1)(ii)) is consistent with the public-facing statements (that may be identified within the information

provided in the materials set forth at proposed § 429.110(f)(1)(iii)) and demonstrates readiness to meet revenue expectations. Accordingly, we believe the approach described previously is both sufficiently transparent and permits holistic consideration of information that is relevant to determining that a significant amount of progress has been made. As such, we decline at this time to change this process.

Comment: A few commenters requested that CMS identify examples of situations under which a product would qualify for an Additional Delay Request. A few commenters recommended criteria under which CMS should grant an Additional Delay Request including: FDA approval of a BLA; BLA under review by FDA; complete response letter sent by the FDA, but BLA resubmitted; disclosures to investors or the SEC that the Biosimilar Manufacturer plans to market the product by the specified date; manufacturing schedules indicating that the Biosimilar Manufacturer is likely to market the product; agreements with FTC or DOJ that do not block the Biosimilar Manufacturer from marketing the product; and attestations by the Biosimilar Manufacturer that it plans to market the product by the applicable date.

Response: We thank these commenters for their suggestions. As described in the Negotiation Program proposed rule (91 FR 36251) and proposed at § 429.110(e)(1)(i) and (ii), Biosimilar Manufacturers of a Biosimilar that was identified in a successfully granted Initial Delay Request (consistent with proposed § 429.110(f)) are eligible to submit an Additional Delay Request if licensure and marketing under section 351(k) of the PHS Act has not commenced between the publication date of the selected drug list for the initial price applicability year for which the Initial Delay Request was granted and the date that is 1 year following that publication date. Additionally, we would determine whether the requirements for the Initial Delay Request, as described in § 429.110(c)(1)(ii), remain met. If the requirements described at § 429.110(e)(1)(i) through (iv) are met, we would then reevaluate and determine whether the requirements in proposed § 429.110(d) regarding whether there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline continue to be met as proposed in § 429.110(e)(2). Finally, in accordance with section 1192(f)(2)(B)(i)(II) of the Act and as described in § 429.110(e)(3), we must determine, on the basis of clear and convincing evidence, that the Biosimilar Manufacturer has made a significant amount of progress towards both licensure and marketing of the Biosimilar since the Biosimilar Manufacturer's submission of the successful Initial Delay Request.

In accordance with section 1192(f)(2)(B)(i)(II) of the Act, we are required to use certain types of information that may constitute ''clear and convincing evidence, the manufacturer of [the] biosimilar biological product has made a significant amount of progress towards both such licensure and marketing of such biosimilar biological product''. As suggested by a commenter, we may consider agreements filed with the FTC, manufacturing schedules, and disclosures to investors. Other suggestions by the commenter do not fall under that scope, but could describe specific facts that are not themselves sources of evidence, but could be part of CMS' assessment if found in one of the sources of evidence. We decline to establish that any of the commenters' alternative criteria for granting Additional Delay Requests, by themselves, are sufficient for granting such requests, as this would be inconsistent with the statutory requirements for granting Additional Delay Requests. Further, these alternatives are inconsistent with CMS' holistic consideration when reevaluating whether there is a high likelihood that the Biosimilar will be licensed and marketed by the High Likelihood Deadline and whether, on the basis of clear and convincing evidence, the Biosimilar Manufacturer has made a significant amount of progress towards both licensure and marketing of the Biosimilar since the submission of the Initial Delay Request.

Comment: A commenter supported CMS' proposed rebates payable by the Reference Manufacturer of a drug that would have otherwise been selected when a Biosimilar fails to launch. A couple of commenters requested that CMS provide additional clarity on how it intends to operationalize administration and payment of retrospective rebates when a Biosimilar fails to launch, and whether prior failures to launch by the Biosimilar Manufacturer will factor into delay determinations. A commenter requested that CMS not make failure to market rebates punitive. A commenter recommended that CMS establish an automatic post-delay audit framework if a manufacturer is granted an Initial Delay Request or Additional Delay Request and require the payment of rebates and refer the matter to the FTC for antitrust review if the Biosimilar Manufacturer fails to engage in Bona Fide Marketing. A commenter requested that CMS clarify how it will treat rebate liability for concurrent Initial Delay Requests when one Biosimilar Manufacturer launches and the other does not.

Response: We thank commenters for their support. We refer readers to § 429.110(i) for additional information on how we intend to operationalize administration and payment of rebates when CMS determines that a Biosimilar has not been licensed and marketed during the applicable period. As stated in proposed § 429.110(h)(1)(ii), we would include the Reference Drug on the selected drug list for the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request, unless a different biosimilar biological product is marketed before the publication of the selected drug list for the applicable initial price applicability year, in which case CMS could also determine, in accordance with section 1192(c) of the Act and described in sections II.B.3 of this final rule, that the Reference Drug no longer meets the criteria to be a selected drug and will be excluded from such applicable list of drugs selected for an initial price applicability year. As stated in the Negotiation Program proposed rule (91 FR 36252) and as described in § 429.110(h)(2)(i), if CMS determines that the Biosimilar is not licensed and marketed during the Second Delay Period, unless a different biosimilar biological product is marketed, CMS would include the Reference Drug on the selected drug list for the initial price applicability year that is two years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request. The question regarding concurrent Initial Delay Request submissions is addressed accordingly; if at least one Biosimilar from an Initial Delay Request or a different Biosimilar biological product is licensed and marketed, the Reference Drug would no longer meet the criteria to be a selected drug and would be excluded from the selected drug list for the initial price applicability year that follows the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request.

Where no MFP is agreed upon because the Reference Drug no longer met the criteria to be a selected drug for an applicable list, the Reference Manufacturer would not be subject to rebates for the years that the manufacturer would have provided access to the MFP for the Reference Drug but for the delay.

To clarify how the rebate owed by the Reference Manufacturer for the initial price applicability year for which an Initial Delay Request was granted will be calculated, we refer readers to section II.B.3.c. of this final rule and reiterate that this rebate is not owed by the Biosimilar Manufacturer that submits an Initial Delay Request. In accordance with sections 1192(f)(2)(B)(ii), 1192(f)(2)(C), and 1192(f)(4)(A) of the Act and as described in § 429.110(i)(1), if (1) CMS delayed the selection and negotiation of a Reference Drug for one or two years, (2) CMS determined that the Biosimilar was not licensed and marketed, and (3) the manufacturer of the Reference Drug agrees to an MFP for the Reference Drug, the Reference Manufacturer is required to pay a rebate for the years that the manufacturer would have provided access to the MFP for the Reference Drug but for the delay. In accordance with section 1192(f)(4)(B) of the Act, as described in § 429.110(i)(4) the rebate owed by the Reference Manufacturer, for the year for which an Initial Delay Request and, if applicable, an Additional Delay Request was granted would be calculated as follows:

- In accordance with section 1192(f)(4)(B)(i) of the Act and as described in § 429.110(i)(4)(ii), in the case of a Reference Drug that is a drug covered under Part D, 75 percent of the difference between the AMP, with respect to each of the calendar quarters of the price applicability period, and the MFP negotiated for the Reference Drug multiplied by the number of units dispensed under Part D for the Reference Drug in each calendar quarter of the price applicability period that would have applied but for the delay.
- In accordance with section 1192(f)(4)(B)(ii) of the Act and as described in § 429.110(i)(4)(iii), in the case of a Reference Drug payable under Part B, 80 percent of the difference between the payment amount under section 1847A(b) of the Act, with respect to each of the calendar quarters of the price applicability period, and the MFP negotiated for the Reference Drug, multiplied by the number of units of the billing and payment code of the Reference Drug administered or furnished under Part B (excluding units that are packaged into the payment amount for an item or service and are not separately payable under Part B) for each calendar quarter of the price applicability period that would have applied but for the delay.
- As described in § 429.110(i)(4)(iv), in the case of a Reference Drug that is a drug covered under Part D and payable under Part B, the rebate amount will be calculated by summing the rebate amount for the units payable under Part B as described in § 429.110(i)(4)(iii) and the rebate amount for units covered under Part D as described in § 429.110(i)(4)(ii).

As discussed previously in this section, CMS is bound by statute for calculation of rebate amounts. We also refer commenters to § 429.130 for further discussion on the approach to how we will evaluate Bona Fide Marketing.

Final Decision: After consideration of public comments received, we are finalizing § 429.110 as proposed, with the following non-substantive technical modifications. For clarity, at § 429.110(i)(5), we are replacing the cross-reference to ''(h)(2)'' with ''(h)(2)(i)'' to more precisely describe the paragraph we intended to cross-reference. Additionally, to address a drafting error and align with section II.B.3.b. of the proposed rule (91 FR 36249), at § 429.110(d)(2)(i)(C), we are adding ''and is not contingent on the outcome of pending litigation''. The paragraph now states: Neither a court nor PTAB has adversely ruled against the Biosimilar Manufacturer's patent assertion(s) pertaining to an unexpired patent or patent(s) relating to the reference product included in the Reference Drug applicable to the Biosimilar and the Biosimilar Manufacturer has publicly announced a precise launch date for the Biosimilar that is a calendar date before the High Likelihood Deadline and is not contingent on the outcome of pending litigation.4.

Identification of Negotiation-Eligible Drugs (§ 429.115)

Section 1192(d)(1) of the Act requires that a ''negotiation-eligible drug'' means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in section 1192(e) of the Act, that is either a Part D high spend drug or a Part B high spend drug. Section 1192(d)(1)(A) of the Act describes a Part D high spend drug as a qualifying single source drug that is among the 50 qualifying single source drugs with the highest total expenditures under part D of Title XVIII, as determined by the Secretary in accordance with section 1192(d)(3) of the Act, during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date). Section 1192(d)(1)(B) of the Act describes a Part B high spend drug as a qualifying single source drug that is among the 50 qualifying single source drugs with the highest total expenditures under part B of Title XVIII, as determined by the Secretary in accordance with section 1192(d)(3) of the Act, during such most recent 12-month period described in section 1192(d)(1)(A) of the Act. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 30.2 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

We proposed to codify the statutory requirements in section 1192(d) of the Act at § 429.115, including that a negotiation-eligible drug for an initial price applicability year is a qualifying single source drug, as identified under proposed § 429.125, that is among the 50 qualifying single source drugs with the highest total expenditures under Part D, or among the 50 qualifying single source drugs with the highest total expenditures under Part B. We proposed to codify our process for identifying the negotiation-eligible drugs for each initial price applicability year, consistent with the process implemented through prior guidance, as follows.

We proposed at § 429.115(a)(1) to identify Part D high spend drugs described in section 1192(d)(1)(A) of the Act using the following steps. We would first remove from negotiation eligibility any qualifying single source drugs that are already selected drugs in accordance with section 1192(d)(3)(A)(i) of the Act. Next, for remaining qualifying single source drugs, CMS would calculate a qualifying single source drug's total expenditures under Part D using the methodology set forth at proposed § 429.120(a) and described in section II.B.5. of this final rule and rank those qualifying single source drugs by total expenditures under Part D during the total expenditures measurement period. Finally, we would identify the 50 qualifying single source drugs that have the highest total expenditures under Part D during the total expenditures measurement period (that is, Part D high spend drugs).

Then, we proposed at § 429.115(a)(2) to identify Part B high spend drugs

described in section 1192(d)(1)(B) of the Act using the following steps. As with Part D high spend drugs, we would first remove from negotiation eligibility any qualifying single source drugs that are already selected drugs in accordance with section 1192(d)(3)(A)(i) of the Act.[23] Next, for remaining qualifying single source drugs, CMS would calculate a qualifying single source drug's total expenditures under Part B using the methodology set forth at proposed § 429.120(b) and described in section II.B.5. of this final rule and rank the remaining qualifying single source drugs by total expenditures under Part B during the total expenditures measurement period. Finally, we would identify the 50 qualifying single source drugs that have the highest total expenditures under Part B during the total expenditures measurement period (that is, Part B high spend drugs).

We proposed at § 429.115(b) that, when identifying Part D high spend drugs and Part B high spend drugs as proposed at § 429.115(a)(1)(iv) and (a)(2)(iv), respectively, if two or more qualifying single source drugs have the same total expenditures to the cent under Part D or Part B, and such total expenditures are the 50th highest among qualifying single source drugs under Part D or Part B, we would rank the qualifying single source drugs based on which drug has the earlier approval or licensure date, as applicable, associated with the earliest-approved FDA application belonging to the NDA/BLA holder and containing the active moiety/active ingredient in the drug, until we have identified 50 Part D high spend drugs and Part B high spend drugs, respectively. These 50 Part D high spend drugs and 50 Part B high spend drugs, identified in accordance with proposed § 429.115(a)(1) and (a)(2), respectively, would be the negotiation-eligible drugs for the initial price applicability year. This proposal is a modification from Negotiation Program Guidance, which established that for initial price applicability years 2026, 2027, and 2028, we would identify qualifying single source drugs with the same total expenditures to the dollar. As noted in section II.B.2. of this final rule, we believe that using information to the cent, rather than to the dollar as under prior policy, is more precise for purposes of determining negotiation-eligible drugs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters shared feedback on CMS' proposed approach to identifying negotiation-eligible drugs. A few commenters opposed CMS' proposal, in particular the proposal to combine total expenditures under Part B and Part D when ranking negotiation-eligible drugs, as proposed in § 429.105(a). A couple of commenters suggested that nothing in statute permits CMS to combine total expenditures under Part B and Part D when evaluating or selecting drugs for negotiation. A commenter supported CMS' proposal to combine total expenditures when ranking and selecting negotiation-eligible drugs.

Response: We thank these commenters for their feedback and appreciate the support from the commenter. Consistent with our response to similar comments in the Negotiation Program Guidance, we disagree with the commenters who stated that the proposal to combine total expenditures under Part B and Part D when ranking negotiation-eligible drugs is inconsistent with statute. Section 1192(b)(1)(A) of the Act requires that CMS rank negotiation-eligible drugs ''according to the total expenditures for such drugs under parts B and D of title XVIII.'' Such statutory language directs CMS to combine total expenditures under Part B and Part D when ranking negotiation-eligible drugs.

Final Decision: After consideration of public comments received, we are finalizing § 429.115 as proposed.

5. Calculation of Total Expenditures (§ 429.120)

As described in sections II.B.2., II.B.4., and II.B.6.c.2. of the proposed rule, we proposed at §§ 429.105(a), 429.115(a), and 429.125(e)(2) to calculate total expenditures under Part B and Part D as a step in the processes for identifying selected drugs, negotiation-eligible drugs, and drugs eligible for the low-spend Medicare drug exclusion, respectively. Section 1191(c)(5) of the Act defines the term ''total expenditures'' to include, in the case of expenditures with respect to Part D, the total gross covered prescription drug costs (as defined in section 1860D–15(b)(3) of the Act). In the case of ''total expenditures'' with respect to Part B, section 1191(c)(5) of the Act specifies that such term excludes expenditures for a drug or biological product that are bundled or packaged into the payment for another service. With respect to initial price applicability years 2026 through 2028, we explained through guidance how we will implement the statutory requirement to calculate total expenditures under Part B and total expenditures under Part D, including, for example, section 30 of the Negotiation Program Guidance with respect to initial price applicability year 2028. We proposed to codify the definition of total expenditures in section 1191(c)(5) of the Act at § 429.20, and we proposed how we would calculate total expenditures under Part B and Part D at § 429.120.

a. Calculation of Total Expenditures Under Part D

At § 429.120(a), we proposed to calculate total expenditures under Part D for a given potential qualifying single source drug, qualifying single source drug, negotiation-eligible drug, or selected drug, as the sum of gross covered prescription drug costs for each PDE record for such drug that meets the criteria in proposed § 429.120(a)(1) through (a)(5). CMS would identify these PDE records as follows: (1) the dates of service are during the total expenditures measurement period (to allow a reasonable time for Part D plan sponsors to submit PDE data, we would use PDE data for the dates of service in the total expenditures measurement period that are available in CMS' data repository by the November 30 following the total expenditures measurement period (or the first business day following November 30 if November 30 does not fall on a business day)); (2) total gross covered prescription drug costs on the PDE record is greater than zero dollars; (3) the PDE record is considered final action; [24] (4) the drug coverage status code indicates the PDE record is for a drug covered under Part D; and (5) the compound code indicates the PDE record is not for a compounded drug.[25]

[23] This removal would encompass qualifying single source drugs that have been selected for initial price applicability years 2026 and 2027 based on Part D total expenditures.

[24] A PDE record is considered final action based on the final action indicator for the claim and claim line.

[25] As described in Negotiation Program Guidance, we provide that, for operational reasons at this time, MFP refunds would not be required for PDE records for selected drugs that were billed as compounds. For alignment, we provide in proposed § 429.120 that PDE records with a compound code indicating the PDE record is for a compounded drug would be excluded from the PDE data used to calculate total expenditures under Part D used for the low-spend Medicare drug exclusion (proposed § 429.125(e)(2)) and to identify negotiation-eligible drugs and selected drugs (proposed §§ 429.115 and 429.105). We proposed to apply this same exclusion to the ceiling for the MFP (proposed § 429.410), the Net Part D Plan Payment and Beneficiary Liability of a therapeutic alternative(s) (proposed §§ 429.20 and 429.510(d)), and the application of the MFP across dosage forms and strengths (proposed § 429.700). A PDE record for a selected drug billed as a compound refers to a PDE record with a compound code field equal to ''2=Compound.'' We would only use PDE records with a compound code field equal

Continued

b. Calculation of Total Expenditures Under Part B

At § 429.120(b), we proposed a methodology for calculating total expenditures under Part B for a given potential qualifying single source drug, qualifying single source drug, negotiation-eligible drug, or selected drug. This methodology would use a combination of total allowed charges from OM Part B claims data (inclusive of beneficiary coinsurance and Medicare payment) and a comparable amount calculated using MA encounter data for Part B items and services, which would reflect the amount that would have been applicable under OM. Then, we would sum total expenditures under Part B based on OM Part B claims data and total expenditures under Part B for MA encounter data. To allow a reasonable time for providers and suppliers to submit OM Part B claims data and Medicare Advantage Organizations to submit MA encounter data for Part B items and services, we would use Part B data for the dates of service in the total expenditures measurement period that are available in CMS' data repository by November 30 following the total expenditures measurement period (or the first business day following November 30 if November 30 does not fall on a business day).

We received many comments on the draft guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028 suggesting that CMS should account for expenditures on drugs payable under Part B and administered to MA enrollees when identifying Part B high spend drugs. In response to these comments, we stated in the Negotiation Program Guidance that we agreed with these commenters that MA expenditures for such drugs should be accounted for and included in the calculation of total expenditures under Part B, and we described CMS' methodology, consistent with the previous paragraph, for including such expenditures in the calculation of total expenditures under Part B. In this final rule, we reiterate and expand upon the discussion in the Negotiation Program Guidance.

More than half (54 percent [26]) of Medicare enrollees were enrolled in MA plans in 2025. We would therefore exclude a significant portion of total spending on drugs payable under Medicare Part B by only using Part B claims data in the calculation of total expenditures under Part B. Such an approach would skew the negotiation-eligible drug list toward drugs with high expenditures under Part D and away from drugs with high expenditures under Part B and therefore could misrepresent the highest spend drugs. There is no indication that statute intends the negotiation-eligible drug list to skew towards drugs with high expenditures under Part D; rather, section 1192(d)(1) of the Act indicates equal treatment of drugs with high expenditures under Part D and drugs with high expenditures under Part B, requiring CMS to identify 50 Part D high spend drugs and 50 Part B high spend drugs beginning in initial price applicability year 2028.

Consistent with the policy adopted in Negotiation Program Guidance, in this final rule we proposed that the term ''total expenditures under part B of Title XVIII'' as defined at section 1191(c)(5) of the Act and as used in the Negotiation Program, is best read to include MA expenditures for drugs payable under Part B and administered to MA enrollees. In the case of expenditures with respect to Part B, section 1191(c)(5) of the Act provides only that the term ''total expenditures'' excludes expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

Statutory language in Title XVIII of the Act and sections 11001 and 11002 of the IRA suggest MA expenditures ought to be included in ''total expenditures under part B of title XVIII'' for purposes of the Negotiation Program. First, section 1852(a)(1) of the Act requires MA plans to provide to enrollees the ''benefits under the original [M]edicare [Fee-For-Service] program option,'' including, as relevant here, drugs payable under Part B. For purposes of determining ''total expenditures'' with respect to Part B for purposes of the Negotiation Program, we believe that MA expenditures for drugs payable under Part B may thus be understood as expenditures provided under this requirement to provide benefits available under Part B, and appropriately included in total expenditures under Part B for such drugs.

Further, section 1191(c)(2)(B) of the Act requires that, for purposes of the Negotiation Program, a ''maximum fair price eligible individual'' includes ''in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of title XVIII, including an individual who is enrolled in an MA plan under part C of such title, if payment may be made under part B for such selected drug.'' Including MA expenditures in the definition of total expenditures under Part B is consistent with the statutory approach reflected in this definition, which considers ''individual[s] enrolled in an MA plan'' to be ''include[ed]'' within the reference to individuals ''enrolled under part B of Title XVIII'' to the extent ''payment may be made under part B'' for a selected drug.

Finally, section 1191(c)(5) of the Act's definition of total expenditures under Part B identifies explicitly one exclusion—expenditures where payment for the drug is bundled with payment for another Part B service—but does not similarly exclude MA expenditures. As noted previously, the exclusion of MA expenditures would result in far more significant consequences for the identification of negotiation-eligible and selected drugs under the Negotiation Program than the exclusion that is identified explicitly. In light of the statutory indicia favoring inclusion of MA expenditures discussed previously and the significant consequences with respect to the Negotiation Program should MA expenditures be excluded, we believe the absence of clear statutory language excluding such expenditures weighs in favor of including MA expenditures in the definition of total expenditures under Part B.

For these reasons, we proposed at § 429.120(b) a methodology to include MA expenditures in the calculation of total expenditures under Part B. As we noted in the Negotiation Program Guidance, MA encounter data for Part B items and services does not reliably include the actual amount paid by the MA plan sponsor. Due to this gap in MA encounter data for Part B items and services, we believe it appropriate to estimate MA expenditures for drugs payable under Part B by using MA encounter data for Part B items and services to identify the units of drugs payable under Part B that were administered under MA and then determining what Medicare would have paid for such units under OM Part B.

to ''1=Not a Compound.'' A Part B claim billed as a compounded drug refers to Part B claims billed with HCPCS code J7999. For consistency with the treatment of compounded drugs covered under Part D, we also would exclude Part B claims billed as compounded drugs when calculating the low-spend Medicare drug exclusion, the identification of negotiation-eligible drugs and selected drugs, the ceiling for the MFP, and the application of the MFP across dosage forms and strengths.

[26] Nancy Ochieng et al., ''Medicare Advantage in 2025: Enrollment Update and Key Trends,'' KFF (July 28, 2025), *https://www.kff.org/medicare/medicare-advantage-enrollment-update-and-key-trends/*.

Accordingly, we proposed to use the following methodology to calculate total expenditures under Part B:

- *Total expenditures under Part B based on OM Part B claims data* would equal the sum of the total allowed charges for each OM Part B claim for a qualifying single source drug that meets the following criteria: (1) date of service is during the total expenditures measurement period; (2) the claim type is associated with an OM Part B claim in an outpatient setting (including but not limited to clinics, Federally Qualified Health Centers, and ambulatory surgical centers), a professional services claim, or durable medical equipment claim (currently, these claim type codes are 40, 71, 72, 81, or 82); (3) the total allowed charges (defined as the amount that is inclusive of the beneficiary coinsurance and Medicare payment for covered Part B items and services) for the claim line is greater than $0; (4) the claim is considered final action; [27] (5) the claim is not billed as a compounded drug; and (6) the claim is not for a drug or biological product that is bundled or packaged into the payment for another service under Part B OM. We have identified rare instances where claims for separate payment have been submitted for drugs payable under Part B when such claims are typically payable only as part of a bundled payment. We proposed to exclude such separately billed claims.

- *Total expenditures under Part B based on MA encounter data for Part B items* would equal the sum of the total allowed charges that would have been applicable under OM Part B for each MA encounter data record for Part B services for such drug that meets the following criteria: (1) date of service is during the total expenditures measurement period; (2) the claim type is associated with an MA encounter record in an outpatient setting (including but not limited to clinics, Federally qualified health centers, and ambulatory surgical centers), professional services, or durable medical equipment record, as determined by CMS (currently, these claim types are 4012, 4013, 4014, 4022, 4023, 4032, 4034, 4071, 4072, 4073, 4074, 4075, 4076, 4077, 4079, 4083, 4085, 4087, 4089, 4700, and 4800); (3) the reported total number of units on the MA encounter data record line is greater than zero; (4) the encounter data record is considered final action; [28] (5) the encounter data record is not denied; (6) the encounter data record is not a chart review record; (7) the encounter data record line is not for a supplemental benefit; (8) the encounter data record is not reported as a compounded drug; and (9) the encounter data record is not for a drug or biological product that is bundled or packaged into the payment for another service under Part B OM. In instances where an encounter data record for separate payment is submitted for a drug payable under Part B when such a claim is typically payable under Part B OM payment rules only as part of a bundled payment, such claim will be considered to be bundled or packaged into the payment for another service and will not be included in the total allowed charges calculation. To calculate the total allowed charges that would have been applicable under OM Part B for each of the aforementioned MA encounter data records, we would first adjust the unit field in MA encounter data for Part B items and services by referencing the Medically Unlikely Edits (MUEs), which are designed to reduce improper payments.[29] Because Medicare Administrative Contractors apply these edits to OM Part B claims, this would bring the MA encounter data for Part B items and services into closer alignment. Then, we would multiply the adjusted units by the appropriate published payment limit (for example, Average Sales Price (ASP)-based or payment rate (for example, Outpatient Prospective Payment System (OPPS), Ambulatory Surgical Center (ASC))).

Typically, ''single source drugs and biologicals'' as defined in section 1847A(c)(6)(D) of the Act are assigned to unique HCPCS codes; however, there may be cases where a qualifying single source drug is assigned to a HCPCS code with other products. In such cases, we proposed to use the apportionment methodology proposed in § 429.120(b)(3) wherein CMS would use ASP sales volume data to apportion Part B total expenditures based on the ratio of reported sales volume of the qualifying single source drug compared to reported sales volume of all products assigned to the HCPCS code to calculate the total expenditures under Part B.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters strongly supported this proposal at § 429.120(b), explaining that, because over half of Medicare enrollees are enrolled in MA plans, and overall use of prescription drugs is similar amongst fee-for-service and MA enrollees, CMS would exclude roughly half of total spending on drugs payable under Medicare Part B by only using Part B claims data. In these commenters' views, an approach that would calculate total expenditures under Part B of Title XVIII of the Act using only Part B claims data would skew the negotiation-eligible drug list toward drugs covered under Part D and away from drugs payable under Part B.

A few commenters opposed the proposal to include MA expenditures in the calculation of total expenditures under Part B, stating that statute prohibits this approach. A commenter stated that CMS did not identify legal authority that supports its decision to categorize MA expenditures as Part B expenditures in the Negotiation Program Guidance or the Negotiation Program proposed rule. A few commenters stated that the statute permits CMS to consider only payments made ''under Part B'' and not payments made under MA plans, which is Part C of the Medicare statute. A commenter stated that by referring to ''total expenditures for drugs payable under Part B'', as opposed to total expenditures under Part B, CMS improperly conflates coverage and payment. A commenter disagreed with our explanations in the Negotiation Program proposed rule for why we believe MA expenditures ought to be included in ''total expenditures under part B of title XVIII'' for purposes of the Negotiation Program. First, they disagreed with our read of section 1852(a)(1) of the Act, which requires MA plans to offer the same benefits as those in Part B fee-for-service, stating that the payments for these drugs are financed under a different mechanism under Part C as compared to Part B. Second, they asserted that the inclusion of ''an individual who is enrolled in an MA plan under part C'' in the definition of a ''maximum fair price eligible individual'' at section 1191(c)(2)(B) of the Act has no bearing on the type of expenditures that should be included when identifying negotiation-eligible drugs. Third, they stated that the exclusion in section 1191(c)(5) of the Act of expenditures for a drug or biological product that are bundled or packaged extends to MA expenditures since CMS makes capitated payments to MA plans on a per member per month basis.

[27] An OM Part B claim is considered final action based on the final action indicator for the claim and claim line.

[28] Final action for MA encounter data for Part B items and services indicates the encounter was accepted by CMS and not subsequently voided by the Medicare Advantage organization or superseded by another encounter accepted by CMS.

[29] See: *https://www.cms.gov/medicare/coding-billing/ncci-medicare.*

Response: We thank the commenters for the support and feedback. We reiterate our statement in the Negotiation Program Guidance and the proposed rule (91 FR 36254) that the statute is best read as permitting the inclusion of MA expenditures for drugs payable under Part B and administered to MA enrollees in total expenditures under Part B. We agree with commenters that contended that, by excluding such data, a significant portion of spending on drugs payable under Part B would be excluded because of the number of enrollees in MA plans.[30]

We disagree with the commenters that contended that the statute does not permit CMS to include MA expenditures in the calculation of total expenditures under Part B, as well as with the claim that we did not identify statutory authority justifying the inclusion of MA expenditures. In both the Negotiation Program Guidance and proposed rule (91 FR 36254 through 36255), we provided robust discussion of our statutory authority for including MA expenditures in ''total expenditures under part B of title XVIII'' for purposes of the Negotiation Program, including as follows: (1) section 1852(a)(1) of the Act requires MA plans to provide to enrollees the ''benefits under the original [M]edicare [Fee-For-Service] program''; (2) including MA expenditures in the calculation of total expenditures under Part B is consistent with the statutory approach reflected in the definition at section 1191(c)(2)(B) the Act of a ''maximum fair price eligible individual'', which considers ''individual[s] enrolled in an MA plan'' to be ''include[ed]'' within the reference to individuals ''enrolled under part B of Title XVIII'' to the extent ''payment may be made under part B'' for a selected drug; and (3) section 1191(c)(5) of the Act's definition of total expenditures under Part B does not exclude MA expenditures, despite explicitly specifying that expenditures where payment for the drug is bundled with payment for another Part B service are excluded from such definition.

Additionally, we disagree with the commenter's position that the exclusion in section 1191(c)(5) of the Act of expenditures for a drug or biological product that are bundled or packaged extends to MA expenditures. MA expenditures do not constitute bundled payments or packaged payments under this provision. CMS pays MA organizations a capitated, risk-adjusted amount per enrollee each month, in accordance with Part C of title XVIII of the Act, including section 1853 of the Act, as further specified in 42 CFR 422, subpart G. This per-enrollee payment covers the full scope of a beneficiary's Medicare-covered services for that period, regardless of the beneficiary's actual utilization. By contrast, we interpret the reference to bundled payment for purposes of section 1191(c)(5) of the Act to refer to reimbursements of a single, predetermined amount for a defined clinical episode of care, such as a surgical procedure bundled under a prospective payment system. Likewise, we interpret the reference to packaged payment in such section to refer to single payments that cover multiple related ancillary items or services, such as drugs and biologicals that function as supplies to a primary procedure. Because MA expenditures reflect per-enrollee capitation rather than episode-based reimbursement or a packaged payment, the exclusion stated in section 1191(c)(5) of the Act does not apply to MA expenditures.

We refer readers to the discussion in the proposed rule, and the discussion earlier in this section of the final rule, for further discussion of each of these points.

Comment: A few commenters supported the methodology CMS proposed at § 429.120(b)(2) for calculating MA expenditures using MA encounter data. A couple of these commenters recommended that CMS continue to refine this methodology to ensure MA expenditures are fully and accurately accounted for and noted that the methodology is only as good as the data underlying it; in their view, MA encounter data is often incomplete and inconsistent, which is likely to lead to CMS underestimating MA expenditures for certain drugs. A commenter recommended that CMS pair codification of § 429.120(b) with (1) concrete steps to improve MA encounter data completeness and accuracy and (2) increased transparency into how CMS validates MA encounter data.

A few commenters stated that CMS' proposed methodology to estimate MA expenditures by identifying MA units from encounter data and then determining what Medicare would have paid under FFS is a poor proxy for expenditures on drugs payable under Part B and paid for by MA plans, stating that it is inappropriate to assume that MA plans' expenditures for drugs payable under Part B will equal or average the Part B FFS limits and fails to satisfy statute's instruction to determine ''expenditures under Part B''. These commenters stated that, in other contexts such as the Part B Drug Inflation Rebate Program, CMS has declined to measure MA utilization due to significant operational complexities and recommended that CMS do the same here. These commenters also raised concerns that CMS faces significant delays in accessing complete and final MA encounter data and asserted that, if Congress had intended CMS to use MA expenditures, it would have given CMS more time to account for the data lag for MA units by permitting a larger gap between the selected drug publication date and the end of the 12-month period over which expenditures must be measured. A commenter stated that MA encounter data does not necessarily indicate which drug was administered, for example, where a drug is assigned to a nonspecific HCPCS code or multiple drugs are assigned to a single HCPCS code. A commenter stated that the data lag and imprecision of MA encounter data make it harder for interested parties to identify which drugs are most likely to be selected.

Response: We appreciate the feedback and suggestions. As we noted in the Negotiation Program Guidance and the proposed rule (91 FR 36255), MA encounter data for Part B items and services does not reliably include the actual amount paid by the MA plan sponsor. Due to this gap in MA encounter data for Part B items and services, we believe it appropriate to estimate MA expenditures for drugs payable under Part B by using MA encounter data for Part B items and services to identify the units of drugs payable under Part B that were administered under MA and then determining what Medicare would have paid for such units under OM Part B. We will monitor this approach and make refinements as needed in the future. We note that the Part B Drug Inflation Rebate Program is governed by separate statutory provisions, and its timelines and uses of data, including how MA encounter data would be used in that Program, differ significantly from that in the Negotiation Program. The operational complexity of incorporating MA encounter data into the Part B Drug Inflation Rebate Program reflects the distinct purposes that the use of that data would serve within that Program; our proposal to incorporate MA encounter data into our measurement of total expenditures under Part B for Negotiation Purposes reflects the

[30] Data through March 2026 shows that MA enrollment has risen to 55 percent of eligible Medicare beneficiaries. Meredith Freed et al., ''Medicare Advantage in 2026: Enrollment Update and Key Trends,'' KFF (June 5, 2026). *https://www.kff.org/medicare/medicare-advantage-enrollment-update-and-key-trends/.*

statutory authority and purposes of this Program. We therefore disagree that the operational constraints we have identified within the Part B Drug Inflation Rebate Program mean that we must also exclude MA expenditure data from the calculation of total expenditures under Part B in the Negotiation Program. We also disagree with the concerns that data lags will prohibit our use of Part B encounter data. In recent internal analysis, we observed that 55 percent of MA encounter data are currently submitted by MA organizations within 30 days and 85 percent of MA encounter data are currently submitted within 60 days of the claim from date. We agree with the commenter that stated that MA encounter data does not always indicate which drug was administered in cases where a qualifying single source drug is assigned to a HCPCS code with other products, though we note that this is also the case for Medicare Part B claims. We refer this commenter to our apportionment methodology set forth in § 429.120(b)(3). We also note that, typically, ''single source drugs and biologicals'' as defined in section 1847A(c)(6)(D) of the Act are assigned to unique HCPCS codes.

Comment: A commenter recommended that, when determining Part B expenditures that would have been applicable for MA enrollees, CMS should account for the reduced payment amounts that CMS would make for 340B drugs if the 340B payment policy in the CY 2027 Hospital Outpatient Prospective Payment System Proposed Rule is finalized.

Response: We thank the commenter for their input but note the comment is related to the *Payment Adjustment for 340B-Acquired Drugs Based on Results of the Medicare OPPS Drug Acquisition Cost Survey* proposed in the CY 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center payment system proposed rule (91 FR 41737). CMS will consider any future changes to Medicare payment policies when they are effective.

Final Decision: After consideration of public comments, we are finalizing § 429.120 as proposed.

6. Identification of Qualifying Single Source Drugs (§ 429.125)

Section 1192(e)(1) of the Act requires that the term ''qualifying single source drugs'' means, with respect to an initial price applicability year, subject to sections 1192(e)(2) through 1192(e)(4) of the Act, a covered part D drug (as defined in section 1860D–2(e) of the Act) that is described in section 1192(e)(1)(A) or section 1192(e)(1)(B) of the Act, or a drug or biological product for which payment may be made under part B of title XVIII that is described in section 1192(e)(1)(A) or section 1192(e)(1)(B) of the Act. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example section 30.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

We proposed that, with respect to each initial price applicability year, a qualifying single source drug is a drug covered under Part D, a drug payable under Part B, or both, as such terms are defined at proposed § 429.20, that meets the statutory criteria set forth in section 1192(e) of the Act. Specifically, we proposed in § 429.125(a)(1) to codify the requirements in section 1192(e)(1)(A) of that Act that, for drug products, a qualifying single source drug is a drug covered under Part D, payable under Part B, or both: (1) that is approved under section 505(c) of the FD&C Act and marketed pursuant to such approval; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 7 years have elapsed since the date of such approval; and (3) that is not the listed drug for any drug approved and marketed under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act. We proposed in § 429.125(a)(2) to codify the requirements in section 1192(e)(1)(B) of the Act that, for biological products, a qualifying single source drug is a drug covered under Part D, payable under Part B, or both: (1) that is licensed under section 351(a) of the Public Health Service Act (''PHS Act'') and marketed pursuant to such licensure; (2) for which, as of the selected drug publication date with respect to a given initial price applicability year, at least 11 years have elapsed since the date of such licensure; and (3) that is not the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act.

a. Identification of Potential Qualifying Single Source Drugs (§ 429.125(b))

To identify drugs or biological products for purposes of identifying qualifying single source drugs that meet the criteria in section 1192(e) of the Act, we proposed to identify drugs and biological products that are potential qualifying single source drugs as described at proposed § 429.125(b).

Sections 11001 and 11002 of the IRA do not define what a ''drug'' or ''biological product'' is for purposes of identifying whether such a drug or biological product is a qualifying single source drug. However, the Act provides that a drug or biological product may have multiple dosage forms, strengths, formulations, package sizes, or package types, and multiple applications and approvals. Specifically, for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug under section 1192(d)(1) of the Act, section 1192(d)(3)(B) of the Act states that CMS shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation, package size, or package type of the drug. Likewise, section 1192(d)(3)(B) of the Act's aggregation rule applies to the calculation of a drug or biological product's total expenditures for purposes of determining whether such drug or biological product meets the low-spend Medicare drug exclusion from a qualifying single source drug, described in section 1192(e)(3)(B) of the Act. Similarly, section 1196(a)(2) of the Act directs CMS to establish procedures ''to compute and apply the MFP different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.'' In addition, section 1194(e)(1)(D) of the Act instructs CMS, for purposes of the negotiation process (discussed in further detail in section II.F. of this final rule), to consider, among other information, ''applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act,'' in the plural, for the ''drug,'' in the singular.

Different dosage forms and strengths, as well as different formulations, of a drug or biological product, containing the same active moiety/active ingredient, may be approved or licensed in multiple NDAs or BLAs. Defining a potential qualifying single source drug on the basis of a single NDA/BLA, and thereby excluding from such potential qualifying single source drug dosage forms and strengths and new formulations of the drug or biological product approved or licensed under other NDAs/BLAs, would be inconsistent with these statutory provisions. To give full effect to all relevant provisions of the statute, including sections 1192(d)(3)(B), 1192(e), 1194(e)(1)(D), and 1196(a)(2) of the Act, we proposed at § 429.125(b) a process, consistent with policies for implementation as described in, for

example, section 30.1 of the Negotiation Program Guidance subject to proposed modifications as noted herein, to identify a potential qualifying single source drug, for purposes of identifying qualifying single source drugs that meet the statutory criteria under section 1192(e) of the Act, using the specific constituent dosage forms and strengths (at the NDC–9 or NDC–11 level) that are identified as aggregated under the same NDA/BLA holder for the same active moiety/active ingredient.[31] The policies proposed in § 429.125(b), like the policies in, for example, section 30.1 of the Negotiation Program Guidance, would address how CMS is interpreting the statutory directive in section 1192(e) of the Act to identify ''drug[s]'' or ''biological product[s]'' for purposes of evaluating whether such drug or biological product satisfies the criteria for qualifying single source drugs.

For drugs, we proposed at § 429.125(b)(1) to identify a potential qualifying single source drug using all dosage forms and strengths of the drug with the same active moiety and the same holder of an NDA, inclusive of products that are marketed pursuant to different NDAs. If there are multiple NDAs with the same active moiety that include non-identical names reported for the NDA holder, including situations where it appears the NDA holder name has not yet been updated, we proposed that we may further investigate whether such NDA(s) are held by the same entity for the purposes of identifying a potential qualifying single source drug using FDA sources as well as relevant publicly available information as CMS deems appropriate. The potential qualifying single source drug would also include all dosage forms and strengths of the drug with the same active moiety and marketed pursuant to the same NDA(s) described in the prior sentences that are: (1) repackaged and relabeled products (defined at proposed § 429.20 to be consistent with 21 CFR 207.1) that are marketed pursuant to such NDA(s); (2) authorized generic drugs (defined in section 1192(e)(2)(B)(i) of the Act and at proposed § 429.20 and described further later in this section) that are marketed pursuant to such NDA(s); or (3) multi-market approval (MMA)[32] products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such NDA(s). Any dosage forms and strengths of the drug with the same active moiety that are distributed by a private label distributor and marketed pursuant to such NDAs would also be aggregated in the potential qualifying single source drug of that NDA holder consistent with the policies for implementation as described in, for example, section 30.1 of the Negotiation Program Guidance.

For biological products, we proposed at § 429.125(b)(2) to identify a potential qualifying single source drug using all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a BLA, inclusive of products that are marketed pursuant to different BLAs. If there are multiple BLAs with the same active ingredient (or the same antigen component for a biological product that is a vaccine for infectious disease(s), as further described later in this section) that include non-identical names reported for the BLA holder, including situations where it appears the BLA holder name has not yet been updated, we proposed that we may further investigate whether such BLA(s) are held by the same entity for the purposes of identifying a potential qualifying single source drug using FDA sources as well as relevant publicly available information as CMS deems appropriate. The potential qualifying single source drug would also include all dosage forms and strengths of the biological product with the same active ingredient and marketed pursuant to the same BLA(s) described in the prior sentences that are: (1) repackaged and relabeled products that are marketed pursuant to such BLA(s); (2) authorized generic drugs, the definition of which at section 1192(e)(2)(B)(ii) of the Act and proposed § 429.20 (described further later in this section) includes unbranded biological products that are marketed pursuant to such BLA(s); or (3) MMA products imported under section 801(d)(1)(B) of the FD&C Act that are marketed pursuant to such BLA(s). Any dosage forms and strengths of the biological product with the same active ingredient that are distributed by a private label distributor and marketed pursuant to such BLAs would also be aggregated in the potential qualifying single source drug of that BLA holder consistent with the policies for implementation as described in, for example, section 30.1 of the Negotiation Program Guidance.

Although assessing biological products on the basis of their active ingredient is appropriate in most circumstances, we understand that vaccines for infectious disease(s) are more appropriately assessed using their antigen component due to the evolving nature of pathogen strains over time. Therefore, and as proposed at § 429.125(b)(3), in the context of vaccines for infectious disease(s), we would identify a potential qualifying single source drug on the basis of such vaccines' antigen component on such vaccines' labeling, as accessed in public sources such as those discussed later in this section. We believe our proposal to identify drugs based on their active moiety and biological products based on their active ingredient, subject to the proposal for vaccines for infectious disease(s), is the best reading of the statutory directives in sections 1192(d)(3)(B), 1192(e), 1194(e)(1)(D), and 1196(a)(2) of the Act as they relate to identifying qualifying single source drugs. We note further that in the context of drugs, ''active moiety'' (as contrasted with ''active ingredient'') describes the active molecule or ion in the drug, as this term excludes those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule.[33] The term ''active moiety'' is not applicable in the context of biological products, and it is thus appropriate to evaluate biological products based on their active ingredient.

Consistent with the policies for implementation as described in Negotiation Program Guidance, we proposed to use public sources such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file to identify the active ingredient/active moiety of the drug or biological product. We may also consult with FDA as appropriate, for example, to clarify whether a suffix or prefix in an active moiety/active ingredient name represents a genuine difference in active moiety/active ingredient.

Section 1192(e)(2)(A) of the Act states that an authorized generic drug and the qualifying single source drug that includes the listed drug or reference

[31] In the context of identifying qualifying single source drugs and calculating total expenditures for purposes of identifying negotiation-eligible drugs and selected drugs, in this final rule we use the term ''aggregation'' to refer to the process of identifying the formulations and dosage forms and strengths that constitute a qualifying single source drug, and that, if applicable, CMS will use to calculate total expenditures when determining whether such drug is a negotiation-eligible drug or selected drug.

[32] See: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/importation-certain-fda-approved-human-prescription-drugs-including-biological-products-and*.

[33] See 21 CFR 314.3(b) (defining the terms ''active ingredient'' and ''active moiety'').

product of that authorized generic drug shall be treated as the same qualifying single source drug. An authorized generic drug is defined in section 1192(e)(2)(B) of the Act and in proposed § 429.20 as: (1) in the case of a drug, an authorized generic drug (as such term is defined in section 505(t)(3) of the FD&C Act); and (2) in the case of a biological product, a product that has been licensed under section 351(a) of the PHS Act [34] and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark than the reference product. We proposed at § 429.125(b)(1)(iii) that a potential qualifying single source drug that is a drug is inclusive of authorized generic drugs that are marketed under the NDA(s) described therein, and at proposed § 429.125(b)(2)(iii) that a potential qualifying single source drug that is a biological product is inclusive of authorized generic drugs that are marketed under the BLA(s) described therein.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: CMS received many comments on its reading of the statute to aggregate all dosage forms and strengths of a drug with the same active moiety and the same holder of a NDA or of a biological product with the same active ingredient and the same holder of a BLA, for the purposes of identifying potential qualifying single source drugs as proposed at § 429.125(b). Many commenters disagreed with CMS' approach to identifying a qualifying single source drug and asserted that the proposal at § 429.125(b) contradicts the statute and stated that they do not believe that CMS has the statutory authority to aggregate qualifying single source drugs across multiple NDAs/BLAs. These commenters claimed that the statute defines a qualifying single source drug in reference to a distinct NDA or BLA, and some of these commenters stated that it would be reasonable and appropriate that such a definition would align with the FDA's approval and licensure processes under section 505(c) of the FD&C Act or section 351(a) of PHS Act. A few commenters claimed that the statute defines a qualifying single source drug by reference to the definition of a ''covered Part D drug'' at section 1860D–2(e) of the Act, which in turn cross-references the definition of a ''covered outpatient drug'' at section 1927(k)(2) of the Act. The commenter asserted that, under section 1927(k)(2) of the Act, whether a single source drug is a distinct ''covered outpatient drug'' is based on whether the product is approved pursuant to a distinct NDA or BLA, and the only exception to this rule is for line extensions. A few commenters asserted that the reference to ''payment under Part B'' in section 1192(e)(1) of the Act requires CMS to identify a qualifying single source drug exclusively by reference to how the CMS identifies the drug for payment purposes and asserted that CMS has long interpreted section 1847A of the Act as identifying distinct single source drugs payable under Part B by reference to whether they have distinct NDAs or BLAs. Some commenters stated that CMS' failure to limit the identification of a potential qualifying single source drug to products approved or licensed under a distinct NDA/BLA will be detrimental to future innovation and patient access to medications and limit manufacturers from researching follow-on innovations such as extended release formulations and new indications, including indications for rare diseases.

Response: We thank these commenters for their input. As discussed in responses to similar comments in the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027, and the Negotiation Program Guidance, section 1192(d)(3)(B) of the Act directs CMS to ''use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug'' for purposes of determining whether a qualifying single source drug is a negotiation-eligible drug. Identifying potential qualifying single source drugs on the basis of active moiety, active ingredient, or antigen component, as applicable, permits us to effectuate these statutory directives. We use ''active ingredient'' and ''active moiety'' (or, for vaccines for infectious disease(s), ''antigen component'') as markers for active substances that remain constant across changes in strength, dosage form, or release mechanism. These terms also comport with the ordinary meaning of ''drug''. See, for example, Drug, Black's Law Dictionary (12th ed. 2024) (''A substance intended for use in diagnosis, cure, treatment, or prevention of disease.''); Drug, Merriam-Webster's Collegiate Dictionary (12th ed. 2025) (''[A] substance used as a medication or in the preparation of medication''). We adopted this approach in guidance for initial price applicability years 2026, 2027 and 2028, and this final rule to ensure that a new dosage form, strength, or new formulation of a drug with the same ''active ingredient'', ''active moiety'', or ''antigen component'', but that received a new FDA approval or licensure, would not avoid or delay eligibility for negotiation contrary to these statutory provisions. Indeed, complying with the statutory requirement to identify a qualifying single source drug using data that is aggregated across different dosage forms and strengths and new formulations has the effect of reducing manufacturer incentives to engage in ''product hopping,'' as well as counteracting the effects of existing ''product hopping'' on the Negotiation Program. Ensuring that drug and biological products are not inappropriately excluded from, or delayed from inclusion in, the Negotiation Program based on modest or minor modifications is consistent with the purpose of the statute, which is to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries. Similarly, section 1196(a)(2) of the Act directs CMS to establish procedures ''to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.'' In addition, section 1194(e)(1)(D) of the Act instructs CMS, for purposes of the negotiation process discussed in further detail in subpart F of this final rule, to consider, among other information, ''applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act,'' in the plural, for the ''drug,'' in the singular. The aggregation rules under sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act are clear and are designed to ensure that the Negotiation Program delivers benefits to the Medicare program and its beneficiaries in accordance with statute. Because different dosage forms and strengths, as well as different formulations, containing the same active moiety/active ingredient may be approved or licensed under multiple NDAs or BLAs, the suggestion from commenters to define a qualifying single

[34] CMS is interpreting the reference to ''licensed under section 351(a) of such Act'' to mean licensed or deemed licensed under section 351(a) of the PHS Act. Section 351(a) of the PHS Act addresses the licensure of a biological product.

source drug in reference to a distinct NDA or BLA is inconsistent with sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act. Contrary to the views of some commenters, sections 1192(d)(3)(B) and 1196(a)(2) of the Act require the aggregation of data across dosage forms and strengths of the drug, including new formulations of the drug, and not based on the specific formulation or package size or package type of the drug, thereby necessarily establishing that the statutory selection and negotiation procedures apply more broadly than to a distinct NDA or BLA.

For these same reasons, we disagree that the references in section 1192(e)(1) of the Act to the definition of a ''covered Part D drug'' and to payment which ''may be made under part B'' require CMS to identify a qualifying single source drug with respect to a distinct NDA or BLA. This language in section 1192(e)(1) of the Act sets forth one of multiple statutory criteria that CMS must use to identify qualifying single sources drugs. Specifically, section 1192(e)(1) of the Act requires that a qualifying single source drug that is a drug as set forth in section 1192(e)(1)(A) of the Act or that is a biological product as set forth in section 1192(e)(1)(B) of the Act must be ''a covered part D drug (as defined in section 1860D–2(e))'' or ''a drug or biological product for which payment may be made under part B of title XVIII'' or both. Were we to accept the commenters' view that this statutory language requires CMS to identify a qualifying single source drug with respect to a distinct NDA or BLA, we would fail to give full effect to the aggregation rules under sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act. Under our understanding of the statutory language, section 1192(e) of the Act, including its references to a ''covered Part D drug'' and to payment which ''may be made under part B'', sets forth the qualifying conditions for drug and biological products; these qualifying conditions do not supersede nor conflict with—and, to the contrary, must be read in concert with—the aggregation rules under sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act. Unlike the views offered by some commenters, our understanding of the statutory language gives full effect to all relevant provisions of the statute, including sections 1192(d)(3)(B), 1192(e), 1194(e)(1)(D), and 1196(a)(2) of the Act; we are applying an interpretation of the statute that follows the statutory criteria for the identification of a qualifying single source drug under section 1192(e) of the Act and, consistent with sections 1192(d)(3)(B), 1194(e)(1)(D), and 1196(a)(2) of the Act, gives effect to the statutory policy that a drug that may be selected for negotiation includes multiple dosage forms and strengths and formulations of that drug.

Comment: A commenter expressed appreciation for CMS' consistent approach to the identification of potential qualifying single source drugs. This commenter stated that section 1192(d)(3)(B) of the Act clarifies the intent of policymakers to apply negotiated prices across dosage forms and strengths of a selected drug, which the commenter asserted necessitates the approach CMS proposes in the rule for identifying potential qualifying single source drugs. This commenter stated that the approach proposed by CMS will prevent gaming and abuse of the Negotiation Program that may occur if manufacturers were able to prevent a high-revenue product from qualifying for negotiation through product hopping and obtaining new NDAs and BLAs, effectively resetting the clock on the statutory 7- and 11-year periods before a drug or biological product may qualify for selection.

Response: We thank the commenter for the support. We agree that the statutory requirement to identify a qualifying single source drug using data that is aggregated across different dosage forms and strengths, as described in the proposed rule, is expected to reduce incentives for pharmaceutical manufacturers to engage in ''product hopping.'' This ensures that the Negotiation Program selects drugs for negotiation that have high total expenditures under Part B and Part D of the Medicare program regardless of variations like differences in formulation or packaging.

Comment: A commenter requested that CMS provide greater transparency regarding its methodologies for identifying the active moiety/active ingredient in a potential qualifying single source drug, stating that public sources cited by CMS (such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Bases of Strength file) aggregate and display FDA information, as well as other data, for secondary purposes, such as clinical terminology standardization, drug information directories, and labeling repositories, and the classifications in these sources do not necessarily track the regulatory distinctions that are determinative for FDA's active moiety/active ingredient identification. The commenter recommended that CMS use NDA and BLA approvals, approved labeling, and Orange Book and Purple Book data, as the primary and binding sources for identifying active moieties/active ingredients, with supplementary databases such as RxNorm, OpenFDA, FDALabel, and DailyMed used only to confirm, and never to override, those records. The commenter requested that CMS publish an analytic plan describing what information from each public source will be used and how CMS will reconcile differences that may arise between the sources, stating that without a defined hierarchy specifying which sources will be used in the event of conflict, manufacturers will have insufficient information about how CMS will treat their products. The commenter also requested that any FDA consultation undertaken to resolve a naming or classification question should be disclosed to the affected manufacturer, with a defined opportunity for the manufacturer to respond, and the consultation—including the information provided to FDA, the FDA division consulted, and FDA's response—should be documented in the administrative record.

Response: We appreciate the input. We maintain that manufacturers have sufficient notice of the information we use to identify active moieties/active ingredients, as described in this final rule. Because information on active moiety/active ingredient names are not always standardized across systems, we believe that using a combination of public sources, including those cited by CMS (for example, FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file, OpenFDA, FDALabel, RxNorm, and DailyMed), in addition to FDA consultation, as applicable, is the best way to accurately identify active moieties/active ingredients. We consider the body of information across sources together, which we believe produces a more accurate and complete identification than relying on any one source alone. This holistic, non-hierarchical approach preserves our ability to incorporate FDA feedback to ensure accurate identification of the active moiety/active ingredient consistent with the statute. Where these sources conflict or CMS seeks additional clarity, we may consult FDA. We recognize that some fields within these sources are not fully standardized because the sources themselves draw on multiple, non-uniform inputs. To that end, CMS incorporates RxNorm to provide normalized names and unique identifiers for medicines and drugs, consistent with RxNorm's stated goal to

provide such normalization.[35] Further, RxNorm incorporates FDA's approved labeling information in the form of FDA SPL. FDA's SPL is a published standard used by FDA for processing and managing labeling and labeling changes. In response to the request that CMS use NDA and BLA approvals, FDA approved labeling, and Orange Book and Purple Book data, we reiterate that our proposal referred to FDA and FDA-derived sources such as FDALabel, DailyMed, and OpenFDA. Further, in addition to FDA's SPL, OpenFDA incorporates many other FDA sources such as Orange Book, Drugs@FDA and the NDC Directory. Lastly, FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file is an FDA publication. Therefore, we believe our proposal already incorporates the sources suggested by the commenter and do not believe it is necessary to add these additional FDA sources to the non-exhaustive list of sources already identified. In response to the request that CMS publish an analytic plan, we believe this final rule provides sufficient detail on how CMS identifies active moieties/active ingredients. Our approach is holistic and sensitive to drug-specific details rather than a rigid assessment of data fields. In response to the request that CMS disclose any FDA consultation to the affected manufacturer, we note that section 1192(e) of the Act sets forth the requirements for the identification of qualifying single source drugs and does not require nor contemplate that CMS disclose such consultations to manufacturers.

Comment: A commenter requested that CMS exclude Part B vaccines from the Negotiation Program and clarify that influenza vaccines do not meet the qualifying single source drug definition due to annual changes in antigen component composition.

Response: We note that nothing in the statute indicates that CMS should categorically exclude such vaccines from being potential qualifying single source drugs nor from the Negotiation Program more broadly. We refer this commenter to our proposals for vaccines for infectious disease(s) at § 429.125(b)(3) and 429.125(c)(2)(i), which account for changes to the antigen component(s) in such vaccines.

Comment: A few commenters supported and recommended that CMS finalize the proposal at § 429.125(b)(3) to identify a potential qualifying single source drug for a vaccine for infectious disease(s) on the basis of such vaccines' antigen component on such vaccines' labeling. A couple of these commenters stated that this approach is consistent with the statute and vaccine science and will support public health goals. One of these commenters stated that this policy reflects the statute's product-specific design and asserted that same statutory logic supports applying the 7- and 11-year periods to each drug product or biological product based on the approval or licensure of its own NDA, BLA, or supplement.

Response: We appreciate the support and feedback. To the commenter who stated that § 429.125(b)(3) supports applying the 7- and 11-year periods to each drug product or biological product based on the approval or licensure of its own NDA, BLA, or supplement, we note that vaccines for infectious disease(s), as we stated in the proposed rule (91 FR 36257, 36261), are more appropriately assessed using their antigen component due to the evolving nature of pathogen strains over time. Some manufacturers of vaccines for infectious disease(s) update the antigen component(s) of their products through supplemental BLAs. In such cases, we would consider the vaccine for infectious disease(s) approved through the supplemental BLA to be a separate potential qualifying single source drug under § 429.125(b)(3) from the product that FDA initially licensed because these products do not have the same antigen component. It is therefore appropriate to use the earliest date of licensure for the earliest-approved FDA application (whether that is a BLA or supplemental BLA) belonging to the BLA holder and that contains the antigen component used to identify that unique potential qualifying single source drug, as we proposed at § 429.125(c)(2)(i), for purposes of identifying the starting date from which to measure the 11-year period described in § 429.125(c)(2). In contrast, it would not be appropriate to use the approval date of a supplemental NDA or BLA with the same active moiety/active ingredient for purposes of identifying the starting date from which to measure the 7- or 11-year periods for drugs and biological products that are not vaccines for infectious diseases because the approval of such a supplemental NDA or BLA would not result in a new potential qualifying single source drug.

Final Decision: After consideration of public comments, we are finalizing § 429.125(a) and (b) as proposed, but with a technical modification to § 429.125(b)(4) to improve organizational clarity that is discussed in the next section of this final rule. We direct readers to the discussion in section II.B.6.a.1. of this final rule for our consideration of public comments received on the policy proposed at § 429.125(b)(4)(i) as well as our summary of the aforementioned technical modification to § 429.125(b)(4).

(1) Fixed Combination Drugs

At proposed § 429.125(b)(4), for the purpose of identifying potential qualifying single source drugs and subject to the proposed policy for specific fixed combination drugs that are new formulations proposed at § 429.125(b)(4)(i) to clarify our treatment of new formulations, we proposed that if a drug is a fixed combination drug (defined in proposed § 429.20) with two or more active moieties, active ingredients, or, for vaccines for infectious disease(s), antigen components, the distinct combination of active moieties, active ingredients, or antigen components would generally be treated as one active moiety, active ingredient, or antigen component. Therefore, all formulations with this distinct combination offered by the same NDA/BLA holder would be aggregated across all dosage forms and strengths of the fixed combination drug (that is, all formulations and dosage forms and strengths of this distinct combination would be considered the same potential qualifying single source drug and, if applicable, CMS would aggregate total expenditures for all such formulations and dosage forms and strengths when determining whether such drug is a negotiation-eligible drug or selected drug). Under this proposal, a product containing only one (but not all) of the active moieties, active ingredients, or antigen components that is offered by the same NDA/BLA holder would generally not be aggregated with the formulations of the fixed combination drug and would be considered a separate potential qualifying single source drug. For example, a corticosteroid inhaler would not be aggregated with a fixed combination inhaler from the same NDA/BLA holder that contains the same corticosteroid combined with a long-acting beta agonist. In this example, the corticosteroid inhaler would be considered as a separate potential qualifying single source drug from the fixed combination inhaler.

In the draft guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028, we stated our belief that treating distinct combinations of active moieties/active ingredients as one active moiety/active ingredient for the purpose of identifying potential

[35] See: *https://www.nlm.nih.gov/research/umls/rxnorm/overview.html#how-is-rxnorm-produced.*

qualifying single source drugs is generally appropriate. However, we acknowledged that there may exist fixed combination drugs for which one of the active ingredients or active moieties contained is not biologically active against the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference. We solicited comments on whether the addition of drugs payable under Part B may impact the fixed combination drug policy described in the draft guidance. In particular, we solicited comments on how CMS might consider grouping such fixed combination drug products with products containing at least one but not all of the active moiety(ies)/active ingredient(s) into the same potential qualifying single source drug for both drugs payable under Part B and/or covered under Part D, including input on terminology that could facilitate the effectuation of such a policy.

We received many comments in response to this previous comment solicitation. Some commenters supported a modification to the fixed combination drug policy as a way to close a loophole for manufacturers to avoid selection by making minor changes to existing drugs, specifically citing the addition of hyaluronidase to drugs payable under Part B. Other commenters opposed such a modification, citing concerns that CMS lacks the statutory authority to do so, that the approach described in the comment solicitation does not align with how FDA regulates and reviews the approvals of fixed combination drugs, or that CMS would not be able to apply a consistent definition to the terminology described in the comment solicitation, including the terms ''biologically active against the disease state'' or ''clinically meaningful difference.'' Some commenters raised concerns that the modification would potentially harm patients and discourage the innovation of pharmaceutical manufacturers. In the Negotiation Program Guidance, we stated that, due to the complexity and scope of the issue as noted in the stakeholder comments, we believed additional time would be necessary to develop objective policy criteria if we were to finalize such a policy, and thus did not make a change to the fixed combination drug policy in the Negotiation Program Guidance. We stated our intent to address the program integrity risk posed by certain fixed combination drugs and that we were continuing to consider appropriate policy to potentially propose in rulemaking for initial price applicability year 2029 and subsequent years.

In the Negotiation Program proposed rule (91 FR 36258), we stated that, since publishing the Negotiation Program Guidance, we have continued to consider program integrity risks posed by certain fixed combination drugs. Specifically, we stated that we were aware of a program integrity risk in which, under Negotiation Program policies for identifying qualifying single source drugs set forth in guidance with respect to previous initial price applicability years, a manufacturer may avoid selection of a qualifying single source drug or, in the case that a qualifying single source drug becomes a selected drug, avoid the application of the MFP, by marketing a new formulation of the qualifying single source drug that includes, in addition to the active moiety(ies)/active ingredient(s)/antigen component(s) in the original product, an active moiety, antigen component, or active ingredient, such as hyaluronidase, that enables an alternative route of administration for the shared active moiety(ies)/active ingredient(s)/antigen component(s) in the original product. Under the general fixed combination drug policy set forth in guidance with respect to previous initial price applicability years, including, for example, section 30.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028, we explained that we were aware that such a manufacturer may avoid having all dosage forms and strengths of a drug, including the new formulation of such drug, with its active moiety(ies)/active ingredient(s)/antigen component(s) included in a qualifying single source drug in instances in which a new formulation differs from other formulations of the qualifying single source drug based on the inclusion of an additional active moiety/active ingredient/antigen component that enables an alternative route of administration for the shared active moiety(ies)/active ingredient(s)/antigen component(s).

We explained that, in this scenario, we were concerned that application of CMS' general fixed combination drug policy would be in tension with statutory requirements under sections 1192(d)(3)(B) and 1196(a)(2) of the Act because we would not aggregate together the original product and the new formulation containing the additional active moiety/active ingredient/antigen component, even though these may be appropriately understood as different formulations of the same drug under sections 1192(d)(3)(B) and 1196(a)(2) of the Act.[36]

First, application of the general fixed combination drug policy to such products would be in tension with section 1192(d)(3)(B) of the Act in the course of drug selection because we would not treat the original product and the new formulation containing the additional active moiety/active ingredient/antigen component as one qualifying single source drug. Thus, when determining whether a qualifying single source drug is a negotiation-eligible drug, as proposed at § 429.115(a), we would calculate the combined total expenditures under Part B and Part D separately for the original product and the new formulation. We stated our belief that separately calculating total expenditures for such products under these circumstances may be inconsistent with the statutory direction at section 1192(d)(3)(B) of the Act to use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, in determining whether a qualifying single source drug is a negotiation-eligible drug. Because under the general fixed combination drug policy we would evaluate the original product and the new formulation separately during the drug selection process, the time since approval or licensure (determined as proposed at § 429.125(c)) for the new formulation would likely be later than for the original product, thereby extending the years before which the new formulation could potentially be selected and, if selected and if an MFP is agreed to, be subject to an MFP. We explained that this dynamic presents program integrity risks because evaluating the time since approval or licensure separately for the original product and the new formulation and splitting combined total expenditures under Part B and Part D between such products could lead to a scenario where the original product or the new formulation or both are never selected or are not selected until a future initial price applicability year, which would reduce or delay the ability of the Negotiation Program to negotiate MFPs

[36] Other provisions of the Act further support our policy to aggregate across NDA/BLAs when identifying the dosage forms and strengths and new formulations that constitute a qualifying single source drug. This policy is described in section II.B.6.a. of this final rule. For purposes of our discussion of fixed combination drugs in this section II.B.6.a.1. of the final rule, we focus on the most relevant provisions for purposes of our proposed policy, which are the instructions at sections 1192(d)(3)(B) and 1196(a)(2) of the Act to aggregate across dosage forms and strengths and new formulations.

for high expenditure, single source drugs and biological products.

Second, if the original product is selected for negotiation, and a negotiated MFP is agreed upon for that drug, the general fixed combination drug policy may be in tension with section 1196(a)(2) of the Act, which directs CMS to apply the MFP across different strengths and dosage forms of a selected drug and not based on the specific formulations or package size or package type of such drug, because the MFP would not apply to the new formulation. We explained that this dynamic presents further program integrity risks. If the new formulation is not part of the selected drug, then the Primary Manufacturer would be able to market the new formulation without the new formulation being subject to MFP effectuation requirements, thereby creating a new incentive for the Primary Manufacturer to drive patient utilization toward the new formulation and circumvent the application of the MFP to the original product for such patients.

To address these program integrity risks, and to clarify how CMS interprets sections 1192(d)(3)(B) and 1196(a)(2) of the Act as applied to new formulations of a drug, including in the context of fixed combination drugs, we proposed at § 429.125(b)(4)(i) a policy for specific fixed combination drugs that are new formulations: if CMS determines that a fixed combination drug with two or more active moiety(ies), active ingredient(s), or, for a vaccine for infectious disease(s), antigen component(s), shares one or more active moiety(ies), active ingredient(s), or antigen component(s) with another drug or biological product(s) with the same NDA/BLA holder, and such products differ in active moiety(ies), active ingredient(s), or antigen component(s) due to the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s), CMS would, for purposes of identifying the potential qualifying single source drug under proposed § 429.125(b)(1) and (b)(2), use all dosage forms and strengths of the drug or biological product with the shared moiety(ies), active ingredient(s), or antigen component(s) and the same NDA/BLA holder. In other words, we would identify the potential qualifying single source drug as including all dosage forms and strengths with the shared active moiety(ies), active ingredient(s), or antigen component(s) that is offered by the same NDA/BLA holder. An example is the inclusion of active ingredient X with a different active ingredient Y, where active ingredient X creates a new formulation and enables an alternative route of administration for active ingredient Y. In the described example and as set forth in proposed § 429.125(b)(4)(i), CMS would identify the potential qualifying single source drug using all dosage forms and strengths of the drug or biological product that contain active ingredient Y and share the same BLA holder.[37]

We proposed the policy at § 429.125(b)(4)(i) because the program integrity concerns this policy would address relate primarily to biological products that are more likely payable under Part B, and drugs were not selected based on total expenditures under Part B until initial price applicability year 2028. The program integrity concerns raised by fixed combination drugs that are new formulations have not yet impacted drug selection but may soon do so as more drugs with significant total expenditures under Part B become qualifying single source drugs and negotiation-eligible drugs. We stated that we did not believe that significant reliance interests have arisen around the fixed combination policy established in Negotiation Program guidance for initial price applicability years 2026 through 2028, as incentives for pharmaceutical manufacturers to develop new formulations like the ones we proposed to address in this policy long predate the Negotiation Program. In the absence of this proposed policy, however, pharmaceutical manufacturers may have increased incentives under Negotiation Program policy to drive patient utilization toward new formulations that would be treated as distinct qualifying single source drugs, and if selected, as distinct selected drugs.

The proposal incorporated previous feedback from commenters that raised concerns about how we would operationalize terms used in the draft guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028, such as ''biologically active against the disease state''. We stated that we understood from these commenters' concerns the importance of developing a modification to the general fixed combination drug policy that is narrowly tailored to the development of new formulations that pose program integrity concerns and does not group products together under the same potential qualifying single source drug beyond what the statute permits. Additionally, we stated that we understood the importance of developing criteria that allow the proposed policy for specific fixed combination drugs that are new formulations to be operationalized in a consistent and objective manner over a large set of active moieties/active ingredients/antigen components. We stated our belief that the terminology proposed at § 429.125(b)(4)(i) would achieve both these goals.

First, we stated our belief that the criteria proposed at § 429.125(b)(4)(i) can be operationalized in a consistent and objective manner using public sources. Specifically, we proposed to use public sources such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file to identify the active moiety(ies)/active ingredient(s)/antigen component(s) of the drug or biological products, as described in section II.B.6.a. of this final rule, and to use public sources such as, but not limited to, Orange Book, Purple Book, Drugs@FDA, and DailyMed to identify the routes of administration of the fixed combination drug and the drug or biological product with the same NDA/BLA holder that shares one or more active moiety(ies)/active ingredient(s)/antigen component(s) with the fixed combination drug. We stated that we may also consult with FDA, as appropriate. We solicited comments on recommended approaches to inform CMS identification of active moiety(ies)/active ingredient(s)/antigen component(s) that enable an alternative route of administration for co-administered active moiety(ies)/active ingredient(s)/antigen component(s), including what types of information or descriptions we should look for within product labeling when identifying such cases.

Second, we stated that focusing on active moieties/active ingredients/antigen components that enable an alternative route of administration would reduce the number of products qualifying for the proposed policy for specific fixed combination drugs that are new formulations as compared to the previous language citing active moieties/active ingredients not biologically active against the disease state(s) for which the drug is indicated. For example, we stated our belief that

[37] If a drug product or biological product included active moiety/active ingredient/antigen component X, active moiety/active ingredient/antigen component Y, and an additional active moiety/active ingredient/antigen component Z that did not meet the criteria set forth in proposed § 429.125(b)(4)(i), CMS would not include such drug product or biological product under the same potential qualifying single source drug.

the terminology proposed at § 429.125(b)(4)(i) would currently only impact biological products licensed under BLAs.

We explained that, in developing this proposed policy, CMS also considered other feedback from commenters on our prior proposal to modify our fixed combination drug policy. As we noted in the Negotiation Program Guidance, many commenters raised concerns that a modification to CMS' fixed combination drug policy would not align with how FDA regulates and reviews the approvals of fixed combination drugs. We considered this feedback but maintain that the language at proposed § 429.125(b)(4)(i) clarifies how CMS would comply with sections 1192(d)(3)(B) and 1196(a)(2) of the Act for fixed combination drugs that are new formulations, and the commenters' suggestion that CMS must treat fixed combination drugs in the same manner as what such commenters assert is how the FDA may treat such products under FDA authorities is not persuasive in this instance. Identifying such products as a single potential qualifying single source drug reflects CMS' proposed interpretation of sections 1192(d)(3)(B) and 1196(a)(2) of the Act and would solely be for the purpose of implementing the Negotiation Program.

We noted that we also considered comments on how a modification to CMS' fixed combination drug policy would potentially impact pharmaceutical innovation. Although a few of the previous commenters stated a modification to the fixed combination drug policy would potentially harm patients by discouraging the innovation of pharmaceutical manufacturers, another commenter noted that manufacturers already have substantial financial motivations beyond the Negotiation Program to pursue the development of new formulations—including new formulations that are fixed combination drugs—to delay generic or biosimilar competition. We agreed with this latter argument and noted further our belief that the policy proposed at § 429.125(b)(4)(i) would effectuate sections 1192(d)(3)(B) and 1196(a)(2) of the Act, address the program integrity concerns in the Negotiation Program that we and commenters have identified, while not meaningfully impacting incentives for innovation. We also reiterated our statement in the Negotiation Program Guidance that we are committed to a negotiation process that recognizes the clinical benefit of products, including products with different dosage forms and strengths, formulations or routes of administration from other products that are aggregated as part of the same qualifying single source drug, and we directed readers to proposed § 429.510(e) and section II.F.3.d.1. of the Negotiation Program proposed rule for discussion of CMS' approach to adjusting the starting point for an initial offer based on section 1194(e)(2) factors, which include factors related to clinical benefit as compared to therapeutic alternatives.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the policy for specific fixed combination drugs that are new formulations proposed at § 429.125(b)(4)(i) and recommended finalizing. Many commenters agreed with CMS that the proposed policy is important for addressing a program integrity risk in which manufacturers may develop minor reformulations of existing drugs to avoid selection of a qualifying single source drug or, in the case that a qualifying single source drug becomes a selected drug, avoid the application of the MFP. A few commenters remarked that the inclusion of a component that enables a different route of administration, including the addition of hyaluronidase to enable subcutaneous administration, largely represents a repackaging of the existing product and should not transform the existing drug into a new one for purposes of Medicare pricing. Some commenters stated that the proposal at § 429.125(b)(4)(i) is appropriately tailored to address this scenario. A commenter stated that the proposal appropriately balances program integrity concerns while preserving the existing framework for other fixed combination drugs, which will appropriately balance the goals of reducing Medicare drug costs and encouraging biosimilar competition. A commenter stated that the proposal is consistent with existing CMS policy, such as Medicaid line extension rules, establishing that minor product modifications should not allow manufacturers to avoid the consequences of competition or price regulation. A few commenters stated that the proposal is consistent with the statutory mandate at sections 1192(d)(3)(B) and 1196(a)(2) of the Act to aggregate data across dosage forms and strengths of a drug, including new formulations.

Response: We thank the commenters for their support.

Comment: Many commenters recommended that CMS withdraw the proposed policy for specific fixed combination drugs that are new formulations and instead treat a product approved under a distinct NDA/BLA, including a fixed combination drug, as a unique qualifying single source drug. Many of these commenters stated that the modification to CMS' fixed combination drug policy would contradict statute because, in their view, statute requires CMS to identify qualifying single source drugs in reference to a distinct NDA or BLA, and FDA approves or licenses fixed combination products separately from products with a single active moiety/active ingredient. In their view, CMS' existing aggregation framework already contradicts statute, and the commenters contended that the proposed policy worsens that asserted contradiction. Many commenters stated that the proposal would result in premature negotiation-eligibility for products that would qualify for the criteria proposed at § 429.125(b)(4)(i) because 7- or 11-years, as applicable, would not have elapsed between that product's own approval or licensure and the selected drug publication date.

Some commenters disagreed with CMS' statement in the proposed rule (91 FR 36258) that certain fixed combination drugs that are new formulations may be appropriately understood as different formulations of the same drug under sections 1192(d)(3)(B) and 1196(a)(2) of the Act; these commenters asserted instead that these statutory provisions are fully satisfied by aggregating expenditures and applying the MFP across the dosage forms and strengths (including new formulations such as an extended-release formulation) that are marketed under a qualifying single source drug's unique NDA or BLA. A few commenters stated that the fixed combination drug policy is unmoored from statute because statute says nothing about route of administration as a basis for determining whether products should be aggregated into the same qualifying single source drug. A couple of commenters stated that, if Congress intended CMS to aggregate fixed combination drug products with products containing only a subset of their active moieties/active ingredients, it would have done so expressly as it did for line extensions under the Medicaid Drug Rebate Program and Part D Drug Inflation Rebate Program.

Response: We appreciate the commenters' feedback. In response to the commenters that asserted that the statute requires CMS to identify qualifying single source drugs in reference to a distinct NDA or BLA, we direct readers to our response to

comments on this topic in section II.B.6.a. of this final rule. In response to comments stating that the proposal at § 429.125(b)(4)(i) would result in premature negotiation-eligibility for products that qualify for the proposal, we refer readers to our discussion in section B.6.b. of the proposed rule (91 FR 36261) and this final rule describing how CMS identifies the date of approval or licensure, as applicable, for a potential qualifying single source drug with more than one FDA application, including a fixed combination drug that qualifies for the policy proposed at § 429.125(b)(4)(i).

We disagree with the commenters who stated that a fixed combination drug described in proposed § 429.125(b)(4)(i) should not be aggregated under the same qualifying single source drug pursuant to section 1192(d)(3)(B) and 1196(a)(2) of the Act and that route of administration should not be used as a component of qualifying single source drug identification. The proposed policy is consistent with the statutory directives. Section 1196(a)(2) of the Act requires that CMS establish ''procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of the drug.'' Likewise, section 1192(d)(3)(B) of the Act requires CMS to use data that is ''aggregated across dosage forms and strengths of the drug, *including* new formulations of the drug, *such as* an extended release formulation'' (emphasis added). The terms ''including'' and ''such as'' in section 1192(d)(3)(B) of the Act make clear that the extended release example is illustrative, not exhaustive. That example, however, illustrates how our proposed policy is consistent with these statutory aggregation directives. With respect to extended release formulations, these directives reflect the understanding that such formulations are new formulations of the same underlying drug, albeit ones that are delivered through a modified release mechanism. Here too, fixed combination drugs in which an additional active moiety, active ingredient, or antigen component enables an alternative route of administration for its co-administered active moiety(ies), active ingredient(s), or antigen component(s) is likewise best understood as part of the same underlying drug as the product with only the co-administered active moiety(ies), active ingredient(s), or antigen component(s), albeit with an alternative route of administration enabled by the additional active moiety, active ingredient, or antigen component. Just as CMS may aggregate extended release formulations under our statutory directives—even though FDA may approve or license those formulations under a separate NDA or BLA from the original formulation—CMS may also consider a fixed combination drug as part of the same qualifying single source drug as the product with the co-administered active moiety(s), active ingredient(s), or antigen component(s), even if FDA approves or licenses the fixed combination drug under a separate NDA or BLA. Finally, including a fixed combination drug described in proposed § 429.125(b)(4)(i) with the original product in the same potential qualifying single source drug, pursuant to sections 1192(d)(3)(B) and 1196(a)(2) of the Act, is consistent with commonly held and plain language understandings of what constitutes the same underlying drug, as evidenced, at least in part, by how the pharmaceutical and financial industries generally view these products. For example, manufacturers commonly market products that meet the criteria of the proposed policy, including formulations of a drug with hyaluronidase, under the same branding as the original, non-hyaluronidase formulation. Similarly, filings (for example, filings with the SEC) pertaining to the marketing of the fixed combination drug and the original formulation commonly refer to and calculate the products' sales and contributions to revenue in the collective. Accordingly, we believe the proposed policy reflects the best understanding of the statutory aggregation directives. Similarly, we disagree with the commenters analogizing to the Medicaid Drug Rebate Program and Part D Drug Inflation Rebate Program line extension provisions to argue that the policy is not authorized under the statute. For the same reasons previously discussed, we believe the proposed policy accords with the best reading of the statutory aggregation provisions, and the lack of even more granular statutory language singling out these types of drugs does not undermine that conclusion.

Comment: A few commenters stated that the proposed modification for fixed combination drugs would violate the holding of *Loper Bright* because, in their view, CMS does not apply the single, best meaning of statute. These commenters stated that CMS is interpreting statute differently beginning in initial price applicability year 2029 than it did in prior initial price applicability years, as well as interpreting the same statutory text differently depending on the category of drug or biological product. A few commenters asserted that the proposed modification is arbitrary and capricious because it singles out products with an additional active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration without providing sufficient statutory, scientific, and regulatory basis for doing so. A few commenters asserted that CMS does not adequately explain its rationale for aggregating products that contain an additional active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration, while continuing to treat as separate products that add a new active moiety, active ingredient, or antigen component that does not create a new formulation and enable an alternative route of administration. One of these commenters stated that CMS did not identify evidence demonstrating that products that contain an additional active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration present a greater program integrity risk than other fixed combination drug products that would be aggregated as a unique qualifying single source drug under the general policy proposed at § 429.125(b)(4).

Response: We appreciate the commenters' perspectives. However, we disagree that the policy proposed at § 429.125(b)(4)(i) would not apply the best meaning of the statute or that it applies an inconsistent interpretation of the statute. Our proposal reflects our consistent interpretation of the statutory provisions requiring aggregation across dosage forms and strengths, inclusive of new formulations. Generally, and as relevant here, we have applied these statutory directives by identifying qualifying single source drugs as all dosage forms and strengths, including new formulations, with shared active moiety(ies), active ingredient(s), or antigen component(s). Our proposed § 429.125(b)(4)(i) continues to identify qualifying single source drugs on the basis of shared active moiety(ies), active ingredient(s), or antigen component(s), consistent with this interpretation of the statutory aggregation directives. Proposed § 429.125(b)(4)(i) marks a specific application of this interpretation to products with multiple active moieties, active ingredients, or antigen components as compared to prior policy. While prior policy always treated each unique combination of

active moieties, active ingredients, or antigen components as distinct potential qualifying single source drugs, proposed § 429.125(b)(4)(i) reflects our determination that for a narrow, limited set of products—that for which the addition of a distinct active moiety, active ingredient, or antigen component enables an alternative route of administration, as compared to a product without such additional active moiety, active ingredient, or antigen component but with otherwise shared active moiety(ies), active ingredient(s), or antigen component(s)—the new product would most appropriately be understood as a new formulation of the original product under section 1192(d)(3)(B) and 1196(a)(2) of the Act. For the reasons discussed in our proposed rule and in this final rule, including in the previous comment response, we believe our interpretation of this statute, and the application thereof represented by this proposed policy, reflects the best reading of the relevant statutory provisions. We disagree with the contention that we interpret the same statutory text differently depending on the category of drug or biological product; rather, the general fixed combination drug policy proposed at § 429.125(b)(4) and the proposed policy for new formulations at § 429.125(b)(4)(i) apply the same interpretation of sections 1192(d)(3)(B) and 1196(a)(2) of the Act to different categories of fixed combination drugs, only one of which fits the statutory description of a new formulation of the same drug. We also note that the proposed policy applies equally to all fixed combination drugs that meet the criteria set forth at proposed § 429.125(b)(4)(i), and likewise, the general fixed combination drug policy applies equally to all fixed combination drugs that do not meet these criteria.

We disagree with commenters who argued that proposed § 429.125(b)(4)(i) demonstrates that CMS is interpreting statute differently beginning in initial price applicability year 2029 than it did in prior initial price applicability years. As previously explained, proposed § 429.125(b)(4)(i) is consistent with our longstanding interpretation of the statutory aggregation directives. Rather, our proposed application of this interpretation with respect to products meeting the criteria at proposed § 429.125(b)(4)(i) is reflective of concerns that our prior policy, if applied to these products, could produce results that are inconsistent with our interpretation and create program integrity risks. We have long heard concerns from interested parties that, under the general fixed combination drug policy, certain fixed combination drugs could pose program integrity risks to the Negotiation Program. In comments on the initial guidance for initial price applicability year 2026 [38] and draft guidance for initial price applicability year 2027 and MFP effectuation for 2026 and 2027,[39] interested parties raised concerns that the general fixed combination drug policy creates program integrity risks in which CMS would treat an original formulation and a fixed combination drug that is a new formulation as separate qualifying single source drugs, which could result in certain drugs not being selected, being selected later than statutorily required, or avoiding application of the MFP if utilization shifts to the fixed combination drug product that is a new formulation of the original formulation. Those guidance documents established policy for initial price applicability years 2026 and 2027 in which we selected drugs based on total expenditures under Part D. Because the fixed combination drug program integrity risks primarily relate to biological products that are more likely payable under Part B, we did not believe it necessary for the implementation of the statute to establish a policy for specific fixed combination drugs that are new formulations at that time. In accordance with section 1192(a) of the Act, CMS was required to select drugs based on total expenditures under Part B and Part D beginning in initial price applicability year 2028. Therefore, when establishing policy for initial price applicability year 2028, we took the opportunity to solicit comments on our treatment of fixed combination drugs since initial price applicability year 2028 was the first initial price applicability year in which we identified and selected drugs based on total expenditures under Part B. Given the complexity of the issue, we deemed it prudent to take more time to evaluate policy options and stated our intent to address this program integrity risk in rulemaking beginning in initial price applicability year 2029. As we noted in the proposed rule (91 FR 36259), the program integrity concerns raised by fixed combination drugs that are new formulations have not yet impacted drug selection but may soon as more drugs with significant total expenditures under Part B become qualifying single source drugs and negotiation-eligible drugs. We therefore believe it necessary at this point to address the program integrity risk posed by certain fixed combination drugs in this rule. The proposed policy thus does not represent an inconsistent interpretation of statute across initial price applicability years but rather an updated policy applying the statute's aggregation requirements in response to the identification of a specific program integrity risk, input from interested parties, and the aggregation issues raised, largely, by the incorporation of total expenditures under Part B into the drug selection process beginning in initial price applicability year 2028.

Finally, commenters asserted that CMS did not adequately explain its rationale for aggregating fixed combination drugs that include an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration in accordance with proposed § 429.125(b)(4)(i). We disagree and refer readers to the robust discussion in the proposed rule (91 FR 36258 through 36259) of our program integrity concerns related to certain fixed combination drugs, which the proposal at § 429.125(b)(4)(i) specifically and narrowly targets. We also refer readers to our response to comments earlier in this section explaining why fixed combination drugs described in proposed § 429.125(b)(4)(i) are reasonably understood as new formulations comparable to extended-release formulations. Finally, we refer readers to comments summarized earlier in this section, which agreed that the inclusion of a component that enables a different route of administration, including the addition of hyaluronidase to enable subcutaneous administration, largely represents a repackaging of the existing product and should not be considered as a separate qualifying single source drug under the Negotiation Program.

Comment: Some commenters disagreed with CMS' statement in the proposed rule that the criteria proposed at § 429.125(b)(4)(i) can be operationalized in a consistent and objective manner using public sources. A few commenters asserted that the public sources cited by CMS in the proposed rule—such as RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file—do not address how CMS will determine whether an added ingredient creates a new formulation or enables an alternative route of administration. Some commenters stated that CMS does

[38] *https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.*

[39] *https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.*

not have the expertise to determine whether an active moiety, active ingredient, or antigen component creates a new formulation or enables an alternative route of administration, and that such expertise sits at FDA instead. A couple of commenters stated that CMS effectively acknowledges that it lacks a framework for determining whether an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration via its solicitation for comments on approaches to inform CMS' identification of such components. A commenter supported CMS' proposed approach to operationalizing proposed § 429.125(b)(4)(i), stating that the approach is a practical and administrable way to address program integrity risks.

Response: We appreciate the feedback. We agree with the commenter that stated that our approach to operationalizing proposed § 429.125(b)(4)(i) is practicable and administrable, and we disagree with commenters' concerns about the potential for inconsistent operationalization of proposed § 429.125(b)(4)(i). As we stated in the proposed rule (91 FR 36259), our proposal incorporated feedback from previous commenters that raised concerns about how we would operationalize terms used in the draft guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028, such as ''biologically active against the disease state,'' which we used to articulate the nature of the issue underlying our concern. In the proposed rule, we proposed to identify fixed combination drugs that qualify for the policy identified at § 429.125(b)(4)(i) using criteria that are available in public sources. To provide additional transparency, we take this opportunity to provide further information about how CMS will use these public sources in a consistent and objective manner.

We will identify the active moieties, active ingredients, or antigen components in a fixed combination drug consistent with how we identify active moieties, active ingredients, and antigen components generally under § 429.125(b) for purposes of identifying potential qualifying single source drugs. Specifically, and as described in section II.B.6.a. of the proposed rule, we will use public sources such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file to identify the active moiety(ies), active ingredient(s), and antigen component(s) of drugs, biological products, and vaccines for infectious disease(s), as applicable. We will identify any fixed combination drug that shares one or more active moiety, active ingredient, or antigen component with another drug, biological product, or vaccine for infectious disease(s), as applicable, with the same NDA/BLA holder. Consistent with section II.B.6.a.1. of the proposed rule, we will use public sources such as, but not limited to, Orange Book, Purple Book, Drugs@FDA, and DailyMed to identify the route(s) of administration for the fixed combination drug and the drug or biological product with the same NDA/BLA holder that shares one or more active moiety(ies)/active ingredient(s)/antigen component(s) with such fixed combination drug. To provide further information on additional public sources we may use, as requested by commenters, we affirm in this final rule that we may also use public sources including, but not limited to, FDA SPL resources such as FDALabel to identify the route(s) of administration.

Then we will identify active ingredients, active moieties, and antigen components, as applicable, that, when co-administered with one or more other active moiety(ies), active ingredient(s), or antigen component(s), enable an alternative route of administration for such co-administered active moiety(ies), active ingredient(s), or antigen component(s). Our determination that a fixed combination drug contains a CMS-identified route-enabling active ingredient, active moiety, or antigen component that meets the criteria proposed at § 429.125(b)(4)(i) is a product-specific evaluation, which may include consideration of whether the original product and the fixed combination drug have different routes of administration and whether the information or descriptions within product labeling for such product indicate that the additional active moiety, active ingredient, or antigen component enables the alternative route of administration. We may also consult with FDA, as appropriate, about the information contained in these public sources. We will consider this information holistically to determine whether the fixed combination drug is best understood under sections 1192(d)(3)(B) and 1196(a)(2) of the Act and proposed § 429.125(b)(4)(i) as a new formulation of the drug or biological product with the same NDA/BLA holder that shares one or more active moiety(ies)/active ingredient(s)/antigen component(s) with such fixed combination drug, and therefore should be aggregated into the same qualifying single source drug as the drug or biological product with the same NDA/BLA holder that shares one or more active moiety(ies)/active ingredient(s)/antigen component(s) with the fixed combination drug. We believe this determination falls squarely within CMS' expertise and aligns with the directives at sections 1192(d)(3)(B) and 1196(a)(2) of the Act.

Comment: Some commenters opposed finalizing the proposed policy for specific fixed combination drugs that are new formulations but made the following recommendations about how CMS should operationalize the policy were it to be finalized. A few commenters recommended that the determination as to whether a fixed combination drug qualifies for the proposed policy should be made in consultation with FDA, the patient community, and using product-specific evidence that the additional component exists solely to enable a different route of administration. A commenter recommended that any such input from the public should be narrow and time-limited so that it does not delay the drug selection process or convert CMS' identification of qualifying single source drugs into a broader adjudicatory proceeding. A commenter asked that the burden of demonstrating that a product is not subject to proposed § 429.125(b)(4)(i) should sit with CMS and manufacturers, not with patients. A couple of commenters urged CMS to apply the proposed policy prospectively only to products approved or licensed after the effective date of the final rule. A few commenters stated that CMS should give affected manufacturers, patients, caregivers, and clinicians advance notice that CMS intends to apply proposed § 429.125(b)(4)(i) to a product and create an appeals process. A commenter asked CMS to clarify how aggregation under proposed § 429.125(b)(4)(i) would operate if the two products carry different FDA-approved indications, and how CMS would treat a product under the proposed policy if the additional active moiety, active ingredient, or antigen component is separately licensed and marketed. A commenter recommended that when CMS determines that a product qualifies for the proposed policy, CMS should publish the relevant NDA or BLA, NDC and HCPCS mapping, shared and added components, route of administration, and FDA sources supporting its conclusion.

Response: We appreciate the suggestions. We refer readers to our

immediate previous response and to the discussion in section II.B.6.a.1. of this final rule for details on how CMS intends to operationalize proposed § 429.125(b)(4)(i). There, we detail the public sources and processes we will use to implement the proposed policy. We affirm that we will use product-specific information to implement the proposed policy and may consult with FDA about information contained in the public sources described previously. We also take this opportunity to clarify for these commenters that nothing in the text of proposed § 429.125(b)(4)(i) suggests that the additional active moiety, active ingredient, or antigen component must exist *solely* to enable an alternative route of administration; rather, the regulatory text states that the additional component ''creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s)''.

We affirm that CMS' implementation of the proposal at § 429.125(b)(4)(i) will not modify the timing of the drug selection process nor require interested parties to demonstrate that a product does or does not qualify for the proposed policy. While we appreciate the suggestions, we decline to create an advance notice or appeals process or to consult interested parties such as patients. Section 1192(e) of the Act sets forth the requirements for the identification of qualifying single source drugs and does not require nor contemplate engagement with patients or with manufacturers via an advance notice or appeals process. Additionally, an advance notice or appeals process and patient consultation is operationally infeasible due to the time constraints required to meet statutory deadlines and the complexity of the preparation that must be undertaken in advance of the publication of the selected drug list by the selected drug publication date. We also decline to apply the proposed policy prospectively only to products approved or licensed after the effective date of the final rule due to the program integrity risks that currently marketed fixed combination drugs that are new formulations pose to the Negotiation Program. Further, prospective-only application of the proposed policy would be inconsistent with the statutory directives at sections 1192(d)(3)(B) and 1196(a)(2) of the Act. In response to the commenter's requested clarifications, we affirm that FDA-approved indications are not considered for purposes of aggregation in the drug selection process, and we reiterate that a qualifying single source drug can include dosage forms and strengths and formulations approved or licensed under different NDA/BLAs. In response to the commenter's suggestion that we publish certain information for products that qualify for the proposed policy, we refer readers to our discussion in section II.B.1. of this final rule and § 429.100, which affirms that, for a selected drug identified under proposed § 429.125(b)(4)(i), we will publish the shared active moiety(ies), active ingredient(s), or antigen component(s) identified under proposed § 429.125(b)(4)(i), plus any additional active moiety, active ingredient, or antigen component included in new formulations of such selected drug. Additionally, for all selected drugs, including those identified under proposed § 429.125(b)(4)(i), we will publish the NDC–11s CMS identifies in accordance with § 429.100(c)(1) and the corresponding NDC–9s and HCPCS codes (as applicable). We decline to publish the routes of administration and NDA(s)/BLA(s) because this information is publicly available. We also decline to publish FDA sources supporting our conclusion that a fixed combination drug is a new formulation because we believe this final rule provides sufficient detail on our operationalization process, including public sources that we may consult.

Comment: Some commenters expressed views on whether proposed § 429.125(b)(4)(i) appropriately targets drug and biological products that pose true program integrity risks to the Negotiation Program. A few commenters supported the proposed policy but stated that CMS should modify the proposal to broaden the scope of products that the provision would target, or at minimum retain flexibility to broaden the proposal in the future based on new fact patterns. These commenters expressed concern that, under the language at proposed § 429.125(b)(4)(i), manufacturers could still avoid or delay selection and application of the MFP by adding an active moiety, active ingredient, or antigen component to an existing qualifying single source drug to create a new formulation that is not different from the original product in a clinically meaningful way but does not meet the proposed § 429.125(b)(4)(i) criteria because: (1) the additional active moiety, active ingredient, or antigen component leaves the route of administration unchanged for the new formulation; or (2) the additional active moiety, active ingredient, or antigen component is not the sole enabler of the alternative route of administration (for example, because the change in route of administration may also depend on factors such as excipients, device design, or stabilizers). To address the first scenario, a couple of commenters recommended that CMS evaluate whether a fixed combination drug is a new formulation using the clinically meaningful difference standard that CMS used to articulate its program integrity concerns related to fixed combination drugs in the draft guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. To address the second scenario, a commenter recommended that CMS modify the text of proposed § 429.125(b)(4)(i) to require that the relevant active moiety, active ingredient, or antigen component ''creates a new formulation and *helps to* enable an alternative route of administration . . .'', and another commenter recommended that CMS define ''enables'' to mean that the added component materially enables or materially facilitates the alternative route of administration for the shared component. In contrast, some commenters expressed concern that the proposal at § 429.125(b)(4)(i) would impact more products than would be appropriate but did not provide specific examples. Similar to the prior commenters, these commenters recommended that CMS consider whether the added active moiety, active ingredient, or antigen component creates a clinically meaningful different product from the original product, but in contrast to the prior commenters' view, they believed that fewer drugs would qualify for the proposal at § 429.125(b)(4)(i) if CMS were to employ a clinically meaningful difference standard.

Response: We appreciate the support and suggestions. We acknowledge the concern that manufacturers could still avoid or delay selection, or if selected, avoid application of the MFP, by including an active moiety, active ingredient, or antigen component in an existing qualifying single source drug that may be considered to result in a new formulation but does not meet the criteria proposed at § 429.125(b)(4)(i). With respect to the first scenario, in which a manufacturer includes an active moiety, active ingredient, or antigen component in an existing qualifying single source drug to create a new formulation that leaves the route of administration unchanged, we acknowledge that the proposed policy would not reach such a product. As we explained previously and in the

proposed rule (91 FR 36259), the proposed policy addresses the specific program integrity concern of which we are currently aware. We acknowledge commenters' concern that broader criteria—such as language in the Negotiation Program Guidance citing active moieties/active ingredients not biologically active against the disease state(s) for which the drug is indicated—could more comprehensively address program integrity risks across a wider range of product modification strategies. As noted in the proposed rule (91 FR 36260), we considered this approach. Commenters did not provide examples of fixed combination drugs that would not qualify for proposed § 429.125(b)(4)(i) but, they believe, should qualify. We continue to believe proposed § 429.125(b)(4)(i) is appropriately tailored to the program integrity risks with the general fixed combination drug policy and the specific elements of the policy that are in tension with section 1192(d)(3)(B) of the Act, which directs CMS to aggregate across dosage forms and strengths, including new formulations of the drug, and section 1196(a)(2) of the Act, which directs CMS to apply the MFP across different strengths and dosage forms of a selected drug and not based on the specific formulations or package size or package type of such drug. We will continue to monitor the Negotiation Program for evidence of program integrity risks that are in tension with sections 1192(d)(3)(B) and 1196(a)(2) of the Act and which pose program integrity risks beyond those addressed by proposed § 429.125(b)(4)(i), and we may consider additional modifications to our fixed combination drug policy in the future.

With respect to the second scenario, in which the change in route of administration depends not only on the additional active moiety, active ingredient, or antigen component but also on other product features such as excipients, device design, injection volume, concentration, or stabilizers, we take this opportunity to clarify that the additional active moiety, active ingredient, or antigen component need not be the sole enabler of the alternative route of administration in order for a product to qualify for proposed § 429.125(b)(4)(i). A product may qualify for the proposed policy if the added component creates a new formulation and enables the alternative route of administration for the co-administered active moiety, active ingredient, or antigen component, even if other product features also contribute to making the alternative route possible. We believe this reading is consistent with proposed § 429.125(b)(4)(i) and addresses the concern raised by these commenters. Requiring the additional component to be the sole enabler of the alternative route of administration would be inconsistent with the purpose of the proposed policy and could allow manufacturers to avoid aggregation by arguing that the alternative route of administration also depended on other product features. We believe the existing regulatory text, as clarified herein, is sufficiently clear, and we do not believe a modification to the regulatory text or definition of ''enables'' is necessary at this time.

In response to the commenters who expressed concern that the scope of products that would be impacted by the proposal at § 429.125(b)(4)(i) is too broad, we respectfully disagree. We note that commenters generally understood the scope of the products affected by proposed § 429.125(b)(4)(i) to be fixed combination drug products that contain hyaluronidase, or a hyaluronidase variant, which aligns with our general expectation of the scope of this policy and the example provided in section VI.C.1. of the Negotiation Program proposed rule. As we previously stated, proposed § 429.125(b)(4)(i) narrowly addresses the program integrity risks with the general fixed combination drug policy and responds to previously received input summarized in the revised guidance for initial price applicability year 2026, final guidance for initial price applicability year 2027, and the Negotiation Program Guidance in which interested parties raised concerns about such program integrity risks.

Comment: Many commenters opposed the proposal at § 429.125(b)(4)(i) because, in their view, it conflicts with FDA's regulatory framework. Many commenters explained that FDA evaluates fixed combination drugs as distinct medicines and requires separate applications, clinical trials, and demonstrations of safety and effectiveness, and therefore, CMS should not disregard FDA's determination that a fixed combination drug constitutes a separate drug. A few commenters raised concerns that overriding FDA's determinations would introduce substantial uncertainty and send conflicting messages to interested parties by subjecting products to different standards within different parts of the federal government. Some commenters appeared to interpret the proposal at § 429.125(b)(4)(i) to mean that CMS would be determining the clinical efficacy of an additional active moiety, active ingredient, or antigen component and stated that it would be incorrect for CMS to assume that the additional component added to enable an alternative route of administration lacks meaningful clinical activity or value, and moreover, that the scientific expertise to make such a determination lies with FDA, not CMS. A commenter pointed to CMS' decisions in the calendar year (CY) 2021 Physician Fee Schedule (PFS) final rule and CY 2022 PFS final rule to not finalize proposals involving clinical evaluation of drugs approved under section 505(b)(2) of the FD&C Act as evidence that CMS has conceded that it does not have the scientific expertise to make such determinations. Some commenters asserted that CMS' continued reliance on 21 CFR 300.50 undermines the logic of the proposal at § 429.125(b)(4)(i), explaining that, in their view, CMS incorporates FDA's definition of a fixed combination drug at 21 CFR 300.50 but disregards FDA's judgements embedded within that definition regarding an active ingredient's contribution to the product's overall safety and effectiveness.

Response: We appreciate the input but disagree with the commenters' suggestion that CMS' treatment of fixed combination drugs when identifying qualifying single source drugs for purposes of the Negotiation Program must, in every instance, align with how FDA treats fixed combination drugs for purposes of 21 CFR 300.50. The proposal at § 429.125(b)(4)(i) does not disregard, diminish, or otherwise impact FDA's judgments embedded within 21 CFR 300.50 regarding an active moiety's, active ingredient's, or antigen component's contribution to a fixed combination drug's safety and efficacy: nothing in the policy proposed at § 429.125(b)(4)(i) suggests that an active moiety, active ingredient, or antigen component may not contribute to the safety and efficacy of a fixed combination drug in accordance with FDA's determination at 21 CFR 300.50. As we noted previously, the proposed policy is solely for the purpose of the Negotiation Program and identifies a specific, narrow category of fixed combination drugs—those in which the inclusion of an active moiety, active ingredient, or antigen component enables an alternative route of administration and creates a new formulation for the co-administered active moiety(ies), active ingredient(s), or antigen component(s)—that are appropriately understood as new formulations of the same drug under

sections 1192(d)(3)(B) and 1196(a)(2) of the Act.

To the commenters who appeared to interpret proposed § 429.125(b)(4)(i) to mean that CMS would be determining the clinical efficacy of the additional active moiety, active ingredient, or antigen component included in a fixed combination drug, we reiterate that a fixed combination drug would meet the criteria in proposed § 429.125(b)(4)(i) if such additional component enables an alternative route of administration and creates a new formulation for the co-administered active moiety(ies), active ingredient(s), or antigen component(s). That is, the policy proposed at § 429.125(b)(4)(i) does not include an evaluation of the clinical efficacy of such additional component. For this same reason, we disagree with the suggestion that our proposal to define a fixed combination drug as having the meaning set forth in 21 CFR 300.50 undermines the logic of the proposed policy. The proposed policy does not contradict 21 CFR 300.50 but rather narrowly modifies how we will treat certain fixed combination drugs for purposes of achieving the Negotiation Program's statutory requirements. Similarly, we disagree with the commenter's suggestion that CMS' decisions with respect to payment policies for drugs approved under section 505(b)(2) of the FD&C Act undermine the proposed policy. The discussion in the PFS rulemakings to which the commenter referred addressed distinct statutory schemes and did not relate to the type of determinations we proposed here.

Comment: A commenter raised concerns that combining distinct formulations, such as a new formulation that is a fixed combination drug and an original formulation, under the same qualifying single source drug could increase the MFP. This commenter recommended that CMS ensure the MFP reflects the value of each product individually and should avoid an approach under which the added value of a new formulation increases the MFP for the original formulation.

Response: Sections 1192(d)(3)(B) and 1196(a)(2) of the Act direct CMS to identify a qualifying single source drug, and to negotiate a single MFP for that drug, inclusive of its dosage forms, strengths, and formulations. The proposal at § 429.125(b)(4)(i) gives full effect to these statutory directives. We decline to adopt this suggestion as it would be in conflict with the directive at section 1196(a)(2) of the Act to establish procedures to compute and apply the MFP across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug. We direct readers to our discussion of the application of the MFP across dosage forms and strengths in section II.H.1. of this final rule and at § 429.700.

Comment: A commenter raised objections to CMS' implementation of policies related to the identification and selection of fixed combination drugs in prior initial price applicability years. A commenter stated that that largest untapped savings for American patients do not lie in redefining what counts as a drug but rather in pharmaceutical benefit manager reform.

Response: These comments are out of scope for this final rule.

Comment: Many commenters stated that fixed combination drugs that are subcutaneous formulations of injectable drugs offer meaningful clinical value, including reduced infusion times, improved adherence, better tolerability, reduced caregiver burden, patient preference for subcutaneous administration, and the benefits and convenience of administering drugs at home or in more accessible practice sites. These commenters stated that CMS' proposal would discount those benefits. Many commenters highlighted that subcutaneous formulations offer benefits to and improve health equity access for underserved patient populations or patients that reside in rural geographic areas where barriers to health care resources may exist, noting that CMS' proposal could result in these patients losing access to beneficial treatment options. A few commenters noted the benefits of subcutaneous formulations, specifically the use of long-acting injectables, for patients with mental health conditions and the providers that serve those communities. Many commenters noted the clinical distinctiveness of subcutaneous products as compared to products that are administered via infusion, stating that a shared active ingredient alone is an incomplete measure of clinical equivalence, noting the differences in bioavailability, safety profiles, differences in tolerability, and dosing and monitoring requirements among products that share an active ingredient. Some commenters recommended that CMS preserve separate qualifying single source drug treatment for products that provide genuine improvements in safety, effectiveness, tolerability, adherence, or delivery, and develop transparent and objective criteria to distinguish genuine clinical innovation from efforts primarily to avoid negotiation eligibility. Some commenters stated that patient choice and individualized care are afforded by the existence of multiple formulations, which allow patients and providers to select the option best suited to individual circumstances, mobility, comorbidities, and access constraints. These commenters recommended that CMS incorporate long-term patient access into its final policy rather than applying an aggregation standard that sacrifices future treatment options for short-term expenditure reductions.

Response: We thank commenters for their input on the clinical value of fixed combination drugs that are subcutaneous formulations of injectable drugs and the benefits those formulations may offer to patients. We acknowledge the concerns commenters raised about the clinical value of subcutaneous formulations and the potential consequences of this policy for patients. Our determination that a fixed combination drug meeting the criteria at proposed § 429.125(b)(4)(i) is not a distinct qualifying single source drug rests on the statutory aggregation requirements at sections 1192(d)(3)(B) and 1196(a)(2) of the Act, not on an assessment of the clinical characteristics of any particular route of administration. The Negotiation Program is designed to address high-expenditure, single source drugs that lack generic or biosimilar competition. If we were to apply the general fixed combination drug policy to a fixed combination drug that includes an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s), and such fixed combination drug has the same NDA/BLA holder as another drug or biological product containing those same co-administered active moiety(ies), active ingredient(s), or antigen component(s), the fixed combination drug would be treated as a distinct qualifying single source drug, resetting the negotiation eligibility clock of that formulation. That outcome would create a significant program integrity risk inconsistent with the statutory purpose of the IRA. The proposal at § 429.125(b)(4)(i) addresses a discrete and well-defined category of products. It reaches only those products whose distinction from the original drug is an added active moiety, active ingredient, or antigen component that creates a new formulation and enables a different route of administration. It does not apply to other types of fixed combination drugs that contain active moieties, active ingredients, or antigen

components that do not meet such criteria and which continue to retain their status as distinct qualifying single source drugs, where applicable, under proposed § 429.125(b)(4). Regarding commenters' concerns about clinical distinctiveness, we note that clinical differences across formulations do not on their own provide a basis for separate qualifying single source drug treatment under the statute. As discussed earlier, sections 1192(d)(3)(B) and 1196(a)(2) of the Act direct CMS to aggregate across dosage forms, strengths, and new formulations of a drug. These aggregation requirements operate notwithstanding the clinical differences that may exist between different dosage forms and strengths and formulations. For example, an extended release formulation may offer real benefits over an immediate-release formulation in dosing frequency and adherence, yet the statute directs CMS to consider it within the scope of the same drug. The same logic applies to the exception proposed at § 429.125(b)(4)(i). Differences in bioavailability, tolerability, or patient population between a subcutaneous and an intravenous formulation do not, by themselves, take a product outside the statute's aggregation directives. This does not mean we discount those differences. Rather, it means they are weighed at a different point in the statutory framework. Section 1194(e)(2) of the Act and § 429.505(d)(3)(iii) ensures we consider comparative clinical effectiveness to therapeutic alternatives outside the selected drug, not between formulations aggregated within the same selected drug, in the course of the negotiation process rather than in selecting drugs under section 1192 of the Act. The clinical value a subcutaneous formulation offers remains part of that selected drug's overall profile; however, it is accounted for when we assess the drug's benefits relative to competing therapeutic alternatives under section 1194(e)(2) of the Act and through other categories of information we consider under section 1194(e)(1) of the Act.

We also disagree that proposed § 429.125(b)(4)(i) sacrifices future treatment options in favor of short-term expenditure reductions. The policy does not restrict the development, approval, or marketing of new formulations, including subcutaneous formulations; it determines only whether such a formulation is aggregated with other products under the same qualifying single source drug or as a separate one for purposes of the Negotiation Program. We further note that patients and providers retain the ability to choose among available formulations of a qualifying single source drug or selected drug, as applicable, consistent with individual clinical circumstances, as discussed previously, regardless of whether those formulations are aggregated under the same qualifying single source drug or selected drug, as applicable.

Regarding commenters' concerns about health equity and access for rural and underserved patients, we share the goal of ensuring that Medicare beneficiaries have access to clinically appropriate treatment options. Consistent with section 1196(a)(2) of the Act and as discussed in II.H.1. of this final rule and at § 429.700, the MFP applies to the qualifying single source drug as a whole, including all dosage forms and strengths. We do not anticipate that this policy will steer patients away from subcutaneous formulations. The policy is intended to ensure that the Negotiation Program can reach high-expenditure drugs regardless of whether a manufacturer has introduced a new formulation with an alternative route of administration. The policy affects only the identification of qualifying single source drugs for purposes of the Negotiation Program. It does not alter FDA approval or licensure status, formulary requirements, or prescribing authority. We also considered but decline to adopt commenters' recommendation that we preserve separate qualifying single source drug treatment for products that provide genuine improvements in safety, effectiveness, tolerability, adherence, or delivery. The policy described at proposed § 429.125(b)(4)(i) covers a limited scope of fixed combination drugs where the additional active moiety, active ingredient, or antigen component serves to create a new formulation and enable an alternative route of administration.

Comment: Many commenters stated the proposed fixed combination drug policy would disincentivize future investments in post-approval innovations of drug products due to the potential for reduced expected returns on separately patented, independently developed products, and as a result would chill long term research and development planning, with some of these commenters recommending that CMS establish a more transparent and predictable regulatory framework to allow manufacturers to develop future investment roadmaps. Many commenters noted the technical and regulatory complexity of developing subcutaneous formulations of drugs, including the requirements to establish separate clinical programs, pharmacokinetic evaluations, manufacturing practices and full FDA review of new to market formulations and stated that CMS' proposal discounts those investments and the resulting patient benefits. Many commenters stated that this proposal would have chilling effects beyond subcutaneous product development and could result in discouraged development in areas such as pediatric formulations, rare disease therapies, inhaled anti-infectives and other delivery and adherence improvements to formulations of drug products, and they stated that legitimate innovation in those areas would be penalized. A few commenters stated that the proposal would negatively impact the U.S. intellectual property and innovation ecosystem by stripping economic value and practical benefits from separately patented delivery improvements. Some commenters questioned whether CMS' approach to fixed combination drugs is clear enough to offset the potential chilling effect on pharmaceutical investment and believed manufacturers would need a more predictable regulatory and investment framework to develop future roadmaps. Some commenters stated that the proposal does not appropriately distinguish between evasive product development and true innovative product development and recommended that CMS develop objective, transparent criteria to make that distinction rather than applying a blanket aggregation standard. A commenter stated that the proposal would discourage the development and availability of both intravenous and subcutaneous formulations, leaving patients with fewer treatment choices. A commenter suggested that the sequential development of intravenous products first and subcutaneous products to follow is rational and beneficial to patients, and CMS' proposal would penalize this development pathway without distinguishing it from evasive reformulation strategies. A commenter stated the proposal risks eroding U.S. biopharmaceutical leadership, shifting research and development investment away from the United States. Some commenters stated that the economic impacts of the proposed § 429.125(b)(4)(i) would reduce the time to recover distinct research and development costs including the post-development costs for a subcutaneous product's development, such as clinical trials, manufacturing, and FDA review, because newer therapies would inherit the older product's negotiation timeline and could be subject to price negotiation

as soon as they enter the market. Some commenters noted that developing subcutaneous formulations requires significant post-approval investment, including in separate clinical programs, pharmacokinetic evaluations, manufacturing, and FDA evaluation, and stated that the proposal would indirectly penalize that investment and signal to the industry that patient-centered improvements to existing drugs will not be appropriately valued. Many commenters noted that the policy would disproportionately harm small biotechnology companies, start-ups, and delivery-technology platform companies whose business models depend on innovations related to combination therapy innovation and that the proposal could foreclose continued development of those patient-centric innovations. Some commenters stated that the uncertainty created by the proposal could have a chilling effect on long-term planning because manufacturers cannot rationally commit resources to develop a product that may collapse into an earlier product's negotiation framework and recommended that CMS distinguish genuine delivery innovation from evasive reformulation and establish a more transparent and predictable framework for manufacturers to assess their investment decisions in advance.

Response: We thank commenters for their input and have carefully considered these comments in developing this final rule. The scope of the policy proposed at § 429.125(b)(4)(i) is limited to fixed combination drugs that differ from the original drug due to the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s), such as the addition of hyaluronidase to enable subcutaneous administration of an existing intravenous product. It does not apply to other types of fixed combination drugs that contain active moieties, active ingredients, or antigen components that do not meet such criteria. Notably, commenters did not identify specific examples of fixed combination drugs that would qualify for proposed § 429.125(b)(4)(i), but should not, supporting CMS' analyses that the modification we proposed at § 429.125(b)(4)(i) is appropriately tailored to the program integrity risks it is designed to address. Its application is limited to fixed combination drugs that differ from the original drug due to the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s). It does not apply to other types of fixed combination drugs that contain active moieties, active ingredients, or antigen components that do not meet such criteria, which remain eligible, where applicable, for separate qualifying single source drug treatment under proposed § 429.125(b)(4). Regarding the question of the potential chilling effects beyond subcutaneous product development, we note that the policy applies only to the narrow category of fixed combination drugs described under proposed § 429.125(b)(4)(i). Regarding commenters' concerns about the impact of the policy on the U.S. intellectual property and innovation ecosystem, we note that the policy intends to effectuate the statutory requirements of the Negotiation Program, which is designed to address high-expenditure, single source drugs that lack generic or biosimilar competition. The statute establishes a predictable framework under which certain drugs become eligible for selection based on total expenditure under Part B and Part D and the length of time they have been on the market without facing generic or biosimilar competition. Treating a new formulation as a distinct qualifying single source drug with a new negotiation eligibility clock would be in tension with sections 1192(d)(3)(B) and 1196(a)(2) of the Act.

We also note that some commenters' projections of reduced innovation are highly dependent on assumptions regarding manufacturer, investor, and market responses whose magnitude and direction are inherently uncertain. These same uncertainties apply to commenters' predictions regarding the specific effect of proposed § 429.125(b)(4)(i) on the development of subcutaneous and other alternative formulations. Researchers have found no association between drug prices and R&D investment levels, noting that treatment costs reflect what the market will bear rather than the cost of R&D.[40] Recent empirical evidence further demonstrates that R&D spending, biotech equity investment, and business development activity all increased in the 6 quarters following IRA enactment compared to the 6 quarters prior, suggesting the biopharmaceutical industry has remained robust and continued investing in innovation despite the IRA's prospective effect on future drug prices.[41] This evidence undercuts the premise that the proposed policy will meaningfully depress investment in drug innovation, specifically given that the industry has continued to invest robustly even as broader IRA drug pricing provisions have been implemented. Commenters' analyses of potential impacts on innovation may not fully account for the range of ways in which manufacturers may adapt to changing market conditions, including by continuing to pursue alternative route of administration innovation for reasons independent of Negotiation Program timing, such as competitive differentiation, patient demand, and anticipated generic or biosimilar entry. Regarding the commenter who stated that the sequential development of intravenous products first and subcutaneous products to follow is rational and beneficial to patients, as discussed previously, projections of the policy's impact on manufacturers' investment and formulation sequencing decisions are inherently uncertain, and the proposed policy will be only one of many factors manufacturers consider in such decisions. We further reiterate that the proposed policy would apply only where the fixed combination drug differs from the original drug because of the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s).

Regarding commenters' concerns about the disproportionate impact of the policy on small biotechnology companies, start-ups, and delivery-technology platform companies, consistent with proposed § 429.440, we note that the Negotiation Program proposed rule (91 FR 36281–36285) and this final rule include a Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030. That provision establishes a temporary floor for the MFP for eligible small biotech drugs, providing additional protection for qualifying smaller manufacturers. On the question of investment uncertainty and the recommendation that we distinguish

[40] O. Wouters, L. Berenbrok, M. He, Y. Li, & I. Hernandez. Association of Research and Development Investments With Treatment Costs for New Drugs Approved From 2009 to 2018. *JAMA Network Open.* 5(9) (2022). doi:10.1001/jamanetworkopen.2022.18623.

[41] Dao S, Ledley FD. Sustaining pharmaceutical innovation after the Inflation Reduction Act: trends in R&D spending, equity investment, and business development. *Drug Discovery Today.* 2025. PMID: 40482994.

genuine delivery innovation from evasive reformulation and establish a more transparent and predictable framework, the proposed policy at § 429.125(b)(4)(i) itself provides clear and defined criteria for qualifying single source drug aggregation purposes.

Comment: A few commenters stated that CMS' program integrity concerns are speculative and that CMS provided no evidence that manufacturers are developing fixed combination drug products to avoid the Negotiation Program. These commenters stated that CMS did not have a sufficient basis or justification to deviate from the established interpretation that all fixed combination drugs are distinct qualifying single source drugs and recommended that CMS retain the established interpretation. Some commenters noted that hyaluronidase-based subcutaneous formulations have been on market since before the IRA was enacted and that CMS' suggestion that these new formulations are being developed to avoid selection in the Negotiation Program or application of the MFP is not supported by evidence. A few commenters noted real-world product development examples to illustrate that products were not developed to circumvent the Negotiation Program, highlighting the clinical validation, years of formulation work, and significant investment required for subcutaneous product development, stating that CMS' proposal would sweep in products developed years before the IRA and that represent legitimate innovation. A commenter noted that if CMS believes program integrity concerns exist, the appropriate remedy is to bring that concern to Congress rather than altering how CMS identifies qualifying single source drugs.

Response: We thank commenters for their input. We disagree that our program integrity concerns are speculative. The use of reformulation strategies to extend market exclusivity and delay competition is well documented in peer-reviewed literature [42] and reflects broader industry dynamics that are not unique to any single manufacturer.[43] Further, we stated in the Negotiation Program Guidance that we intended to address this specific program integrity risk associated with fixed combination drugs that are new formulations in rulemaking. We also disagree that the pre-IRA market history of hyaluronidase-based subcutaneous formulations undermines the program integrity rationale for this policy. The program integrity risk identified by CMS does not depend on when a particular formulation was developed or approved, or on any manufacturer's intent in developing it. A program integrity risk can arise where a generally applicable policy does not fully capture the nuances of specific situations, not only from intentional fraud, abuse, or bad conduct. Absent the proposal at § 429.125(b)(4)(i), a product that CMS has determined constitutes a new formulation of an existing drug under sections 1192(d)(3)(B) and 1196(a)(2) of the Act would not be aggregated with that existing drug for purposes of identifying a qualifying single source drug and applying the MFP. As discussed in the proposed rule (91 FR 36260), the program integrity concerns raised by fixed combination drugs that are new formulations have not yet impacted drug selection but may soon as more drugs with significant total expenditures under Part B become qualifying single source drugs and negotiation-eligible drugs. CMS is addressing that vulnerability through the proposed policy for specific fixed combination drugs that are new formulations to ensure that these formulations are properly aggregated and selected consistent with the statute so that the Negotiation Program achieves its intended statutory aims. Regarding the commenter who stated that the appropriate remedy for program integrity concerns is Congressional action, we disagree that Congressional action is the sole recourse to address our program integrity concerns. The policy proposed at § 429.125(b)(4)(i) is based on and consistent with the statutory directives at sections 1192(d)(3)(B) and 1196(a)(2) of the Act. It does not alter CMS' general framework for identifying qualifying single source drugs but rather is applicable only to a discrete type of product that CMS has determined constitutes a new formulation under the statute's aggregation provisions and that would otherwise be treated as a separate qualifying single source drug under the general fixed combination drug policy.

Comment: A few commenters stated that CMS should evaluate the total cost of treatment associated with a therapy, not acquisition price alone, noting that subcutaneous formulations can reduce facility administration expenses, staffing, monitoring, transportation costs, and caregiver burden. These commenters recommended that CMS assess total treatment costs, healthcare resource use, and long-term market effects before adopting classifications that discourage resource-saving improvements. A few commenters stated that by implementing proposed § 429.125(b)(4)(i), CMS would undermine its intended savings goals because the additional costs and burden associated with the administration of intravenous products—including facility fees, nursing time, and monitoring costs—would offset any acquisition price reduction achieved through negotiation. Some commenters suggested that the proposed policy would discourage more convenient treatment options and create more reliance on infusion centers and other resource-intensive care sites.

A few commenters believed that, if finalized, the proposal would set precedents affecting other Medicare reimbursement contexts, specifically the actions of Medicare Administrative Contractors (MACs) and coverage decisions related to intravenous and subcutaneous formulations. These commenters recommended that CMS codify in regulatory text that aggregation under § 429.125(b)(4)(i) is solely for purposes of the Negotiation Program and creates no presumption regarding clinical interchangeability, coverage, or preferred route of administration in any other Medicare policy context. A commenter raised concerns that a broader qualifying single source drug definition might cause Part D plans to place selected drugs on less favorable formulary tiers or impose utilization management restrictions and requested that CMS issue explicit guidance to Part D plans prohibiting utilization management restrictions on selected drugs solely on the basis of route of administration.

Response: We thank commenters for their feedback. On the question of total treatment costs and the potential for the policy to undermine our savings goals, we note that the Negotiation Program selects drugs based on total expenditures under Part B and Part D, which represent a significant and direct cost to Medicare and its beneficiaries. We recognize that site-of-care costs, facility fees, nursing time, and monitoring costs are relevant considerations in the broader assessment of treatment value. Regarding commenters' concerns about infusion capacity and the potential for the policy to discourage more convenient treatment options and the potential to steer patients toward higher-cost infusion settings, the policy

[42] See: Jones, G. H., Carrier, M. A., Silver, R. T., & Kantarjian, H. (2016). Strategies that delay or prevent the timely availability of affordable generic drugs in the United States. *Blood, 127*(11), 1398–1402.

[43] See: Horrow, C., Gabriele, S., Tu, S. S., Sarpatwari, A., & Kesselheim, A. S. (2024). Patent portfolios protecting 10 top-selling prescription drugs. JAMA Internal Medicine, 184(7), 737–744.

proposed at § 429.125(b)(4)(i) does not restrict the availability of subcutaneous or intravenous formulations. Prescribers and patients retain the ability to select from available formulations best suited to individual clinical circumstances, mobility, comorbidities and access constraints. Regarding commenters' concerns that the policy would set precedents affecting other Medicare reimbursement contexts, specifically the actions of MACs and coverage decisions related to intravenous and subcutaneous formulations, the policy proposed at § 429.125(b)(4)(i) reflects the Negotiation Program's statutory directives regarding aggregation and applies solely for purposes of the Negotiation Program. Regarding the commenter who recommended that we issue explicit guidance to Part D plans prohibiting utilization management restrictions on selected drugs solely on the basis of route of administration, consistent with our policies proposed at § 423.120(b)(2)(vii) and (viii), Part D plan sponsors are required to include each Part D drug that is a selected drug with an MFP in effect on their formularies, inclusive of the exception that permits Part D plan sponsors to remove such a selected drug if the removal would be permitted under the successor regulation at § 423.120(e)(2)(i), (f)(2), (3), and (4). We refer readers to section III.A. of the Negotiation Program proposed rule and this final rule for further discussion of CMS' use of its comprehensive formulary review process to assess any practices that may undermine beneficiary access to selected drugs and ensure that Part D plan sponsors comply with existing statutory and regulatory restrictions on formulary design.

Comment: Some commenters recommended that CMS examine the full range of impacts of the proposed policy—including effects on patients, infusion providers, access, competitive market forces, Medicare spending, and future innovation—before finalizing any policy change. A few commenters stated that an exclusive focus on immediate negotiation expenditures would overlook treatments that were delayed, narrowed, or never developed and recommended that CMS evaluate the dynamic effects of delayed or never-pursued treatments and recognize that program performance should be measured through patient-centered outcomes and long-term innovation, not solely through immediate reductions in Medicare expenditures. A few commenters recommended that CMS monitor the impact of the proposed policy and commit to reconsidering the policy if evidence after implementation shows reduced development of meaningful improvements, fewer treatment choices, or disproportionate access effects. A commenter recommended that CMS address program integrity concerns through objective, individualized, and evidence-based review rather than categorical aggregation.

Response: We thank commenters for their recommendations. We share commenters' interest in ensuring that the Negotiation Program operates effectively, efficiently, and in compliance with Federal law while serving the best interests of Medicare beneficiaries. The proposed policy was developed with the input of comments from patients, clinicians, healthcare providers, manufacturers, and other interested parties. The comments we received reflect the breadth and depth of that engagement. We have carefully considered all of that input in developing this final rule. We appreciate commenters' recommendation that we monitor the impacts of the policy and commit to reconsidering it if implementation evidence shows reduced development of meaningful improvements, fewer treatment choices, or disproportionate access effects. We will assess the real-world impacts as the policy described at proposed § 429.125(b)(4)(i) is implemented, including program integrity risks, and we will remain engaged with patients, clinicians, and other affected communities as we consider future rulemaking. Regarding the commenter who recommended that we address program integrity concerns through objective, individualized, and evidence-based review, not categorical aggregation, the policy proposed at § 429.125(b)(4)(i) is only applicable where a fixed combination drug differs from a drug or biological product with the same NDA/BLA holder due to the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s). For all other fixed combination drugs not subject to the policy proposed at § 429.125(b)(4)(i), we reiterate that, where applicable, we continue to treat it as a distinct qualifying single source drug under the policy proposed at § 429.125(b)(4).

Comment: A few commenters recommended that CMS engage patients, clinicians, healthcare providers, and innovators in further evaluating the clinical, economic, and patient-centered impacts of the proposed change before adopting a final policy, stating that the agency cannot adequately assess the real-world consequences of reshaping the pricing framework governing subcutaneous therapies without meaningful input from the communities most directly affected. A commenter stated that some of the most meaningful effects of a formulation change may not be captured by product labeling or administrative data and that patient and clinician input should be indispensable before finalizing the proposal. A commenter asked CMS to explore further with the wider patient community and subject matter experts the degree to which application of an MFP on a qualifying single source drug that includes a fixed combination drug constitutes a deterrent for investment and research into novel indications.

Response: We thank commenters for their input, and we share commenters' commitment to ensuring that Medicare beneficiaries have access to clinically appropriate treatment options and that the real-world consequences of our policies are fully understood. The policy proposed at § 429.125(b)(4)(i) was developed through a notice-and-comment rulemaking process that provided patients, clinicians, healthcare providers, manufacturers, and other interested parties a meaningful opportunity to submit input on the proposed change. We have carefully considered all of that input in developing this final rule. We agree that patient and clinician perspectives are essential inputs into our policy development. Regarding the commenter who recommended that we explore with the wider patient community and subject matter experts the degree to which application of an MFP on a qualifying single source drug that includes a fixed combination drug constitutes a deterrent for investment and research into novel indications, we appreciate this recommendation. As discussed elsewhere in this final rule, we do not anticipate that proposed § 429.125(b)(4)(i) will meaningfully affect investment in innovation given the narrow scope of products that it covers and that, as previously discussed, researchers have found no association between drug prices and R&D investment levels. We will continue to seek input from patients, clinicians, and other stakeholders as the Negotiation Program is implemented and as we consider future rulemaking.

Final Decision: After consideration of public comments, we are finalizing the general fixed combination drug policy, as well as the proposed policy for specific fixed combination drugs that

are new formulations, with technical modifications to improve organizational clarity. Specifically, we are finalizing the general fixed combination drug policy—which we proposed at § 429.125(b)(4)—at § 429.125(b)(4)(i), and we are finalizing the specific fixed combination drug policy for new formulations—which we proposed at § 429.125(b)(4)(i)—at new § 429.125(b)(4)(ii). We also are adding a paragraph header containing the word ''General'' to finalized § 429.125(b)(4)(i). Finally, in finalized § 429.125(b)(4)(i), we are replacing the reference to ''paragraph (b)(4)(i)'' with a reference to ''paragraph (b)(4)(ii)''. These technical modifications do not substantively change the proposed policy, and the language finalized at § 429.125(b)(4)(ii) is identical to the language proposed at § 429.125(b)(4)(i). CMS will monitor the implementation of the policy for specific fixed combination drugs that are new formulations and will consider potential modifications after gaining experience with the policy.

(2) Alternatives Considered

We considered expressly limiting the proposed modification of the application of the general fixed combination drug policy to biological products (other than vaccines for infectious disease(s) identified at proposed § 429.125(b)(3)), as currently such biological products licensed in BLAs pose the program integrity risks of which we are currently aware. However, in line with our aim to apply the statutory requirements at sections 1192(d)(3)(B) and 1196(a)(2) of the Act equally to all new formulations of a drug, whether the new formulation is approved in an NDA or licensed in a BLA, and to account for the possibility that the policy proposed at § 429.125(b)(4)(i) could apply to drugs in the future, we did not propose to limit the proposed modification to these biological products. This approach would ensure that we are treating new formulations equally, whether that new formulation is a drug or biological product.

We also considered proposing an alternative modification to the general fixed combination drug policy that would target the program integrity risk as described in the Negotiation Program Guidance wherein CMS identification of potential qualifying single source drugs under the fixed combination drug policy would not take into account an active moiety, active ingredient, or antigen component that is not biologically active against the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference from other drug or biological products that otherwise have the same active moiety(ies)/active ingredient(s)/antigen component(s). However, we instead proposed to focus on products that differ in active moiety(ies)/active ingredient(s)/antigen component(s) due to the inclusion of an active moiety/active ingredient/antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies)/active ingredient(s)/antigen component(s). As noted in section II.B.6.a.1. of this final rule, we believe the proposed approach narrowly addresses the program integrity risks with the general fixed combination policy and the specific elements of the policy that are in tension with section 1192(d)(3)(B) of the Act, which directs CMS to aggregate across dosage forms and strengths, including new formulations of the drug, and section 1196(a)(2) of the Act, which directs CMS to apply the MFP across different strengths and dosage forms of a selected drug and not based on the specific formulations or package size or package type of such drug.

We considered maintaining the policy established for initial price applicability years 2026 through 2028, wherein, for a fixed combination drug with two or more active moieties/active ingredients/antigen components, we would treat the distinct combination of active moieties/active ingredients/antigen components as one active moiety/active ingredient/antigen component. However, for the reasons described in section II.B.6.a.1. of this final rule, we believe that this policy poses program integrity risks and is in tension with sections 1192(d)(3)(B) and 1196(a)(2) of the Act.

Finally, we considered proposing a policy to address program integrity risks posed by co-packaged drugs. In the Negotiation Program Guidance, we stated that the general fixed combination drug policy would apply to a co-packaged drug, in which two active moieties/active ingredients are not co-formulated but rather co-packaged and sold in a single package, but that we may address co-packaged drugs in rulemaking for initial price applicability year 2029 and subsequent years. That is, for purposes of the Negotiation Program in initial price applicability year 2028, if a drug (including a co-packaged drug) contained two or more active moieties/active ingredients/antigen components, the distinct combination of active moieties/active ingredients/antigen components would be considered as one active moiety/active ingredient/antigen component for the purpose of identifying potential qualifying single source drugs, whether such drug was co-formulated or co-packaged. After further consideration, and based on our assessment that at this time co-packaged drugs do not appear to pose substantive program integrity risks to the Negotiation Program because manufacturers are not adopting co-packaging practices that undermine current program policies, we proposed that the general fixed combination drug policy at proposed § 429.125(b)(4) continue to apply to co-packaged drugs. We are monitoring this approach and potential gaming of co-packaged drugs and may consider revisiting this policy in the future.

We solicited comments on our proposal and these alternatives.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters stated that CMS' proposal inadvertently creates a loophole for co-packaged products, stating that, in their view, the evidentiary requirements for co-packaging are generally significantly lower than those for reformulating an alternative route of administration, making this pathway both accessible and commercially attractive, and requested that CMS close this potential loophole before it is exploited. These commenters also noted that the proposal creates a distinction between fixed-combination products and co-packaged products that is not grounded in clinical differences and that CMS should clarify whether co-packaged products would be treated the same as fixed combination products under the final rule.

Response: We thank commenters for their feedback. We are not finalizing a change to the treatment of co-packaged drugs in this final rule. Under our existing policy, co-packaged products continue to be treated in the same manner as fixed combination drugs for purposes of identifying qualifying single source drugs under the policy proposed at § 429.125(b)(4). The policy proposed at § 429.125(b)(4)(i) applies only to fixed combination products that differ from the original drug because of an added active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration. It does not extend to co-packaged products as a category. We recognize that commenters raised concerns about the potential for manufacturers to use co-packaging as a means of achieving the same route-of-administration change while avoiding the policy at proposed at § 429.125(b)(4)(i). We take these concerns seriously. Consistent with our

response to similar comments in the Negotiation Program Guidance, we will continue to monitor the use of co-packaged products in the context of the Negotiation Program. Commenters did not identify specific documented instances of manufacturers using co-packaging to circumvent the policy proposed at § 429.125(b)(4)(i) and the underlying statutory provisions. Should our monitoring indicate that co-packaged products present program integrity risks similar to those addressed by proposed § 429.125(b)(4)(i), we will consider whether additional rulemaking is warranted. We will consider these comments in our policy development for this issue in future rulemaking. Regarding commenters' concerns that the policy creates a distinction between fixed combination products and co-packaged products that is not grounded in clinical differences, the policy proposed at § 429.125(b)(4)(i) addresses a discrete and well-defined category of products. We do not agree that extending that policy to all co-packaged products is warranted at this time.

Final Decision: After consideration of public comments, we are not finalizing any of the alternatives considered in section II.B.6.a.2. of the Negotiation Program proposed rule.

b. Time Since Approval or Licensure (§ 429.125(c))

In accordance with section 1192(e)(1) of the Act and consistent with policies for implementation as described in Negotiation Program Guidance, and accounting for the treatment of certain former orphan drugs in accordance with section 1192(e)(4) of the Act as addressed in proposed § 429.125(c)(3), we proposed at § 429.125(c)(1) and (c)(2) that at least 7 years (for drugs) or 11 years (for biological products) must have elapsed between the FDA date of approval or licensure of the potential qualifying single source drug identified at proposed § 429.125(b) and the selected drug publication date with respect to an initial price applicability year. To determine the date of approval for a potential qualifying single source drug that is a drug with more than one FDA application number, we would use the initial date of approval associated with the earliest-approved FDA application belonging to the NDA holder and containing the active moiety (or in the case of a potential qualifying single source drug identified under the general fixed combination drug policy proposed at § 429.125(b)(4), for the distinct combination of active moieties). For a potential qualifying single source drug identified under proposed § 429.125(b)(4)(i) that is a drug, we would use the initial date of approval associated with the earliest-approved FDA application belonging to the NDA holder and containing the shared active moiety(ies) used to identify the potential qualifying single source drug. To determine the date of licensure for a potential qualifying single source drug that is a biological product (except in the case of a vaccine for infectious disease(s), for which we would determine the date of licensure as described later in this section) with more than one FDA application number, we would use the initial date of licensure associated with the earliest-approved FDA application belonging to the BLA holder and containing the active ingredient (or in the case of a potential qualifying single source drug identified under the general fixed combination drug policy proposed at § 429.125(b)(4), for the distinct combination of active ingredients). For a potential qualifying single source drug identified under proposed § 429.125(b)(4)(i) that is a biological product, we would use the initial date of licensure associated with the earliest-approved licensure of the FDA application belonging to the BLA holder and containing the shared active ingredient(s) used to identify the potential qualifying single source drug.[44] Consistent with prior initial price applicability years, we proposed that the identification of the earliest-approved FDA application belonging to the NDA/BLA holder and containing the active moiety/active ingredient, respectively, would be made irrespective of whether the indication(s) approved in such NDA/BLA were or are covered under Part D or payable under Part B or both. We would determine whether a product is not covered under Part D or payable under Part B at the NDC–11 level via the Primary Manufacturer's submission of information on NDC–11s as proposed at § 429.100(d) and described in section II.B.1. of this final rule.

As described in section II.B.6.a. of this final rule, to give full effect to all relevant provisions of the statute, including sections 1192(d)(3)(B), 1192(e), 1194(e)(1)(D), and 1196(a)(2) of the Act, we proposed to identify a potential qualifying single source drug using the specific constituent dosage forms and strengths that are identified as aggregated under the same NDA/BLA holder for the same active moiety/active ingredient, inclusive of products that are marketed under different NDAs/BLAs. Therefore, to identify the date of approval or licensure, as applicable, for a potential qualifying single source drug with more than one FDA application, sections 1192(e)(1)(A)(ii) and 1192(e)(1)(B)(ii) of the Act require CMS to use the initial approval or licensure date associated with the earliest-approved FDA application for such potential qualifying single source drug to ensure that CMS captures the full time since the earliest product in the potential qualifying single source drug was approved or licensed.

To provide an example for how we would determine the approval or licensure date set forth at proposed § 429.125(c)(1) and (c)(2), respectively, the selected drug publication date for initial price applicability year 2029 is February 1, 2027, consistent with section 1191(b)(3) of the Act and proposed § 429.20. As such, for initial price applicability year 2029, the initial date of approval for a drug to be considered a qualifying single source drug must have been on or before February 1, 2020, and the initial date of licensure for a biological product to be considered a qualifying single source drug must have been on or before February 1, 2016.

We are aware that some manufacturers of vaccines for infectious disease(s) update the antigen component(s) of their products through supplemental BLAs. Consistent with the policies for implementation as described in Negotiation Program Guidance, for each unique potential qualifying single source drug that CMS identifies based on its antigen component(s) in accordance with proposed § 429.125(b)(3), we proposed at § 429.125(c)(2)(i) that CMS will use the initial date of licensure for any BLA or supplemental BLA for that unique potential qualifying single source drug for purposes of identifying the starting date from which to measure the 11 years described in proposed § 429.125(c)(2).

Additionally, consistent with the policies for implementation as described in Negotiation Program Guidance and as proposed in § 429.125(c)(2)(ii), for biological products with an approved NDA that was deemed to be a BLA on March 23, 2020, in accordance with section 7002(e)(4)(A) of Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and that are currently licensed biological products under section 351 of the PHS Act (hereinafter

[44] The determination of the date of licensure for a potential qualifying single source drug that is a biological product, including a potential qualifying single source drug identified under proposed § 429.125(b)(4)(i), is subject to the proposals at § 429.125(c)(2)(i) and (c)(2)(ii) for a biological product that is a vaccine for infectious disease(s), and a biological product with an approved NDA that was deemed to be a BLA.

''deemed biologics''), we would consider March 23, 2020 to be the licensure date for purposes of identifying the starting date from which to measure the 11 years described in proposed § 429.125(c)(2).[45]

In accordance with section 1192(e)(4) of the Act and as proposed at § 429.125(c)(3), if, as of the date of a drug or biological product's initial approval or licensure, such drug or biological product met or meets the criteria for the orphan drug exclusion proposed at § 429.125(e)(1), we would measure the 7- and 11-year periods identified in proposed § 429.125(c)(1) and (c)(2) starting from the first day after such initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion at proposed § 429.125(e)(1). We would identify this day as the earlier of (1) the date on which the FDA approves such drug or biological product for an indication for a disease or condition that is not a rare disease or condition for which the drug or biological product is designated under section 526 of the FD&C Act; or (2) the date on which an orphan drug designation is withdrawn, if that withdrawal results in the drug or biological product no longer qualifying for the orphan drug exclusion.[46]

As noted previously, section 1192(e)(4) of the Act requires that CMS measure the 7- and 11-year periods set forth in proposed § 429.125(a)(1)(ii) and (a)(2)(ii) starting from ''the first day'' after the drug's initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion. We proposed that the determination of the date on which the FDA approves the drug or biological product for an indication for a disease or condition that is not a rare disease or condition for which the drug or biological product is designated under section 526 of the FD&C Act would be made irrespective of whether approval of such indication is later withdrawn. We are aware that this proposal could result in a scenario where the 7- and 11-year periods set forth in proposed § 429.125(a)(1)(ii) and (a)(2)(ii) would not yet have elapsed between the last day that the drug most recently qualified for the orphan drug exclusion at section 1192(e)(3)(A) of the Act and proposed at § 429.125(e)(1) and the selected drug publication date, but we believe this approach aligns best with the statute given the requirement at section 1192(e)(4) of the Act to measure the 7- and 11-year periods starting from ''the first day'' after the drug's initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion. We are not currently aware of any instances in which this scenario—wherein the 7- and 11-year periods would not yet have elapsed between the last day that the drug most recently qualified for the orphan drug exclusion and the selected drug publication date—would occur in practice and believe the chances of this scenario occurring in the future are low.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters acknowledged that proposed § 429.125(c)(1) and (c)(2) appropriately implement the statutory requirement at sections 1192(e)(1)(A)(ii) and (e)(1)(B)(ii) of the Act but asserted that this distinction disadvantages certain innovative therapies and can distort research and development incentives based solely on a product's regulatory classification. One of these commenters recommended that CMS work with Congress to establish a uniform 11-year period following FDA approval or licensure before a small molecule drug or biological product becomes eligible for selection under the Negotiation Program.

Response: We agree that § 429.125(c)(1) and (c)(2) would appropriately implement the statutory requirements at sections 1192(e)(1)(A)(ii) and (e)(1)(B)(ii) of the Act. As discussed in CMS' response on page 15 of the final guidance for initial price applicability year 2027 and page 17 of the Negotiation Program Guidance, section 1192(e)(1)(A)(ii) of the Act states that for a drug to be considered a qualifying single source drug, at least 7 years must have elapsed since the drug was approved by the FDA. Section 1192(e)(1)(B)(ii) of the Act states that for a biological product to be considered a qualifying single source drug, at least 11 years must have elapsed since the biological product was licensed by the FDA.

Comment: A few commenters raised concerns with our proposal at § 429.125(c)(2)(ii) to consider March 23, 2020 to be the date of licensure of a potential qualifying single source drug that is a biological product with an approved NDA that was deemed to be a BLA under section 351 of the PHS Act on March 23, 2020, in accordance with section 7002(e)(4)(A) of Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and that is currently a licensed biological product under section 351 of the PHS Act. These commenters stated that the proposal undermines the Negotiation Program because it resets the negotiation eligibility timeline for certain high-cost drugs, works against the BPCI Act's intent to address high drug costs, and represents a departure from the framework used in initial price applicability year 2026. A couple of commenters recommended that CMS measure the time eligibility for such products from the date of the initial NDA approval, with one of these commenters specifying that CMS should continue to consider these products to be biological products subject to the 11-year period for negotiation eligibility. A commenter supported proposed § 429.125(c)(2)(ii), stating that this approach would give effect to section 1192(e)(1)(B)(ii) of the Act. This commenter stated that years during which the product was not licensed under section 351 should not count towards that 11-year period.

Response: We thank these commenters for their feedback and input. CMS clarifies that CMS' proposal at § 429.125(c)(2)(ii) for deemed biologics is an implementation of sections 11001 and 11002 of the IRA. CMS believes that the proposal at § 429.125(c)(2)(ii) to consider March 23, 2020 to be the licensure date for deemed biologics for purposes of identifying the time since licensure under section 1192(e) of the Act is consistent with section 1192(e)(1) of the Act. Sections 1192(e)(1)(A) and 1192(e)(1)(B) of the Act separately describe the qualifying single source drug criteria for drug products and biological products. Section 1192(e)(1)(B)(i) of the Act describes a biological product as a biological product that is licensed under section 351(a) of the PHS Act and is marketed under section 351 of such Act, and section 1192(e)(1)(B)(ii) of the Act requires that at least 11 years will have elapsed since the date of such licensure. FDA's final guidance entitled ''Interpretation of the ''Deemed to be a License'' Provision of the Biologics

[45] For a biological product with an approved application under section 505(c) of the FD&C Act that was deemed to be a BLA under section 7002(e)(4)(B) of the BPCI Act, as amended by the Further Consolidated Appropriations Act of 2020, we would consider the approval date determined in accordance with section 7002(e)(4)(B) of the BPCI Act to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B)(ii) of the Act.

[46] For orphan drug designations withdrawn after August 12, 2013, the FDA Orphan Drug Product designation database includes the date of such withdrawal. For orphan drug designations withdrawn prior to or on August 12, 2013, we would use August 12, 2013, as the date on which the orphan designation is withdrawn for purposes of identifying the first day after the drug or biological product's approval or licensure that such drug or biological product does not qualify for the orphan drug exclusion.

Price Competition and Innovation Act of 2009'' explains that, as of March 23, 2020, applications for biological products approved under section 505 of the FD&C Act will no longer exist as their NDAs and will be replaced by approved BLAs under section 351 of the PHS Act.[47] Accordingly, it is appropriate to treat deemed biologics as biological products under section 1192(e)(1)(B)(i) of the Act because they are marketed under section 351 of the PHS Act. It is likewise appropriate to consider March 23, 2020 to be the date of licensure under section 1192(e)(1)(B)(ii) of the Act[48] as that is the date on which the approved applications for such products under section 505 of the FD&C Act were deemed to be licenses for such biological products under section 351 of the PHS Act. This interpretation was adopted for initial price applicability year 2027. For initial price applicability year 2026, no interested party suggested interpreting section 1192(e)(1) of the Act to consider the March 23, 2020 deeming date for deemed biologics to be the licensure date for such products, and CMS treated the earliest NDA approval date associated with such products as the approval date for purposes of determining the time since approval under section 1192(e)(1) of the Act. For drug selection for initial price applicability year 2027, in response to interested party feedback received through Negotiation Program Guidance, CMS considered March 23, 2020 to be the licensure date for deemed biologics. To promote transparency under the Negotiation Program and consistent with statute including the statutory directive at sections 11001(c) and 11002(c) of the IRA to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA for 2026, 2027, and 2028 by program instruction or other forms of program guidance, CMS chose to notify interested parties of this interpretation via the selected drug infographic for initial price applicability year 2027[49] and via the Negotiation Program Guidance. Section 429.125(c)(2)(ii) would codify this framework.

Final Decision: After consideration of public comments, we are finalizing § 429.125(c) with technical modifications. Specifically, we are updating cross-references in § 429.125(c)(1) and (c)(2) to reflect that we are finalizing the general fixed combination drug policy at § 429.125(b)(4)(i) (rather than at § 429.125(b)(4), as we proposed), and that we are finalizing the proposed policy for specific fixed combination drugs that are new formulations at § 429.125(b)(4)(ii) (rather than at § 429.125(b)(4)(i), as we proposed).

c. Exclusions From Qualifying Single Source Drugs (§ 429.125(e))

Section 1192(e)(3) of the Act requires that the term ''qualifying single source drug'' not include certain orphan drugs described in section 1192(e)(3)(A) of the Act, low-spend Medicare drugs described in section 1192(e)(3)(B) of the Act, or plasma-derived products described in section 1192(e)(3)(C) of the Act. With respect to initial price applicability years 2026 through 2028, CMS implemented these requirements through guidance, including, for example, sections 30.1.1 through 30.1.3 of the Negotiation Program Guidance with respect to initial price applicability year 2028. We are proposing at § 429.125(e) to exclude certain drugs when identifying qualifying single source drugs.

(1) Orphan Drug Exclusion From Qualifying Single Source Drugs (§ 429.125(e)(1))

Section 1192(e)(3)(A) of the Act excludes certain orphan drugs from the definition of a qualifying single source drug (hereinafter ''the orphan drug exclusion''). As such, and in accordance with section 30.1.1 of the Negotiation Program Guidance, in proposed § 429.125(e)(1), we proposed to codify the existing policy established in section 30.1.1 of the Negotiation Program Guidance, which incorporated amendments to the orphan drug exclusion in accordance with the ''Working Families Tax Cut'' legislation (Pub. L. 119–21), to exclude from the definition of a qualifying single source drug a drug or biological product that is designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act and for which the only approved indication (or indications)[50] is for one or more such rare diseases or conditions (as such term is defined in section 526(a)(2) of the FD&C Act and proposed § 429.20).

To be considered for the orphan drug exclusion with respect to each initial price applicability year beginning with initial price applicability year 2029, the drug or biological product must: (1) be designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act; and (2) be approved by the FDA only for one or more indications within such designated rare disease(s) or condition(s). We would not consider withdrawn orphan drug designations or withdrawn approvals when determining whether a drug meets the orphan drug exclusion.[51]

To determine whether a potential qualifying single source drug qualifies for the orphan drug exclusion, we proposed to consider all dosage forms and strengths of the potential qualifying single source drug, as described previously and as identified in proposed § 429.125(b). We would use the FDA Orphan Drug Product designation database[52] and information on FDA-approved indications from other publicly available databases and documents (such as, but not limited to, FDALabel,[53] FDA Online Label Repository,[54] Drugs@FDA,[55] and NLM DailyMed[56]) to determine whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the orphan drug exclusion. We would also consult with FDA, as appropriate, including as to whether the approved indication(s) is for a rare disease(s) or condition(s) for which the drug or biological product is designated under section 526 of the FD&C Act. We would not consider whether an FDA-approved indication was or is covered under Part D or payable under Part B or both when determining whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the orphan drug exclusion.

[47] See: *https://www.fda.gov/media/119590/download?attachment.*

[48] For a biological product with an approved application under section 505(c) of the FD&C Act that was deemed to be a BLA pursuant to section 7002(e)(4)(B) of the BPCI Act, as amended by the Further Consolidated Appropriations Act of 2020, CMS will consider the approval date determined in accordance with section 7002(e)(4)(B) of the BPCI Act to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B)(ii) of the Act.

[49] See: *https://www.cms.gov/files/document/medicare-drug-price-negotiation-selection-process.pdf.*

[50] For purposes of applying the orphan drug exclusion, CMS understands ''approved indication,'' as that term is used in section 1192(e)(3)(A) of the Act, to refer to the FDA-approved indication that is described in information included in drug labeling per 21 CFR 201.57(c)(2) or other applicable FDA regulation(s).

[51] For purposes of the Negotiation Program, we use the term ''withdrawn'' with respect to an orphan drug designation to refer to a voluntary withdrawal of an orphan drug designation as described at 23 CFR 316.24 or a revoked orphan drug designation as described at 23 CFR 316.29.

[52] See: *https://www.accessdata.fda.gov/scripts/opdlisting/oopd.*

[53] See: *https://nctr-crs.fda.gov/fdalabel/ui/search.*

[54] See: *https://labels.fda.gov.*

[55] See: *https://www.accessdata.fda.gov/scripts/cder/daf.*

[56] See: *https://dailymed.nlm.nih.gov/dailymed.*

(2) Low-Spend Medicare Drug Exclusion From Qualifying Single Source Drugs (§ 429.125(e)(2))

Section 1192(e)(3)(B) of the Act also excludes low-spend Medicare drugs or biological products with combined expenditures under Medicare Part B and Part D during the total expenditures measurement period less than the inflation-adjusted threshold for the previous initial price applicability year, increased by the annual percentage increase in the CPI–U for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to a given initial price applicability year, when identifying qualifying single source drugs (''the low-spend Medicare drug exclusion''). As such, in proposed § 429.125(e)(2), we proposed to codify the policy established in section 30.1.2 of the Negotiation Program Guidance to exclude such low-spend Medicare drugs or biological products from the definition of a qualifying single source drug.

To identify drugs and biological products meeting the statutory criteria for the low-spend Medicare drug exclusion with respect to each initial price applicability year beginning with initial price applicability year 2029, we proposed to calculate combined total expenditures under Part B and Part D for a potential qualifying single source drug as the sum of total expenditures under Part B plus total expenditures under Part D, calculated as set forth in proposed § 429.120 and described in section II.B.5. of this final rule. We would exclude from the final list of qualifying single source drugs for the initial price applicability year any drugs for which the sum of total expenditures under Part B and Part D is less than the inflation-adjusted threshold for that initial price applicability year. As set forth in sections 1192(e)(3)(B)(i) and (e)(3)(B)(ii) of the Act and codified in proposed § 429.125(e)(2)(ii), the inflation-adjusted threshold for an initial price applicability year is equal to the inflation-adjusted threshold for the previous initial price applicability year, increased by the annual percentage increase in the CPI–U for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date for such initial price applicability year, starting from the inflation-adjusted threshold for initial price applicability year 2028 equal to $212,907,518.30.

(3) Plasma-Derived Product Exclusion From Qualifying Single Source Drugs (§ 429.125(e)(3))

Additionally, section 1192(e)(3)(C) of the Act excludes plasma-derived products from the definition of a qualifying single source drug. As such, in proposed § 429.125(e)(3), we proposed to codify the existing policy established in section 30.1.3 of the Negotiation Program Guidance to exclude plasma-derived products when identifying qualifying single source drugs (''the plasma-derived product exclusion'') with respect to each initial price applicability year beginning with initial price applicability year 2029. Under section 1192(e)(3)(C) of the Act, a plasma-derived product is a biological product that is derived from human whole blood or plasma. In implementing this statutory exclusion, we would identify plasma-derived products by referring to product information, including approved product labeling, available on the FDA Approved Blood Products website, including the list of fractionated plasma products,[57] and would refer to databases such as, but not limited to, FDALabel [58] and the FDA Online Label Repository [59] to verify if the product is derived from human whole blood or plasma. CMS also would consult with FDA, as appropriate. Consistent with existing policy under the Negotiation Program Guidance and the text of the statute, for purposes of applying the exclusion, we consider only whether the active ingredient is derived from human whole blood or plasma.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported CMS' proposed approach at § 429.125(e)(1). Many commenters specifically appreciated the criteria to broaden the scope of the orphan drug exclusion to include drugs with multiple orphan drug designations. Many commenters stated that they specifically appreciated, and encouraged CMS to codify, the proposal to evaluate eligibility for the orphan drug exclusion, with respect to a particular initial price applicability year, based on the drug's approval and designation status at the time the drug becomes a selected drug. A few commenters urged CMS to finalize an approach that supports the innovation and development of orphan drugs for rare diseases. A few commenters opposed CMS' proposed approach to broaden the scope of the orphan drug exclusion to include drugs with multiple orphan designations. A couple of commenters urged CMS to apply the exclusion as narrowly as the law permits. A commenter stated that the expansion of the orphan drug exclusion prevents negotiation for high-cost drugs, forcing patients to wait longer for lower prices. A couple of commenters recommended that CMS apply the orphan drug exclusion at the level of the individual drug or biological product approved under a single NDA or BLA, rather than across all products sharing an active moiety/active ingredient with the same NDA or BLA holder. A commenter recommended that CMS retroactively apply the expanded orphan drug exclusion to drugs selected with respect to initial price applicability years 2026 and 2027, rather than just applying the amended exclusion to initial price applicability years beginning with initial price applicability year 2028. This commenter stated the price applicability period for a selected drug should end when a drug no longer meets the definition for a qualifying single source drug because a selected drug's price applicability period is the period during which the MFP applies and during which the Primary Manufacturer is obligated to provide access to the MFP and that section 1191(b)(2) of the Act defines that period as, with respect to a qualifying single source drug, the period beginning with the first initial price applicability year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug that the price applicability period is defined ''with respect to a qualifying single source drug.'' This commenter recommended that drugs selected for initial price applicability years 2026 or 2027 that would otherwise meet the criteria for the revised orphan drug exclusion should no longer have the agreed-upon MFP apply as of January 1, 2028, because the selected drugs would no longer meet the definition of a qualifying single source drug due to the revised orphan drug exclusion. A couple of commenters recommended CMS explain the event that triggers loss of the orphan drug exclusion and the date used to measure time since approval or licensure. A commenter recommended CMS study and report mechanisms for reinvesting Negotiation Program savings into public rare-disease research, possibly through an expanded orphan drug grants structure.

[57] See: *https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.*

[58] See: *https://nctr-crs.fda.gov/fdalabel/ui/search.*

[59] See: *https://labels.fda.gov/.*

Response: We appreciate the commenters' feedback. As stated in the Negotiation Program proposed rule (91 FR 36262–36263), section 1192(e)(3)(A) of the Act excludes certain orphan drugs from the definition of a qualifying single source drug (hereinafter ''the orphan drug exclusion''). As such, and in accordance with section 30.1.1 of the Negotiation Program Guidance, in proposed § 429.125(e)(1), we proposed to codify the existing policy established in section 30.1.1 of the Negotiation Program Guidance, which incorporated amendments to the orphan drug exclusion in accordance with the ''Working Families Tax Cut'' legislation (Pub. L. 119–21), to exclude from the definition of a qualifying single source drug a drug or biological product that is designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act and for which the only approved indication (or indications) [60] is for one or more such rare diseases or conditions (as such term is defined in section 526(a)(2) of the FD&C Act and at proposed § 429.20).

To be considered for the orphan drug exclusion with respect to each initial price applicability year beginning with initial price applicability year 2029, the drug or biological product must: (1) be designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act; and (2) be approved by the FDA only for one or more indications within such designated rare disease(s) or condition(s). We would not consider withdrawn orphan drug designations or withdrawn approvals when determining whether a drug meets the orphan drug exclusion.[61]

To determine whether a potential qualifying single source drug qualifies for the orphan drug exclusion, we proposed to consider all dosage forms and strengths of the potential qualifying single source drug, as described previously and as identified in § 429.125(b). We would use the FDA Orphan Drug Product designation database [62] and information on FDA-approved indications from other publicly available databases and documents (such as, but not limited to, FDALabel,[63] FDA Online Label Repository,[64] Drugs@FDA,[65] and NLM DailyMed [66]) to determine whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the orphan drug exclusion. We would also consult with FDA, as appropriate, including as to whether the approved indication(s) is for a rare disease(s) or condition(s) for which the drug or biological product is designated under section 526 of the FD&C Act. We would not consider whether an FDA-approved indication was or is covered under Part D or payable under Part B or both when determining whether a drug meets the requirements in section 1192(e)(3)(A) of the Act to qualify for the orphan drug exclusion.

In response to the commenters recommending that CMS apply the orphan drug exclusion at the level of the individual drug or biological product approved under a single NDA or BLA, rather than across all products sharing an active moiety/active ingredient, CMS disagrees with this recommendation as it would be in contention with proposed § 429.125(b) and discussed previously.

In response to the commenter's recommendation to retroactively apply the revised orphan drug exclusion to include drugs selected for initial price applicability years 2026 and 2027, CMS disagrees with the commenter's recommendation and interpretation of statute. As stated in the Negotiation Program Guidance, on July 4, 2025, the ''Working Families Tax Cut'' legislation (P. L. 119–21) was signed into law. Section 71203(a) of the ''Working Families Tax Cut'' legislation amended section 1192(e)(3)(A) of the Act and added section 1192(e)(4) to the Act, and section 71203(b) of the ''Working Families Tax Cut'' legislation specifies that these amendments shall apply with respect to initial price applicability years (as defined in section 1191(b) of the Act) beginning on or after January 1, 2028. CMS interprets this new amendment to apply to the identification of qualifying single source drugs, and thus selected drugs, with respect to initial price applicability years beginning on or after January 1, 2028, and does not affect CMS' identification of qualifying single source drugs and selected drugs with respect to initial price applicability years 2026 and 2027. CMS disagrees with the argument that the amendments to the orphan drug exclusion require the termination of the negotiated MFPs for selected drugs with respect to initial price applicability years 2026 and 2027 that would have qualified for the amended orphan drug exclusion applicable to drug selection with respect to initial price application years beginning on or after January 1, 2028. This interpretation conflicts with the effective date in the ''Working Families Tax Cut'' legislation and also the clear statutory language in sections 1191(b)(2) and 1192(c) of the Act which specify the limited circumstances in which a selected drug ceases to be a selected drug and therefore is no longer in its price applicability period. Interpreting the term ''qualifying single source drug,'' as used in section 1191(b)(2) of the Act, to import into these provisions an additional time at which a selected drug's price applicability period (that is, when such drugs no longer meets the requirements for a qualifying single source drug under section 1192(e) of the Act) would conflict with a plain reading of that provision and render its reference to section 1192(c) of the Act superfluous. We believe our interpretation is more consistent with a plain reading of these provisions, under which the reference to ''qualifying single source drug'' in section 1191(b)(2) of the Act denotes that the price applicability period, as defined in section 1191(b)(2) of the Act, is specific to each product that CMS determined was a ''qualifying single source drug'' at the time of selection with respect to a given initial price applicability period and which, for a period of time described in sections 1191(b)(2) and 1192(c) of the Act, is considered a ''selected drug'' within its ''price applicability period.'' We believe that this interpretation gives effect to all relevant provisions and is in accord with the structure of the statute which does not otherwise contemplate a continued requirement that selected drugs remain qualifying single source drugs as defined under section 1192(c) after they are selected.

As stated in the Negotiation Program Guidance, in accordance with section 1192(e)(3)(A) of the Act, as modified by section 71203(a)(2) of the ''Working Families Tax Cut'' legislation, CMS excluded certain orphan drugs when identifying qualifying single source drugs by applying the revised orphan drug exclusion for initial price applicability year 2028. Specifically, CMS excluded a drug or biological product that is designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act and

[60] For purposes of applying the orphan drug exclusion, CMS understands ''approved indication,'' as that term is used in section 1192(e)(3)(A) of the Act, to refer to the FDA-approved indication that is described in information included in drug labeling per 21 CFR 201.57(c)(2) or other applicable FDA regulation(s).

[61] For purposes of the Negotiation Program, we use the term ''withdrawn'' with respect to an orphan drug designation to refer to a voluntary withdrawal of an orphan drug designation as described at 21 CFR 316.24 or a revoked orphan drug designation as described at 21 CFR 316.29.

[62] See: *https://www.accessdata.fda.gov/scripts/opdlisting/oopd.*

[63] See: *https://nctr-crs.fda.gov/fdalabel/ui/search.*

[64] See: *https://labels.fda.gov.*

[65] See: *https://www.accessdata.fda.gov/scripts/cder/daf.*

[66] See: *https://dailymed.nlm.nih.gov/dailymed.*

for which the only approved indication (or indications) is for one or more such rare diseases or conditions (as such term is defined in section 526(a)(2) of the FD&C Act).

In response to the commenters recommending that CMS explain the event that triggers loss of the exclusion and the date used to measure time since approval or licensure, CMS directs the commenters to § 429.125(e) of this final rule which states the exclusion criteria a potential qualifying single source drug identified in paragraph (b) of that section must meet to qualify for the orphan drug exclusion. If a potential qualifying single source drug identified in paragraph (b) had met the orphan drug exclusion criteria in an initial price applicability year 2028 or later, but no longer meets the criteria listed at § 429.125(e) of this final rule in a subsequent initial price applicability year, then the orphan drug exclusion would no longer apply to that qualifying single source drug for that respective initial price applicability year. Regarding the date used to measure time since approval and licensure, CMS directs the commenters to § 429.125(c)(3) of this final rule which states the date used to measure time since approval or licensure.

The recommendation for CMS to study and report on mechanisms for reinvesting Negotiation Program savings into public rare-disease research is out of scope for this final rule.

Comment: Many commenters stated that they oppose CMS' proposed approach at § 429.125(c)(3)(i). These commenters disagree with CMS' interpretation of the statute and proposal to measure time since FDA approval of an indication that is not for a rare disease or condition ''irrespective of whether approval of such indication was or is withdrawn after its approval.'' Many commenters recommended that CMS give the orphan drug exclusion a full effect by ''tolling'' (pausing) the negotiation clock whenever a withdrawn indication leaves a product with only rare-disease indications, for the full period the product qualifies and for CMS to only look at the active indications as of the drug selection date. A commenter stated they support CMS' interpretation of statute in the proposed approach and agree that the determination of the date on which the FDA approves an orphan drug or biological product for a non-orphan indication should be made ''irrespective of whether approval of such indication was or is withdrawn after its approval.'' A commenter stated that they appreciate CMS being aware that no current instances of this scenario have occurred yet and recommended CMS to defer the proposal until a case or situation of a drug qualifies for this approach.

Response: We appreciate these comments and feedback. In accordance with section 1192(e)(4) of the Act and as described at § 429.125(c)(3), if, as of the date of a drug or biological product's initial approval or licensure, such drug or biological product met or meets the criteria for the orphan drug exclusion proposed at § 429.125(e)(1), we would measure the 7- and 11-year periods identified in § 429.125(c)(1) and (c)(2) starting from the first day after such initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion at proposed § 429.125(e)(1). As stated in the Negotiation Program proposed rule (91 FR 36262), we would identify this day as the earlier of (1) the date on which the FDA approves such drug or biological product for an indication for a disease or condition that is not a rare disease or condition for which the drug or biological product is designated under section 526 of the FD&C Act; or (2) the date on which an orphan drug designation is withdrawn, if that withdrawal results in the drug or biological product no longer qualifying for the orphan drug exclusion.[67]

As noted previously, section 1192(e)(4) of the Act requires that CMS measure the 7- and 11-year periods set forth in proposed § 429.125(a)(1)(ii) and (a)(2)(ii) starting from ''the first day'' after the drug's initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion. We thus proposed that the determination of the date on which the FDA approves the drug or biological product for an indication for a disease or condition that is not a rare disease or condition for which the drug or biological product is designated under section 526 of the FD&C Act would be made irrespective of whether approval of such indication is later withdrawn.

We are aware that this policy could result in a scenario where the 7- and 11-year periods set forth in § 429.125(a)(1)(ii) and (a)(2)(ii) would not yet have elapsed between the last day that the drug most recently qualified for the orphan drug exclusion at section 1192(e)(3)(A) of the Act and proposed at § 429.125(e)(1) and the selected drug publication date, but we believe this approach aligns best with statute given the requirement at section 1192(e)(4) of the Act to measure the 7- and 11-year periods starting from ''the first day'' after the drug's initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion.

We are not currently aware of any instances in which this scenario—wherein the 7- and 11-year periods would not yet have elapsed between the last day that the drug most recently qualified for the orphan drug exclusion and the selected drug publication date—would occur in practice and believe the chances of this scenario occurring in the future are low.

CMS disagrees with the commenter recommending delaying codifying the policy until a case or situation comes up. As stated previously, we believe that this policy is the best interpretation of statute and alignment with section 1192(e)(4) of the Act and we do not see a legitimate reason to delay codifying the proposal.

Comment: A couple of commenters expressed concern that the FDA Orphan Drug Product designation database and the FDA approvals database will not allow CMS to identify whether an indication falls within an orphan drug designation, stating that CMS cannot rely on FDA's databases because those databases principally track orphan exclusivity rather than orphan drug designation. These commenters recommended that CMS should also establish a pathway for manufacturers and other interested parties to demonstrate that an indication falls within an orphan drug designation.

Response: We appreciate the commenters' feedback. Consistent with our response to similar comments in the Negotiation Program Guidance, we believe that consulting the FDA Orphan Drug Product designation database, along with other publicly available databases and documents, in addition to consultation with FDA, as needed, will allow CMS to successfully implement the Orphan Drug Exclusion. The Orphan Drug Product designation database contains drugs with an orphan drug designation. We review designations and approved indications to determine whether the indication falls within a designation. Further, we will consult with FDA if needed. We acknowledge commenters' request to have the opportunity to submit supporting documentation regarding orphan drug

[67] For orphan drug designations withdrawn after August 12, 2013, the FDA Orphan Drug Product designation database includes the date of such withdrawal. For orphan drug designations withdrawn prior to or on August 12, 2013, we would use August 12, 2013, as the date on which the orphan designation is withdrawn for purposes of identifying the first day after the drug or biological product's approval or licensure that such drug or biological product does not qualify for the orphan drug exclusion.

designations but believes that is unnecessary at this time.

Comment: A few commenters provided feedback on the plasma-derived product exclusion from the definition of a qualifying single source drug. A couple of commenters supported CMS' proposal. A commenter stated that the approach is consistent with the statutory text, longstanding FDA regulatory principles, and Congressional intent underlying the plasma-derived product exclusion. A commenter suggested that CMS codify the proposal in § 429.125(e)(3), but also include in the regulatory text the discussion in the preamble that CMS will only consider the active moiety/active ingredient of a product being derived from human whole blood or plasma because this approach would prevent the inappropriate exclusion of products that include plasma-derived material as an inactive ingredient or in the manufacturing process. A commenter opposed CMS' proposal and stated that CMS should not apply the statutory exclusion for plasma-derived products based on whether the product's ''active ingredient'' alone is derived from human whole blood or plasma as discussed in the preamble. This commenter requested for CMS to state in regulatory text which sources it will use to identify plasma-derived products and how it will reconcile conflicting sources.

Response: We thank these commenters for their feedback and appreciate the support from the commenters. In response to the commenters suggesting additional language be added to the regulatory text, we believe that the regulatory text is consistent with the statutory language.

We disagree with the commenter that stated that CMS should not apply the statutory exclusion for plasma-derived products based on whether the product's active ingredient alone is derived from human whole blood or plasma. When identifying whether biological products satisfy the statutory criteria for qualifying single source drugs, we identify the qualifying single source drug as all dosage forms and strengths of the biological product with the same active ingredient. We believe it is appropriate and consistent with this approach to determine whether such products qualify for the plasma-derived product exclusion based on the biological product's active ingredient alone rather than inactive ingredients or a combination thereof.

In response to the commenter requesting which sources CMS will use and how it will reconcile conflicting sources, consistent with our response to similar comments in the Negotiation Program Guidance and as stated in the Negotiation Program proposed rule (91 FR 36263), we continue to believe that referring to product information available on the FDA Approved Blood Products website, including the list of fractionated plasma products,[68] and databases such as, but not limited to, FDALabel[69] and the FDA Online Label Repository to verify if the product is derived from human whole blood or plasma, are the best ways to identify plasma-derived products for the purpose of implementing the plasma-derived product exclusion in a consistent manner. The sources previously listed in this section are typically consistent in their identification of products that are derived from human whole blood or plasma. Thus, we do not anticipate conflicts among these sources. If differences were identified, we would consult with FDA, as appropriate, to ensure accurate identification of products that are derived from human whole blood or plasma.

Final Decision: After consideration of public comments received, we are finalizing § 429.125(e) as proposed.

d. Bona Fide Marketing of an Approved Generic Drug or Licensed Biosimilar and Deselection of a Selected Drug (§ 429.125(d), § 429.130, and § 429.135)

Key provisions of the Negotiation Program statute govern CMS' evaluation of generic and biosimilar competitors to potential qualifying single source drugs and CMS' further consideration of such products in the deselection of selected drugs. First, section 1192(e)(1)(A)(iii) of the Act states that, to be considered a qualifying single source drug, a drug cannot be the listed drug for any drug approved and marketed under an ANDA under section 505(j) of the FD&C Act. For a biological product, section 1192(e)(1)(B)(iii) of the Act states that the biological product cannot be the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act (that is, a biosimilar). Second, section 1192(c)(1) specifies a selected drug that is included on the list of selected drugs for an initial price applicability year will remain a selected drug for that year and each subsequent year beginning before the first year that begins at least nine months after the date on which CMS determines: (1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference-listed drug a product that is included in the selected drug, or FDA has licensed a biosimilar under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and (2) the generic drug or biosimilar, as applicable, is marketed pursuant to such approval or licensure.

Based on the authorities described previously, CMS conducts the following inquiry to determine whether a drug or biological product can be considered a qualifying single source drug. First, using FDA reference sources including the Orange Book and Purple Book, CMS would evaluate whether at least one generic drug is approved under section 505(j) of the FD&C Act using any dosage form or strength of the potential qualifying single source drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using any dosage form or strength of the potential qualifying single source drug as the reference product, consistent with proposed § 429.125(d)(1). This approach is consistent with the approach of aggregating different dosage forms and strengths as a single potential qualifying single source drug as required under section 1192(d)(3)(B) of the Act (stating that a qualifying single source drug is inclusive of all strengths and dosage forms, which is described in further detail in section II.B.6.a. of this final rule). In other words, consistent with proposed in § 429.125(d), if CMS determines there is a generic drug or biosimilar that is approved or licensed, as applicable, for any dosage form or strength of a drug or biological product, and such generic drug or biosimilar is subject to Bona Fide Marketing, then that drug or biological product would not meet the statutory criteria in section 1192(e)(1)(A)(iii) or section 1192(e)(1)(B)(iii) of the Act to be a qualifying single source drug. We proposed that the determination of whether a potential qualifying single source drug includes the listed drug or reference product for an approved generic drug or licensed biosimilar, respectively, would be made irrespective of whether the indication(s) approved for the listed drug or reference product were or are covered under Part D, payable under Part B, or both.

We note that because section 1192(e)(2)(A) of the Act provides that an ''authorized generic'' drug ''shall be treated as the same qualifying single source drug,'' we will not consider an authorized generic drug to be a generic drug or biosimilar for the purposes of identifying whether there is an

[68] See: *https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/approved-blood-products.*

[69] See: *https://nctr-crs.fda.gov/fdalabel/ui/search.*

approved generic drug or licensed biosimilar for any strength or dosage form of a potential qualifying single source drug. An authorized generic drug is defined in section 1192(e)(2)(B) of the Act as: (1) in the case of a drug, an authorized generic drug (as such term is defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act); and (2) in the case of a biological product, a product that has been licensed under section 351(a) of such Act[70] and is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the reference product.

Second, consistent with the policies for implementation of section 30.1 of the Negotiation Program Guidance, we would conduct a holistic inquiry based on the totality of the circumstances when evaluating whether any approved generic drug(s) or licensed biosimilar(s) is or are subject to Bona Fide Marketing as defined at proposed § 429.20 and described in proposed § 429.130. CMS must evaluate, as part of the determination described in section 1192(e) of the Act, whether a generic drug or biosimilar ''is. . .marketed'' and whether the potential qualifying single source drug is a listed drug ''for any drug that is approved and marketed under section 505(j) of the FD&C Act'' or a reference product ''for any biological product that is licensed and marketed under section 351(k) of the PHS Act.'' The terminology specified in sections 1192(e) of the Act for purposes of the Negotiation Program is distinct from the terminology specified elsewhere in the Act for purposes of the Medicare Part B Drug Inflation Rebate Program (section 1847A(i) of the Act) and the Medicare Part D Drug Inflation Rebate Program (section 1860D–14B of the Act), also established through the IRA. For Medicare inflation rebates, the statute refers to the date that a drug is ''first marketed''. The absence of the term ''first marketed'' in section 1192 of the Act indicates that, for purposes of the Negotiation Program, a generic drug or biosimilar must have a continuing presence on the market in order to affect the status of a listed drug/reference product. Consistent with the statutory purpose of lowering drug prices through the mechanisms described in Title I, Subtitle B, Part 1 of the Inflation Reduction Act, and as CMS has explained in response to comment on the Negotiation Program Guidance, CMS will consider whether meaningful competition exists on an ongoing basis between any dosage form or strength of a potential qualifying single source drug that includes the listed drug or reference product and any one or more generic drug(s) or biosimilar(s). Therefore, as reflected in proposed § 429.130(a)(1) and (2), we understand that whether a product ''is marketed'' requires more than solely token or de minimis availability. We appreciate that, while sales and utilization data provide important indicators of market competition, they are not the only sources of information that may illustrate whether such competition exists between a listed drug or reference product and a generic drug or biosimilar. For example, we are also aware there may be situations in which a manufacturer of a brand name drug or biological product has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar, where the generic drug or biosimilar manufacturer agrees to limit production or distribution of the generic drug or biosimilar, such that only a nominal quantity of product is allowed to enter the market. The result is a lack of meaningful price competition, and in that circumstance the generic drug or biosimilar is not ''marketed'' within the meaning of that term as it is used in section 1192 of the Act (for example, specifically within the context of marketed at section 1192(e) of the Act). Therefore, as proposed in § 429.130(b), whether such competition exists between a listed drug or reference product and an approved generic drug or licensed biosimilar would depend on a holistic inquiry based on the totality of circumstances in existence at the time that CMS evaluates whether an approved generic drug or licensed biosimilar is subject to Bona Fide Marketing and not on the presence, or absence, of any single factor.

Specifically, in accordance with sections 1192(e) of the Act, to consider whether there are ongoing sales and/or utilization of a generic drug or biosimilar in the market, we proposed at § 429.130(a)(1)(i) through (iii) to review the following data sources: PDE data, AMP data, and ASP data. Additionally, as part of CMS' holistic consideration of whether one or more manufacturers of a generic drug or biosimilar are engaging in Bona Fide Marketing of the approved generic drug or licensed biosimilar, we proposed at § 429.130(a)(1)(iv) that CMS may also review sales and/or utilization data from additional data sources, including, but not limited to, Medicaid State Drug Utilization Data, and data from nationally representative and commercially available databases. Further, to consider whether there is meaningful competition, CMS may also consider other factors proposed at § 429.130(a)(2) and (3) that include whether the approved generic drug or licensed biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain, whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the generic drug or biosimilar, and other available data and informational sources on market share and relative market competition of the approved generic drug or licensed biosimilar that CMS may identify.

If any dosage form or strength of a potential qualifying single source drug is the listed drug or reference product for one or more generic drugs or biosimilars that CMS determines are approved or licensed and subject to Bona Fide Marketing based on the information as described in proposed § 429.130(a), the potential qualifying single source drug would not be considered a qualifying single source drug for the applicable initial price applicability year (as described in proposed § 429.125(d)). As set forth in proposed § 429.125(d) and in accordance with § 429.130(c)(1), we would review the information set forth in proposed § 429.130(a) for any potential qualifying single source drug for initial price applicability year 2029 and any initial price applicability year thereafter in January prior to the selected drug publication date (proposed at § 429.20 and described in section II.A.2. of this final rule). For example, for initial price applicability year 2029, CMS would review this information for any potential qualifying single source drugs in January 2027, prior to the February 1, 2027 selected drug publication date.

Consistent with section 1192(c)(1) of the Act, a drug selected for negotiation for an initial price applicability year would remain a selected drug for that initial price applicability year and each subsequent year beginning before the first year that begins at least nine months after the date as of which CMS determines at least one generic drug is approved under section 505(j) of the FD&C Act using the selected drug as the

[70] CMS is interpreting the reference to ''licensed under section 351(a) of such Act'' to mean licensed or deemed licensed under section 351(a) of the PHS Act. Section 351(a) of the PHS Act addresses the licensure of a biological product.

listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using the selected drug as the reference product, and such generic drug or biosimilar is marketed pursuant to such approval or licensure, as applicable. As discussed previously in this section, we understand that whether a product ''is marketed'' requires more than solely token or de minimis availability. Therefore, when evaluating whether a generic drug or biosimilar for a selected drug is subject to Bona Fide Marketing for the purposes of determining if a selected drug ceases to be a selected drug consistent with section 1192(c) of the Act and proposed § 429.135(a), we would implement the same approach that we proposed for evaluating whether a generic drug or biosimilar for a potential qualifying single source drug is subject to Bona Fide Marketing.

If CMS determines that a generic drug is approved or a biosimilar is licensed for the selected drug, and such generic drug or biosimilar is subject to Bona Fide Marketing (as set forth in proposed § 429.130(a)) on a date during the period beginning on the selected drug publication date (as defined in proposed § 429.20) and ending on November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug is selected for negotiation, consistent with section 1192(c)(2) of the Act and proposed § 429.135(b)(1)(i), the selected drug is no longer subject to the negotiation process—including, for example, any applicable negotiation meeting(s) or offer and counteroffer exchanges—for such initial price applicability year. Similarly, consistent with section 1194(f)(5)(B) of the Act and proposed § 429.135(b)(2), if CMS determines that a generic drug is approved or a biosimilar is licensed for a selected drug and that such generic drug or biosimilar is subject to Bona Fide Marketing (as set forth in proposed § 429.130(a)) on a date during the period beginning on the selected drug publication date (as defined in proposed § 429.20) and ending on November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug is selected for renegotiation, then the selected drug is no longer subject to the renegotiation process. Therefore, for drugs selected for negotiation and renegotiation (if any) for an initial price applicability year, we proposed we would review the information set forth in proposed § 429.130(a) on a monthly basis starting in March of the calendar year of the negotiation period (or renegotiation period, as applicable) until November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for negotiation (or renegotiation, as applicable) (see proposed § 429.130(c)(4) and (c)(5).

Pursuant to section 1192(c)(1) of the Act, once the negotiation period concludes, a selected drug would cease to be a selected drug if CMS determines that a generic drug is approved or a biosimilar is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing based on the information considered in proposed § 429.130(a). We proposed that we would review the information set forth in proposed § 429.130(a), biannually in March and October, starting in October of the calendar year after CMS and the Primary Manufacturer reached an agreement on an MFP for the initial price applicability year for which the drug was selected originally for negotiation and until CMS determines that a selected drug meets the requirements at proposed § 429.135(a) to cease being a selected drug.

Section 1194(f)(5) of the Act clarifies that a renegotiation-eligible drug for which CMS determines there is a generic drug that is approved or biosimilar that is licensed, and such generic drug or biosimilar is subject to Bona Fide Marketing before or during the renegotiation period shall not be subject to the renegotiation process. Thus, for any renegotiation-eligible drug, we would review the information set forth in proposed § 429.130(a), in January, prior to the selected drug publication date (defined at § 429.20 and described in section II.A.2. of this final rule) as proposed in § 429.130(c)(3).

Finally, after determining that a generic drug is approved or biosimilar is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing, we would monitor that the approved generic drug or licensed biosimilar continues to be subject to Bona Fide Marketing. We would review the information set forth in proposed § 429.130(a) to monitor whether such generic drug(s) or biosimilar(s) continues to be subject to Bona Fide Marketing consistent with the schedule proposed at § 429.130(c)(2) and (7), which includes, but is not limited to January of each calendar year.

For each of these points in time CMS reviews the applicable data to determine whether a generic drug is approved or a biosimilar is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing (which includes prior to selection for negotiation or renegotiation of selected drugs, after selection of drugs for negotiation or renegotiation, or after a selected drug ceases to be a selected drug), beginning with drug selection for negotiation and renegotiation for initial price applicability year 2029 and initial price applicability years thereafter, we proposed a schedule for reviewing the data at proposed § 429.130(c) that varies from the policies in the applicable guidance for drugs that were potentially eligible for selection or have been selected for initial price applicability years 2026, 2027, and 2028. We have observed across the administration of the Negotiation Program to date that there are certain points in time across a calendar year that are key to the drug selection process of the Negotiation Program and/or have an impact on CMS and manufacturer operations related to plan year coverage contracts and related determinations. For example, it is necessary for CMS to review whether any applicable generic drugs and biosimilars are subject to Bona Fide Marketing as part of the review steps CMS undertakes to identify qualifying single source drugs for purposes of drug selection for negotiation (proposed at § 429.130(c)(1)) and to identify selected drugs ineligible to be selected for renegotiation (proposed at § 429.130(c)(3)) prior to the selected drug publication date. Once a drug is selected, but prior to the agreement of an MFP or the end of the negotiation period during the negotiation process, CMS must regularly review if any applicable generic drugs and biosimilars are subject to Bona Fide Marketing as an essential part of determining if a selected drug remains subject to the negotiation process. Therefore, consistent with the policies for implementation as described in Negotiation Program Guidance, CMS would maintain monthly reviews of data during this period as proposed at § 429.130(c)(4) for drugs selected for negotiation and as proposed at § 429.130(c)(5) for drugs selected for renegotiation (if any) for initial price applicability years 2029 and thereafter. However, after the negotiation period ends, we believe that less frequent reviews are sufficient and would provide manufacturers, Part D plan sponsors, and other interested parties with notice regarding the specific points in time across a calendar year at which CMS would review the specified data and provide public notice of any selected drugs that are deselected (consistent with proposed § 429.135(a) and (d)) because CMS determined that a generic drug is approved or a biosimilar is licensed for the selected

drug and such generic drug or biosimilar is subject to Bona Fide Marketing. For example, we understand that manufacturers, plan sponsors, and other relevant parties may begin negotiations for Part D plan bids more than a year prior to the plan year and CMS' deadline for Part D sponsor bids (see § 423.265(b)). Therefore, we believe that one key date includes October to ensure manufacturers and Part D plan sponsors are aware prior to the subsequent June due date for Part D plan sponsors to provide CMS with any required plan bids for the next Medicare plan contract year (as indicated in § 423.265(b)(1)) of any selected drugs that may be deselected. For example, if we determine in October 2028 that a generic drug or biosimilar is approved or licensed, as applicable, for a selected drug for initial price applicability year 2029 and that generic drug or biosimilar is subject to Bona Fide Marketing, that selected drug ceases to be a selected drug on January 1, 2030 and the MFP would not be applicable for that year. Manufacturers and plan sponsors would then be aware in November 2028 that the selected drug would cease to be a selected drug in contract year 2030, bids for which are due in June 2029. Finally, as described in proposed § 429.130(c)(2) and (7), we would periodically monitor, including at least annually in January prior to each selected drug publication date, the marketing of any applicable generics and biosimilars in the following circumstances: (1) if a potential qualifying single source drug was determined by CMS not to qualify as a qualifying single source drug for any prior initial price applicability year because CMS determined that at least one generic drug was approved using the potential qualifying single source drug as the listed drug or at least one biosimilar was licensed using the potential qualifying source drug as the reference product, and such generic drug or biosimilar was subject to Bona Fide Marketing, and (2) if a selected drug ceases to be a selected drug in accordance with proposed § 429.135(a) (in other words, because CMS determined that a generic drug is approved or a biosimilar is licensed for the selected drug and such generic drug or biosimilar is subject to Bona Fide Marketing).

For awareness for manufacturers and other interested parties, we proposed in § 429.130(a)(1)(i) through (iv) that CMS would review the last 12 months or the four quarters of data, as applicable, ending with the last full month or quarter of data available to CMS at the time of its review. Specifically, for PDE data, consistent with proposed § 429.130(a)(1)(i) and using the example of CMS' review in October, this means that CMS would review PDE data reported from October of the prior calendar year through September of the current calendar year. Submission deadlines for the data source would determine the data available to CMS at the time of review. For example, AMP and ASP data are submitted to CMS by manufacturers on a monthly or quarterly basis in accordance with regulations (42 CFR 447.510 and 42 CFR 414.805(a)(5)), whereas PDE data for selected drugs are submitted to CMS by Part D plan sponsors within 7 days from the date the Part D plan sponsor receives the claim for selected drugs or within 30 days for all other drugs (per 42 CFR 423.325).

CMS would pull such data in the month specified for CMS' review, and the specific date on which CMS may pull the data would vary year to year and may be impacted, for example, by the date of Federal holidays. To provide further clarity to manufacturers and interested parties in this final rule, we provide the following example. If, in accordance with proposed § 429.130(c)(4), CMS conducts a review in March 2027 to consider whether an approved generic drug or licensed biosimilar is subject to Bona Fide Marketing for a selected drug selected for negotiation for initial price applicability year 2029, this means CMS may pull the relevant data on any day on or between March 1, 2027 and March 31, 2027. However, as specified in proposed § 429.130(a), the information reviewed is the information ''available to'' CMS when CMS pulls the data. Due to lags in data reporting for various sources, this means the data reviewed may cover a period that ends days, weeks, or months prior to the date of the data pull. For example, if CMS pulled AMP data on March 31, 2027, CMS would review the most recent 12 months of AMP data available as of March 31, 2027. Due to lags in the availability of AMP data, this means CMS would review AMP data covering the period from February 2026 through January 2027.

Further, to continue the previous example, CMS' review of the information pulled on or between March 1, 2027 and March 31, 2027 may extend into the following month to ensure a fulsome consideration of the data available as of the date the information was pulled and may lead CMS to determine as of March 2027 that the drug selected for initial price applicability year 2029 has an approved generic drug or licensed biosimilar, and such generic drug or biosimilar is subject to Bona Fide Marketing. Consequently, CMS may announce after March 2027 that the drug selected for negotiation for initial price applicability year 2029 had an approved generic drug or licensed biosimilar, and such generic drug or biosimilar was subject to Bona Fide Marketing as of March 2027 such that, in accordance with proposed § 429.135(b)(1), the selected drug would cease to be subject to the negotiation process, the selected drug would be deselected as of January 1, 2030, and no MFP would be published for, or apply to, the selected drug.

Consistent with the policies for implementation as described in Negotiation Program Guidance, we provide the following examples of potential factors considered in CMS' review of whether an approved generic drug or licensed biosimilar is subject to Bona Fide Marketing. While the circumstances illustrated in these examples weigh in favor of, or against, considering a generic drug or biosimilar to be subject to Bona Fide Marketing, CMS' inquiry for any particular drug would be based on the totality of the circumstances and not on the presence, or absence, of any single factor. First, as an example, if a potential qualifying single source drug has at least one approved generic drug or licensed biosimilar that has high and consistent PDE utilization, AMP sales, and/or ASP sales, we would consider the generic(s) or biosimilar(s) of the potential qualifying single source drug to be subject to Bona Fide Marketing. As a second example, a potential qualifying single source drug might have a newly or recently approved generic drug or licensed biosimilar and the product has relatively low PDE utilization, AMP sales, and/or ASP sales. In this example, if CMS finds in additional review of public information that the generic drug or biosimilar manufacturer has successfully launched their product, and there is no evidence of agreements limiting distribution of the generic drug or biosimilar, then we may consider the generic drug or biosimilar of the potential qualifying single source drug to be subject to Bona Fide Marketing. As a third example, a potential qualifying single source drug might have an approved generic drug or licensed biosimilar product with no PDE utilization, AMP sales, and/or ASP sales. In this example, if CMS finds in additional review of public information that there are ongoing patent disputes and no generic drug or biosimilar manufacturer has successfully launched their product, then we may consider the

generic drug or biosimilar of the potential qualifying single source drug as not subject to Bona Fide Marketing.

As discussed in section I.A.2. of this final rule, because sections 11001(c) and 11002(c) of the IRA require CMS to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA for 2026, 2027, and 2028 through program instruction or other forms of program guidance, prior to January 1, 2029, the requirements and processes, including with respect to Bona Fide Marketing and deselection of a selected drug, for a selected drug that was included on the list of selected drugs with respect to initial price applicability year 2026, 2027, or 2028 are set forth with respect to such years in the applicable program guidance. Revisions to the implementation of such policies for 2026, 2027, and 2028 with respect to drugs selected for initial price applicability years 2026, 2027, and 2028 would be addressed by CMS through publication of revised guidance. In accordance with the expiration of the statutory program instruction requirement at the end of 2028, we described in section I.A.2. of this final rule that the provisions of this final rule, including the policies set forth in §§ 429.130 and 429.135 with respect to Bona Fide Marketing and deselection of a selected drug, as applicable, would apply starting in 2029 with respect to the drugs selected for initial price applicability years of 2026, 2027, or 2028.

Section 1192(c)(1) of the Act specifies that each negotiation-eligible drug included on the list of drugs published for an initial price applicability year consistent with section 1192(a) of the Act will be a ''selected drug'' with respect to that year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug is approved under section 505(j) of the FD&C Act using the selected drug as the listed drug or at least one biological product is licensed under section 351(k) of the PHS Act using the selected drug as the reference product, and that such drug or biological product is marketed pursuant to such approval or licensure. Additionally, section 1192(c)(2) of the Act states that a negotiation-eligible drug shall not be subject to the negotiation process under section 1194 of the Act for the applicable negotiation period but shall continue to be considered a selected drug for purposes of the number of negotiation-eligible drugs published on the list with respect to such initial price applicability year if the Secretary determines that the criteria in section 1192(c)(1) of the Act are met before or during the negotiation period for that initial price applicability year. Therefore, in accordance with sections 1192(c)(1) and (2) of the Act, we proposed in § 429.135 to codify provisions related to deselection of a selected drug subject to the timeline and situations proposed in § 429.135(b).

Specifically in proposed § 429.135(a), each drug selected for negotiation for an initial price applicability year would remain a selected drug, with respect to such initial price applicability year and each subsequent year beginning before the first year that begins at least 9 months after the date on which CMS determines that at least one generic drug is approved under section 505(j) of the FD&C Act using any dosage form or strength of the selected drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using any dosage form or strength of the selected drug as the reference product, and that such generic drug or biosimilar is subject to Bona Fide Marketing.[71] First, we would use FDA reference sources, including the Orange Book and Purple Book, to determine whether a generic drug or biosimilar is approved or licensed for any strength(s) or dosage form(s) of a selected drug as proposed in § 429.135(a)(1). Second, if we determine that a generic drug or biosimilar has been approved or licensed, we would consider whether such generic drug or biosimilar is subject to Bona Fide Marketing as proposed in 429.130(a) and consistent with proposed § 429.135(a)(2). For clarity, we note that a selected drug remains a selected drug unless and until it is deselected as proposed in § 429.135(a) without regard to whether the Primary Manufacturer decides to execute a Negotiation Program Agreement as proposed in § 429.200, to terminate a Negotiation Program Agreement as proposed in § 429.205, or to transfer the Negotiation Program Agreement to a new Primary Manufacturer as proposed in § 429.210.

Proposed § 429.135(b) clarifies that the circumstances described in § 429.135(b) would apply to such selected drug based on the date as of which we determine the conditions described in § 429.135(a) are met. As detailed in proposed § 429.135(b)(1), if we determine as of a date during the period beginning on the selected drug publication date (as defined in § 429.20) and ending on November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for negotiation, that a selected drug has a generic drug that is approved or biosimilar that is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing, pursuant to section 1192(c)(2) of the Act, the selected drug ceases to be subject to the negotiation process under section 1194 of the Act; an MFP would not be published for, or apply to, such drug; and the selected drug would remain a selected drug only for that initial price applicability year but would not be replaced by another selected drug. As discussed in proposed § 429.130(c)(7), after CMS determines a selected drug would cease to be a selected drug consistent with § 429.135(a), CMS would monitor whether the generic drug or biosimilar for the selected drug continues to be subject to Bona Fide Marketing.

We proposed that, if CMS determines as of a date during the period of time beginning on November 2 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for negotiation and ending on March 31 of that initial price applicability year that a selected drug has a generic drug that is approved or biosimilar that is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing, then the selected drug would cease to be a selected drug on January 1 of the year following the initial price applicability year for which such drug was selected for negotiation and the MFP would apply only for the initial price applicability year for which such drug was selected for negotiation (consistent with proposed § 429.135(b)(3)).

If CMS determines as of a date during the selected drug's price applicability period after March 31 of the initial price applicability year for which the selected drug is selected for negotiation that a selected drug has a generic drug that is approved or biosimilar that is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing, then the selected drug would cease to be a selected drug on January 1 of the year that begins at least 9 months after the date as of which CMS determines that the selected drug has a generic drug that is approved or biosimilar that is licensed and such generic drug or biosimilar is subject to Bona Fide Marketing and the MFP would apply until such date that the selected drug ceases to be a selected drug (consistent with proposed § 429.135(b)(4)).

These different scenarios for the timing of deselection in accordance with proposed § 429.135(b) are summarized in Table II.B1 using a drug

[71] Such date of determination is distinct from, and prior to, the date of Primary Manufacturer notification.

selected for negotiation for initial price applicability year 2029 as an illustrative example.

TABLE II.B1: DESELECTION OF A SELECTED DRUG FOLLOWING GENERIC DRUG OR BIOSIMILAR APPROVAL/LICENSURE AND MARKETING

Date as of which CMS Determines that a Generic Drug or Biosimilar is Approved/Licensed and Marketed	Result with Respect to Selected Drug for the Negotiation Program
The selected drug publication date for initial price applicability year 2029 through November 1, 2027 (the end of the Negotiation Period for initial price applicability year 2029)	Selected drug remains a selected drug for initial price applicability year 2029, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2030.
November 2, 2027 through March 31, 2029	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029; selected drug ceases to be a selected drug on January 1, 2030.
April 1, 2029 through March 31, 2030	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029 and calendar year 2030; selected drug ceases to be a selected drug on January 1, 2031.
April 1, 2030 through March 31, 2031	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029 and calendar years 2030 and 2031; selected drug ceases to be a selected drug on January 1, 2032.
April 1, 2031 through March 31, 2032	Selected drug remains a selected drug and MFP applies for initial price applicability year 2029 and calendar years 2030, 2031 and 2032; selected drug ceases to be a selected drug on January 1, 2033.

As we proposed at § 429.135(c), if CMS determines a generic drug is approved or biosimilar is licensed for a selected drug, and such generic drug or biosimilar is subject to Bona Fide Marketing prior to the selected drug publication date for the next initial price applicability year (including drugs previously selected for renegotiation), a drug selected for a prior initial price applicability year is not eligible for renegotiation for such next initial price applicability year consistent with section 1194(f)(5) of the Act.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters shared their perspectives about the interplay of the definition of a qualifying single source drug and Bona Fide Marketing. Specifically, a commenter suggested that a manufacturer might manipulate the policies by focusing marketing on new formulations and permitting biosimilar competition on the older formulation. The commenter suggested that CMS consider the formulations without a generic drug or biosimilar when considering spending for selection and after selection retain formulations that lack marketing. A couple of commenters expressed concern that generic entry for a minimally utilized dosage form and strength would mean the MFP no longer applies to highly utilized dosage forms and strengths that may not face generic competition and recommended CMS consider the share of utilization when evaluating whether Bona Fide Marketing is occurring. Another commenter suggested measuring utilization across the aggregated dosage forms and strengths may prolong the period the product is subjected to the negotiation process. Another commenter noted their support for CMS' approach to identifying qualifying single source drugs and the interplay with Bona Fide Marketing.

Response: We thank the commenters for their feedback. Consistent with our response to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, and with respect to a commenter's concern that competition on older formulations or specific dosage forms and strengths could result in a qualifying single source drug avoiding selection or being deselected, we acknowledge this, but for consistency, will continue to mirror the approach to aggregation across dosage forms and strengths of a drug for selection pursuant to section 1192(d)(3)(B) of the Act.

Comment: Many commenters stated that CMS lacks statutory authority to review Bona Fide Marketing to implement the statutory requirement of determining if a generic or biosimilar is ''approved and marketed'' or ''licensed and marketed'' under sections 1192(c) and (e) of the Act. Many commenters stated that ''marketing'' is already a term defined in the pharmaceutical industry, including by FDA and CMS. In addition, these commenters stated that any review of ''marketing'' for purposes of drug selection under section 1192(e) of the Act or deselection under section 1192(c) of the Act must be based on the first ''market date,'' consistent with the plain meaning of ''to market.'' One of these commenters noted this is consistent with the best meaning of the statute. Additionally, a commenter recommended CMS have manufacturers certify that the generic or biosimilar is marketed consistent with such definition. Some commenters recommended CMS withdraw proposed § 429.130. Many commenters recommended CMS utilize an alternative approach when evaluating Bona Fide Marketing, such as distinguishing between market entry

and patient access, and emphasized the importance of transparent and predictable standards. A couple of commenters stated that the FTC would regulate any areas of marketing concern. A few commenters raised concerns about the impact of CMS' review of Bona Fide Marketing on the biosimilar (including a request for a biosimilar delay) and generics markets. Additionally, some commenters suggested that CMS lacks statutory authority to monitor marketing after a drug/biological is determined ineligible for selection or is deselected. A commenter supported the approach, including the ongoing monitoring of selected drugs removed from selection.

Response: Consistent with our response to similar comments in Negotiation Program Guidance, the final guidance for initial price applicability year 2027, and proposed §§ 429.125(d), 429.130 and 429.135, section 1192 of the Act requires CMS to make a determination whether a generic drug or biosimilar ''is marketed'' in order to determine whether a listed drug/reference product should be selected as a qualifying single source drug or whether a selected drug should be deselected. The statute uses different terminology in section 1192 of the Act than in section 1860D–14B of the Act, which established the new Medicare Part D Drug Inflation Rebate Program. In the latter provision, the statute referred to the date that a drug is ''first marketed.'' The absence of similar terminology in section 1192 of the Act demonstrates that, for purposes of the Negotiation Program, a generic drug or biosimilar would have a continuing presence on the market in order to affect the status of a listed drug/reference product. Consistent with the purpose of the statute to lower prices for Medicare through negotiation or price competition, the statute contemplates that, in making this determination, we would consider whether meaningful competition exists on an ongoing basis between a listed drug or reference product and a generic drug or biosimilar. This determination requires more than solely token or de minimis availability of the products. For example, we are aware of situations in which a manufacturer of a brand name drug or biological product has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar. In the event only a nominal quantity of the generic drug or biosimilar enters the market, the generic drug or biosimilar would not be ''marketed'' within the meaning of that term as it is used in section 1192 of the Act. Given the Negotiation Program is targeted at single source drugs and biological products that have been on the market for some time, for which no generic drug or biosimilar competition currently exists, the statutory directive would not be met if a qualifying single source drug were to avoid selection or be removed from the selected drug list where generic drug or biosimilar availability is limited by the Primary Manufacturer. It is consistent with the purpose of the statute to avoid selection or remove a qualifying single source drug from the selected drug list only when there is evidence that the selected drug is subject to meaningful competition. For example, section 1192(e)(2)(A) of the Act provides that an ''authorized generic'' drug or biosimilar product ''shall be treated as the same qualifying single source drug.'' Although an authorized generic may appear to be competing with the reference drug, authorized generics are marketed by the brand name drug company or another company under the brand company's NDA, meaning that the relationship between the brand drug and its authorized generic is not meaningful competition. Whether such competition exists between a listed drug or reference product and a generic drug or biosimilar will depend on the totality of circumstances in existence at the time that we perform the function of evaluating whether a generic drug or biosimilar is subject to Bona Fide Marketing.

Comment: Some commenters raised concerns with using a ''totality of the circumstances'' approach to review Bona Fide Marketing as a vague standard that may vary by case, while a commenter shared support for the review of Bona Fide Marketing, and another commenter appreciated additional transparency. A commenter stated that CMS' previously stated concern that a manufacturer might ''launch into the market a token or de minimis amount of a generic drug or biosimilar for the selected drug and the manufacturer of that selected drug could claim that the MFP should no longer apply'' is not a scenario they are aware of ever happening with a biosimilar and a reference product.

Response: We thank commenters for sharing their specific observations of the market and feedback on potential scenarios for review. Consistent with our response to similar comments in Negotiation Program Guidance and the final guidance for initial price applicability year 2027 and as described at § 429.130(b), we reiterate that the determination whether an approved generic drug or licensed biosimilar is subject to Bona Fide Marketing on an ongoing basis is a totality-of-the circumstances inquiry that will not necessarily turn on any one source of data. Further, it is consistent with the purpose of the statute to avoid selection or remove a qualifying single source drug only when there is evidence that the selected drug is subject to meaningful competition and not just when there are ''any'' sales of the generic drug or biosimilar as suggested by a commenter. We are aware of situations in which a manufacturer of a brand name drug or biological product has entered into a market-limiting agreement with a manufacturer of a generic drug or biosimilar. In the event only a nominal quantity of the generic drug or biosimilar enters the market, the generic drug or biosimilar would not be ''marketed'' within the meaning of that term as it is used in section 1192 of the Act (for example, specifically within the context of marketed at section 1192(e) of the Act). We note that such a situation has not materialized to date because, in accordance with the statute and CMS' policies established in previous program guidance, such availability would not allow for a manufacturer to claim that the drug should be deselected and no longer subject to an MFP.

Comment: A few commenters shared feedback on the examples provided of when CMS may or may not consider Bona Fide Marketing to be occurring. A commenter stated that the modification to the second example to state CMS ''may'' consider Bona Fide Marketing to be occurring rather than ''will'' introduces additional uncertainty to the example. A couple of commenters raised concerns that the examples do not provide sufficient predictability to manufacturers of the Bona Fide Marketing standard. A commenter disagreed with the third example and recommended it be deleted—according to this comment, this example would result in the wrong outcome where a particular biosimilar has recently launched, for example, at risk or based on a settlement without any patent litigation proceedings as to its biosimilar (notwithstanding the existence of other patent disputes as to biosimilars of the same reference product), but PDE, AMP, and ASP sales do not yet reflect the launch.

Response: We thank commenters for their feedback. The examples provided in section II.B.6. of the proposed rule (91 FR 36266) are for illustrative purposes only to provide interested parties with some instances of how certain factors might weigh in favor of, or against, consideration of Bona Fide Marketing. CMS endeavored to provide

examples both for a drug payable under Part B and a drug covered under Part D, along with including the availability of differing factors in the scenarios. In response to the commenter's feedback on the third example, in its review for Bona Fide Marketing CMS considers whether meaningful competition exists on an ongoing basis between a listed drug or reference product and a generic drug or biosimilar and, therefore, a biosimilar with no utilization or one that has yet to be launched due to pending patent litigation, may not be considered subject to Bona Fide Marketing because there is no current distribution of the biosimilar and there are potential barriers to its future distribution. However, we reiterate, as stated in section II.B.6. of the proposed rule (91 FR 36263), that CMS' ultimate consideration will be based on the totality of the circumstances and not on the presence, or absence, of any single factor.

Comment: A commenter appreciated the clarifications on timing for review of Bona Fide Marketing offered in the proposed rule. A commenter expressed concerns with CMS' proposal to review up to 12 months of data and stated ordinary data lags may not reflect a recent launch and expressed concerns about the implications for timing of deselection. A commenter recommended CMS consider real-world evidence to consider the practical availability of a generic or biosimilar. A couple of commenters supported CMS' efforts to review additional data sources and recommended CMS consider additional data sources, such as listings in pharmaceutical compendia and Drugs@FDA. The other commenter recommended CMS adopt monthly review for all selected drugs. A couple of commenters recommended CMS conduct reviews more often than monthly, ensure data sources are updated frequently, and allow manufacturers to request review. Another commenter recommended CMS maintain monthly reviews and prompt notification throughout the negotiation period. A commenter recommended CMS conduct the biannual review earlier to allow MA plans and Part D sponsors additional time for plan sponsor bids. A commenter recommended CMS conclude the March review as soon as practicable. Another commenter recommended CMS announce in March and October decisions based on data collected through February and September, respectively, and emphasized the importance of this timing for the March review due to plan sponsor bids.

Response: We thank commenters for their suggestions related to additional data sources with timely utilization data for drugs payable under Part B and/or covered under Part D. We may consider additional data sources to review utilization as available. We clarify in this response to comments that additional data sources may include, for example, MA encounter data (subject to data use and release limitations in 42 CFR 422.310(f)) or OM Part B claims. Consideration of Bona Fide Marketing is based on a review of the totality of the circumstances. Therefore, an uptick in the data alone is not determinative of whether Bona Fide Marketing is occurring. We direct commenters to the additional relevant factors specified in § 429.130, which include, for example, whether the approved generic drug or licensed biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and an approved generic drug or licensed biosimilar manufacturer limit the availability or distribution of the approved generic drug or licensed biosimilar.

We appreciate the commenter's concern about data lags that may not reflect the recent launch of a product. We recognize that the timing for CMS to pull data and compile materials for review may include data covering an earlier time period for lagged data sources. We are finalizing our policy as proposed at § 429.130(a) with modifications at § 429.130(a)(1)(i) through (iii) to clarify the information considered in CMS' review of Bona Fide Marketing, specifically that CMS evaluates the most recent 12 months of PDE data, 12 months of AMP data and 4 quarters of ASP data, as applicable, available to the agency when CMS conducts its review and that the period of such data to be reviewed need not end with the last ''full month'' or ''full quarter'' of data available. Additionally, we clarify in § 429.130(a)(1)(iv) that CMS may evaluate sales and utilization data for the generic drug or biosimilar for the most recent 12 months, 4 quarters, or 52 weeks of a data source, if available and as applicable to such data source, other than those data sources listed in paragraph (a)(1)(i) through (iii) of this section including, but not limited to, Medicaid State Drug Utilization Data and data from nationally representative and commercially available databases, available to CMS at the time CMS reviews such data consistent with paragraph (c) of § 429.130. This modification provides CMS with the flexibility to include data from sources that are updated on a weekly basis so as to not artificially limit the agency's consideration of sales and utilization data that are updated at an interval not included in the proposed rule.

We appreciate commenter feedback on the timing of review. We proposed in § 429.130(c)(6) that we would conduct our review biannually in March and October, starting in October of the calendar year after CMS and the Primary Manufacturer reached an agreement on an MFP for the initial price applicability year for which the drug was selected originally for negotiation and until CMS determines that a selected drug meets the requirements at § 429.135(a) to cease being a selected drug. The review in March enables us to determine any selected drugs that must be deselected by the following January. Additionally, we understand that manufacturers, plan sponsors, and other relevant parties may begin negotiations for Part D plan bids more than a year prior to the plan year and CMS' deadline for Part D sponsor bids (see § 423.265(b)). Therefore, we proposed to review in October to ensure manufacturers and Part D plan sponsors are aware prior to the subsequent June due date for Part D plan sponsors to provide CMS with any required plan bids for the next Medicare plan contract year (as indicated in § 423.265(b)(1)) of any selected drugs that may be deselected. We proposed in § 429.130(c)(4) and (5) to conduct monthly reviews during the negotiation and renegotiation period, respectively, because monthly reviews during these periods enable us to promptly determine any selected drugs that are no longer subject to the negotiation or renegotiation process, as applicable. We proposed in § 429.130(c)(1) and (3) to review annually in January to identify potential qualifying single source drugs and any selected drugs ineligible for renegotiation, respectively, prior to the selected drug publication date. After any determination in which CMS finds a generic drug was approved or a biosimilar was licensed and such generic or biosimilar is subject to Bona Fide Marketing, CMS engages in periodic reviews to monitor that meaningful competition exists on an ongoing basis between a listed drug or reference product and a generic drug or biosimilar as contemplated by the statute. We believe the timing of the review articulated here allows the agency to consider the most recent available information for considering whether an approved generic or licensed biosimilar is subject to Bona

Fide Marketing in accordance with key dates for the Negotiation Program or the submission of Part D plan bids, and thus we decline to alter or conduct more frequent reviews. We believe conducting more frequent reviews would be administratively infeasible at this time and altering the timing of the review to announce decisions earlier would result in less information being available for determining whether a generic drug was approved or a biosimilar was licensed and such generic or biosimilar is subject to Bona Fide Marketing by the key dates previously articulated.

Comment: A commenter requested, based on the commenter's reading of section 1192(c)(1) of the Act, confirmation that, for a selected drug from initial price applicability year 2029, if a generic or biosimilar is approved and marketed by March 31, 2028, the MFP is no longer applicable beginning January 1, 2029.

Response: Consistent with Table II.B1, if CMS determines that as of a date between November 2, 2027 through March 31, 2028, a generic drug or biosimilar is approved or licensed, as applicable, and such generic drug or biosimilar is subject to Bona Fide Marketing for a drug selected for initial price applicability year 2029, the MFP would apply for initial price applicability year 2029 and the selected drug would cease to be a selected drug on January 1, 2030. In other words, the selected drug remains a selected drug and MFP applies for initial price applicability year 2029; the selected drug ceases to be a selected drug on January 1, 2030.

Final Decision: After consideration of public comments, we are finalizing §§ 429.125(d) and 429.135 as proposed, and we are finalizing the policy as proposed at § 429.130 with certain modifications as described later in this section. We also are clarifying as described in section II.B.6 of the proposed rule (91 FR 36264) that CMS has included revisions to more uniformly describe reviews about whether any approved generic drug(s) or licensed biosimilar(s) are subject to Bona Fide Marketing, including the timing of such reviews, as a matter of consistency. As stated previously, we are finalizing our policy as proposed at § 429.130(a) with modifications at § 429.130(a)(1)(i) through (iii) to clarify the information considered in CMS' review of Bona Fide Marketing, specifically that CMS evaluates the most recent 12 months of PDE data, 12 months of AMP data and 4 quarters of ASP data, as applicable, available to the agency when CMS conducts its review and that the period of such data to be reviewed need not end with the last ''full month'' or ''full quarter'' of data available. Additionally, we clarify in § 429.130(a)(1)(iv) that CMS may evaluate sales and utilization data for the generic drug or biosimilar for the most recent 12 months, 4 quarters, or 52 weeks of a data source, if available and as applicable to such data source, other than those data sources listed in paragraph (a)(1)(i) through (iii) of this section including, but not limited to, Medicaid State Drug Utilization Data and data from nationally representative and commercially available databases, available to CMS at the time CMS reviews such data consistent with paragraph (c) of § 429.130. This modification provides CMS with the flexibility to include data from sources that are updated on a weekly basis so as to not artificially limit the agency's consideration of sales and utilization data that are updated at an interval not included in the proposed rule. We are also clarifying in this preamble that other available data sources may include, for example, MA encounter data and OM Part B claims.

Consistent with the modifications made to § 429.130(a)(1)(i) described previously, we are clarifying the example included in the preamble of the proposed rule regarding CMS' review in October to mean that CMS would review PDE data reported from mid-October of the prior calendar year through mid-October of the current calendar year. The clarification of this example is consistent with CMS' process as described in the Negotiation Program Guidance.

We are finalizing as proposed our proposal at § 429.130(a)(2) and (3) with clarification that CMS considers whether an approved generic drug or licensed biosimilar is marketed as described in § 429.130 based on CMS' evaluation of certain information, including information related to additional factors available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section and that CMS may also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar including sales and utilization data for the generic drug or biosimilar not otherwise captured by paragraphs (a)(1)(i) through (iv).

We are finalizing our policy as proposed at § 429.130(b) without modification. We are finalizing our proposal at § 429.130(c) with modifications to change the title from ''Timing for CMS review of Bona Fide Marketing'' to ''Timing'' and to remove ''that is available.'' We also are making modifications at § 429.130(c)(4) and (c)(5) that for drugs selected for negotiation and renegotiation (if any) for an initial price applicability year, we would review the information set forth in proposed § 429.130(a) on a monthly basis starting in March of the calendar year of the negotiation period (or renegotiation period, as applicable) until the earlier of either: (1) November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for negotiation (or renegotiation, as applicable) or (2) the date as of which CMS determines that a selected drug meets the requirements at § 429.135(b)(1) or § 429.135(b)(2) to cease being subject to the negotiation or renegotiation process, as applicable.

Consistent with the clarifications we provided about the timing of our review in this final rule using the example of a selected drug for initial price applicability year 2029 when we conduct our review in March 2027, we are clarifying in this preamble the timing for our review of Bona Fide Marketing as proposed in § 429.130(c)(4) and (c)(5). Pursuant to these provisions, we will conduct monthly reviews starting in March of the negotiation period (or renegotiation period, as applicable) until November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for negotiation (or renegotiation, as applicable) unless CMS determines as of an earlier date that the selected drug meets the requirements at § 429.135(b)(1) or (b)(2), as applicable, to cease being subject to the negotiation or renegotiation process, as applicable. As described previously, CMS' review refers to the timing for CMS to pull data and compile materials for review which, for lagged data sources, may include data covering an earlier time period. For reviews conducted pursuant to § 429.130(c)(4)(i) or § 429.130(c)(5)(i), CMS clarifies that CMS may pull data from certain sources one or more days prior to November 1 for circumstances in which CMS anticipates the information to be identical to a data pull on November 1. In certain circumstances, CMS may pull data on November 1. However, as previously described, CMS' review and analysis of the data may continue into the next month such that, for reviews conducted in accordance with § 429.130(c)(4)(i) or § 429.130(c)(5)(i), CMS pulls the data and compiles the materials on or before November 1 and continues review of the data into November prior to announcing whether a selected drug ceases to be

subject to the negotiation process or renegotiation process, as applicable, consistent with § 429.135(b)(1) or (b)(2), as applicable, because CMS determined as of November 1, the selected drug has a generic drug that is approved or a biosimilar that is licensed, and such generic drug or biosimilar is subject to Bona Fide Marketing.

We are finalizing § 429.135 as proposed.

C. Negotiation Program Agreement (§§ 429.200 Through 429.210)

1. Entrance Into an Agreement With CMS (§ 429.200)

Section 1193(a) of the Act directs CMS to enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than February 28 following the selected drug publication date and provides for certain requirements of such agreements. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 40.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of ''manufacturer'' established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate, or renegotiate, as applicable, an MFP with ''the manufacturer'' of the selected drug. To the extent that more than one entity meets the definition of manufacturer for a selected drug for purposes of initial price applicability year 2029 and subsequent years, we would designate the entity that holds the NDA(s)/BLA(s) for the selected drug to be ''the manufacturer'' of the selected drug, hereinafter referred to as the ''Primary Manufacturer'' (as defined in proposed § 429.20). We would refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either: (1) is listed as a manufacturer in an NDA or BLA for the selected drug; or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer but is not listed on the NDA or BLA, as a Secondary Manufacturer (as defined in proposed § 429.20). Consistent with sections 1193(a)(4) and 1193(a)(5) of the Act, and as described in part 429, the Primary Manufacturer of a selected drug that enters into a Negotiation Program Agreement must collect and report all necessary information applicable to the selected drug, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer. Likewise, as the entity that is party to the Negotiation Program Agreement, the Primary Manufacturer will be solely responsible for compliance with all provisions of the Negotiation Program Agreement and will be accountable for ensuring compliance with respect to units of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer.

With respect to initial price applicability year 2029 and subsequent years, consistent with the policies for implementation as described in section 40.1 of the Negotiation Program Guidance, proposed § 429.200 establishes the Negotiation Program Agreement and the requirements of which a willing Primary Manufacturer is subject to upon executing a Negotiation Program Agreement with CMS. We would not enter into a Negotiation Program Agreement with any Secondary Manufacturer of a selected drug with respect to that selected drug. In accordance with section 1193(a) of the Act, as proposed in § 429.200(a)(1), the deadline for a Primary Manufacturer to enter into a Negotiation Program Agreement is 11:59 p.m. Pacific Standard Time (PST) on February 28 following the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation. We proposed at § 429.200(a)(2) that the negotiation period would begin on the earlier of two dates: (1) February 28 of the year of the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation; or, (2) the date that the Negotiation Program Agreement is fully executed by 11:59 p.m. PST. The Negotiation Program Agreement would be executed on the day that the last party to sign the Negotiation Program Agreement signs the Negotiation Program Agreement and would be in effect until terminated in accordance with proposed § 429.205(a).

We have established a model Negotiation Program Agreement in accordance with section 1193(a) of the Act. A Primary Manufacturer's obligation to make the MFP available applies during the entirety of the selected drug's price applicability period for which the manufacturer has a Negotiation Program Agreement in place. At proposed § 429.200(b), consistent with the provisions of such model Negotiation Program Agreement, we proposed to codify requirements that a willing Primary Manufacturer will agree to comply with upon execution of the Negotiation Program Agreement, namely: (1) to comply with all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including in part 429, implementing those provisions and any changes to the Act that affect the Negotiation Program; (2) to negotiate to determine an MFP for the selected drug with CMS, during the negotiation period for the initial price applicability year for the selected drug, in accordance with section 1194 of the Act, including as described in subpart F of this part (as described in II.F. of this final rule); (3) as applicable, to renegotiate to determine an MFP for the drug selected for renegotiation with CMS, during the renegotiation period for the initial price applicability year for the drug selected for renegotiation, in accordance with section 1194 of the Act, including as described in subpart G of this part (as described in II.G. of this final rule); (4) to provide access to the MFP, including as renegotiated, with respect to the selected drug, during the selected drug's price applicability period, in accordance with section 1193(a)(3), including as described in subpart B and subpart I of this part (as described in II.B. and II.I. of this final rule); (5) to submit to CMS, in a form and manner specified by CMS, the information specified in sections 1191 to 1198 of the Act, the Negotiation Program Agreement, or this part, including but not limited to, the information as specified at §§ 429.100(d), 429.405, 429.505(b), and, if applicable, § 429.615(b)(1) (as described in sections II.B.1., II.E.2., II.F.2., and if applicable, section II.G.4. of this final rule), in accordance with sections 1193(a)(4) and 1193(a)(5) of the Act; and (6) to comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, in accordance with section 1193(a)(5) of the Act, including as described in subpart J of this part (as described in section II.J. of this final rule).

Consistent with policies for implementation as described in section 40.1 of the Negotiation Program Guidance, we proposed in § 429.200(c) that the Negotiation Program Agreement must be signed by an Authorized Representative of the Primary Manufacturer as defined in proposed § 429.20 and by CMS. In § 429.20, we proposed that an Authorized Representative of the Primary Manufacturer must be the Primary

Manufacturer's Chief Executive Officer (CEO), Chief Financial Officer (CFO), an individual with equivalent authority to a CEO or CFO, or an individual that has been granted delegation of signature authority on behalf of one of these categories of individuals. We also proposed in § 429.20 that the Authorized Representative(s) of the Primary Manufacturer must be legally authorized to bind the Primary Manufacturer to the terms and conditions contained in the Negotiation Program Agreement, including any Addenda. CMS would specify a form and manner to access and sign the Negotiation Program Agreement as indicated in proposed § 429.200(c). Consistent with prior initial price applicability years, we intend to continue to use the CMS Health Plan Management System (''the CMS HPMS'') for electronic access and signing of the Negotiation Program Agreement. Specifically, to make a request to obtain electronic signature access via the CMS HPMS, an Authorized Representative of the Primary Manufacturer must prepare an official letter that states the user's name(s), role(s) (for example, Chief Executive Officer), CMS user ID, the P number that would be used for CMS and the Primary Manufacturer to interact for the purposes of the Negotiation Program related to the relevant selected drug, and that electronic signature access is required. We note that it is a requirement of the CMS HPMS that the person accessing the CMS HPMS have a Social Security Number (SSN), among other requirements, to meet the identity proofing requirements for system access.

Consistent with policies for implementation as described in section 40.1 of the Negotiation Program Guidance, we proposed in § 429.200(d) that the Negotiation Program Agreement will take effect on the date that the Negotiation Program Agreement is signed both by an Authorized Representative of the Primary Manufacturer and by CMS. The term of the Negotiation Program Agreement shall be from the effective date until the Negotiation Program Agreement is terminated in accordance with § 429.205(a). As proposed in § 429.200(e), the Primary Manufacturer and CMS will formalize the agreement to an MFP through the execution of an Addendum to the Negotiation Program Agreement. The Addendum to the Negotiation Program Agreement will be made available to the Primary Manufacturer in a form and manner specified by CMS and must be signed by an Authorized Representative of the Primary Manufacturer and CMS. Instructions for completing the Negotiation Program Agreement and a template of the Negotiation Program Agreement are available on the CMS website.[72]

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed the requirement for Primary Manufacturers to report data of Secondary Manufacturers, such as NDCs, and expressed concerns regarding the distinction between Primary and Secondary Manufacturers as it relates to the Negotiation Program Agreement. One of these commenters stated the use of ''manufactured, marketed, controlled, or sold'' adds ambiguity to the scope of information to be reported. Another commenter recommended CMS allow the Primary Manufacturer or Secondary Manufacturer to determine which should enter into an agreement with CMS. A couple commenters recommended CMS clarify that Primary Manufacturers not be held accountable for noncompliance with the Negotiation Program Agreement based on third party actions outside the manufacturer's control.

Response: As discussed in CMS' response in Negotiation Program Guidance and in the final guidance for initial price applicability year 2027, given that section 1193(a)(1) of the Act instructs CMS to negotiate with ''the manufacturer'' to arrive at the MFP for a given selected drug to which ''the manufacturer'' would provide access in accordance with the statute, and given that the term ''the manufacturer'' appears repeatedly throughout the statutory provisions establishing the Negotiation Program, the best statutory interpretation is to interpret the term ''manufacturer'' as a single entity for the negotiation process, responsible for negotiation of a single MFP for a given selected drug. Thus, in accordance with section 1193(a)(1) of the Act and other statutory references to ''the manufacturer,'' CMS will enter into a Negotiation Program Agreement with ''the manufacturer'' of a selected drug, where ''the manufacturer'' is the NDA/BLA holder. CMS has adopted the designations of ''Primary Manufacturer'' and ''Secondary Manufacturer,'' respectively, to establish a process to negotiate the maximum fair price with ''the manufacturer'' to align with the meaning of the statutory language and establish responsibilities and requirements of the Primary Manufacturer related to data collection and submission and MFP availability for the selected drug sold by the Secondary Manufacturer(s).

Consistent with sections 1193(a)(3) through 1193(a)(5) of the Act, and as described in part 429, the Primary Manufacturer of a selected drug that enters into a Negotiation Program Agreement must collect and report all necessary information applicable to the selected drug, and must provide access to the MFP for the selected drug, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer. The use of the ''manufactured, marketed, controlled, or sold by a Secondary Manufacturer'' language is intended to clarify and standardize the scope of the selected drug for which the Primary Manufacturer is responsible for data collection and submission and MFP availability.

Therefore, as the entity that is party to the Negotiation Program Agreement, in accordance with section 1193(a) of the Act, the Primary Manufacturer will be solely responsible for compliance with all provisions of the Negotiation Program Agreement and will be accountable for ensuring compliance with respect to units of the selected drug, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer.

Final Decision: After consideration of public comments, we are finalizing § 429.200 as proposed, but with a clarifying change to § 429.200(c) to add ''as defined in § 429.20'' after Authorized Representative of the Primary Manufacturer.

2. Termination (§ 429.205)

Section 1193(b) of the Act requires that, when the Primary Manufacturer enters into the Negotiation Program Agreement described in proposed § 429.200, the Negotiation Program Agreement will remain in effect, including through renegotiation, as applicable, until the selected drug is no longer a selected drug consistent with CMS' determination in accordance with section 1192(c) of the Act (as described in proposed § 429.135 and section II.B.7. of this final rule). With respect to 2026 through 2028, CMS implemented these requirements in section 40.6 of the Negotiation Program Guidance. With respect to initial price applicability year

[72] See ''Instructions for this Agreement'' and the ''Medicare Drug Price Negotiation Program Agreement'' at *https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-negotiated-prices.*

2029 and subsequent years, consistent with the policies for implementation as described in section 40.6 of the Negotiation Program Guidance, we proposed at § 429.205 that when the Primary Manufacturer enters into the Negotiation Program Agreement described in proposed § 429.200, the Negotiation Program Agreement will remain in effect, including through renegotiation, as applicable, until the selected drug is no longer a selected drug consistent with CMS' determination in accordance with section 1192(c) of the Act (as described in proposed § 429.135 and section II.B.7. of this final rule) unless the Negotiation Program Agreement is terminated sooner by the Primary Manufacturer under the process established in proposed § 429.205(b).

Participation in the Negotiation Program is voluntary. And so, in accordance with section 1193(a)(5) of the Act, a Primary Manufacturer may terminate its Negotiation Program Agreement with respect to a selected drug with respect to a price applicability period, before reaching an agreement with CMS as to the MFP for the selected drug or after such an MFP is agreed to, if the Primary Manufacturer meets certain conditions for termination consistent with the provisions in 26 U.S.C. 5000D(c). Specifically, a Primary Manufacturer seeking to terminate its Negotiation Program Agreement with respect to a selected drug must submit to CMS a Request to Terminate, as defined in proposed § 429.20, that meets all requirements established in proposed § 429.205(b)(1). Section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program, the Coverage Gap Discount Program,[73] and the Manufacturer Discount Program. The provisions enacted in 26 U.S.C. 5000D give the Primary Manufacturer choices with regard to the Negotiation Program. One option is that the Primary Manufacturer may participate in the Negotiation Program. Another option is that the Primary Manufacturer may opt out of the Negotiation Program, and the excise tax may be imposed under 26 U.S.C. 5000D. Alternatively, the Primary Manufacturer may opt out of the Negotiation Program but avoid the excise tax on sales of the selected drug during periods for which the Primary Manufacturer does not have applicable program agreements, as defined in proposed § 429.20, with the aforementioned Medicare and Medicaid programs and none of its drugs are covered by an agreement under the Manufacturer Discount Program under section 1860D–14C of the Act. Promoting continuity in the administration of the Negotiation Program warrants extending parallel options to a Primary Manufacturer with respect to potential CMP liability, as described in proposed subpart K and section II.C.10. of this final rule. A Primary Manufacturer with a Negotiation Program Agreement with respect to the price applicability period with respect to a selected drug may opt out of the Negotiation Program and pay CMPs associated with violations of program requirements. Alternatively, a Primary Manufacturer seeking to cease participation in the Negotiation Program through the end of the price applicability period for a selected drug may avoid civil monetary penalty liability by terminating its Negotiation Program Agreement if it also ceases participation in the Medicaid Drug Rebate Program and the Manufacturer Discount Program through the end of the price applicability period for the selected drug.

In proposed § 429.205(a)(1) and (a)(2), we proposed the processes by which termination from the Negotiation Program may occur. Specifically, we proposed that a Negotiation Program Agreement will terminate effective as of the date of the earlier of: (1) The first date that the selected drug covered by the Negotiation Program Agreement is no longer a selected drug consistent with CMS' determination in accordance with section 1192(c) of the Act as described at § 429.135; or (2) The date of termination established in proposed § 429.205(b)(5) in connection with a Request to Terminate by the Primary Manufacturer submitted under proposed § 429.205(b), that is, absent a Primary Manufacturer request to rescind its Request to Terminate in accordance with proposed § 429.205(d), the first date following the receipt of a Request to Terminate that CMS determines none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program in accordance with 42 CFR 423.2752(c)(1).

In proposed § 429.205(b)(1), in accordance with section 1193(a)(5) of the Act, CMS proposed that a Primary Manufacturer that wishes to terminate a Negotiation Program Agreement may submit in writing a Request to Terminate, in a form and manner specified by CMS, which must include both: (1) a request for termination of the Primary Manufacturer's applicable program agreements under the Medicaid Drug Rebate Program and the Manufacturer Discount Program, consistent with the requirements as set forth in 26 U.S.C. 5000D(c)(1)(A)(i); and, (2) an attestation that through the end of the price applicability period for the selected drug, the Primary Manufacturer: (i) shall not seek to enter into any subsequent applicable program agreement; and (ii) shall not seek coverage for any of its drugs under the Manufacturer Discount Program under section 1860D–14C of the Act, consistent with the requirements as set forth in 26 U.S.C. 5000D(c)(1)(B). In proposed § 429.205(f), CMS proposed that a Primary Manufacturer that terminates in accordance with proposed § 429.205(b) and later seeks to re-enter any applicable program agreement or obtain coverage for any of its drugs under the Manufacturer Discount Program during the selected drug's price applicability period would be deemed to have provided an invalid attestation that was a condition of termination, and the Negotiation Program Agreement would once again become operative as of the date of re-entry into the applicable program agreement(s) or coverage for any of the Primary Manufacturer's drugs under the Manufacturer Discount Program. If a Primary Manufacturer terminated its Negotiation Program Agreement pursuant to the process described at § 429.205(b)(1) prior to completing the negotiation process and agreeing to an MFP, and such Primary Manufacturer later sought to re-enter any applicable program agreement or obtain coverage for any of its drugs under the Manufacturer Discount Program, the negotiation process would be initiated or resumed in accordance with the negotiation process proposed in subpart F and section II.C.6. of this final rule. In addition, the timing of the Primary Manufacturer's decision to resume participation in the Negotiation Program may implicate the renegotiation process described in proposed subpart G and section II.C.7. of this final rule.

We proposed in § 429.205(b)(2) that if the Primary Manufacturer's notice of termination contains all required elements under proposed § 429.205(b)(1), CMS will confirm receipt of the Primary Manufacturer's notice and execute the actions with

[73] The CGDP, established under section 1860D–14A of the Act, remained in place through December 31, 2024. Because the IRA sunset the CGDP effective December 31, 2024 and all manufacturer CGDP agreements automatically terminated as of such date, CMS has removed references to the CGDP in discussion of Primary Manufacturer termination. CGDP requirements are codified in subpart W of 42 CFR part 423.

respect to termination of the Primary Manufacturer's applicable program agreements as described in the proposed § 429.205(b)(3), (b)(4), and (b)(5). As noted previously, section 11003 of the IRA expressly connects a Primary Manufacturer's financial responsibilities under the voluntary Negotiation Program to that manufacturer's voluntary participation in the Medicaid Drug Rebate Program and the Manufacturer Discount Program. As described in proposed § 429.205(b)(3), if a Primary Manufacturer determines after executing its Negotiation Program Agreement that it is unwilling to continue its participation in the Negotiation Program and provides a Request to Terminate that CMS determines complies with the requirements in proposed § 429.205(b)(1), the Primary Manufacturer's Request to Terminate will constitute good cause for CMS to terminate the Primary Manufacturer's applicable program agreement(s) under the Manufacturer Discount Program, as applicable, in accordance with section 1860D–14C(b)(4)(B)(i) of the Act and 42 CFR 423.2752(c)(1) of this chapter, and to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program in accordance with 42 CFR 423.2752(c)(1). CMS will automatically grant a Request to Terminate that complies with the requirements of proposed § 429.205(b)(1). Consistent with section 1860D–14C(b)(4)(B)(i) of the Act and 42 CFR 423.2752(c)(1) of this chapter, a termination of a Manufacturer Discount Program agreement by CMS will not be effective earlier than 30 calendar days after the date of notice from CMS to the manufacturer of such termination after CMS determines that the Primary Manufacturer's Request to Terminate complies with proposed § 429.205(b)(1). CMS has proposed codifying the established deadlines for the Negotiation Program in proposed subpart F, including the date by which CMS will provide the final offer to Primary Manufacturers, to provide a Primary Manufacturer with sufficient time to ensure all conditions for termination are met by the end of the negotiation period set forth in section 1191(b)(4)(B) of the Act.

As described in proposed § 429.205(b)(4), if CMS determines the Primary Manufacturer's Request to Terminate complies with the requirements in proposed § 429.205(b)(1), the Request to Terminate also will constitute good cause for CMS to terminate the Primary Manufacturer's applicable program agreement(s) under the Medicaid Drug Rebate Program in accordance with section 1927(b)(4)(B)(i) of the Act and the Medicaid National Drug Rebate Agreement (NDRA). CMS will automatically grant a Request to Terminate that complies with the requirements in proposed § 429.205(b)(1). The Primary Manufacturer's applicable program agreements include all the NDRAs of the Primary Manufacturer. Consistent with section 1927(b)(4)(B)(i) of the Act and the NDRA, such termination by CMS will not be effective earlier than 60 days after the date of CMS' notice to the Primary Manufacturer of such termination.

As discussed previously, in the proposed § 429.205(b)(5), unless a Primary Manufacturer rescinds its Request to Terminate in accordance with the proposed § 429.205(d), CMS will terminate the Negotiation Program Agreement effective on the first date following the receipt of a Request to Terminate that CMS determines complies with the requirements in proposed § 429.205(b)(1) on which none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program in accordance with 42 CFR 423.2752(c)(1).

Consistent with policies as described in section 40.1 of the Negotiation Program Guidance, § 429.205(c) proposed the process by which a Primary Manufacturer may decide not to execute a Negotiation Program Agreement with CMS and expedite its exit from the Manufacturer Discount Program to meet the conditions of 26 U.S.C. 5000D(c). As described in proposed § 429.200(a)(2), the negotiation period will begin on the earlier of two dates: (1) February 28 of the year of the selected drug publication date; or, (2) the date that the Negotiation Program Agreement is fully executed. If a Negotiation Program Agreement is not fully executed by February 28 following the publication of the selected drug list, a period will begin on March 1 of the year in which the selected drug list is published, during which the Primary Manufacturer could be exposed to potential excise tax liability, in accordance with 26 U.S.C. 5000D(b)(1). Section 429.205(c) proposed that a Primary Manufacturer that does not wish to participate in the Negotiation Program and that sought to avoid potential excise tax liability may submit to CMS in writing a Request to Terminate, in a form and manner specified by CMS, that meets the requirements described in proposed § 429.205(b)(1), consistent with the requirements set forth in 26 U.S.C. 5000D(c). In response to such a Request to Terminate, we proposed to take the steps described in § 429.205(b)(2) through (5), as applicable.

If a Primary Manufacturer decides not to execute a Negotiation Program Agreement with CMS, and follows the process proposed at § 429.205(c), and later enters into applicable program agreements or obtains coverage under the Manufacturer Discount Program for any of its drugs, but never executes a Negotiation Program Agreement, the tax suspension period described in 26 U.S.C. 5000D(c) will end. See 26 U.S.C. 5000D(c)(1)(B).

Section 429.205(d) proposed the process by which a Primary Manufacturer may rescind the Primary Manufacturer's Request to Terminate submitted pursuant to proposed § 429.205(b) or (c). A Primary Manufacturer may request to rescind the Request to Terminate by submitting to CMS a written request for a hearing, in a form and manner specified by CMS. If a Primary Manufacturer provides a Request to Terminate that complies with the requirements in proposed § 429.205(b)(1), in accordance with section 1860D–14C(b)(4)(B)(i) of the Act, upon written request to rescind from such Primary Manufacturer, we proposed to provide a hearing concerning termination of the Primary Manufacturer's applicable program agreements under the Manufacturer Discount Program. Such a hearing would be held prior to the effective date of termination of the applicable program agreements with sufficient time for such effective date to be repealed. Such a hearing would be held solely on the papers; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. CMS intends to automatically grant a request from the Primary Manufacturer to rescind its Request to Terminate.

Likewise, as proposed at § 429.205(d), if a Primary Manufacturer submits a Request to Terminate that CMS determines complies with the requirements in proposed § 429.205(b)(1), in accordance with section 1927(b)(4)(B)(i) of the Act, upon written request to rescind from such Primary Manufacturer, we proposed to provide a hearing concerning

termination of the Primary Manufacturer's applicable NDRA(s) under the Medicaid Drug Rebate Program. Such a hearing would be held prior to the effective date of termination of the applicable program agreements with sufficient time for such effective date to be repealed. Such a hearing would be held solely on the papers; because CMS' determination that there is good cause for termination depends solely on the Primary Manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its termination request prior to the effective date of the termination. We intend to automatically grant a request from the Primary Manufacturer to rescind its Request to Terminate. If a Primary Manufacturer's request to rescind termination of the applicable program agreements under the Manufacturer Discount Program and the Medicaid Drug Rebate Program is granted, the Primary Manufacturer's Request to Terminate will also be rescinded.

In proposed § 429.205(e), CMS proposed requirements about the effect of termination and the Primary Manufacturer's continuing responsibilities under the Negotiation Program Agreement. That is, we proposed that notwithstanding any termination of the Negotiation Program Agreement for a selected drug in accordance with either § 429.205(a)(1) or (a)(2), the Primary Manufacturer would continue to be responsible for making the MFP for the selected drug available, in accordance with subpart I, with respect to any unit of the selected drug dispensed, administered, or furnished prior to the effective date of termination under § 429.205(a). Also, we proposed that notwithstanding the termination of the Negotiation Program Agreement, any confidentiality, record retention, or data requirements and any requirements for Primary Manufacturer participation in audit and other Negotiation Program oversight activities shall continue to apply.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.205 as proposed.

3. Other Provisions of the Negotiation Program Agreement (§ 429.210)

With respect to initial price applicability year 2029 and subsequent years, consistent with policies for implementation as described in section 40.7 of the Negotiation Program Guidance, we proposed at § 429.210(a) to codify that if any provision of the Negotiation Program Agreement is found to be invalid by a court of law with competent jurisdiction, the Negotiation Program Agreement would be construed in all respects as if any invalid or unenforceable provision(s) were eliminated, and without any effect on any other provision. Further, as proposed at § 429.210(b), CMS retains the authority to amend the Negotiation Program Agreement to reflect changes in law, regulations, or guidance as applicable. When possible, CMS would give the Primary Manufacturer at least 60 days of notice of any change to the Negotiation Program Agreement.

In accordance with section 1193(a)(5) of the Act, consistent with policies for implementation as described in section 40.7 of the Negotiation Program Guidance, we proposed at § 429.210(c) to codify that if, after entering in a Negotiation Program Agreement with CMS, the Primary Manufacturer of a selected drug transfers ownership of one or more NDAs or BLAs, as applicable, of a selected drug to another entity, the Primary Manufacturer remains responsible for all requirements of the Negotiation Program Agreement associated with the transferred NDA(s) or BLA(s), including the requirement to provide access to the MFP as described in proposed subpart I, unless and until the Primary Manufacturer transfers all the NDAs or BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer. CMS proposed in § 429.210(c)(1)(ii) that the acquiring entity's assumption of responsibility as the new Primary Manufacturer must be evidenced by a novation to the transferring Primary Manufacturer's original Negotiation Program Agreement, which, as discussed later in this section, must be provided to CMS for review and approval at least 30 calendar days before the intended effective date of the transfer. In proposed § 429.210(c)(1)(ii), CMS also requires that the novation be signed by the transferring Primary Manufacturer and the acquiring entity and must include, at minimum, the legal name of the acquiring entity (which would be the new Primary Manufacturer), the effective date of the transfer of ownership of all transferred NDAs or BLAs of the selected drug that the transferring Primary Manufacturer holds and of the transfer of responsibility for all requirements of the Negotiation Program Agreement to the acquiring entity, a list of all transferring NDAs or BLAs of the selected drug, and agreement that the acquiring entity assumes all obligations and liabilities under the transferring Primary Manufacturer's Negotiation Program Agreement as the successor in interest.

We proposed at § 429.210(c)(2), that if the transferring Primary Manufacturer submits a novation agreement that meets the requirements proposed at § 429.210(c)(1)(ii), and is approved by CMS, the acquiring entity becomes the successor in interest to the transferring Primary Manufacturer's Negotiation Program Agreement and the Primary Manufacturer of the applicable selected drug as of the novation's effective date of the transfer of responsibility for all requirements of the Negotiation Program Agreement.

We proposed at § 429.210(c)(1)(ii), that the transferring Primary Manufacturer must provide CMS with documentation of the intended transfer of responsibility for all requirements of the Negotiation Program Agreement to the acquiring entity, in the form of a novation, at least 30 calendar days before the intended effective date of any such transfer, for CMS review and approval. We encourage Primary Manufacturers to consult with CMS regarding their potential novation before submission of the novation to CMS at least 30 calendar days before the intended effective date of any such transfer.

We proposed at § 429.210(c)(3) that the transferring Primary Manufacturer remains responsible for any outstanding Negotiation Program rebate liabilities related to the Biosimilar Delay under section 1192(f) of the Act unless, and until, such liabilities are transferred to the acquiring entity as the new Primary Manufacturer.

If the Primary Manufacturer of a selected drug transfers all NDAs or BLAs of the selected drug, and the acquiring entity assumes responsibility as the new Primary Manufacturer of the selected drug for purposes of the Negotiation Program, we recognize that this transfer of ownership could enable the original Primary Manufacturer to avoid potential excise tax liability for future sales, as well as render unnecessary the efforts by the original Primary Manufacturer to comply with the statutory suspension of the excise tax and the termination process for a Primary Manufacturer seeking to invoke the statutory suspension of the excise tax. We recognize that whether this transfer of ownership would have these impacts may depend on whether the transfer of the NDA(s) or BLA(s) was made to an entity that is not a related party and complied with relevant principles of tax law.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple commenters shared appreciation for the proposed novation agreement provision. A few commenters emphasized the importance of clarity regarding which entity is responsible for making the MFP available. A couple of these commenters recommended CMS implement specific safeguards to ensure continuity during a transfer in ownership. Some commenters expressed concern that the novation agreement may interfere with commercial transactions, goes beyond what is required by statute, and lacks specific standards, such as defined timelines and an appeals process. One of these commenters recommended new requirements be prospective only and not impact novation agreements for drugs selected for initial price applicability years 2026 through 2028.

Response: We appreciate commenters' feedback. We agree that promoting continuity during a transfer of ownership and ensuring clarity as to which entity is the Primary Manufacturer of a selected drug responsible for compliance with program requirements are important for successful implementation of the Negotiation Program. Consistent with these goals, the novation agreement provision at § 429.210(c) is intended to ensure that all parties to the Negotiation Program Agreement as well as interested parties know who is the Primary Manufacturer and on which date all of the obligations and liabilities under the Negotiation Program Agreement transfer to an acquiring entity as the successor in interest, including the obligation to provide access to the MFP. Consistent with the Negotiation Program Guidance and as described in § 429.210(c), the Primary Manufacturer of a selected drug remains responsible for all requirements of the Negotiation Program Agreement associated with transferred NDA(s) or BLA(s) of the selected drug, including the requirement to provide access to the MFP, unless and until the Primary Manufacturer transfers all NDA(s) or BLA(s) of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer in accordance with § 429.210(c). If the requirements of § 429.210(c)(1) are met and, as set forth in § 429.210(c)(2), if the transferring Primary Manufacturer submits a novation agreement that meets the requirements proposed at § 429.210(c)(1)(ii), and is approved by CMS, the acquiring entity becomes the successor in interest to the transferring Primary Manufacturer's Negotiation Program Agreement and the Primary Manufacturer of the applicable selected drug as of the novation's effective date of the transfer of responsibility for all requirements of the Negotiation Program Agreement.

A novation is a standard instrument by which the parties to an agreement may agree to update a party to such agreement to reflect an original signatory's successor in interest and memorialize the effective date on which the liabilities and obligations under the agreement transfer to the successor in interest. Accordingly, we disagree with commenters that § 429.210(c), which is consistent with the Negotiation Program Guidance and is intended to provide additional details related to the process by which such a novation would be effectuated, interferes with commercial transactions or goes beyond the statute. Section 1193(a) of the Act requires CMS to enter into an agreement with ''the manufacturer'' of a selected drug. If such Primary Manufacturer of a selected drug would like to transfer its NDA(s) or BLA(s) of the selected drug and its Negotiation Program Agreement, including the liabilities and obligations thereunder, to another entity, then § 429.210(c) provides the Primary Manufacturer with a process to do so in a manner that offers clarity and continuity, while ensuring there remains an agreement between CMS and ''the manufacturer'' in accordance with section 1193(a) of the Act.

Additionally, we have specified the requirements for such a novation agreement in § 429.210(c) and do not believe additional details are necessary. As discussed in the proposed rule, CMS encourages Primary Manufacturers to consult with CMS regarding their potential novation before submission to ensure that it meets the requirements of § 429.210(c), including specifying the effective date of such transfer and ensuring that the acquiring entity assumes all obligations and liabilities as the successor in interest. Consistent with the Negotiation Program Guidance, § 429.210(c)(1)(ii) requires at least 30 days' notice to ensure sufficient time for CMS, as the counterparty to the Negotiation Program Agreement, to review and, if approved, for all interested parties to prepare for the transfer of responsibilities, including the transferring and acquiring manufacturers, dispensing entities, Part B providers, and the MTF.

With respect to the commenter's recommendation regarding timing, we reiterate that these regulations are applicable to the Negotiation Program beginning with respect to initial price applicability year 2029 and will apply starting in 2029 with respect to the drugs selected for initial price applicability years of 2026, 2027, or 2028. Requirements for novation of the Negotiation Program Agreement for drugs selected for initial price applicability years 2026, 2027, and 2028 are currently set forth in guidance. As previously discussed, consistent with the Negotiation Program Guidance, § 429.210(c) is intended to provide additional details related to the process for transferring responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity. Prior to 2029, we still encourage Primary Manufacturers to consult with CMS regarding a potential novation before the required submission of the novation to CMS at least 30 calendar days before the intended effective date of any such transfer to ensure that all requirements are met.

Comment: A commenter recommended CMS require notice-and-comment rulemaking for substantive changes to the Negotiation Program Agreement, that such changes operate prospectively, that manufacturers receive at least 90-day notice, and that CMS identify whether future changes are binding, contractual, or non-binding.

Response: We appreciate the commenter's feedback. As described in § 429.210(b), CMS retains the authority to amend the Negotiation Program Agreement to reflect changes in law, regulations, or guidance as applicable. This provision is consistent with the existing Negotiation Program Agreement and is intended to ensure that the Negotiation Program Agreement remains up-to-date in the event of any future changes to law, regulation, or guidance, as applicable. Without such a provision, Negotiation Program Agreements between CMS and Primary Manufacturers would be at risk of including provisions that become out-of-date and inapplicable in the event of, for example, changes to the Negotiation Program statute. As stated in section IV(b) of the Negotiation Program Agreement, when possible, CMS will give the Primary Manufacturer at least 60 days' notice of any change to the Negotiation Program Agreement. We believe this timing is sufficient to provide the Primary Manufacturer with advance notice, but acknowledge that CMS may not be able to provide such notice in cases where changes in law, regulation, or guidance necessitate a more expeditious amendment to the Negotiation Program Agreement to ensure that the Negotiation Program Agreement accurately reflects the law.

We disagree with the commenter's recommendation that any changes to the Negotiation Program Agreement made pursuant to § 429.210(b) require notice-and-comment rulemaking. As previously discussed, CMS reserves the right to amend the Negotiation Program Agreement to ensure that it accurately and timely reflects changes in law, regulation, or guidance, as applicable. Since the Negotiation Program Agreement implements the requirements established for Primary Manufacturers by regulation in this final rule, interested parties have had the opportunity to comment on such requirements through the notice-and-comment process for this final rule.

As described in § 429.205(a), the Negotiation Program Agreement would be executed on the day that the last party to sign the Negotiation Program Agreement signs the Negotiation Program Agreement and would be in effect until terminated. Participation in the Negotiation Program is voluntary. A Primary Manufacturer's options with respect to declining to execute or terminating a Negotiation Program Agreement are discussed earlier.

Final Decision: After consideration of public comments, we are finalizing § 429.210 as proposed.

D. Program Administration (§ 429.300)

1. Confidentiality Policy and Data Use (§ 429.300)

Section 1193(c) of the Act directs CMS to consider manufacturer-submitted information that CMS deems proprietary to only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 40.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

We proposed at § 429.300(a) to codify the requirement that Primary Manufacturer submitted information that CMS deems proprietary would only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program and we proposed at § 429.300(b) to establish a confidentiality policy that would deem proprietary information, as described in proposed § 429.300(a), including trade secrets and confidential commercial or financial information, as confidential information exempt from disclosure if the information meets the requirements set forth under Exemption 3 or Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(3), (4)). We proposed that CMS would not disclose PHI or PII, except in accordance with applicable laws, where received by CMS as proposed in §§ 429.505 and 429.615 or information received by CMS in engagement with interested parties specified in §§ 429.515 and 429.620(e), as proposed in § 429.300(b)(1).

We proposed at § 429.300(c) to codify certain data elements submitted by a Primary Manufacturer of a selected drug proposed in §§ 429.405 and 429.505(b), or of a drug selected for renegotiation proposed in § 429.615(b)(1), as applicable, that shall be considered confidential information of the Primary or Secondary Manufacturer and would be deemed proprietary information by CMS, unless the information is publicly available. We proposed at § 429.300(c)(1) through 429.300(c)(5) that CMS would consider non-FAMP and associated non-FAMP data collection, research and development costs of the Primary Manufacturer for the selected drug, current unit costs of production and distribution of the selected drug, data on pending patent applications for the selected drug, and market data and revenue and sales volume for the selected drug in the United States as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. We would consider prior Federal financial support, approved patent information, exclusivities, and approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that are publicly available to be non-proprietary. Information submitted by a Primary Manufacturer to CMS on a particular data element as a part of the data submission in proposed §§ 429.405, 429.505, and 429.615, as applicable, and described in sections II.E.2., II.F.2., and II.G.4.b. of this final rule (which CMS anticipates collecting via the Drug Price Negotiation ICR) may include information that is non-proprietary because it is publicly available or does not represent trade secrets and confidential commercial or financial information, such as the introductory language within an explanation field of a data element. Additionally, we proposed in § 429.300(c)(6) that if a Primary Manufacturer submits a Common Technical File/Drug Master File/''drug dossier'' as a part of their submission, in accordance with proposed § 429.505(d)(3) or § 429.615(b)(1)(i) (if applicable), we would consider this to be proprietary information.

Finally, as a part of the Drug Price Negotiation ICR for data submissions in proposed §§ 429.505(b)(2) and (d)(3), and 429.615(b), as applicable, a Primary Manufacturer may indicate for CMS which information the Primary Manufacturer believes should be withheld from disclosure by CMS consistent with existing Federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA, and that are not included under proposed § 429.300(c) as data that must be deemed proprietary information by CMS.

A Primary Manufacturer may choose to publicly disclose information regarding its ongoing negotiations with CMS at its discretion. If a Primary Manufacturer discloses information that is made public regarding any aspect of the negotiation process prior to the explanation of the MFP being released by CMS, we reserve the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer. CMS would not publicly discuss ongoing negotiations with a Primary Manufacturer, otherwise. If a Primary Manufacturer chooses to disclose any material that is made public that CMS has previously deemed to be proprietary information of that Primary Manufacturer, CMS would no longer consider that specific material proprietary consistent with proposed § 429.300.

As proposed in § 429.705(b) (as described in section II.H.2. of this final rule), we proposed to make public the explanation for the MFP, which includes: the narrative explanation of the MFP; redacted information regarding the negotiation meetings, as applicable, including exchanges of offers and counteroffers, as applicable; and the redacted information submitted by a Primary Manufacturer in proposed in § 429.505(b)(2) or § 429.615(b)(1) (as described in section II.F.2. or II.G.4. of this final rule), as applicable, and the redacted information submitted by interested parties in proposed § 429.505(d)(3) or § 429.615(b)(3), as applicable. We proposed at § 429.300(d) that CMS must redact any information deemed proprietary or covered by the confidentiality policy described in § 429.300(a) and (b), including the publication of the MFP. The narrative explanation of the negotiation process would not include any information that CMS deemed to be proprietary information of the Primary Manufacturer, PHI or PII (defined in proposed § 429.20), or information that

is protected from disclosure under other applicable law that may have been submitted through a Primary Manufacturer's data submission or an individual's data submission. In advance of this public narrative, CMS may share certain aggregate or non-selected drug specific information, for example regarding status of the negotiation process or conclusion of negotiations without sharing any information that CMS deemed to be proprietary information of the Primary Manufacturer, PHI, PII, or information that is protected from disclosure under other applicable law. If the Primary Manufacturer chooses to disclose proprietary information prior to the explanation of the MFP, then it would not be redacted in the explanation of the MFP.

Within the explanation of the MFP, CMS may also make public high-level comments about the data submitted to CMS, as proposed in § 429.405 and proposed in §§ 429.505 or 429.615 (as applicable) that are determined to be proprietary, without sharing any PHI/PII or any proprietary information reported to CMS under section 1193(a)(4) of the Act for purposes of the negotiation. For example, CMS will not make public the research and development costs reported by a Primary Manufacturer, as CMS would treat that data as proprietary, but CMS may state ''the manufacturer has recouped its research and development costs.'' Any proprietary information obtained during an audit will also remain confidential, except as necessary to use that information in the course of a judicial enforcement proceeding.

As proposed in § 429.515(a)(5) and described in section II.F.4.a. of this final rule, CMS would prohibit audio or video recording of any negotiation meetings between CMS and a Primary Manufacturer. We would maintain written records of the negotiation process, including negotiation meetings, in compliance with applicable Federal law, including the Federal Managers Financial Integrity Act and the Federal Records Act. A Primary Manufacturer may maintain its own written record of the negotiation process.

We would retain all records pertaining to the Negotiation Program, including but not limited to records submitted by a Primary Manufacturer, in compliance with the Federal Records Act, as implemented by the CMS Policy for Records and Information Management.[74] Data submitted by Primary Manufacturers, as described in proposed in §§ 429.405, 429.505, and 429.615 (as applicable) would be classified as Bucket 3: financial records in the CMS Records Schedule and would be managed in accordance with the CMS Records schedule.[75]

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters requested CMS share additional information regarding the procedures used for protecting confidential information and proprietary information included in the information submitted by Primary Manufacturers. A few commenters suggested CMS develop and publish data privacy and security protection protocols and safeguards for storage and limited access by personnel and, for example, a notification process to Primary Manufacturers of use or disclosure of confidential information outside of the Negotiation Program. A couple of these commenters recommended CMS continue to allow manufacturers to indicate which information submitted they deem to be confidential or proprietary. One of these commenters recommended that CMS indicate that other non-public information related to research and development, such as FDA applications and approvals.

Response: We thank the commenters for their comments on safeguarding data submitted by manufacturers. Consistent with our response to similar comments in Negotiation Program Guidance, we reaffirm our commitment to protect sensitive and confidential data submitted by Primary Manufacturers and continue to acknowledge the importance of data security. Upon establishment of the Negotiation Program, starting with procedures and data related to initial price applicability year 2026, we implemented internal controls to ensure the safeguarding of these data and to provide select CMS staff with access that appropriately aligns with their role and duties. We include later in this section the information previously provided in response to similar comments received for initial price applicability years 2026, 2027, and 2028, and we believe this information is both adequate to detail the protocols and safeguards used in handling manufacturer-submitted data and, as discussed in further detail later in this section, is consistent with other CMS programs suggested by the commenters because of agency-wide CMS requirements. Over the course of the negotiation process, Primary Manufacturers will submit information to CMS via the CMS HPMS or, in some instances, an authorized secure platform such as Box. Box provides a secure way to share content and improve collaboration both within CMS and with outside entities. Box has been authorized as a High Federal Information and Security Modernization Act (FISMA) categorization, which means it can support the storage of all CMS data types, inclusive of PII, PHI, and agency sensitive information. Inviting collaborators through named email addresses of authorized individuals is the preferred method for this collaboration to help ensure the confidentiality and integrity of the content being shared. The CMS HPMS adheres to all applicable policies, procedures, controls, and standards required by HHS and CMS information security and privacy programs to ensure the confidentiality, integrity, and availability of manufacturer information and government information systems. The CMS HPMS system is the primary CMS system for exchange of information between CMS and Medicare Advantage and Medicare Prescription Drug Plans, and as such is designed to receive and keep confidential proprietary and commercially sensitive information. As required by CMS, the CMS HPMS integrates security into every aspect of the system development life cycle. The CMS HPMS is subject to the agency's Security Assessment and Authorization (SA&A) process, a rigorous methodology during which the system must demonstrate a sound and comprehensive information security posture. To achieve and maintain an Authority to Operate (ATO), the CMS HPMS routinely undergoes system penetration testing as well as a Security Control Assessment (SCA), where independent auditors perform a detailed assessment to ensure that the system's security controls meet the CMS Acceptable Risk Safeguards (ARS). An individual must apply for and obtain a CMS-issued user account and password to access the CMS HPMS. In addition to the CMS issued user ID and password, internal CMS staff must use an HHS identification badge (referred to as a ''PIV card'') when accessing the website on the CMS network, while all users accessing the system from outside of the CMS network must use multi-factor authentication. The CMS HPMS further employs role-based access, ensuring that each user is granted access only to those functions required by their position. The CMS HPMS is hosted at a CMS approved cloud service provider. The

[74] See: *https://www.cms.gov/files/document/cms-records-management-policy-2022.pdf.*

[75] See: *https://www.cms.gov/medicare/regulations-guidance/guidance.*

system is protected by a suite of firewall and intrusion detection services, including Akamai Content Delivery Network (CDN), which serves as an additional web application firewall that offers robust distributed denial of services protection and access control. The CMS HPMS utilizes a multizone architecture comprised of a presentation zone, an application zone, and a data zone, designed to provide further defense against security attacks. CMS will employ encryption at rest in the database for sensitive manufacturer data (for example, proprietary information, including trade secrets and confidential commercial or financial information) in addition to encryption in transit. The CMS HPMS adheres to the CMS Information Security Incident Handling Procedures, which are supplemented by the CMS HPMS Security Incident Handling Procedures. These documents outline the procedures for managing known or suspected security or privacy incidents, including, but not limited to, roles and responsibilities, escalation procedures, and guidelines for notifying impacted individuals or organizations. CMS may provide additional information regarding record retention and destruction of section 1194(e) data collected and stored in the CMS HPMS in future rulemaking or in updates to the CMS Record Management Policy, as appropriate. Additionally, as described in section II.D.I of the proposed rule (91 FR 36273), as a part of the Drug Price Negotiation ICR for data submissions in §§ 429.505(b)(2) and (d)(3), and 429.615(b), as applicable, a Primary Manufacturer may indicate for CMS which information the Primary Manufacturer believes should be withheld from disclosure by CMS consistent with existing Federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA, and that are not included under § 429.300(c) as data that must be deemed proprietary information by CMS.

Comment: A couple of commenters supported the confidentiality policy as described in § 429.300(b) but asked CMS to confirm if the Negotiation Program also maintains the confidentiality of information protected against disclosure under all other applicable privacy and confidentiality laws.

Response: Consistent with our response to similar comments in the Negotiation Program Guidance, section 1193(c) of the Act requires that information submitted to CMS by the manufacturer of a selected drug that is proprietary information, as determined by CMS, shall be used only by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. We are committed to protecting confidential and proprietary information obtained from manufacturers throughout the negotiation process. In addition, CMS is also committed to protecting information that is obtained from Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA–PDs) plans that will inform the negotiation and renegotiation processes. For initial price applicability year 2029, as described in § 429.300, CMS will treat information on non-Federal Average Manufacturer Price (non-FAMP) as proprietary, as well as treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with sections 1194(e)(1) and 1194(e)(2) of the Act as proprietary, if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer that meets the requirements set forth under Exemptions 3 and/or 4 of FOIA (5 U.S.C. 552(b)(3), (4)). In addition to the protections under the FOIA for trade secrets and commercial or financial information obtained from a person that is privileged or confidential, the Trade Secrets Act at 18 47 U.S.C. 1905 requires executive branch employees to protect trade secrets and certain other information from disclosure unless authorized by law. We understand commenters' concerns pertaining to the confidentiality of proprietary information and will protect confidential and proprietary information as required by applicable law. However, if a Primary Manufacturer chooses to publicly disclose any material that CMS has previously deemed to be proprietary information of that Primary Manufacturer, we will no longer consider that material proprietary as described in section II.D.1. of the proposed rule (91 FR 36273).

Comment: A few of commenters encouraged CMS to publish the maximum amount of information publicly within the confines of the law for the purposes of transparency, stakeholder engagement, and public accountability.

Response: Consistent with our responses to similar comments in the Negotiation Program Guidance, we are committed to negotiation and renegotiation processes that are transparent and respect confidentiality of proprietary information. We appreciate the need to balance transparency in these processes with the need to maintain the confidentiality of certain information, including manufacturers' proprietary data. As described in § 429.705, we will release a narrative explanation of the negotiation process and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. All information that we publish as part of the MFP explanation and any other public documents related to the MFP and negotiation or renegotiation process, as applicable, will be protected under the confidentiality policy described in § 429.300 of this final rule, and we will, as appropriate, redact or de-identify proprietary information, PHI/PII, and information that is protected from disclosure under other applicable law.

Final Decision: After consideration of public comments, we are finalizing § 429.300 as proposed with non-substantive, technical modifications to § 429.300(b), replacing ''CMS would deem'' with ''CMS deems'' *proprietary information, including trade secrets and confidential commercial or financial information, as confidential information exempt from disclosure if the information meets the requirements set forth under Exemption 3 or Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(3), (4)).* We also are making technical modifications to § 429.300(c)(6) to capitalize the drug dossier name ''Common'' in the ''Common Technical File'' and to remove erroneous cross-reference ''§ 429.615(b)(1)(i)'' and replace it with ''429.615(b)(3)''.

E. Establishment of a Single MFP and Determination of the Ceiling (§§ 429.400 Through 429.445)

1. Establishment of a Single MFP for Negotiation and Renegotiation Purposes (§ 429.400)

Section 1191(c)(3) of the Act states that an MFP means, with respect to a year during a price applicability period and with respect to a selected drug with respect to such period, the price negotiated under section 1194 of the Act, and updated under section 1195(b) of the Act, as applicable, for such drug and year. We interpret this language to refer to negotiation of a selected drug with respect to the price applicability period for that selected drug. Consistent with respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including for example, with respect to initial price applicability year 2028, section 60.1 of the Negotiation Program Guidance. Consistent with the

policies for implementation as described in section 60.1 of the Negotiation Program Guidance, we proposed in § 429.400 to identify a single price for each selected drug, including for selected drugs with multiple dosage forms and strengths. This single price would be used at each step in the negotiation process, as described in proposed §§ 429.510 through 429.535 and sections II.F.3. through II.F.8. of this final rule, and for each step in the renegotiation process, as described in proposed § 429.620 and section II.G.5. of this final rule. Accordingly, each offer and counteroffer, as described in proposed §§ 429.520 through 429.535 for negotiation and § 429.620(f) through (i) for renegotiation, would include a single price, including for a selected drug with multiple dosage forms, strengths, and formulations. We also proposed in § 429.400(a)(1) to base the single price on the cost of the selected drug per 30-day equivalent supply (rather than per unit—such as tablet, capsule, injection—or per volume or weight-based metric) for all formulations (including drugs payable under Part B, covered under Part D, or both, as applicable), weighted across dosage forms and strengths for the purposes of determining a single price included in an initial offer proposed in §§ 429.510(d) and § 429.520 and as described in sections II.F.3.c. through II.F.3.d. and section II.F.5. of this final rule and for the purpose of additional offers during the negotiation as proposed in §§ 429.525 through 429.535 and as described in sections II.F.4. and II.F.6. through II.F.8. of this final rule. This approach of negotiating a single price across all dosage forms and strengths based on a 30-day equivalent supply of the selected drug both aligns with the statutory requirement at section 1194(a)(1) of the Act to negotiate a single MFP for each selected drug and would allow for a more direct comparison between the selected drug and its therapeutic alternative(s) (described in proposed § 429.510(b)), if any, which might also have different dosage forms, strengths, and treatment regimens (for example, daily consumption of tablets versus monthly injections of solutions) when developing the initial offer. The 30-day equivalent supply methodology is proposed in § 429.415 and described in section II.E.4. of this final rule.

Final Decision: We did not receive public comments on this provision; and therefore, we are finalizing § 429.400 as proposed.

2. Collection of Non-FAMP (§ 429.405)

Section 1193(a)(4)(A) of the Act establishes that a Primary Manufacturer that has entered into a Negotiation Program Agreement with CMS (proposed in § 429.200 and described in section II.C.1. of this final rule), in accordance with the requirements of its Negotiation Program Agreement, is required to submit, for the negotiation period for the price applicability period, and, if applicable, before any period of renegotiation, information on the non-FAMP (as defined in 38 U.S.C. 8126(h)(5)) for the selected drug for the applicable year or period. Section 1194(c)(1)(C)(ii) of the Act, with respect to a selected drug selected for initial price applicability year of 2027 or later, provides that the MFP negotiated for the selected drug shall not exceed the lower of the amount calculated pursuant to section 1194(c)(1)(B) of the Act or section 1194(c)(1)(C) of the Act, where the calculation pursuant to section 1194(c)(1)(C) of the Act requires identifying the lower of: (1) the average non-FAMP price for the selected drug for 2021 (or, in the case that there is not an average non-FAMP available for such selected drug for calendar year 2021, for the first full calendar year following the market entry for such drug), as adjusted for inflation; or (2) the average non-FAMP for the selected drug for the calendar year prior to the selected drug publication date for the selected drug. Section 1194(c)(6) of the Act further provides that the term ''average non-Federal average manufacturer price'' means the average of the non-Federal average manufacturer price (as defined in 38 U.S.C. 8126(h)(5)) for the four calendar quarters of the year involved.

With respect to initial price applicability years 2027 and 2028, CMS implemented these requirements through guidance, including, for example, with respect to initial price applicability year 2028, section 50.1.1 of the Negotiation Program Guidance. Consistent with the policies implemented through section 50.1.1 of the Negotiation Program Guidance, we proposed at § 429.405(a) to codify the requirement that, in accordance with the requirements of its Negotiation Program Agreement, a Primary Manufacturer of a selected drug must submit to CMS, in a form and manner specified by the agency, by 11:59 p.m. PST on March 1 of the calendar year of the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, the non-FAMP, unit type, and total unit volume for each NDC–11 of the selected drug for all quarters of the four quarters of calendar year 2021 in which the selected drug was sold and non-FAMP data was reported (or, in the case that there is not an average non-FAMP available for such selected drug for calendar year 2021, the non-FAMP, unit type, and total unit volume for each NDC–11 of the selected drug for the four quarters of the first full calendar year following the market entry for such drug), and for the calendar year prior to the selected drug publication date with respect to the initial price applicability year for which the selected drug, was selected for negotiation. This requirement to submit information is not inclusive of NDC–11s of the selected drug that are not manufactured, marketed, controlled, or sold by the Primary Manufacturer or a Secondary Manufacturer, or NDC–11s to which the MFP would not apply, such as sample packages, inner packages, and discontinued products. We intend to consider the average non-FAMP to be available for a selected drug for calendar year 2021 if non-FAMP data has been reported for at least one NDC–11 of the selected drug for at least one quarter in calendar year 2021. For a given NDC–11 of a selected drug, when there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) or the calendar year prior to the selected drug publication date for the selected drug, the non-FAMP reported by the Primary Manufacturer to CMS for that calendar quarter should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price, as described in the Department of Veterans Affairs (VA) 2025 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102–585 (including any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA).

In accordance with sections 1193(a)(4)(A), 1194(b)(2)(A), 1194(c)(1)(C)(ii), 1194(c)(6), and 1193(a)(5) of the Act, as described in proposed § 429.405(a)(1), we proposed that this data collection would be mandatory for Primary Manufacturers

and would be due by March 1 of the year of the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation. This due date also aligns with the due date for submission of information related to the factors listed at section 1194(e) of the Act (further described in proposed § 429.505 and II.F.2. of this final rule). We intend to collect the non-FAMP through an Information Collection Request (ICR), which will include additional parameters for this data collection.

Additionally, in accordance with section 1193(a)(5) of the Act, we proposed at § 429.405(b) that if the non-FAMP is restated due to requirements of 38 U.S.C. 8126 and implementing regulations and guidance issued by the VA, then in accordance with the requirements of its Negotiation Program Agreement as set forth in § 429.200, the Primary Manufacturer is required to update the submission of non-FAMP to CMS for the selected drug.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter had a few recommendations regarding the collection of non-FAMP. The commenter noted that with this rule, there exists the statutory basis for two Federal ceilings calculated by two agencies under statutes whose Social Security Act cross-references are three decades apart. As such, the VA has an established process for calculating and restating the non-FAMP. The commenter recommended that CMS state how it will verify submitted non-FAMP against the figure reported to the VA for the same product and period. The commenter also recommended stating what occurs when a Primary Manufacturer restates non-FAMP after an MFP has been agreed upon and whether the Calculation of Information and Suggestion of Error stated in § 429.445 would reopen and if it would, on what timeline. Another recommendation from this commenter was to address whether definitional differences arise from the section 8126(g)(1) freeze, if so, whether such definitional differences produce divergent non-FAMP figures for the same product, and if so, to clarify which version governs. Lastly, the commenter recommended CMS align data definitions and audit findings with VA's, to the extent feasible, to reduce duplicative burden on Primary Manufacturers already subject to non-FAMP audit exposure.

Response: We appreciate this commenter's feedback and recommendations. As stated in the Negotiation Program proposed rule (91 FR 36274), section 1193(a)(4)(A) of the Act establishes that a Primary Manufacturer that has entered into a Negotiation Program Agreement with CMS (as described in § 429.200 and section II.C.1. of this final rule), in accordance with the requirements of its Negotiation Program Agreement, is required to submit, for the negotiation period for the price applicability period, and, if applicable, before any period of renegotiation, information on the non-FAMP (as defined in 38 U.S.C. 8126(h)(5)) for the selected drug for the applicable year or period. Also as stated in the Negotiation Program proposed rule (91 FR 36275), in accordance with sections 1193(a)(4)(A), 1194(b)(2)(A), 1194(c)(1)(C)(ii), 1194(c)(6), and 1193(a)(5) of the Act, as described in § 429.405(a)(1), this data collection would be mandatory for Primary Manufacturers and would be due by March 1 of the year of the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation. This due date also aligns with the due date for submission of information related to the factors listed at section 1194(e) of the Act (further described in § 429.505 and II.F.2. of this final rule). We intend to collect the non-FAMP through an ICR, which will include additional parameters for this data collection.

Additionally, in accordance with section 1193(a)(5) of the Act, we proposed at § 429.405(b) that if the non-FAMP is restated due to requirements of 38 U.S.C. 8126 and implementing regulations and guidance issued by the VA, then in accordance with the requirements of its Negotiation Program Agreement as set forth in § 429.200, the Primary Manufacturer is required to update the submission of non-FAMP to CMS for the selected drug.

The comments regarding how CMS will verify submitted non-FAMP against the figure reported to the VA for the same time period and whether definitional differences arising from the section 8126(g)(1) freeze provision produce divergent non-FAMP figures for the same product are out of scope for this final rule.

In response to the recommendation for CMS to state what occurs when a Primary Manufacturer restates non-FAMP after an MFP has been agreed upon between CMS and the Primary Manufacturer, we note that a Primary Manufacturer of a selected drug has an obligation to provide complete and accurate non-FAMP data in accordance with § 429.405(a) and to update their submitted data as warranted in accordance with § 429.405(b). Failure to report accurately and completely, including failure to comply with information update requirements, may subject a Primary Manufacturer to liability for CMPs. We would evaluate such misreporting on a case-by-case basis. Our evaluation of liability for such misreporting is separate and distinct from any enforcement action that may be taken by any other entity with respect to inaccurate or incomplete non-FAMP reporting.

As for the comment regarding whether the Calculation of Information and Suggestion of Error processes would ''reopen'' in instances in which a Primary Manufacturer restates non-FAMP after an MFP has been agreed to, we direct the commenter to § 429.445 and discussion in section II.E.10. of this final rule.

Final Decision: After consideration of public comments received, we are finalizing § 429.405 as proposed.

3. Determination of the Ceiling (§ 429.410)

a. Limitations on Offer Amount (§ 429.410(a))

Section 1194(b)(2)(F) of the Act states the limitations on an offer amount and requires that in negotiating the MFP of a selected drug, including during renegotiation, we will not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling as determined in section 1194(c) of the Act or, if applicable, is less than the Temporary Floor for Small Biotech Drugs as determined in section 1194(d) of the Act. Consistent with section 60.2.1 of Negotiation Program Guidance, we proposed at § 429.410(a) to codify the requirement that CMS would not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling amount under section 1194(c) of the Act. We also proposed at § 429.440(a) that CMS would not make an offer or agree to a counteroffer for an MFP that is less than the Temporary Floor for Small Biotech Drugs, if applicable.

b. Determination of the Ceiling (§ 429.410(b))

Section 1194(c)(1)(A) of the Act states that the MFP negotiated for a selected drug, with respect to the first initial price applicability year of the price applicability period with respect to such drug, shall not exceed the lower of the amount under section 1194(c)(1)(B) of the Act or the amount under section 1194(c)(1)(C) of the Act. In section

60.2.1 of the Negotiation Program Guidance, CMS developed a process to calculate the amounts described in section 1194(c)(1)(B) and (c)(1)(C) of the Act. We proposed to codify that process at § 429.410(b). Provisions regarding the ceiling calculation for drugs selected for renegotiation are proposed at § 429.620(b) and discussed at section II.G.5.a. of this final rule. The process we proposed to codify at § 429.410(b) provides for a single ceiling amount to apply for each selected drug, in accordance with the references in sections 1194(b)(2)(F) and 1194(c)(1)(A) of the Act to ''the ceiling'' or ''the lower of the amount under subparagraph (B) or the amount under subparagraph (c),'' respectively, both in the singular.

In proposed § 429.410(b)(1), we proposed to identify the amount under section 1194(c)(1)(B) of the Act, consistent with section 60.2.1 of the Negotiation Program Guidance, as one of the following amounts, as applicable to the selected drug:

- As described in proposed § 429.410(b)(1)(i), for a selected drug that is covered under Part D but is not payable under Part B, the sum of the plan-specific enrollment weighted amounts, described in section 1194(c)(1)(B)(i) of the Act and as determined under proposed § 429.420 and discussed in section II.E.5. of this final rule.
- As described in proposed § 429.410(b)(1)(ii), for a selected drug that is payable under Part B and paid according to section 1847A(b)(4) of the Act, but is not covered under Part D, the payment amount under section 1847A(b)(4) of the Act for the year prior to the year of that selected drug's publication date with respect to the initial price applicability year for that selected drug, described in section 1194(c)(1)(B)(ii) of the Act and as determined under proposed § 429.425 and discussed in section II.E.6. of this final rule.
- As described in proposed § 429.410(b)(1)(iii), for a selected drug that is payable under Part B and paid according to section 1847A(b)(4) of the Act, and covered under Part D, an amount equal to the combined Part B and Part D amount, as determined under proposed § 429.430 and discussed in section II.E.7. of this final rule.
- As described in proposed § 429.410(b)(1)(iv), for a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act [76], and is covered under Part D, an amount based on the sum of the plan-specific enrollment weighted amounts, described in section 1194(c)(1)(B)(i) of the Act and as determined under proposed § 429.420 and discussed in section II.E.5. of this final rule.
- As described in proposed § 429.410(b)(1)(v), for a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act, and is not covered under Part D, there is no amount as determined under proposed paragraph § 429.410(b)(1).

The previous two bullet points describe scenarios where a selected drug is payable under Part B but is not paid according to the methodology provided in section 1847A(b)(4) of the Act. Since such selected drugs would not have a ''payment amount'' determined under such section, we proposed that the ceiling amount described under section 1194(c)(1)(B)(ii) of the Act would not be applicable to the determination because no such amount exists. In such instances, we proposed to calculate and consider the other ceiling amounts specified under section 1194(c)(1) of the Act for such drugs, as applicable. When such a selected drug is payable under Part B but not paid according to section 1847A(b)(4) of the Act and is covered under Part D, we proposed to use the sum of the plan-specific enrollment weighted amount. However, for a selected drug that is payable under Part B but not paid according to section 1847A(b)(4) of the Act and is not covered under Part D, there would be no applicable ceiling amount described in section 1194(c)(1)(B) of the Act, and so we proposed to use only the applicable percent of average non-FAMP described in section 1194(c)(1)(C) of the Act and determined as proposed in § 429.410(b)(2) to calculate the ceiling.

Section 1194(c)(1)(C)(ii) of the Act requires that for initial price applicability year 2027 and subsequent years, the lower of two different average non-FAMP amounts described in sections 1194(c)(1)(C)(ii)(I) and 1194(c)(1)(C)(ii)(II) of the Act be used as the amount described under section 1194(c)(1)(C) of the Act. CMS implemented these requirements through guidance, including, for example, section 60.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028. We proposed in § 429.410(b)(2), that the applicable percent, as applicable to the selected drug, will be the lower of the average non-FAMP amounts described in section 1194(c)(6) of the Act. We will compare the amounts described in § 429.410(b)(2) to determine which is lower and serve as the payment amount to compare the amount described in § 429.410(b)(1). In accordance with 1194(c)(1)(A) of the Act, the selected drug's ceiling is the lower of the amount determined under § 429.410(b)(1) or (b)(2).

The amounts determined under proposed § 429.410(b)(2) would be the lower of the average non-FAMP for each selected drug for calendar year 2021 (or in the case that there is not an average non-FAMP for such drug for calendar year 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the CPI–U from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year that is 3 years prior to the initial price applicability year of the selected drug proposed in § 429.410(b)(2)(i) and the average non-FAMP for such selected drug for the calendar year prior to the selected drug publication date proposed in § 429.410(b)(2)(ii). Regarding the first referenced amount, we interpret section 1194(c)(1)(C)(i) of the Act to indicate that if there is no non-FAMP for any of the NDCs for the selected drug for calendar year 2021, then we would use the first full year following market entry of the selected drug. Similarly, regarding the second referenced amount, in a situation where none of the NDCs for the selected drug are reported in the calendar year prior to the selected drug publication date, we would then apply the average non-FAMP reported for such NDCs from the first full year prior to the year of the selected drug publication date.

We proposed at § 429.410(b)(3), to calculate a single amount, a 30-day equivalent supply as described in § 429.415, across all dosage forms and strengths of the selected drug for the amounts calculated in §§ 429.420 through 429.435 to determine which of these amounts is the lowest and would serve as the ceiling for the MFP for the selected drug. We solicited comments on recommended approaches for CMS to our proposals throughout this section, including calculation of the 30-day equivalent supply, the determination of the different ceiling amounts, and the Temporary Floor for Small Biotech Drugs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

[76] When discussing a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act in § 429.410(b)(1)(iv) and (v), an example would be a selected drug which is paid on the basis of 95 percent of Average Wholesale Price (AWP).

Comment: A commenter had a recommendation to use international reference prices as a ceiling and to tie the MFP to what other high-income countries pay.

Response: We thank the commenter for the suggestions. Section 429.410, as proposed, codifies the limitations on CMS' offer amount, including the ceiling amounts specified in section 1194(c) of the Act, and the Temporary Floor for Small Biotech Drugs specified in section 1194(d) of the Act. The commenter's suggestion to impose a ceiling based on amounts other than those described in section 1194(c) of the Act is out of scope.

Final Decision: After consideration of public comments received, we are finalizing § 429.410 as proposed.

4. Calculation of the 30-Day Equivalent Supply (§ 429.415)

Consistent with the policies for implementation as described in section 60.2.1.1 of the Negotiation Program Guidance, we proposed at § 429.415 a methodology for determining the 30-day equivalent supply for a selected drug and therapeutic alternative(s), as applicable. The price per 30-day equivalent supply methodology facilitates the determination of a single ceiling price, and the negotiation of a single MFP, across dosage forms and strengths of a selected drug where units (for example, milligrams versus milliliters) and treatment regimens (for example, daily consumption of tablets versus monthly injections of solutions) differ. The proposed 30-day equivalent supply methodology also provides a standardized methodology to calculate a price for a standardized treatment duration for all dosage forms and strengths of selected drugs and its therapeutic alternative(s), if any; gives a more complete picture of beneficiary utilization when compared to a unit-based approach; and allows for comparison across the selected drug and the respective therapeutic alternative(s), if any.

We considered several alternatives, including those submitted through public comment for the Negotiation Program Guidance. The alternatives that we considered included a per-unit approach; price per course of treatment; consulting with the Primary Manufacturer of each selected drug to determine a methodology; and a flexible methodology to accommodate the clinical disease state and treatment landscape. We do not believe these alternatives provide for the standardization needed across different formulations, dosage forms, and strengths of a selected drug and its therapeutic alternative(s), if any, necessary to consider the selected drug as described in section 1194(e) of the Act and apply a single ceiling and a single MFP across dosage forms and strengths of the selected drug as required in section 1191(c)(3) of the Act. In addition, using a different methodology for selected drugs that are covered under Part D from selected drugs that are payable under Part B or for selected drugs that are both covered under Part D and payable under Part B could lead to inconsistencies and issues with comparing the selected drug to therapeutic alternative(s), if any.

Using a per-unit price approach, particularly for drugs payable under Part B, would not provide the standardization necessary to compare a selected drug with a therapeutic alternative nor to apply a single ceiling and a single MFP for a selected drug. This is because for drugs payable under Part B, unit type may differ both across HCPCS codes within a selected drug and across therapeutic alternatives payable under Part B, especially if a drug is both payable under Part B and covered under Part D. Using a price-per-course of treatment approach to creating a 30-day equivalent supply is time and resource intensive because treatment duration and dosing may be specific to individual patients and can also differ due to factors such as individual adherence, delays due to adverse events, or expected gaps due to adjuvant therapy or procedures. The option wherein we would work with the Primary Manufacturer on an individual methodology for each selected drug would be time and resource intensive and potentially not lead to a standardized approach and methodology that could be used for selected drugs and its therapeutic alternative(s), if any. This approach would also create inconsistency across selected drugs. We also believe that a 30-day equivalent supply methodology to accommodate the clinical disease state and treatment landscape, wherein we would use FDA labeling and treatment guidelines to tailor the methodology, would not capture patient-specific dosing regimens whereas the proposed approach using days between services approach would capture such patient-specific variation.

After considering these alternatives, we proposed at § 429.415(a)(1), that for selected drugs that are covered under Part D, we would use the methodology as described at 42 CFR 423.104(d)(2)(iv)(A)(2) which relies on the ''days' supply'' field in PDE records to calculate the 30-day equivalent supply for each PDE record associated with the selected drug.

Consistent with the policies for implementation as described in section 60.2.1.1 of the Negotiation Program Guidance, we proposed at § 429.415(a)(2) that CMS will use a different methodology to calculate the 30-day equivalent supply for selected drugs payable under Part B because Part B data does not contain a ''days' supply'' field like the PDE records for selected drugs that are covered under Part D. The methodology we proposed to use for calculating the 30-day equivalent supply for drugs payable under Part B involves calculating a ''days between services'' amount for each instance of Part B data associated with the selected drug. As an example of the approach proposed at § 429.415(a)(2)(ii), consider if the date of service for the first instance of Part B data is January 12, 2025, and the immediately subsequent instance of Part B data with the same active moiety/active ingredient has a date of service of March 12, 2025, then the first claim or record's ''days between services'' amount would be calculated as 59 days. If the beneficiary's third instance of Part B data was August 1, 2025, the number of ''days between services'' amount, for days between March 12, 2025, and August 1, 2025, would be calculated as 142 days for the second claim or record. The resulting ''days between services'' amounts in this example would be the same amount if the subsequent claim was a PDE record rather than an instance of Part B data. We proposed at § 429.415(a)(2)(i)(B) that the subsequent instance of Part B data or any PDE record be for a drug or biological product with the same active moiety/active ingredient identified as set forth at § 429.125(b), as the selected drug.[77] We proposed at § 429.415(a)(2)(ii)(A) if the beneficiary has an instance of Part B data that does not have a subsequent instance of Part B data or PDE record with the same active moiety/active ingredient, identified as set forth at § 429.125(b), CMS would assign a ''days between services'' amount equal to the median ''days between services'' amount for all prior instances of Part B claims or records or PDE records for that selected drug associated with that beneficiary during the applicable claims period. Thus, if the beneficiary's last instance of Part B data was August 1, 2025, and there is no subsequent

[77] CMS did not use the term ''selected drug'' in this proposal because there could be a shared HCPCS code or different NDA/BLA holders, especially for therapeutic alternative(s) of the selected drug.

instance of Part B data or PDE record of the same active moiety/active ingredient, it would be assigned a median of 59 days and 142 days, which is 100.5 days. We proposed at § 429.415(a)(2)(ii)(B) that if there is only one instance of Part B data for the selected drug and there are no other instances of Part B data or PDE records with the same active moiety/active ingredient associated with the beneficiary during the applicable claims period then we would not assign a ''days between services'' amount and furthermore not include the single instance of Part B data in the calculation of 30-day equivalent supply. The proposal at § 429.415(a)(2)(ii)(B) would not apply for drugs typically administered one time because there would most likely never be subsequent instances of Part B data. We discuss our proposed approach for drugs typically administered one time later in this section.

We understand that drugs payable under Part B often have recurrent administrations and variable dosing depending on body weight, indication, treatment phase, or response to treatment. The proposed ''days between services'' methodology addresses these concerns by using observed data from individual patients, which can potentially capture if providers are using patient-specific dosing regimens which can cause the variations. The ''days between services'' methodology would reduce the possibility of undervaluing the costs of drugs payable under Part B when attempting to determine the cost per 30-day equivalent supply.

Part B data is billed at the HCPCS code level, and some calculations using the 30-day equivalent supply of the selected drug require NDC-level 30-day equivalent supply amounts, so we proposed at § 429.415(a)(2)(iv) to allocate a portion of the 30-day equivalent supply calculated at the level of each HCPCS code to each NDC within the HCPCS code that includes a selected drug to calculate a 30-day equivalent supply at the NDC level. We proposed at § 429.415(a)(2)(v) steps to determine the total Part B 30-day equivalent supply at the NDC level.

We proposed at § 429.415(a)(2)(v)(E)*(2)* to assign a value of ''12'' for the 30-day equivalent supply for drugs that are typically administered one time (for example, some vaccines and cancer therapies), by identifying HCPCS codes that generally have a median of one claim per calendar year. This value would apply to any selected drug and therapeutic alternative(s) of the selected drug, if any, for purposes of determining the initial offer as described in § 429.510, that are typically administered one time and payable under Part B. However, unlike for claims described in § 429.415(a)(2)(ii)(B), the reason for a lack of a second claim for these drugs is because these drugs are typically administered once for the lifetime of a patient. A ''days between services'' amount would therefore generally not be calculated for any claim associated with such drugs under the proposed methodology at § 429.415(a)(2)(ii) without this second claim. To calculate a single amount for the ceiling and for offers and counteroffers for the MFP under the methodologies proposed under this subpart E, a value for the 30-day equivalent supply needs to be assigned for these drugs in order to be included in the calculation. We proposed that assigning a value of ''12'' as a 30-day equivalent supply facilitates the necessary calculations in a manner that reasonably and accurately reflects such drugs usage. This approach is also consistent with our policy of developing a standardized methodology to calculate a price for all dosage forms and strengths of selected drugs and its therapeutic alternative(s).

We considered an alternative approach to the proposed 30-day equivalent supply methodology for drugs typically administered one time described previously, wherein we would use a price-per-administration or price per HCPCS billing unit for such drugs. Under this alternative approach, instead of calculating a 30-day equivalent supply and price per 30-day equivalent supply, we would instead calculate a price-per-administration or price-per-HCPCS billing unit for a selected drug. However, if such selected drug includes multiple HCPCS codes, calculating a single price per administration across HCPCS codes may not be appropriate (for example, if the existing price-per-administration differs significantly across HCPCS codes due to different treatment patterns). Calculating a price-per-administration would also not account for different volumes of the drug used in different instances of administration, which would conflict with our typical use of a payment limit per HCPCS billing unit for payment under Part B.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters suggested for CMS to use a unit of measure approach, rather than a 30-day equivalent supply, for calculation of a single ceiling price and MFP of a selected drug. One of these commenters suggested this approach only for selected drugs payable under Part B. A commenter suggested CMS adopt a lower unit of measure approach for drugs payable under Part B and/or covered under Part D to promote accuracy, transparency, and operational feasibility. A commenter supported CMS' proposed 30-day equivalent supply methodology for calculating the ceiling and MFP because it uses a consistent and uniform approach. A commenter stated they appreciate CMS' proposed methodology and stated that it will be appropriate for many medications and they support the methodology in those cases, but they continue to have concerns if applied to all selected drugs. A commenter stated that a unit-based approach anchored to the price of the product would promote accuracy, transparency, and operational feasibility. Many commenters opposed or expressed concern with CMS' approach of using a 30-day equivalent supply to apply MFP across dosage forms and strengths, particularly with drugs with dosing variation across indications or dosing that involves titration, loading, weight-based, or severity-based variation. A few commenters recommended that CMS calculate the 30-day equivalent supply based on the dosing schedule provided in the prescribing information approved by the FDA (label-based) for selected drugs where dose quantity and schedule do not vary based on patient characteristics. Some commenters suggested CMS work with Primary Manufacturers of a selected drug and to come to an agreement with the Primary Manufacturer on the best approach to use for that selected drug in order to calculate the ceiling and negotiate a single MFP. Some commenters opposed the use of a 30-day equivalent supply, especially applying to drugs payable under Part B and using a ''days between supply'' methodology. A few commenters stated that Part B and Part D claims are fundamentally different and that comparing a 30-day equivalent supply across them produces unequal, untenable, distorted, and invalid comparisons. A commenter stated that nothing in statute requires CMS to calculate the MFP as a price per 30-day equivalent supply, but that statute specifically refers to a ''unit'' with respect to each drug or biologic and that this reference supports the use of a per-unit basis for when determining the MFP.

Response: We appreciate these commenters for their feedback and suggestions. We appreciate the support

from the commenters regarding the 30-day equivalent supply methodology. Section 1196(a)(2) of the Act directs CMS to establish procedures to compute and apply agreed-upon MFPs across different dosage forms and strengths of a selected drug and not based on the specific formulation or package size or package type of such drug. Section 1194(a)(1) of the Act directs CMS to develop and use a consistent methodology and process for negotiations that aim to achieve the lowest MFP for each selected drug. Consistent with these statutory directives, in the Negotiation Program proposed rule, and consistent with the Negotiation Program Guidance, we proposed to use a 30-day equivalent supply methodology as it allows CMS to calculate a price for a standardized treatment duration for all dosage forms and strengths of a given drug, and it allows comparison of such standardized prices across drugs. Using the price per 30-day equivalent supply to calculate this amount facilitates aggregation across dosage forms and strengths of a selected drug where units (for example, mg versus mL) and treatment regimens (for example, daily consumption of tablets versus monthly injections of solutions) differ. We believe that the 30-day equivalent supply methodology provides accurate and consistent calculations that can be used for most selected drugs and therapeutic alternative(s) and therefore supports CMS' ability to carry out sections 1194(a)(1) and 1196(a)(2) of the Act. A 30-day equivalent supply methodology is the most transparent and operationally feasible approach.

We disagree with commenters advocating a unit-based methodology. We believe a 30-day equivalent supply creates a more direct comparison for drugs that have different dosage forms, strengths, and treatment regimens than a unit-based approach. We believe that a 30-day equivalent supply methodology also gives a more complete picture of beneficiary utilization. A unit-based approach is less preferable given that unit types may differ across HCPCS codes to which a selected drug payable under Part B is assigned and across therapeutic alternative(s) for a selected drug. We do not believe that a methodology based on the unit of measure assigned to the HCPCS code would work as well as the 30-day equivalent supply methodology because unit types can vary across HCPCS codes to which a selected drug is assigned, and across therapeutic alternatives, especially if the selected drug and/or a therapeutic alternative has both Part B and Part D utilization. Although Part B and Part D claims may differ from one another, a 30-day equivalent supply methodology allows a consistent methodology for comparison of a selected drug and therapeutic alternative(s) that have Part B only, Part D only, or both Part B and Part D utilization. A unit-based approach lacks the benefits of a 30-day equivalent supply methodology that are previously described.

In response to the commenters concerned with CMS' 30-day equivalent supply methodology being used for drugs with dosing variation across indications or dosing that involves titration, loading, weight-based, or severity-based variation and the commenters' recommendation that CMS calculate the 30-day equivalent supply based on dosing schedule provided in the prescribing information approved by the FDA (label-based) for selected drugs where dose quantity and schedule do not vary based on patient characteristics, using an approach to reference the FDA label rather than using actual real-world utilization data, we note that dosing schedules may vary individually for patients (both for patients taking Part B drugs as well as Part D drugs) and statute requires us to have a consistent process and methodology, and the 30-day equivalent supply approach is the most consistent methodology which can be used across selected drugs and which best reflects real-life patterns of use of the drugs among Medicare beneficiaries.

In response to the commenters' suggestion for CMS to work with Primary Manufacturers of a selected drug and to come to an agreement with the Primary Manufacturer on the best approach to use for that selected drug in order to calculate the ceiling and negotiate a single MFP, working with each Primary Manufacturer on an individual methodology for each selected drug would be time and resource intensive and potentially not lead to a standardized approach and methodology that could be used for other selected drugs and its therapeutic alternative(s), if any.

In response to the commenters opposed to the use of a 30-day equivalent supply applying to drugs payable under Part B and CMS using a ''days between supply'' methodology, we understand that drugs payable under Part B often have recurrent administrations and variable dosing depending on body weight, indication, treatment phase, or response to treatment. The proposed ''days between services'' methodology addresses these concerns by using observed data from individual patients, which can potentially capture if providers are using patient-specific dosing regimens which can cause the variations. The ''days between services'' methodology would reduce the possibility of undervaluing the costs of drugs payable under Part B when attempting to determine the cost per 30-day equivalent supply.

In response to the commenter referencing ''unit'' in statute, the meaning is defined at section 1191(c)(6) of the Act, which states that the term ''unit'' means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules or grams) of the drug or biological product that is dispensed or furnished, we disagree that this definition requires the use of a unit based approach to determining offers and counteroffers for selected drugs. For example, there is no reference to ''unit'' in section 1194(c) of the Act, which describes the determination of the ceiling for MFP. The only reference to ''unit'' within section 1194 of the Act, which describes the process for negotiation and renegotiating MFPs for selected drugs, is the requirement in section 1194(e)(1)(B) of the Act that we consider the ''current unit costs of production and distribution'' for a selected drug in determining offers and counteroffers. We do not believe this spare reference is best interpreted as requiring a unit-based approach, particularly when, as previously described, such an approach would be in tension with the statutory directives in sections 1194(a)(1) and 1196(a)(2) of the Act. Therefore, we disagree with the commenter's interpretation of having to use a unit-based methodology versus a 30-day equivalent supply methodology as proposed and finalized in § 429.415. As stated previously in this section, we believe that the 30-day equivalent supply methodology for selected drugs provides accurate and consistent calculations that can be used for most selected drugs and therapeutic alternative(s) and therefore supports our ability to carry out sections 1194(a)(1) and 1196(a)(2) of the Act.

Comment: Many commenters provided feedback on CMS' plans to assign a value of ''12'' for the 30-day equivalent supply for drugs typically administered one time (for example, some vaccines and cancer therapies), whereby CMS would identify HCPCS codes that generally have a median of one claim per calendar year. Many commenters opposed CMS assigning a value of ''12'' for the 30-day equivalent supply for drugs typically administered

one time. Some commenters recommended for CMS to establish a more tailored and flexible methodology for these selected drugs. A commenter recommended that CMS create an ''outlier policy'' for selected drugs. A commenter encouraged CMS to continue to assess feedback from stakeholders on an adequate approach to use. A couple of commenters stated that they appreciate or understand CMS' goal of standardization but cautioned that this convention does not resolve the underlying problem in that it systematically misvalues therapies whose clinical benefit is decoupled from a monthly dosing and that the proposed methodology is unlikely to produce accurate results for many selected drugs. A commenter stated that regardless of the methodology, it is critically important that CMS use consistent inputs across all phases of the ceiling calculation, MFP determination, and application process.

Response: We thank these commenters for their feedback. Assigning a value of ''12'' as a 30-day equivalent supply for drugs typically administered one time facilitates the necessary ceiling calculations in a manner that is reasonable and accurately reflects the drug's usage because when we look for utilization data, we look within a year's timeframe, so the value of ''12'' represents the maximum value possible in the calculation. Thus, the value of ''12'' for drugs typically administered one time accurately captures and covers a full year and allows comparison to drugs that may be administered multiple times within a year's timeframe. As a commenter suggested, this approach uses consistent inputs that allows for accurate and consistent ceiling calculations, negotiation of a single MFP, and application of the MFP.

As stated in the Negotiation Program proposed rule (91 FR 36277), this approach is also consistent with our policy of developing a standardized methodology to calculate a price for all dosage forms and strengths of selected drugs and its therapeutic alternative(s). We considered an alternative approach to the proposed 30-day equivalent supply methodology for drugs typically administered one time described previously, wherein we would use a price-per-administration or price per HCPCS billing unit for such drugs. Under this alternative approach, instead of calculating a 30-day equivalent supply and price per 30-day equivalent supply, we would instead calculate a price-per-administration or price-per-HCPCS billing unit for a selected drug. However, if such selected drug includes multiple HCPCS codes, calculating a single price per administration across HCPCS codes may not be appropriate (for example, if the existing price-per-administration differs significantly across HCPCS codes due to different treatment patterns). Using this approach could preclude us from comparison with therapeutic alternatives, including those not payable under Part B or those that may be taken daily. Calculating a price-per-administration would also not account for different volumes of the drug used in different instances of administration, which would conflict with our typical use of a payment limit per HCPCS billing unit for payment under Part B.

We appreciate the commenters' suggestion to establish a more tailored methodology, the commenter's recommendation to assess feedback from stakeholders on an adequate approach to use, and the commenter's suggestion to create an ''outlier policy.'' We are still considering an outlier policy for future rulemaking and encourages stakeholder input, suggestions, and feedback.

Final Decision: After consideration of public comments received, we are finalizing § 429.415 as proposed, but with a technical modification to the title of § 429.415(a)(2) to change ''selected drug covered under Part B'' to ''selected drug payable under Part B'' for consistency with the use of such term throughout this final rule.

5. Determination of the Sum of the Plan-Specific Enrollment Weighted Amounts (§ 429.420)

Section 1194(c)(2) of the Act describes the calculation for the sum of the plan-specific enrollment weighted amount for prescription drug plan or an MA–PD plan with respect to a covered Part D drug for purposes of section 1194(c)(1)(B)(i) of the Act. Consistent with the policies for implementation as described in section 60.2.2.1 of the Negotiation Program Guidance, we proposed at § 429.420(b) to use a 30-day equivalent supply methodology to calculate the sum of the plan-specific enrollment weighted amounts.

Plan sponsors report Part D PDE data to CMS at the NDC–11 level and report direct and indirect remuneration data to CMS at the NDC–11 level in the annual Detailed Direct and Indirect Remuneration (DIR) Report. As directed by statute, and proposed at § 429.420(a) and (b)(1), we proposed to use plan sponsors' reported Part D PDE data and DIR data for the year that is 4 years prior to the initial price applicability year of the selected drug, which would be the most recent year for which data would be available, for purposes of determining the sum of the plan-specific enrollment weighted amounts for selected drugs that are covered under Part D. As proposed at § 429.420(a), we would include all Part D plans found in the PDE data that meet the inclusion criteria described in the definition of ''total expenditures under Part D'' at proposed § 429.20. We intend to identify Part D plans based on the combination of the Part D contract identifier and the plan benefit package identifier.

We proposed at § 429.420(a)(1) to use the list of NDC–11s of the selected drug (as determined in proposed § 429.100(c) and discussed in section II.B.1. of this final rule), to determine which NDC–11s of the selected drug are included in this ceiling calculation.

We note that because we would not have PDE data for Part D plans in the following circumstances, such Part D plans would, by definition, be excluded from the calculation proposed at § 429.420(b):

- Plans that have no utilization of the selected drug; and
- Plans that have no enrollment for the year that is 4 years prior to the initial price applicability year of the selected drug.[78]

We proposed at § 429.420(b)(1) to use the most recent year for which all data is available, which is generally the year that is 4 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation. We proposed at § 429.420(b)(2) for each Part D plan and each NDC–11 we would sum the total direct and indirect remuneration amounts found in the DIR Report for the year that is 4 years prior to the initial price applicability year of the selected drug and subtract the total ERPOSA calculated in proposed § 429.420(b)(3) to avoid double counting price concessions applied at the point of sale. The amount calculated under proposed § 429.420(b)(4) is the NDC–11 price per unit, net of all price concessions received by such Part D plan or pharmacy benefit manager on behalf of such Part D plan. To determine which month(s) of enrollment to include in our analysis, we conducted an analysis of monthly Part D plan enrollment changes during 2022 and determined that monthly enrollment changes were the lowest from November to December, so we proposed at § 429.420(b)(5) that December would be the most stable

[78] Employer sponsored plans that receive the retiree drug subsidy and health plans that offer creditable prescription drug coverage would not be included because they are not Part D plans.

month to identify Part D plan enrollment. The choice of one month to identify enrollment, rather than an average annual enrollment, also allows the weights calculated at proposed § 429.420(b)(6) to sum to one.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters had feedback on and recommendations regarding the sum of the plan-specific enrollment weighted amounts. A commenter recommended CMS incorporate all price concessions from manufacturers to Part D plans, including those required under the Manufacturer Discount Program, when calculating the ceiling for the MFP. This commenter believed that including these discounts would meet the definition of a price concession and should be incorporated into the ceiling. A commenter recommended that when rebate and direct and indirect remuneration data are used as inputs to the MFP that CMS should neutralize the percentage-of-price component so that the calculated MFP reflects the actual net acquisition cost and not a figure inflated by compensation that rises with the gross price. A commenter recommended for CMS to explain, with specificity, the data that manufacturers may request to validate the sum of the plan-specific enrollment weighted amounts, what confidentiality protections would apply to any such disclosure, and what recourse exists if a manufacturer identifies a discrepancy that it cannot fully substantiate without access to the plan level data.

Response: We thank these commenters for their feedback and suggestions. Consistent with our response to similar comments in the Negotiation Program Guidance, we disagree with the commenter's suggestion of including the Manufacturer Discount Program discounts as they are not a price concession based on current regulation at § 423.100; we will continue to use the CFR definition of direct and indirect remuneration (DIR) and will not incorporate the Manufacturer Discount Program discounts in the ceiling calculation.

We interpret the commenter's recommendation regarding inputs to the MFP as meaning the MFP is based on the sum of the plan-specific enrollment weighted amounts alone. This interpretation is incorrect as the sum of the plan-specific enrollment weighted amounts is just one component of the ceiling and there are multiple pricing factors that go into the determination of the ceiling as outlined in § 429.410 of this final rule.

In response to the commenter's recommendation regarding the data that a Primary Manufacturer may request to validate the sum of the plan-specific enrollment weighted amounts, confidentiality, and suggestion of error, we note that, as stated in the Negotiation Program proposed rule (91 FR 36278), as directed by statute, and as finalized at § 429.420(a) and (b)(1), we will use plan sponsors' reported Part D PDE data and DIR data to determine the sum of the plan-specific enrollment weighted amounts. Due to the nature of the data described previously as being confidential, we are only able to provide a Primary Manufacturer with limited information and specific numbers in calculations of the sum of the plan-specific enrollment weighted amounts. However, we direct the commenter to § 429.445(c) of this final rule, which states that a Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraphs (a)(1), (a)(2), or (a)(3) of this section may submit a Suggestion of Error pertaining to such calculations for CMS 'consideration. We also direct the commenter to § 429.300 of this final rule, which is discussed in section II.D.1. of this final rule, regarding confidentiality policy and data use.

Final Decision: After consideration of public comments received, we are finalizing § 429.420 as proposed, with a non-substantive technical modification at § 429.420(b)(8)(i) for an omitted word. We are adding in ''quantity'' for clarity so § 429.420(b)(8)(i) states that for each NDC–11, CMS calculates the quotient of total quantity dispensed and total 30-day equivalent supply to calculate the NDC–11 average number of units per 30-day equivalent supply.

6. Determination of the Payment Amount Under Section 1847A(b)(4) of the Act (§ 429.425)

Section 1194(c)(1)(B)(ii) of the Act provides for the use of an amount equal to the payment amount under section 1847A(b)(4) for a selected drug that is payable under Part B for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the selected drug. Consistent with the policies for implementation as described in section 60.2.2.2 of the Negotiation Program Guidance and in accordance with section 1194(c)(1)(B)(ii) of the Act, CMS proposed at § 429.425 to calculate for a selected drug payable under Part B and paid under section 1847A(b)(4) of the Act, an amount equal to the payment amount under section 1847A(b)(4) of the Act for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for that drug or biological product (that is, 3 years prior to the initial price applicability year of the selected drug). We interpret ''payment amount under section 1847A(b)(4)'' under section 1194(c)(1)(B)(ii) of the Act to refer to an amount calculated for such year calculated using the methodology specified in section 1847A(b)(4) of the Act which is, for single source drugs and biological products, separately calculating the annual ASP and WAC described at proposed § 429.425(a)(2)(i) and taking the lesser of, as proposed at § 429.425(a)(2)(ii). When calculating this amount, we proposed at § 429.425(a)(1) to use the list of NDC–11s of the selected drug (as determined in proposed § 429.100(c) and discussed in section II.B.1. of this final rule).

Additionally, as directed by statute, we proposed to calculate the payment amount under section 1847A(b)(4) of the Act by using the quarterly reported ASP and WAC data for the calendar year 3 years prior to the initial price applicability year of the selected drug, for the purpose of determining the payment amount under section 1847A(b)(4) of the Act. This calculated amount proposed in § 429.425(a)(2) would apply for only selected drugs that are payable under Part B and paid according to section 1847A(b)(4) of the Act. When calculating the payment amount under 1847A of the Act for each HCPCS code we would use NDC-level data from the ASP Data Collection System (that is, the ASP portal). ASP data are required to be submitted to the ASP portal within 30 days after the close of each calendar quarter, and CMS uses that data to calculate payment amounts under section 1847A of the Act for the subsequent quarter, which results in a two-quarter lag between the quarter of ASP data used and when the Part B payment limits apply. We would apply this two-quarter lag when conducting all relevant calculations of the ceiling and application of MFP that rely on data from the ASP portal. For example, when calculating the annual ASP to determine the ''payment amount under section 1847A(b)(4)'' of the Act for calendar year 2028, CMS would use ASP portal data reported for the third quarter of 2027 through the second quarter of 2028.

To calculate a payment amount under section 1847A(b)(4) of the Act as described in section 1194(c)(1)(B)(ii) of the Act for a 30-day equivalent supply across all dosage forms and strengths of

a selected drug, we proposed at § 429.425(a)(2) to calculate such amount for each HCPCS code to which NDC–11s of the selected drug are assigned using data from manufacturers of all NDC–11s that are assigned to the HCPCS code and are part of the selected drug, and then assign such payment amount to each NDC–11 of the selected drug within such HCPCS code. We proposed at § 429.425(a)(3) to allocate HCPCS code-level utilization from Part B data across each NDC–11 assigned to such HCPCS code, so that we may then use the NDC-level utilization as weights when calculating a single payment amount under section 1847A(b)(4) of the Act, across all dosage forms and strengths of the selected drug. We would achieve this allocation by using the proportion of ASP units reported by manufacturers to CMS for each NDC–11 that is assigned to the HCPCS code.

We proposed at § 429.425(a)(2)(i) to convert the quarterly ASP and WAC reported by the manufacturer for the year as set forth in § 429.425(a) for each NDC–11 for a selected drug that is associated with a HCPCS code to an annual calendar year ASP or WAC amount for each HCPCS code. We proposed to do so by taking an average of the reported ASP or WAC amounts for the HCPCS code across all four quarters of such calendar year, weighted by the total number of billing units in the Part B data within that HCPCS code each quarter.

We proposed at § 429.425(a)(2)(i)(A), that if the total number of billing units in the Part B data within the HCPCS code are zero for a given quarter, we would assign that quarter the lowest positive total units from among the other quarters in the same calendar year for that HCPCS code.

We proposed at § 429.425(a)(2)(i)(B), that for each of the separate ASP and WAC calculations, if the reported price is negative, zero, or missing for all applicable NDC–11s assigned to the HCPCS code in a given quarter for the calendar year as set forth in § 429.405(a), we would exclude that quarter from the applicable calculation.

We proposed at § 429.425(a)(2)(i)(C), that if the WAC reported to the ASP portal is negative, zero, or missing for all applicable NDC–11s assigned to the HCPCS code for all four quarters for the calendar year as set forth in § 429.405(a), then we would use the WAC reported by the Primary Manufacturer of the selected drug to CMS under section 1194(e)(1) of the Act as described in § 429.505(b)(2)(v).

We proposed at § 429.425(a)(2)(iii), if ASP, WAC reported to the ASP payer portal, and WAC reported by the Primary Manufacturer pursuant to section 1194(e)(1) of the Act as described in § 429.505(b)(2) are all negative, zero, or missing for all applicable NDC–11s assigned to the HCPCS code for all four quarters of the calendar year as set forth in § 429.405(a), we would calculate the payment amount under section 1847A(b)(4) of the Act by taking the average of the published payment limits in the Medicare Part B Drug Payment Limit File (or in the OPPS Addendum B file, if it is not available in the Medicare Part B Drug Payment Limit File) for the HCPCS code across all four quarters, weighted by the total number of billing units in the Part B data for that HCPCS code for the four quarters of the calendar year as set forth in § 429.415(a)(2)(i) (including the adjustments made when billing units are zero). We believe this approach is appropriate because the prices in these files are typically calculated following the methodology described in section 1847A(b)(4) of the Act but may be adjusted as necessary to accommodate the underlying data (for example, negative, zero, or missing ASP and/or WAC). This amount would apply to all applicable NDC–11s assigned to the associated HCPCS code.

We proposed at § 429.425(a)(2)(ii) that we would use the lesser of the annual ASP and the annual WAC as determined under proposed § 429.425(a)(2)(i) to yield the payment amount under section 1847A(b)(4) of the Act for the associated HCPCS code. As proposed at § 429.425(a)(1)(iv), we proposed to exclude from the determination of the payment amount under section 1847A(b)(4) NDC–11s of the selected drug that are self-administered drugs. Self-administered drugs that are adjudicated through pharmacy claims are not used in the CMS calculation of the payment amounts under section 1847A(b)(4) of the Act for drugs that are not selected for negotiation. Therefore, we believe the exclusion of self-administered drugs from the determination of the payment amount for selected drugs under section 1847A(b)(4) of the Act is appropriate since self-administered drugs are not factored into payment amounts under section 1847A(b)(4) for drugs that are not selected for negotiation.

We proposed at § 429.425(a)(3) the steps for allocating HCPCS code-level utilization from Part B data for Part B services. For the steps proposed at § 429.425(a)(3)(ii), we have streamlined the steps given our experiences from previous initial price applicability years, specifically initial price applicability year 2028. The units, measured as the Part B data converted to the NCPDP level units that are used in PDE records, are used in cases where we need to sum together the Part D quantity dispensed and the Part B quantity administered, (that is, for non-FAMP proposed at § 429.435 and application of MFP proposed at § 429.700). To do so, we need the Part B billing units to be converted to the NCPDP level to match the units on PDE records. We recognize that the Part B data converted to the NCPDP level to match the units in PDE records are not needed for the calculation of the payment amount under section 1847A(b)(4) of the Act as we weight across the Part B and Part D amounts of the selected drug using the 30-day equivalent supply (as set forth in § 429.430), if applicable; however, we still conduct the NCPDP unit conversion to calculate the PDE equivalent number of units here for later use in the non-FAMP ceiling and MFP calculations.

We proposed at § 429.425(a)(4) how we would calculate the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of the selected drug.

We proposed at § 429.425(b), that the sequestration payment adjustment is not applied to the amount described under section 1847A(b)(4) of the Act. The amount described under section 1847A(b)(4) of the Act is not adjusted to account for sequestration. Therefore, we do not intend to apply sequestration to the payment amount under section 1847A(b)(4) of the Act as part of the methodology to calculate the payment amount under section 1847A(b)(4) of the Act.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter questioned how CMS calculates the temporary increase in the Part B add-on payment for qualifying biosimilars that Congress provided when the reference product is or has been subject to an MFP. The commenter also questioned whether a biosimilar entering the market after a period of negotiated pricing is disadvantaged in this calculation compared to a biosimilar that entered before negotiated pricing began.

Response: We appreciate this commenter's feedback, but payment for qualifying biosimilars is out of scope for this final rule.

Final Decision: After consideration of public comments received, we are finalizing § 429.425 as proposed, with the following non-substantive technical modifications to the steps described in

§ 429.425(a), (a)(2), (a)(3) and (a)(4) of this final rule:

- At § 429.425(a), we are inserting the words ''for the year'' into the second sentence for clarity and it so it states that CMS calculates the payment amount under section 1847A(b)(4) of the Act, for the year which is 3 years prior.;
- At § 429.425(a)(2)(iii), we are inserting the word ''are'' into the statement in the last parenthetical for clarity and so it states that . . .(including the adjustments made when billing units are zero). . .;
- For improved clarity, we are combining proposed paragraphs § 429.425(a)(3)(i) and § 429.425(a)(3)(ii); all references to these subparagraphs are updated in this section and throughout the rule accordingly;
- For improved clarity, we are deleting the words ''of the total Part B billing units'' from § 429.425(a)(3)(i) so the paragraph now states: ''CMS allocates HCPCS code-level utilization from Part B data using the proportion of ASP units reported by manufacturers to CMS for each NDC–11 that is assigned to the HCPCS code and converts the total billing units in Part B data for the HCPCS code that includes the selected drug to determine the units that are comparable to NCPDP units that are used in PDE records for the NDC–11 of the selected drug using the following steps:'';
- To be consistent with Negotiation Program Guidance, which the agency had intended to codify, we are adding the following step to allocate HCPCS code-level utilization from Part B data across each NDC–11 of the selected drug assigned to the HCPCS code, in new subparagraph (D), which states thatmultiplies the total Part B billing units from Part B data for that NDC–11, as calculated in paragraph (a)(3)(i)(C) of this section, by the billing unit to NCPDP conversion ratio (calculated by dividing the product of the standard package size and package quantity for an NDC–11 by the number of billing units per NDC–11 reporting unit for the NDC–11) to determine the PDE equivalent of the total Part units for that NDC–11;
- Due to the addition of new paragraph (D), we are renumbering proposed subsequent (D) to (E) and we are revising notwithstanding paragraphs (a)(3)(i)(A) through (C) of this section, to notwithstanding paragraphs (a)(3)(i)(A) through (D) of this section, to capture the entire prior applicable paragraphs;
- For improved clarity, we are striking the words ''set forth in paragraph (a) of this section, for'' at § 429.425(a)(4)(i)(A) and we are modifying regulatory text to clarify the determination of the annual calendar year with cross-reference to paragraph (a)(2) of the section;
- To be consistent with Negotiation Program Guidance, which the agency had intended to codify, we are changing the following cross-reference, at § 429.425(a)(4)(iii), from ''§ 429.425(a)'' to ''§ 429.415(a)(2)'';
- To correct a drafting error involving a citation, at § 429.425(a)(4)(vii), we are changing the cross-reference from ''(a)(4)(v)(B)'' to ''(a)(4)(vi)'' which is now referencing the correct preceding step.

7. Determination of the Combined Part B and Part D Amount (§ 429.430)

Section 1194(c)(1)(B) of the Act provides for the calculation of ''an amount,'' in the singular, under such subparagraph for each selected drug. Section 1194(c)(1)(B)(ii) of the Act then specifies the payment amount under section 1847A(b)(4) of the Act as an amount to be used under section 1194(c)(1)(B) of the Act for selected drugs that are payable under Part B and paid under section 1847A(b)(4) of the Act and separately specifies at section 1194(c)(1)(B)(i) of the Act the sum of the plan-specific enrollment weighted amounts as an amount to be used for under section 1194(c)(1)(B) of the Act for selected drugs covered under Part D. It does not specify that we should select only one of these two different amounts when calculating the amount for under section 1194(c)(1)(B) of the Act for a selected drug is both covered under Part D and payable under Part B.

For such selected drugs, we interpret section 1194(c)(1)(B) of the Act, which states ''. . . an amount equal to . . .'' when referring to calculating a single amount under such subparagraph for each selected drug, to mean that we should calculate an amount that captures both the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amounts, where both amounts are available for such drug (that is, where such drug is payable under Part B and is paid according to section 1847A(b)(4) of the Act). Our proposed interpretation gives effect to the entirety of section 1194(c)(1)(B) of the Act for such drugs when both amounts described thereunder are applicable. In contrast, we do not believe section 1194(c)(1)(B) of the Act is best read as permitting the selection and use of just one of the two applicable amounts under such subparagraph. Such subparagraph offers no criteria by which CMS would choose which of the amounts described thereunder to apply for selected for which both amounts are applicable. Moreover, we do not believe section 1194(c)(1) of the Act is best read as permitting CMS to use only the amount described in section 1194(c)(1)(C) of the Act for such drugs, because both amounts described under section 1194(c)(1)(B) of the Act are applicable to such drugs and CMS can calculate a single amount that accounts for both such amounts.[79]

To calculate the amount specified at section 1194(c)(1)(B) of the Act for such selected drugs, we proposed at § 429.430, consistent with the policies for implementation as described in section 60.2.2.3 of the Negotiation Program Guidance, a methodology to calculate a weighted average of the payment amount under section 1847A(b)(4) of the Act, proposed at § 429.425 and discussed at section II.E.6. of this proposed rule, and the sum of the plan-specific enrollment weighted amounts, proposed at § 429.420 and discussed at section II.E.5. of this proposed rule. We proposed at § 429.430(a) that this proposed amount be referred to as the combined Part B and Part D amount. The combined Part B and Part D amount would be for all dosage forms and strengths of a selected drug that are payable under Part B and paid according to section 1847A(b)(4) of the Act and covered under Part D as proposed at § 429.410(b)(2)(iii) and discussed at section II.E.3. of this final rule. We proposed at § 429.430 how the 30-day equivalent supply will be calculated for the combined Part B and Part D amount.

For the utilization weighting proposed at § 429.430(a)(2), we would treat the NDC–11s of drugs payable under Part B and covered under Part D as having two distinct versions and keep those versions separate in the utilization weighting so that the NDC–11s of drugs payable under Part B and covered under Part D contribute separately to the single amount, based on their applicable proportions to the total. We believe this step is necessary to account for differences in the pricing data between Part D and Part B.

Final Decision: We did not receive public comments on this provision,[80]

[79] In contrast, for selected drugs not covered under Part D but which are payable under Part B and not paid according to section 1847A(b)(4) of the Act, we do not believe any of the amounts described in section 1194(c)(1)(B) of the Act are applicable, so we proposed that section 1194(c)(1) of the Act is best read as permitting the agency to apply only the amount described under section 1194(c)(1)(C) of the Act for such drugs.

[80] CMS refers readers to the comments and responses under section II.E.5. of this final rule for more information about the sum of the plan specific

Continued

and therefore, we are finalizing § 429.430 as proposed, with the following non-substantive technical modifications:

- For clarity, at § 429.430(a)(1)(iii) we are adding to a cross-reference to more directly correspond to the steps in the cross-referenced section. The cross-reference changes from ''§ 429.425(a)(4)'' to ''§ 429.425(a)(4)(i) through (v)'';
- For clarity, at § 429.430(a)(2)(ii), in the parenthetical, we are adding the word ''and'' between '' . . . PDE records . . .'' and '' . . . associated with HCPCS codes . . .'' and the parenthetical in the paragraph is revised to specify that . . . (including both the Part B version and the Part D version of NDC–11s that are present in both PDE records and associated with HCPCS codes present in Part B data) . . .;
- To address a drafting error at § 429.430(a)(3), we are changing ''NDC–9s'' to ''NDC–11s'' and the paragraph now states: Paragraphs (a)(2)(i) and (ii) of this section, result in the combined sum of the plan-specific enrollment weighted amounts and payment amounts under section 1847A(b)(4) of the Act across all NDC–11s of the selected drug.

8. Determination of the Applicable Average Non-FAMP Amounts and Applicable Percent of the Average Non-FAMP (§ 429.435)

Section 1194(c)(1)(C)(ii) of the Act requires that for initial price applicability year 2027 and subsequent years, that the lower of the average non-FAMP amounts described in sections 1194(c)(1)(C)(ii)(I) and 1194(c)(1)(C)(ii)(II) of the Act is used as the average non-FAMP amount. Section 1194(c)(1)(C)(ii)(I) of the Act describes the first amount as the average non-FAMP for such drug for 2021 (or, in the case that there is not an average non-FAMP available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the CPI–U from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year. Section 1194(c)(1)(C)(ii)(II) of the Act describes the second amount as the average non-FAMP for such drug for the year prior to the selected drug publication date with respect to such initial price applicability year. Consistent with the policies for implementation as described in section 60.2.3 of the Negotiation Program Guidance and in accordance with section 1194(c)(1)(C)(ii) of the Act, we proposed at § 429.435(a) to use the methodology and comparison described to determine the lower of the two applicable non-FAMP amounts and apply the applicable percent described in section 1194(c)(3) of the Act.

We proposed at § 429.435(a)(1)(i) to use the list of NDC–11s of the selected drug (as determined in proposed § 429.100(c) and discussed in section II.B.1. of this f rule), to determine which NDC–11s of the selected drug are included in this ceiling calculation.

Consistent with the policies for implementation as described in section 60.2.3 of the Negotiation Program Guidance, we proposed at § 429.435(a)(2)(ii) to use the same methodology for calculating the average non-FAMP for the calendar year 3 years prior to the initial price applicability year of the selected drug as used for the calculation proposed at § 429.435(a)(1)(ii) through (iv) for calendar year 2021, noting that the set of NDCs used to calculate the annual average non-FAMP calculation for each may differ.

To directly compare the amount calculated based on the applicable percent of average non-FAMP proposed in § 429.435 to the amount calculated based on the sum of the plan-specific enrollment weighted amounts proposed in § 429.420, the payment amount under section 1847A(b)(4) of the Act § 429.425, and the combined Part B and Part D amount described in proposed § 429.430, as applicable, we proposed to base the average non-FAMP calculations on a 30-day equivalent supply. We proposed to use the approach set forth in proposed § 429.435(a)(3) to calculate the average non-FAMP for a 30-day equivalent supply because it is necessary for the calculated non-FAMP amounts to account for different units and treatment regimens across dosage forms and strengths.

We proposed at § 429.435(a)(4) to determine the average non-FAMP across all NDC–11s of the selected drug by conducting the steps outlined in this section separately for the average non-FAMP in calendar year 2021 (or for the first full year following market entry for such drug if there is not a non-FAMP for such drug or an average non-FAMP cannot be calculated) and for the calendar year that is 3 years prior to the initial price applicability year of the selected drug. Consistent with the policies for implementation as described in section 60.2.3 of the Negotiation Program Guidance, we proposed at § 429.435(a)(4) to calculate an average non-FAMP that is comparable to the sum of the plan-specific enrollment weighted amount (as set forth in § 429.420), the payment amount under section 1847A(b)(4) of the Act (as set forth in § 429.425), or the combined Part B and Part D amount (as set forth in § 429.430), as applicable, and determine the total number of NCPDP units per NDC–11 package. We proposed at § 429.435(a)(4)(i) and (ii) the calculations to account for non-FAMP unit volume fluctuations that may occur across quarters.

Consistent with policies for implementation as described in section 60.2.3 of the Negotiation Program Guidance and in accordance with section 1194(c)(1)(C)(ii)(I) of the Act, we proposed at § 429.435(a)(4)(v) to increase the average non-FAMP per unit for calendar year 2021 (or for the first full year following market entry for such drug if there is not a non-FAMP for such drug or an average non-FAMP cannot be calculated), which would be calculated in § 429.435(a)(4)(iv) by the percentage increase in CPI–U from September 2021 to September of the calendar year that is 3 years prior to the initial price applicability year of the selected drug.

Consistent with the policies for implementation as described in section 60.2.3 of the Negotiation Program Guidance and in accordance with section 1194(c)(3) of the Act, we proposed at § 429.435(a)(4)(vi) to apply the applicable percent to the average non-FAMP associated with the monopoly type for the selected drug that is described in section 1194(c)(3)(A) through (C) of the Act. The applicable percent is determined based on the initial approval date, as set forth in § 429.125(a)(1)(i), of the selected drug and the initial price applicability year for which the drug is selected for negotiation. We note that applying the applicable percent at proposed § 429.435(a)(4)(vi) results in the same ultimate amount calculated at proposed § 429.435(a)(4)(viii) as it would if we were to apply the applicable percent to the average non-FAMP per 30-day equivalent supply for the selected drug at proposed § 429.435(a)(4)(viii). Consistent with section 1194(c)(3)(A) of the Act, the applicable percent for short monopoly drugs and vaccines (that is, other than an extended-monopoly drug and long-monopoly drug) will be 75 percent. Consistent with section 1194(c)(3)(B) of the Act, the applicable percent with respect to an extended-monopoly drug will be 65 percent. Consistent with section 1194(c)(4)(C) of the Act, the applicable percent with

enrollment weighted amount component of the combined Part B and Part D amount.

respect to long-monopoly drug will be 40 percent.

We proposed at § 429.435(a)(4)(vii) and (viii) the steps that we would take for each NDC–11 to calculate the average non-FAMP per 30-day equivalent supply. We proposed at § 429.435(a)(4)(ix) the method to compare the amounts calculated for the two separate applicable percent of the average non-FAMP amounts and to determine the lower amount.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters had feedback and recommendations regarding the applicable average non-FAMP amounts. Both commenters noted that the proposal at § 429.435(a)(4)(iv) is inconsistent with the Negotiation Program Guidance and recommended modifying the weighting to rely on the 30-day equivalent supply product mix as opposed to utilizing the product mix based on total units.

Response: We thank these commenters for their feedback and suggestion. We have considered the commenters' feedback and will adjust the steps outlined in § 429.435(a)(4) of this final rule to align with our proposal to adopt a methodology consistent with the Negotiation Program Guidance and the intended steps that we will follow to determine the applicable average non-FAMP amounts and applicable percent of the average non-FAMP.

Final Decision: After consideration of public comments received, we are finalizing § 429.435 as proposed, with the following non-substantive technical modifications to the steps described in § 429.435(a)(4) of this final rule:

- To align with our proposal to adopt a methodology consistent with the Negotiation Program Guidance and the steps the agency intended to codify and will follow to determine the applicable average non-FAMP amounts and applicable percent of the average non-FAMP, we are removing proposed subparagraph (iv);
- Due to subparagraph (iv) removal, we are renumbering subparagraphs (v) through (vii) to (iv) through (vi); all references to these subparagraphs are renumbered in this section and throughout the rule accordingly;
- To align with our proposal to adopt a methodology consistent with the Negotiation Program Guidance and the steps the agency intended to codify and will follow to determine the applicable average non-FAMP amounts and applicable percent of the average non-FAMP, we are adding subparagraph (vii), which states: ''For each NDC–11, CMS then divides the total 30-day equivalent supply for that NDC–11 by the total 30-day equivalent supply across all NDC–11s of the selected drug and multiplies this quotient by the amount calculated in paragraph (a)(4)(vi) of this section.''

9. Temporary Floor for Small Biotech Drugs (§ 429.440)

a. Definitions

In proposed § 429.440, we proposed to codify the following definitions applicable to § 429.440 based on policies detailed in this final rule.

(1) ''Part B 2021 Manufacturer''

We proposed to define ''Part B 2021 Manufacturer'' to mean the NDA holder or the BLA holder for the qualifying single source drug on December 31, 2021.

(2) ''Part D 2021 Manufacturer''

We proposed to define ''Part D 2021 Manufacturer'' as the entity that either (1) had a Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D–14A of the Act in effect for the qualifying single source drug on December 31, 2021, or (2) had an arrangement whereby the manufacturer's labeler codes were listed on another manufacturer's Medicare CGDP Agreement, consistent with section 1860D–14A of the Act, in effect on December 31, 2021.

(3) ''Part B 2021 Manufacturer and Its Controlled Group''

We proposed to define ''Part B 2021 Manufacturer and its controlled group'' as comprising all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part B 2021 Manufacturer.

(4) ''Part D 2021 Manufacturer and its controlled group''.

We proposed to define ''Part D 2021 Manufacturer and its controlled group'' as comprising all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part D 2021 Manufacturer and had a CGDP Agreement in effect on December 31, 2021.

Final Decision: We did not receive public comments on these definitions, and therefore, we are finalizing § 429.440(a) as proposed.

b. Implementation of the Temporary Floor for Small Biotech Drugs

Section 1192(d)(2) of the Act established the Small Biotech Exception (SBE), which states that a negotiation eligible drug shall not include, with respect to initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either the criteria at section 1192(d)(2)(A)(i) or section 1192(d)(2)(A)(ii) of the Act. With respect to initial price applicability years 2026 through 2028, CMS implemented the requirements set forth in section 1192(d)(2) of the Act for a qualifying single source drug to be determined a Small Biotech Drug and therefore eligible for the SBE through guidance, including for example, section 30.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

Section 1194(d) of the Act requires that for a selected drug that is a qualifying single source drug that meets the requirements set forth in section 1192(d)(2) of the Act to be determined a Small Biotech Drug, and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, CMS will not offer or agree to a counteroffer for an MFP that is lower than the Temporary Floor for Small Biotech Drugs. To fulfill the statutory obligation at section 1194(f)(4)(B) of the Act, which states that reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the maximum fair price established pursuant to renegotiation applies, drugs selected for renegotiation also would be eligible to be considered for the Temporary Floor for Small Biotech Drugs described in section 1194(d). Section 1194(d) of the Act states that the Temporary Floor for Small Biotech Drugs shall be equal to 66 percent of the average non-FAMP for such drug for 2021 (or, in the case that there is not an average non-FAMP available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the CPI–U from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year.

With respect to a drug selected for negotiation for initial price applicability year 2029 and 2030, or a drug selected for renegotiation for initial price

applicability year 2029 or 2030, for which the Primary Manufacturer submits information in accordance with § 429.440(b)(1), we proposed at § 429.440(b) to establish the Temporary Floor for Small Biotech Drugs for a selected drug that is determined to be a Small Biotech Drug based on the criteria that were used and implemented with respect to the SBE for initial price applicability year 2028, as proposed in § 429.440(b)(2). We will not make an offer or agree to a counteroffer for an MFP (as proposed in § 429.500(b) and described in section II.F.1. of this final rule) that is lower than the Temporary Floor for Small Biotech Drugs, which shall be equal to the amount specified in proposed § 429.440(b)(3). A determination by CMS that a given selected drug is eligible for the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030 is not based on whether or not CMS previously determined that the qualifying single source drug was eligible or not eligible for the SBE for initial price applicability years 2026, 2027, or 2028.

We proposed at § 429.440(b)(1) to establish a process whereby a Primary Manufacturer that would like its selected drug to be considered eligible for the Temporary Floor for Small Biotech Drugs must submit information to allow CMS to determine whether its selected drug meets the requirements of a Small Biotech Drug. This submission is a prerequisite for the Temporary Floor for Small Biotech Drugs to apply to a selected drug. We proposed at § 429.440(b)(2) to establish requirements for determining whether a selected drug is a Small Biotech Drug that are consistent with the eligibility requirements for the SBE for initial price applicability year 2028, which were implemented through section 30.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028. If a selected drug is determined to be a Small Biotech Drug, CMS would then calculate the Temporary Floor for Small Biotech Drugs, as proposed at § 429.440(b)(3). We proposed at § 429.440(b)(4) to establish a stepwise approach to adjust the ceiling for a selected drug in the event that the ceiling identified in § 429.410(b) (or § 429.620(b) as applicable) is below the Temporary Floor for Small Biotech Drugs, if applicable.

As discussed in further detail in section IV. of this final rule, for a Primary Manufacturer to be considered for the Temporary Floor for Small Biotech Drugs, we proposed revisions to a currently approved information collection request, titled the Negotiation Program Drug Price Negotiation for Initial Price Applicability Year 20XX under section 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS–10849, OMB 0938–1452) (hereinafter, the ''Drug Price Negotiation ICR''), for a 60-day public comment period concurrently with the proposed rule. A form and manner for submitting an application for the Temporary Floor for Small Biotech Drugs, consistent with proposed § 429.440(b)(1), would be specified in the ICR for initial price applicability year 2029 and initial price applicability year 2030. Information submitted in an application for the Temporary Floor for Small Biotech Drugs that is a trade secret or confidential commercial or financial information will be protected from disclosure if the information meets the requirements set forth under Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(3), (4)).

In accordance with section 1194(d) of the Act, to determine eligibility for the Temporary Floor for Small Biotech Drugs, and proposed at § 429.440(b)(2), we would determine whether the selected drug meets the criteria set forth in section 1192(d)(2) [81] of the Act. Section 1192(d)(2)(A)(i) of the Act establishes that for a selected drug that is covered under Part D to be considered a Small Biotech Drug, the Total Expenditures under Part D during 2021 for such drug must be: equal to or less than 1 percent of the Total Expenditures under Part D for all covered Part D drugs during 2021; and equal to or greater than 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the manufacturer had a Coverage Gap Discount Program Agreement in effect during 2021. Section 1192(d)(2)(A)(ii) of the Act establishes that for a selected drug that is payable under Part B to be considered a Small Biotech Drug, the Total Expenditures under Part B for such drug during 2021 must be: equal to or less than 1 percent of the Total Expenditures under Part B for all qualifying single source drugs for which payment may be made under Part B during 2021; and equal to or greater than 80 percent of the Total Expenditures under Part B for all qualifying single source drugs of the manufacturer for which payment may be made under Part B during 2021. A selected drug that meets either the criteria set forth in section 1192(d)(2)(A)(i) of the Act or the criteria set forth in section 1192(d)(2)(A)(ii) of the Act will qualify as a Small Biotech Drug. Section 1192(d)(2)(B)(i) of the Act establishes the aggregation rule, which establishes that all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer when determining whether a selected drug is a Small Biotech Drug. Additionally, section 1192(d)(2)(B)(ii) of the Act establishes that a selected drug shall not be considered a Small Biotech Drug if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025. With respect to initial price applicability years 2026 through 2028, CMS implemented the requirements set forth in sections 1192(d)(2)(A)(i), 1192(d)(2)(A)(ii), 1192(d)(2)(B)(i), and 1192(d)(2)(B)(ii) of the Act through guidance, including, for example, section 30.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability years 2029 and 2030, and consistent with the policies for implementation of the SBE through section 30.2.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028, we proposed at § 429.440(b)(2)(i) to establish the Part D Track, which outlines the criteria for determining whether a selected drug covered under Part D qualifies as a Small Biotech Drug in accordance with section 1192(d)(2)(A)(i) of the Act. In our assessment, we would consider Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures under Part D for the selected drug during 2021, and Total Expenditures under Part D during 2021 for all covered Part D drugs for which the Part D 2021 Manufacturer (as

[81] Section 1192(d) of the Act implemented the SBE for initial price applicability years 2026, 2027, and 2028, which included criteria for determining if a qualifying single source drug was a Small Biotech Drug. Section 1194(d) of the Act directs CMS to use the same criteria when determining whether a selected drug is a Small Biotech Drug. Section 1194(f)(4)(B) of the Act extends the Temporary Floor for Small Biotech Drug provisions to certain drugs selected for renegotiation. Therefore, when discussing the criteria to determine a Small Biotech Drug to determine the eligibility of the Temporary Floor for Small Biotech Drugs, we use the term ''selected drug'' as defined in proposed § 429.20 and ''drug selected for renegotiation'' in lieu of ''qualifying single source drug''.

defined in proposed § 429.440(a)(2)) and its controlled group (as defined in proposed § 429.440(a)(4)) had a CGDP Agreement in effect on December 31, 2021, as calculated using the methodology proposed in § 429.120(a) and described section in II.B.5.a. of this final rule, except the date of service as described in § 429.120(a)(1) is during 2021. Specifically, we would consider whether, for dates of service in calendar year 2021, the Total Expenditures during 2021 under Part D for the selected drug were: (1) equal to or less than 1 percent of the Total Expenditures under Part D for all covered Part D drugs during 2021; and (2) equal to or greater than 80 percent of the Total Expenditures under Part D for all covered Part D drugs during 2021 for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021. For the purpose of performing the calculations described at proposed § 429.440(b)(2)(ii), CMS would identify the NDC–11s of the selected drug determined under § 429.100(d) with respect to the initial price applicability year for which the Primary Manufacturer of the selected drug applied for the Temporary Floor for Small Biotech Drugs in accordance with proposed § 429.440(b)(1). We would identify the drugs covered under Part D for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021 as the NDC–11s corresponding to the labeler codes of the Part D 2021 Manufacturer and its controlled group.

For the purposes of determining whether a selected drug qualifies as a Small Biotech Drug via the Part D Track, we need to collect information to accurately identify the Part D 2021 Manufacturer, which is the entity that had the CGDP Agreement under section 1860D–14A of the Act in effect for the selected drug on December 31, 2021, and described at proposed § 429.440(a)(2). In addition, in accordance with section 1192(d)(2)(B)(i) of the Act, we proposed at § 429.440(a)(4) that the Part D 2021 Manufacturer and its controlled group comprise all persons that, as of December 31, 2021, were treated as a single employer with the Part D 2021 Manufacturer and had a CGDP Agreement in effect on December 31, 2021. However, CMS does not have information about which entities were treated as a single employer with the Part D 2021 Manufacturer under the applicable IRC provisions and the Treasury regulations thereunder. Therefore, we proposed that a Primary Manufacturer that seeks the Temporary Floor for Small Biotech Drugs for its selected drug covered under Part D would be required to submit information to CMS about the Part D 2021 Manufacturer and its controlled group to be considered for the Part D Track.

With respect to initial price applicability years 2029 and 2030, and consistent with the policies for implementation of the SBE, we proposed at § 429.440(b)(2)(ii) to establish the Part B Track, which outlines the criteria for determining whether a selected drug payable under Part B qualifies as a Small Biotech Drug in accordance with section 1192(d)(2)(A)(ii) of the Act. In our assessment, we would consider Total Expenditures under Part B during 2021 for all qualifying single source drugs, Total Expenditures under Part B during 2021 for the selected drug, and Total Expenditures under Part B in 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer (as defined in proposed § 429.440(a)(1)) and its controlled group (as defined in proposed § 429.440(a)(3)), calculated using the methodology proposed in § 429.120(b) and described in II.B.5.b. of this final rule, except the date of service as described in § 429.120(b)(1)(i) and (b)(2)(i) is during 2021. We would consider whether, for Part B data, as defined in § 429.20, with dates of service during 2021, the Total Expenditures under Part B during 2021 for the selected drug were: (1) equal to or less than 1 percent of the Total Expenditures under Part B for all qualifying single source drugs payable under Part B during 2021; and (2) equal to at least 80 percent of the Total Expenditures under Part B during 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group for which payment may be made under Part B. For the purpose of performing the calculations described at proposed § 429.440(b)(2)(ii), CMS would identify the NDC–11s of the selected drug determined under § 429.100(d)(1) with respect to the initial price applicability year for which the Primary Manufacturer of the selected drug applied for the Temporary Floor for Small Biotech Drugs in accordance with proposed § 429.440(b)(1). CMS would identify the NDC–11s of other applicable qualifying single source drugs using the policies for identifying qualifying single source drugs proposed in § 429.125. Accordingly, we would identify the qualifying single source drug(s) payable under Part B for the Part B 2021 Manufacturer and its controlled group using the NDC–11(s) associated with the qualifying single source drug(s) that correspond to the NDA(s) and/or BLA(s) held by the Part B 2021 Manufacturer or any member of its controlled group on December 31, 2021. For the purposes of determining whether a selected drug qualifies as a Small Biotech Drug via the Part B Track, we need to collect information to accurately identify the Part B 2021 Manufacturer, which is the entity that is the NDA(s) holder or BLA(s) holder for the selected drug on December 31, 2021, and described at proposed § 429.440(a)(1). In addition, in accordance with section 1192(d)(2)(B)(i) of the Act, we proposed at § 429.440(a)(3) that the Part B 2021 Manufacturer and its controlled group comprise all persons that, as of December 31, 2021, were treated as a single employer with the Part B 2021 Manufacturer. However, CMS does not have information about which entities were treated as a single employer with the Part B 2021 Manufacturer under the applicable IRC provisions and the Treasury regulations thereunder. Therefore, we proposed that a Primary Manufacturer that seeks the Temporary Floor for Small Biotech Drugs for its selected drug payable under Part B would be required to submit information to CMS about the Part B 2021 Manufacturer and its controlled group to be considered for the Part B Track.

In addition, in accordance with section 1192(d)(2)(B)(i) of the Act, we proposed at § 429.440(b)(2)(iii) to preclude a selected drug from being eligible for the Temporary Floor for Small Biotech Drugs if the Primary Manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.[82] For purposes of implementing this limitation, we would use the determinations of the Manufacturer Discount Program as to whether the acquiring entity met the definition of specified manufacturer in the applicable period. We would consider an acquiring entity to have met the Manufacturer Discount Program definition of specified manufacturer for purposes of this limitation if the acquiring entity is identified by CMS under the Manufacturer Discount

[82] *See* 42 CFR 423.2724.

Program as either a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act or a specified small manufacturer under section 1860D–14C(g)(4)(C)(ii) of the Act.[83] For an acquisition of a Primary Manufacturer to be relevant to the limitation, and therefore to potentially preclude a selected drug from being considered a Small Biotech Drug, we proposed that the transaction must occur after 2021 and must involve the acquisition of the Primary Manufacturer after it held the NDA(s) or BLA(s) for the drug.

In accordance with section 1194(d) of the Act, we proposed at § 429.440(b)(3) to calculate the Temporary Floor for Small Biotech Drugs for each Small Biotech Drug as 66 percent of the average non-FAMP in calendar year 2021. The methodology for calculating average non-FAMP in calendar year 2021 is set forth in § 429.435(a)(1) and § 429.435(a)(3), and CMS would apply the temporary floor percentage (66 percent) in place of the applicable percent for the monopoly type. If a selected drug did not have a non-FAMP for 2021, we would use the average non-FAMP for the first full year following the market entry, increased by the percentage increase in the CPI–U from December of the first full year following market entry to September of the year prior to the selected drug publication date for which the drug is selected for negotiation or, as applicable, renegotiation.

In accordance with section 1194(b)(2)(F)(ii) of the Act and as proposed in § 429.410(a), we would not offer or agree to a counteroffer for an MFP that is below the Temporary Floor for Small Biotech Drugs. However, we noted that there is a possibility under the statute that the ceiling calculated as described in proposed § 429.410(b) (or § 429.620(b), as applicable) is below the Temporary Floor for Small Biotech Drugs. The statute does not expressly address how to apply section 1194(b)(2)(F)(ii) of the Act in such cases, though such a scenario is possible under the statute—for example, if a selected drug is eligible for the Temporary Floor for Small Biotech Drugs in initial price applicability year 2030 and is an extended-monopoly drug, the applicable percent of average non-FAMP for 2021 used in the ceiling calculation for an extended-monopoly drug under proposed § 429.435(a)(4)(vii)(A)(2) would be less than that of the Temporary Floor for Small Biotech Drugs under proposed § 429.440(b)(3) (65 percent and 66 percent, respectively).

Additionally, as proposed in § 429.620(b) and further described in section II.G.5. of this final rule, for the purpose of calculating the ceiling for renegotiation, we proposed to determine the ceiling applicable to renegotiation using the ceiling amounts determined with respect to the selected drug's original negotiation, with limited updates, including to account for the statutory directive to update the applicable percent for certain renegotiation-eligible drugs. However, for drugs selected for renegotiation that are eligible for the Temporary Floor for Small Biotech Drugs, the ceiling determined under § 429.620(b) may be lower than the Temporary Floor for Small Biotech Drugs.

To address such a scenario, and to ensure the negotiation process gives effect to the Temporary Floor for Small Biotech Drugs provision at section 1194(d) of the Act that establishes a specific limitation to the general rules for MFP negotiations, we proposed at § 429.440(b)(4) a stepwise approach to calculate an adjusted ceiling that would apply to the negotiation, or renegotiation, process for selected drugs that qualify for the Temporary Floor for Small Biotech Drugs. We would first determine if an adjusted ceiling is needed by calculating the unadjusted ceiling as described at proposed § 429.410(b) or the renegotiated unadjusted ceiling as described in § 429.620(b) (as applicable), as well as the Temporary Floor for Small Biotech drugs as described at proposed § 429.440(b)(3), and then would determine if the unadjusted ceiling is below the Temporary Floor for Small Biotech Drugs. If the unadjusted ceiling is greater than or equal to the Temporary Floor for Small Biotech Drugs, then this ceiling would apply, and we would not offer or accept a counteroffer for an MFP that is below the Temporary Floor for Small Biotech Drugs or greater than the ceiling for the selected drug. If, however, such ceiling is below the Temporary Floor for Small Biotech Drugs, we would calculate an adjusted ceiling, as described in proposed § 429.440(b)(4)(i) or (ii), as applicable. To calculate an adjusted ceiling, we proposed in § 429.440(b)(4)(i) that, for purposes of determining the potential ceiling amount described under section 1194(c)(1)(C) of the Act, rather than selecting the lower of the average non-FAMP available for such drug in 2021 (or the first full year following market entry for such drug if there is not a non-FAMP for such drug or an average non-FAMP cannot be calculated), as described in section 1194(c)(1)(C)(i) or section 1194(c)(1)(C)(ii)(I) of the Act and proposed § 429.435(a)(1) or § 429.620(b) (as applicable), or the average non-FAMP for such drug for the year prior to the selected drug publication date, as described in section 1194(c)(1)(C)(ii)(II) of the Act and proposed § 429.435(a)(2) or § 429.620(b) (as applicable), to calculate the lower amount of the applicable percent of the average non-FAMP, as described in proposed § 429.410(b) (or § 429.620(b) for both non-FAMPs as applicable), we would only consider the average non-FAMP for such drug for the prior year to the selected drug publication date (that is, the amount described in section 1194(c)(1)(C)(ii)(II) of the Act). Therefore, the adjusted ceiling proposed in § 429.440(b)(4)(i) would determine the ceiling as described in § 429.410(b) (or § 429.620(b) as applicable) except that the lower amount of the applicable percent of the average non-FAMP, as proposed in § 429.435 (or § 429.620(b) as applicable), would consider only the average non-FAMP for such drug for the prior year to the selected drug publication date, as described in § 429.435(a)(2) (or § 429.620(b), as applicable). We believe that removing the average non-FAMP available for such drug in 2021 from the calculation of the lower amount of the applicable percent of the average non-FAMP allows for the implementation of the Temporary Floor for Small Biotech Drugs while preserving the ceiling calculation, giving effect to both provisions, and is the most appropriate and narrowly tailored way to reconcile cases where the Temporary Floor for Small Biotech Drugs exceeds the ceiling for a selected drug, as the average non-FAMP available for such drug in 2021 may be in direct tension when calculating the ceiling and the Temporary Floor for Small Biotech Drugs, due to the applicable percent being applied in contradictory ways in the ceiling and the Temporary Floor for Small Biotech Drugs. If this adjusted ceiling is greater than or equal to the Temporary Floor for Small Biotech Drugs, then such adjusted ceiling would be used as the ceiling for the negotiation

[83] For purposes of the Temporary Floor for Small Biotech Drugs and implementing section 1192(d)(2)(B)(ii) of the Act, to determine whether the acquiring entity meets the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act, CMS will use the determination made by CMS under the Manufacturer Discount Program as to whether the acquiring entity is a ''specified manufacturer.'' The Part D Manufacturer Discount Program ICR (CMS–10846, OMB control no. 0938–1451) is available for viewing at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202307-0938-003* (select ''all'' to see full details).

between CMS and the Primary Manufacturer, and we would not offer or agree to a counteroffer for an MFP that is below the Temporary Floor for Small Biotech Drugs or greater than this adjusted ceiling for the selected drug.

If this adjusted ceiling is still below the Temporary Floor for Small Biotech Drugs, then, as described in proposed § 429.440(b)(4)(ii), we would raise the ceiling to be equal to the Temporary Floor for Small Biotech Drugs. We believe that raising the ceiling to be equal to the Temporary Floor for Small Biotech Drugs appropriately balances the statutory requirements to establish a ceiling for a selected drug while ensuring the negotiation process also gives full effect to the Temporary Floor for Small Biotech Drugs provision at section 1194(d) of the Act. We note that the Temporary Floor for Small Biotech Drugs provision applies only with respect to negotiations and renegotiations that occur for initial price applicability years 2029 and 2030 for eligible drugs, and it would not apply to any subsequent renegotiations of drugs selected for renegotiation with respect to an initial price applicability year after initial price applicability year 2030. We considered disregarding the ceiling entirely, but we do not believe this approach would align with the statutory requirements for both a ceiling and a Temporary Floor for Small Biotech Drugs. We also considered using the amount calculated in section 1194(c)(1)(B) of the Act (as proposed in § 429.410(b)(1) or § 429.620(b)) as the sole amount for the ceiling, however we do not believe this approach would align with the statutory requirements to apply an applicable percent in section 1194(c)(1)(C) of the Act, and would result in a ceiling that would not distinguish between a short-monopoly drug, a long-monopoly drug, and an extended-monopoly drug (beginning in initial price applicability year 2030). In accordance with section 1194(b)(2)(F) of the Act, because the ceiling and the Temporary Floor for Small Biotech Drugs for a selected drug would equal the same price, we would only offer or agree to a counteroffer for an MFP that is equal to such price. We believe that this stepwise approach addresses circumstances in which the ceiling is below the Temporary Floor for Small Biotech Drugs while maintaining the integrity of the negotiation process and implementing the statutory responsibility to not offer or accept a counteroffer of an MFP that is above the ceiling or below the Temporary Floor for Small Biotech Drugs.

As proposed in § 429.440(b)(5), if a Primary Manufacturer submits an application for the Temporary Floor for Small Biotech Drugs, we would provide a notice in writing to the Primary Manufacturer, alongside the calculation information provided as set forth in § 429.445(a), which would include: a determination of whether the selected drug is a Small Biotech Drug; and, if the selected drug is eligible for the Temporary Floor for Small Biotech Drugs, the calculation of the Temporary Floor for Small Biotech Drugs as proposed in § 429.440(b)(3) (or adjusted ceiling, if applicable, as proposed in § 429.440(b)(4)). We proposed in § 429.440(b)(6) to allow a Primary Manufacturer that believes in good faith that CMS has made an error in calculations pertaining to the calculation of the Temporary Floor for Small Biotech Drugs, as proposed in § 429.440(b)(3), or the adjusted ceiling, if applicable, calculated for a drug that receives the Temporary Floor for Small Biotech Drugs, as proposed in § 429.440(b)(4), to submit a Suggestion of Error as proposed in § 429.445(c).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters offered feedback on our proposal for a stepwise approach to determining an adjusted ceiling in circumstances in which we determine that the statutory ceiling for a selected drug that qualifies for the Temporary Floor for Small Biotech Drugs is below the Temporary Floor for Small Biotech Drugs. While these commenters acknowledged the Temporary Floor for Small Biotech Drugs provision can conflict with provisions governing the ceiling, these commenters expressed differing views over how we should resolve this conflict. Many commenters proposed eliminating the ceiling in cases where the ceiling determined under proposed § 429.410(b) (negotiation) or § 429.620(b) (renegotiation) is lower than the Temporary Floor for Small Biotech Drugs. Some commenters rationalized that Congress did not intend for any statutory ceiling to apply to long-monopoly and extended-monopoly drugs that qualify for the Temporary Floor for Small Biotech Drugs because, for such drugs, it is mathematically impossible to calculate a ceiling that exceeds the Temporary Floor for Small Biotech Drugs. Other commenters maintained that the proposal for a stepwise approach in these circumstances is arbitrary and capricious because they contended that the ''adjusted'' ceiling has no basis in statute. A couple of commenters stated that the use of ''or'' in section 1194(b)(2)(F) of the Act's prohibition against offering or agreeing to a counteroffer for any MFP that exceeds the ceiling *or* is less than the Temporary Floor for Small Biotech Drugs for the selected drug allows for CMS to apply either the ceiling, or as applicable, the Temporary Floor for Small Biotech Drugs, effectively allowing these provisions to operate as ''separate constraints.'' Further, a few commenters stated that the proposed adjusted ceiling calculation undermines the negotiation process for Small Biotech Drugs. Specifically, these commenters contended that in instances in which the adjusted ceiling would be equal to the Temporary Floor for Small Biotech Drugs, small biotech manufacturers would be obligated to submit data based on factors described under section 1194(e) of the Act and comply with the Negotiation Program Agreement, which would impose substantial and unnecessary burden on both manufacturers and CMS, even though CMS would have ''no need'' to consider data submitted because there would only be one possible MFP available for consideration.

On the other hand, a couple of commenters suggested that for circumstances in which the Temporary Floor for Small Biotech Drugs is above the statutory ceiling for a Small Biotech Drug, CMS should instead raise the ceiling to be equal to the Temporary Floor for Small Biotech Drugs, which the commenters contended gives effect to the provision described under section 1194(b)(1) of the Act (''aim to achieve the lowest maximum fair price''). Finally, another commenter suggested CMS revise its proposal for a stepwise approach under which it would disregard all non-FAMP-based amounts under section 1194(c)(1)(C) of the Act and instead use the specified amount under section 1194(c)(1)(B) of the Act, as applicable, as the ceiling.

Response: We thank the commenters for their feedback, including suggestions for alternative approaches to implementation of the Temporary Floor for Small Biotech Drugs. We proposed the stepwise approach described in proposed § 429.440(b)(4) for selected drugs that qualify for the Temporary Floor for Small Biotech Drugs to address the limited, although possible, scenario in which the ceiling determined under proposed § 429.410(b) (negotiation) or § 429.620(b) (renegotiation) is lower than the Temporary Floor for Small Biotech Drugs. For example, in cases where a long-monopoly drug is selected for negotiation in IPAY 2029 and is determined to be a Small Biotech Drug, the ceiling amount determined under

section 1194(c)(1)(C)(ii)(I) of the Act equals 40 percent of the drug's non-FAMP in 2021, which would be less than the Temporary Floor for Small Biotech Drugs (66 percent of the drug's non-FAMP in 2021). Our proposed stepwise approach would only be triggered in these (and similar) circumstances (that is, where the unadjusted ceiling calculation as described in proposed § 429.410(b) (negotiation) or § 429.620(b) (renegotiation) is less than that of the Temporary Floor calculated under proposed § 429.440(b)(3) for such Small Biotech Drug). Our proposed stepwise approach would not apply for a selected drug that qualifies for the Temporary Floor for Small Biotech Drugs in initial price applicability years 2029 or 2030 for which these conditions are not met, nor for a selected drug that does not qualify for the Temporary Floor for Small Biotech Drugs in initial price applicability years 2029 or 2030.

We disagree that the proposed stepwise approach exceeds the agency's authority or is otherwise inconsistent with statute. Instead, our proposal reflected our intention to give effect to all the relevant statutory provisions governing the determination of offers and counteroffers and negotiation of an MFP for a selected drug. Section 1194(b)(1) of the Act requires the development and use of a consistent methodology and process, in accordance with the requirements set forth in section 1194(b)(2) of the Act, for negotiation that ''aims to achieve the lowest maximum fair price.'' Section 1194(b)(2) of the Act provides for a process that requires an initial offer for the MFP to the manufacturer and allows for an exchange of subsequent offers and counteroffers. Moreover, section 1194(b)(2)(F) of the Act directs that CMS shall not offer (or agree to a counteroffer for) an MFP for a selected drug that exceeds the ceiling determined under section 1194(c) of the Act for the selected drug and year; or, as applicable, is less than the floor determined under section 1194(d) of the Act. In turn, section 1194(c) of the Act requires that an MFP negotiated under section 1194 of the Act for a selected drug, with respect to the first initial price applicability year of the price applicability period with respect to such drug, shall not exceed the lower of the amounts under section 1194(c)(1)(B) or section 1194(c)(1)(C) of the Act. Section 1194(d) of the Act expressly directs that for certain qualifying selected drugs, and with respect to initial price applicability years 2029 and 2030, the MFP for such drugs shall not be below the Temporary Floor for Small Biotech Drugs as provided under that subsection.

Our stepwise approach, as finalized in this rule, reflects our interpretation that section 1194(d) of the Act, which provides for the Temporary Floor for Small Biotech Drugs, is not best read as eliminating the rest of the statutory requirements in section 1194 of the Act, as described previously. Instead, our policy reflects our interpretation that the possibility of a direct conflict, with respect to certain drugs as previously described, between the Temporary Floor for Small Biotech Drugs, determined under section 1194(d) of the Act, and the potential ceiling amount is best resolved by removing all non-FAMP (as identified under sections 1194(c)(1)(C)(ii)(I) and 1194(c)(1)(C)(ii)(II)) per our updated stepwise approach, as described in more detail later in this section.

Similarly, we believe that the alternative recommended by commenters that would eliminate the ceiling altogether for Small Biotech Drugs would fail to give effect to all statutory provisions and is inconsistent with the IRA's text, structure, and purpose. We disagree with commenters suggesting that the use of ''or'' in section 1194(b)(2)(F) of the Act's prohibition against offering or agreeing to a counteroffer for any maximum fair price that exceeds the ceiling *or* is less than the floor for the selected drug is best read as requiring CMS to ignore the statutory ceiling provisions for Small Biotech Drugs. We believe that the statutory directive that the MFP cannot be greater than the ceiling *or* less than the floor is more naturally and best read as accounting for the simple proposition that because a ceiling cannot be below a floor, a single offer or counteroffer cannot both ''exceed the ceiling'' *and* be ''less than the floor.'' Accordingly, we believe section 1194(b)(2)(F) of the Act's use of ''or'' is best read as effectuating two distinct prohibitions on offer amounts. Moreover, the commenters' suggestion to read section 1194(b)(2)(F) of the Act as to eliminate the ceiling provisions with respect to Small Biotech Drugs would also fail to give effect to the separate prohibition in section 1194(c) of the Act against an MFP exceeding the amount determined under such subsection; there is nothing in section 1194(d) of the Act to suggest that the Temporary Floor for Small Biotech Drugs should be applied in place of that prohibition. Accordingly, when read in light of the overall structure and purpose of the Negotiation Program statute, including the establishment of a ceiling for MFP negotiations and renegotiations to establish a maximum price above which an MFP cannot be agreed to, we disagree that section 1194(b)(2)(F) of the Act is best read as implicitly nullifying the applicability of the ceiling for Small Biotech Drugs.

For the same reasons, we also disagree that section 1194(b)(2)(F) of the Act can be read as removing the ceiling for selected drugs that qualify for the Temporary Floor for Small Biotech Drugs and whose floor is greater than the applicable ceiling, but not for others that qualify for the Temporary Floor for Small Biotech Drugs. Under such a reading, certain Small Biotech Drugs that have longer periods since the date of approval or licensure would be more likely to qualify for an otherwise unique and unstated exception where their negotiations would have no limitations on the maximum MFP that can be agreed upon. Such a reading conflicts with the ordinary operation of the ceiling provisions, particularly the ceiling amounts determined under section 1194(c)(1)(C) of the Act, which provide for lower ceiling amounts for selected drugs with longer periods since the date of approval or licensure. We do not believe there is any indicia in the statute that in circumstances where the Temporary Floor for Small Biotech Drugs applies, the statute is best read as operating otherwise.

With respect to the comments that the Temporary Floor for Small Biotech Drugs provision is designed to be mathematically impossible to calculate the ceiling for long-monopoly and extended-monopoly drugs at a numerical value that exceeds the Temporary Floor for Small Biotech Drugs, we agree that in limited circumstances with respect to certain selected drugs qualifying for the Temporary Floor for Small Biotech Drugs, the potential ceiling amount determined under section 1194(c)(1)(C)(ii)(I) of the Act would not exceed the Temporary Floor for Small Biotech Drugs determined under section 1194(d) of the Act. However, we disagree that this possibility for a limited set of potential selected drugs is best read as evidence that the statute was drafted to implicitly eliminate the ceiling for such drugs. We believe it would be more likely that such a requirement, which would rewrite much of section 1194 of the Act with respect to a limited and specific set of selected drugs, including eliminating section 1194(c) of the Act for such drugs, would be made explicit. As previously discussed, we believe that the interpretation suggested by the commenters that the statute intends for long-monopoly and extended-monopoly

selected drugs to be negotiated without a ceiling would be contrary to the statute's typical treatment of long-monopoly and extended-monopoly drugs, which are generally subject to lower ceilings.

For the reasons provided previously and in the proposed rule, we disagree with commenters' suggestions not to apply the ceiling otherwise determined under § 429.410(b) or § 429.620(b) when it is below the Temporary Floor for Small Biotech Drugs. However, we agree with the commenter's suggestion regarding the treatment of the other non-FAMP amount described in section 1194(c)(1)(C) of the Act in the adjusted ceiling calculations. We believe that in the event that removing from consideration the potential ceiling amount described in section 1194(c)(1)(C)(ii)(I) of the Act (that is, the non-FAMP for 2021 or first year after market entry) does not result in a ceiling that exceeds the Temporary Floor for Small Biotech Drugs, it is appropriate to include a subsequent step that removes the potential ceiling amount described in section 1194(c)(1)(C)(ii)(II) of the Act (that is, the non-FAMP for the year prior to the selected drug publication date). While our proposal was narrowly tailored to the amount described in section 1194(c)(1)(C)(ii)(I) of the Act, as that amount is determined using the same non-FAMP amount as the Temporary Floor for Small Biotech Drugs, we note that the potential ceiling amount described under section 1194(c)(1)(C)(ii)(II) of the Act may create a similar conflict. Accordingly, we believe we can better resolve such potential conflicts for more Small Biotech Drugs, while preserving a negotiation process subject to a ceiling as described in section 1194(c) of the Act, by incorporating into our stepwise approach an additional step that addresses the potential ceiling amount described in section 1194(c)(1)(C)(ii)(II) of the Act. We believe this revision is consistent with the intent of our proposed stepwise approach, in that it aims to address the direct conflict between the Temporary Floor for Small Biotech Drugs and the ceiling determined under § 429.410(b), while still both providing the Small Biotech Drug the benefit of the floor under section 1194(d) of the Act and preserving a negotiation process subject to a ceiling as described in section 1194(c) of the Act.

In particular, we will consider the treatment of non-FAMP in two distinct stages before determining whether to exclude it from the ceiling calculation. At § 429.440(b)(4)(i), we will exclude the average non-FAMP in 2021 identified under section 1194(c)(1)(C)(ii)(I) of the Act from the ceiling determination made under § 429.410(b) or § 429.620(b), as applicable, with respect to such selected drug. Under new § 429.440(b)(4)(i), if the resulting amount is equal to or above the Temporary Floor for Small Biotech Drugs, then we will apply that amount as the adjusted ceiling, notwithstanding § 429.410(b) or § 429.620(b). However, under new § 429.440(b)(4)(ii), if the resulting amount determined under § 429.440(b)(4)(i) is lower than the Temporary Floor for Small Biotech Drugs, we will then, notwithstanding § 429.410(b) or § 429.620(b), exclude the average non-FAMP for the year preceding the selected drug publication with respect to the first initial price applicability period for which the drug is being negotiated, or, as applicable, the most recent year prior for which data is available, as set forth in § 429.435(a)(2), identified under section 1194(c)(1)(C)(ii)(II) of the Act, from the ceiling determination made under § 429.410(b) or § 429.620(b), as applicable. Under new § 429.440(b)(4)(ii), if the resulting amount as determined under paragraph § 429.440(b)(4)(ii) is equal to or above the Temporary Floor for Small Biotech Drugs established in § 429.440(b)(3), we will apply that amount, as applicable, as the adjusted ceiling. Lastly, in § 429.440(b)(4)(iii) (previously § 429.440(b)(4)(ii) in the proposed rule), we stated that the adjusted ceiling will equal the Temporary Floor for Small Biotech Drugs established in § 429.440(b)(3), notwithstanding § 429.410(b) or § 429.620(b), if the resulting amount determined under § 429.440(b)(4)(ii) is still below the Temporary Floor.

Finally, we also disagree with the proposed alternative to raise the ceiling as otherwise determined under § 429.410(b) or § 429.620(b) to be equal to the Temporary Floor for Small Biotech drugs in lieu of a stepwise approach. We believe our stepwise approach—as revised based on public comments received—is consistent with the text, structure, and purpose of the statute in that it provides a methodology for calculating the Temporary Floor for Small Biotech Drugs for negotiations, allows CMS and the Primary Manufacturer to conduct negotiations subject to a ceiling as described in section 1194(c) of the Act, and provides for the limitations on an offer or counteroffer amount in accordance with sections 1194(b)(2)(F) and 1194(c) of the Act. The approach recommended by the commenters would effectively limit the offers which CMS could consider or make to an amount equal to the Temporary Floor for Small Biotech Drugs in every instance in which the Temporary Floor for Small Biotech Drugs exceeded the amount determined to be the ceiling under section 1194(c) of the Act. Consistent with our response to commenters suggesting that CMS eliminate the ceiling for selected drugs that qualify for the Temporary Floor for Small Biotech Drugs when the ceiling is lower than the Temporary Floor for Small Biotech Drugs, we disagree that the statute is best read as requiring CMS to so limit the negotiation process provided under section 1194 of the Act in every instance because, in limited circumstances, there may be conflict between the ceiling provisions and the Temporary Floor for Small Biotech Drugs. Rather, we believe our stepwise approach, as revised, would give effect to as much of section 1194 of the Act as possible. Under our stepwise approach, the applicable ceiling would be raised to equal the Temporary Floor for Small Biotech Drugs only in instances in which the conflict between the amounts provided under sections 1194(c)(1)(C) and 1194(d) of the Act cannot be resolved; in instances where the conflict can be resolved, the resulting ceiling would be higher than the Temporary Floor for Small Biotech Drugs. Finally, we note our stepwise approach, consistent with section 1194(d) of the Act, would be limited to initial price applicability years 2029 and 2030.

Comment: A commenter expressed concern about CMS' formula for calculating total expenditures for the purposes of determining eligibility for the Temporary Floor for Small Biotech Drugs. This commenter stated that CMS should limit the Total Expenditure calculation of the 80 percent threshold to the manufacturer's qualifying single source drugs and should exclude non-innovator and multi-source drugs. They note that including such drugs in the denominator used for the Total Expenditure calculation may distort the result and potentially disqualify a small biotech manufacturer from being eligible for the Temporary Floor for Small Biotech Drugs. Additionally, this commenter recommended CMS consider a full year of sales to more fully capture a manufacturer's total Medicare expenditures for drugs launched during calendar year 2021.

Response: We thank the commenter for its concern. We note that section 1192(d)(2) of the Act expressly sets forth the denominator and time period to be used for calculating total expenditures

for the purposes of determining whether a drug is a Small Biotech Drug. Sections 1192(d)(2)(A)(i)(II) and 1192(d)(2)(A)(ii)(II) of the Act require that the 80 percent threshold be calculated with respect to all qualifying single source drugs of the manufacturer for which payment may be made under Part B during such year (for calculations involving drugs payable under Part B) or with respect to all drugs covered under Part D for which the manufacturer of the drug has an agreement in effect under section 1860D–14A of the Act during such year (for drugs covered under Part D). With regards to the recommendation to consider a full year of sales for drugs launched in 2021, we similarly note that section 1192(d)(2) of the Act limits us in determining eligibility for the Temporary Floor for Small Biotech Drugs to consider only total expenditures under Part D and Part B ''during 2021.''

Comment: Some commenters supported CMS' proposals related to the implementation of the Temporary Floor for Small Biotech Drugs because it helps protect small biotech manufacturers that may have small business portfolios and less ability to absorb financial risk. One of these commenters also supported CMS' treatment of manufacturers under common control. Another of these commenters suggested CMS explain how corporate relationships, acquisitions, and ownership changes affect a selected drug's eligibility for the Temporary Floor for Small Biotech Drugs or CMS' calculation of the temporary floor amount. Lastly, a commenter recommended CMS should clarify that licensing, co-marketing, and distribution arrangements that in essence function as a transfer of control should render a drug ineligible for the Temporary Floor for Small Biotech Drugs.

Response: We appreciate the support of these commenters. With respect to the commenter's question regarding how corporate relationships, acquisitions, and ownership changes affect eligibility, the policies discussed in section § 429.440 as finalized regarding eligibility for the Temporary Floor for Small Biotech Drugs explain the relevant statutory criteria for eligibility for the Temporary Floor for Small Biotech Drugs. Section 1192(d)(2)(B)(i) of the Act precludes a selected drug from being a Small Biotech Drug if the Primary Manufacturer of the selected drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025. With respect to the recommendation that CMS extend ineligibility for the Temporary Floor for Small Biotech Drugs based on licensing, co-marketing, and distribution arrangements, our proposal reflects the statutory criteria specified in section 1192(d)(2) of the Act.

Comment: Some commenters suggested various refinements to the proposal to further protect small biotech manufacturers, including revising eligibility standards and extending the Temporary Floor for Small Biotech Drugs provisions beyond initial price applicability years 2029 and 2030. One of these commenters suggested CMS and the Administration work with Congress to preserve and extend the Small Biotech Exception and the Temporary Floor for Small Biotech Drugs. Another commenter suggested that CMS start evaluating whether a temporary floor limited to initial price applicability years 2029 and 2030 is sufficient to protect small biotech manufacturers and to determine if an extension is warranted.

Response: We appreciate commenters' suggestions. The statute provides specific eligibility criteria for the Temporary Floor for Small Biotech Drugs and provides that it applies only for initial price applicability years 2029 and 2030. We do not have the authority to amend the statute to provide additional eligibility standards or extend the Temporary Floor for Small Biotech Drugs.

Comment: A commenter recommended CMS report whether a selected drug was deemed eligible for the Temporary Floor for Small Biotech Drugs in its explanation of the MFP, noting that doing so would not raise confidentiality concerns since CMS has already made the determination and because providing this information could help demonstrate effectiveness of the negotiation process. Additionally, this commenter stated that CMS should publish the drugs excluded under the Small Biotech Exception for previous initial price applicability years to allow stakeholders to understand how the provision affected drug selection. Another commenter suggested that CMS track and publicly report on whether the Temporary Floor for Small Biotech Drugs sufficiently protects small biotech manufacturer innovation.

Response: We thank the commenters for their suggestions to provide public reporting on the Temporary Floor for Small Biotech Drugs, including adding specific information in MFP explanations. Consistent with § 429.705(b), the MFP explanation will include a narrative explanation of the negotiation process that occurred with that Primary Manufacturer and redacted information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. If a selected drug qualifies for the Temporary Floor for Small Biotech Drugs in initial price applicability years 2029 or 2030, we will consider whether to disclose such status in the MFP explanation consistent with our approach to redact confidential information and proprietary information, as well as with our policies finalized at § 429.300. Consistent with our approach to initial price applicability years 2026, 2027, and 2028 to date, we decline to publish the drugs that qualified for the Small Biotech Exception in previous initial price applicability years. The comment to track and report on whether the Temporary Floor for Small Biotech Drugs sufficiently protects small biotech manufacturer innovation is outside the scope of this final rule.

Comment: A commenter stated that CMS should reconsider its proposal to extend the Temporary Floor for Small Biotech Drugs to renegotiation based on section 1194(f)(4)(B) of the Act and instead exercise discretion by adopting a narrower interpretation under section 1194(d) of the Act that the Temporary Floor for Small Biotech Drugs applies only when negotiating the initial MFP for drugs selected for negotiation. This commenter suggested that applying the Temporary Floor for Small Biotech Drugs to drugs selected for renegotiation may limit CMS' ability to fully account for the circumstances that warranted selection for renegotiation or other landscape changes for the pharmaceutical market and constrain the renegotiation process.

Response: We decline to adopt the commenter's suggestion to adopt a narrower interpretation such that drugs selected for renegotiation for initial price applicability years 2029 or 2030 would not be eligible to be considered for the Temporary Floor for Small Biotech Drugs described in section 1194(d) of the Act. Section 1194(f)(4)(B) of the Act describes the statutory requirements that aspects of the renegotiation process be consistent with the negotiation process and states that for purposes of applying section 1194(d) of the Act (that is, the section that establishes the Temporary Floor for Small Biotech Drugs), reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as

the first initial price applicability year of such period for which the maximum fair price established pursuant to renegotiation applies. This reference indicates that the Temporary Floor for Small Biotech Drugs applies with respect to renegotiation under section 1194(f) of the Act. Because of this statutory directive, drugs selected for renegotiation also will be eligible to be considered for the Temporary Floor for Small Biotech Drugs described in section 1194(d) of the Act and § 429.440 as finalized and we do not have the discretion to otherwise limit such eligibility.

Comment: A commenter expressed concern that in therapeutic classes with only two drugs, if CMS applies the Temporary Floor for Small Biotech Drugs to an eligible selected drug and not its competitor in cases where the competitor is also a selected drug, this could distort the market and hurt the manufacturer selling a drug at a lower WAC. To address this concern, this commenter recommended that CMS first request information from the applicant for the Temporary Floor for Small Biotech Drugs regarding the number of competing manufacturers in a class and then grant the Temporary Floor for Small Biotech Drugs to the drug of the other manufacturer, if selected for negotiation.

Response: We appreciate the commenter raising this concern and recommending an approach. We decline to adopt the commenter's suggestion to automatically apply the Temporary Floor for Small Biotech Drugs to both the selected drug and the competing selected drug of another manufacturer in cases when there are only two drugs in a therapeutic class. Section 1194(d) of the Act states that the Temporary Floor for Small Biotech Drugs is only applicable in the case of a selected drug that meets the Small Biotech Exception criteria under section 1192(d)(2) of the Act. As a result, we do not have the authority to extend the Temporary Floor for Small Biotech Drugs to other selected drugs in a therapeutic class when such drugs do not meet the criteria in section 1192(d)(2) of the Act to qualify for the Temporary Floor for Small Biotech Drugs section.

Comment: A commenter recommended CMS apply the Temporary Floor for Small Biotech Drugs to the small biotech company instead of the selected drug to support innovation for certain drugs and help protect small biotech companies that are acquired by another manufacturer. The commenter recognized the statute sets forth limits for drugs being acquired by another manufacturer, but suggested CMS use its rulemaking discretion to apply the Temporary Floor for Small Biotech Drugs to a company and signal this issue for Congress.

Response: We recognize the commenter's interest in having the Temporary Floor for Small Biotech Drugs apply to the small biotech company instead of the selected drug. However, the statute is clear at sections 1192(d) and 1194(d) of the Act that the Small Biotech Exception and the Temporary Floor for Small Biotech Drugs, respectively, apply to the drug specifically that meets the eligibility criteria, not the ''small biotech company'' generally. Furthermore, consistent with section 1192(d)(2)(B)(ii) of the Act, a selected drug is precluded from being eligible for the Temporary Floor for Small Biotech Drugs if the Primary Manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025. We do not have the authority to change these statutory requirements via rulemaking.

Comment: A commenter identified structural concerns with CMS' implementation of the Temporary Floor for Small Biotech Drugs for drugs and biological products owned by a tribal corporation as the arm of a sovereign government. The commenter requested CMS establish a foundational structure for this provision—and across the Negotiation Program where applicable—whereby CMS consults the tribal corporation before selection and negotiation of a selected drug owned by a tribal corporation and documents a record of selection and agreement on an MFP for such selected drug.

Response: We appreciate the commenter raising these concerns. CMS' Tribal Technical Advisory Group (TTAG), which provides advice and input to CMS on policy and program issues impacting American Indians and Alaska Natives served by CMS programs, as applicable, was informally consulted and they did not provide feedback on either the proposed rule or the final rule. As part of our ongoing implementation of the Negotiation Program, we will engage with CMS' TTAG. CMS, in this final rule, codifies the Medicare Drug Price Negotiation Program under part 429 consistent with the law and with policies established in the Negotiation Program Guidance. We respectfully decline to add a provision to part 429 to establish exceptions to the Negotiation Program or specific requirements governing drug selection, manufacturer agreements, and negotiation and renegotiation processes with respect to federally recognized tribes because the IRA does not contain such provisions.

During our consideration of comments we received on this topic, we identified typographical errors in section II.E.9. of the Negotiation Program proposed rule. First, there are typographical errors in a citation within the third column, line 52 (91 FR 36282) and the second column, line 7 (91 FR 36283). The intended citations should read ''§ 429.100(c)'' instead of ''§ 429.100(d)''. The intended citations (that is, § 429.100(d)) align with data sources used across ceiling calculations (that is, specifically with § 429.420(a)(1), § 429.425(a)(1), and § 429.435(a)(1)(i)). Second, there is a typographical error within the last sentence of the paragraph in the first column that begins with ''In accordance with section 1194(b)(2)(F)(ii) of the Act and as proposed in § 429.405'' (91 FR 36284). The cross-reference to the proposed regulation contains a typographical error. The intended sentence should have read as follows in the proposed rule: ''The statute does not expressly address how to apply section 1194(b)(2)(F)(ii) of the Act in such cases, though such a scenario is possible under the statute—for example, if a selected drug is eligible for the Temporary Floor for Small Biotech Drugs in initial price applicability year 2030 and is an extended-monopoly drug, the applicable percent of average non-FAMP for 2021 used in the ceiling calculation for an extended-monopoly drug under proposed § 429.435(a)(4)(v)(A)(2) would be less than that of the Temporary Floor for Small Biotech Drugs under proposed § 429.440(b)(3) (65 percent and 66 percent, respectively).'' Because there is ample discussion of our proposal within the Negotiation Program proposed rule, and the proposed regulatory text reflected our proposal accurately, we believe that the public has had adequate notice and opportunity to comment on our proposal. Additionally, due to the changes made to § 429.435(a)(4) previously discussed, we note that the provision in the final rule that discusses the applicable percent of average non-FAMP for 2021 used in the ceiling calculation for an extended-monopoly drug is now § 429.435(a)(4)(v)(A)(2).

Final Decision: After consideration of public comments received, we are finalizing § 429.440(b) as proposed with modifications to the stepwise approach to calculate an adjusted ceiling in the event that the ceiling identified in

§ 429.410(b) (or § 429.620(b) as applicable) is below the Temporary Floor for Small Biotech Drugs, if applicable. Specifically, we will consider the treatment of non-FAMP in two distinct stages of the adjusted ceiling calculation. At § 429.440(b)(4)(i), we will first exclude the average non-FAMP in 2021 identified under section 1194(c)(1)(C)(ii)(I) of the Act from the ceiling determination made under § 429.410(b) or § 429.620(b), as applicable, with respect to such selected drug. We revised § 429.440(b)(4)(i) to state that if the resulting amount determined under § 429.440(b)(4)(i) is equal to or above the Temporary Floor for Small Biotech Drugs established in § 429.440(b)(3), then CMS applies that amount as the adjusted ceiling. Under revised § 429.440(b)(4)(ii), we stated that if the resulting amount determined under § 429.440(b)(i) is lower than the Temporary Floor for Small Biotech Drugs, as determined in § 429.440(b)(3), we will then exclude the average non-FAMP for the year preceding the selected drug publication with respect to the first initial price applicability period for which the drug is being negotiated, or, as applicable, the most recent year prior for which data is available in accordance with §§ 429.410(b)(2)(ii) and 429.435(a)(2), identified under section 1194(c)(1)(C)(ii)(II) of the Act from the ceiling determination made under § 429.410(b) or § 429.620(b), as applicable. Additionally, under revised § 429.440(b)(4)(ii), we stated that if the resulting amount as determined under paragraph § 429.440(b)(4)(ii) is equal to or above the Temporary Floor for Small Biotech Drugs established in § 429.440(b)(3), CMS applies that amount, as applicable, as the adjusted ceiling. Lastly, we added § 429.440(b)(4)(iii) to state that the adjusted ceiling will equal the Temporary Floor for Small Biotech Drugs established in § 429.440(b)(3) if the resulting amount determined under § 429.440(b)(4)(ii) is still below the Temporary Floor for Small Biotech Drugs.

We also are making non-substantive, technical modifications. In § 429.440(b)(3)(i), we are relocating the words ''calculated using the methodology set forth in § 429.435'' to the end of the provision. In § 429.440(b)(3)(ii), we are adding the words ''calculated using the methodology set forth in § 429.435'' to the end of the provision. In § 429.440(b)(4)(i), we are changing the words ''non-FAMP ceiling amount'' to read ''average non-FAMP in 2021''. To accommodate the revisions described in the previous paragraph to the stepwise approach, we are renumbering § 429.440(b)(4)(ii) as § 429.440(b)(4)(iii), and in § 429.440(b)(4)(iii), we are changing the words ''adjusted ceiling'' to ''resulting ceiling amount'' and are updating the ''§ 429.440(b)(4)(i)'' citation to ''§ 429.440(b)(4)(ii)'' to refer to the new provisions described previously. Lastly, in § 429.440(b)(5)(ii), we are adding a missing '')'' following ''(or adjusted ceiling, if applicable''.

10. Calculation Information and Suggestion of Error (§ 429.445)

In implementing the statutory provisions of the Negotiation Program, CMS is required to execute a number of multi-step calculations. Section 1194(b)(2)(F)(i) of the Act requires that, in negotiating the MFP of a selected drug, including during renegotiation, CMS would not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling specified in section 1194(c) of the Act. Section 1196(a) of the Act describes certain of CMS' administrative duties, including section 1196(a)(2) of the Act, which requires CMS to establish procedures to compute and apply the MFP across dosage forms and strengths of a selected drug and not based on the specific formulation or package size or package type of such drug. Section 1194(d) of the Act requires that for a selected drug that is a qualifying single source drug that meets the requirements set forth in section 1192(d)(2) of the Act to be determined a Small Biotech Drug, and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, CMS will not offer or agree to a counteroffer for an MFP that is lower than the Temporary Floor for Small Biotech Drugs. With respect to initial price applicability years 2026 through 2028, we implemented a suggestion of error process for Primary Manufacturers if they believe in good faith that CMS has made an error in calculating the ceiling or in applying the MFP across dosage forms and strengths of a selected drug, including, for example, in section 40.5 of the Negotiation Program Guidance with respect to initial price applicability year 2028. With respect to initial price applicability year 2029 and subsequent years, consistent with the policies for implementation as described in section 40.5 of the Negotiation Program Guidance, as revised based on the proposed modifications discussed in this section, we proposed in § 429.445 to provide a Primary Manufacturer the opportunity to submit a suggestion of error if they believe in good faith that CMS has made an error in the calculation of the ceiling or the computation of how CMS intends to apply a single MFP across dosage forms and strengths of the selected drug.

We proposed at § 429.445(a) to provide a Primary Manufacturer with the following information, as applicable: information on CMS' calculation of the ceiling, as described in §§ 429.410 through 429.435; the computation of how we will apply a single MFP across dosage forms and strengths of the selected drug, as described in § 429.700(b) and (c); and information on CMS' calculations of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, as applicable), as described in § 429.440(b)(3) and (b)(4). The information on CMS' calculations of the ceiling would include each intermediate step in the calculation of the section 1847A(b)(4) of the Act payment amount as described in § 429.425, and the non-FAMP amounts as described in § 429.435. The plan-specific enrollment weighted amount as described in § 429.420 would also be included in the information on CMS' calculations of the ceiling but the intermediate steps that make up the plan-specific weighted amount would not, as the plan sponsor's reported Part D PDE data is proprietary data of the plan sponsors and is protected from disclosure, as described in the confidentiality policy proposed in § 429.300(b). The computation of how we will apply a single MFP across dosage forms and strengths of the selected drug would include each intermediate step in our calculation for all applicable NDCs associated with a selected drug, as described in § 429.700 to demonstrate how we will apply a single MFP across dosage forms and strengths. If a selected drug is eligible for the Temporary Floor for Small Biotech Drugs, the information on the calculations of the Temporary Floor for Small Biotech Drugs would include each intermediate step in the calculation of the Temporary Floor for Small Biotech Drugs as described in § 429.440(b)(3). We would also include the information on CMS' calculation of the ceiling, as described previously, and information on CMS' calculation of the adjusted ceiling, if applicable. The information on CMS' calculations of the alternative ceiling will include a modified version of the ceiling calculations, based on whether the selected drug's adjusted ceiling is calculated using proposed § 429.440(b)(4)(i), (ii), or (iii).

We proposed in § 429.445(b)(1) to provide the information on CMS'

calculation of the ceiling, the computation of how we will apply a single MFP across dosage forms and strengths of the selected drug, and, as applicable, information on CMS' calculations of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, as applicable) following the Primary Manufacturer's submission of the section 1194(e)(1) data described in proposed §§ 429.100(d), 429.405(a), 429.440(b)(1), and 429.505(b)(2) and following the Primary Manufacturer's submission of the section 1194(e)(1) data described in proposed § 429.615(b)(1). Additionally, in proposed § 429.445(b)(2), we would also provide the computation of how we will apply a single MFP across dosage forms and strengths of the selected drug following the Primary Manufacturer's submission of any updates to the list of NDC–11s, as proposed in § 429.100(e) and following the determination that an NDC with insufficient data, as described in section II.H.1. of this final rule and proposed in § 429.700(c)(3) has sufficient data, as proposed in § 429.700(c)(4)(i)(B)(2).

Further, we proposed in § 429.445(c) that Primary Manufacturers would have 10 days to submit a suggestion of error with respect to these calculations if they believe that CMS has made a calculation error. A calculation error is any error related to the mathematical equations that make up the calculation of the ceiling, the computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug, or the calculations of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, if applicable) for a selected drug eligible for the Temporary Floor for Small Biotech Drugs. This includes errors in the sums, products, and quotients of values in the mathematical equations. In contrast, objections to policies and methodologies for implementing the relevant calculations would not be considered a relevant suggestion of error.

Under the applicable guidance for initial price applicability years 2027 and 2028, Primary Manufacturers have 21 days to submit a suggestion of error. We proposed to change the length of time that a Primary Manufacturer has to submit a suggestion of error with respect to the information provided under proposed § 429.445(a)(1) and (a)(3) in order to ensure we can meet deadlines for the negotiation process established in statute. As described in section II.C.1. of this final rule, in accordance with section 1194(b)(2)(A) of the Act, the Primary Manufacturer of a selected drug must submit, no later than March 1 of the year of the selected drug publication date, with respect to the selected drug, certain information, including non-FAMP data and other information required to carry out the negotiation process, including the information specified at section 1194(e)(1) of the Act. In accordance with section 1194(b)(2)(B) of the Act, and as proposed at § 429.520(a), CMS would provide the Primary Manufacturer with the written initial offer no later than June 1 following the selected drug publication date. Therefore, CMS has only 3 months to process and analyze Primary Manufacturer data that the agency must consider when preparing the written initial offer. Our experience implementing the Negotiation Program to date has demonstrated that a suggestion of error period of 21 days (or more) impedes our ability to perform the analysis necessary to meet the June 1st statutory deadline. In particular, we have found that additional time is needed beyond March 1st to engage with Primary Manufacturers regarding their required data submissions to ensure that they have submitted the data necessary for us to perform the required calculations and that such information is presented with sufficient clarity for us to be able to use it, in accordance with their obligations under the Negotiation Program Agreement. We cannot provide the ceiling calculation information described in proposed § 429.410 through § 429.435, until we have engaged in this process. Reducing the time for Primary Manufacturers to submit a suggestion of error to 10 days will allow for a timely review of Primary Manufacturer submissions of the section 1194(e)(1) factors, the opportunity for Primary Manufacturers to supplement and clarify submissions in accordance with agency requests in accordance with proposed § 429.900(b), and allow for the delivery of the information to the Primary Manufacturer and the suggestion of error window to be complete prior to the June 1st statutory deadline for written initial offers.

Additionally, we proposed to change the length of time that a Primary Manufacturer has to submit a suggestion of error with respect to the information provided under proposed § 429.445(a)(2) in order to incorporate Primary Manufacturer feedback to the extent practicable and as appropriate, into MFP application calculations prior to the MFP going into effect. As described in section II.B.1. of this final rule, a Primary Manufacturer of a selected drug has an ongoing obligation to report, at least 30 calendar days prior to the change taking effect, any changes to the list of NDC–11s provided in proposed § 429.100(d) to ensure the list of NDC–11s of the selected drug remains complete and accurate. Our experience implementing the Negotiation Program to date has demonstrated that a suggestion of error period of 21 days does not leave the agency sufficient time to consider Primary Manufacturer feedback prior to implementation of revised MFPs and MFPs for new NDCs. Reducing the time for Primary Manufacturers to submit a suggestion of error to 10 days will allow for CMS to consider, and incorporate, to the extent practicable and as appropriate, Primary Manufacturer feedback prior to implementation of revised MFPs and MFPs for new NDCs.

As further specified in proposed § 429.445(c), the suggestion of error process would not affect a Primary Manufacturer's obligation to comply with Negotiation Program requirements and would not alter or change any timelines or requirements of the Negotiation Program.

A Primary Manufacturer must submit any suggestion of error on the calculation of the ceiling, the computation of how CMS would apply a single MFP across dosage forms and strengths, and information on CMS' calculation of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, as applicable) of the selected drug in a form and manner specified by CMS, as proposed in § 429.445(d).

We solicited comments on our proposed approach for the suggestion of error process. In addition, we solicited comment on whether the regulatory text should expressly identify each of the calculations for which this suggestion of error process would be available.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters opposed the reduction of the Suggestion of Error review window from 21 days to 10 days. These commenters stated that the suggestion of error process is the only mechanism by which manufacturers can identify and resolve errors in submitted data before they are used by CMS in the initial offer. They stated the calculations are complex multiple-step computations that can include hundreds of NDC–11s and multiple data sources and stated that the proposal would significantly reduce their review time. A couple of commenters suggested that CMS streamline internal processes instead of shortening the review window for manufacturers. Another commenter

suggested that CMS disclose any analysis or workpapers that support the conclusion that a suggestion of error period of 10 days is adequate for manufacturers.

Response: We thank these commenters for their feedback. As recognized by the commenters, CMS proposed this change in the suggestion of error period for CMS' calculation of the ceiling and for CMS' calculation of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, as applicable), as applicable, to ensure that CMS meets the statutory deadlines for the Negotiation Program, where in accordance with section 1194(b)(2)(A) of the Act, the Primary Manufacturer of a selected drug must submit requested information regarding the selected drug not later than March 1 following the selected drug publication date, and, in accordance with section 1194(b)(2)(B) of the Act, CMS must provide the Primary Manufacturer with a written initial offer no later than June 1 following the selected drug publication date. This change in the suggestion of error period provides more time for CMS to engage with Primary Manufacturers regarding their data submissions, provide Primary Manufacturers with the opportunity to supplement or clarify their submissions, and consider their feedback prior to providing the initial offer to the Primary Manufacturer. The proposed review window is based on our experience implementing the Negotiation Program. Given the limited scope of the suggestion of error process as described in § 429.445, CMS expects that the 10-day period will be sufficient for manufacturers to perform their reviews.

Comment: A commenter opposed the identification of the calculations for which a suggestion of error can be made in response to the comment solicitation on whether the regulatory text should expressly identify each of the calculations for which this suggestion of error process would be available. Given the array of potential circumstances that may arise, the commenter encouraged CMS to maintain flexibility to work with manufacturers on suggestions of error. Another commenter supported the clarity provided by the identification of topics in-scope for the suggestion of error process in regulatory text and urged CMS to reconsider the exclusion of objections to policies and methodologies from suggestions of error.

Response: We thank these commenters for their feedback. As described in § 429.445(c), the suggestion of error process is intended to provide Primary Manufacturers with the opportunity to identify potential errors in CMS' calculation of the ceiling, the application of the single MFP across dosage forms and strengths of the selected drug, and CMS' calculation of the Temporary Floor for Small Biotech Drugs, as specified in paragraphs (a)(1), (a)(2), or (a)(3) of § 429.445. Furthermore, the sections referenced in § 429.445(a)(1) through (a)(3) (that is, §§ 429.410 through 429.435, § 429.700(b) and (c), and § 429.440(b)(3) and (4)) specify the provisions describing calculations that may be subject to the suggestion of error process (see § 429.410(c) (specifying the calculation in § 429.410(b) is subject to the suggestion of error process), § 429.415(b) (specifying the calculation in section § 429.415(a) is subject to the suggestion of error process), § 429.420(c) (specifying the calculation in § 429.420(b) is subject to the suggestion of error process), § 429.425(c) (specifying the calculations in § 429.425(a)(2) and (a)(4) are subject to the suggestion of error process), § 429.430(b) (specifying the calculation in § 429.430(a) is subject to the suggestion of error process), § 429.435(b) (specifying the calculations at § 429.435(a) are subject to the suggestion of error process), § 429.440(b)(6) (specifying the calculations in § 429.440(b)(3) and (4) are subject to the suggestion of error process), and § 429.700(d) (specifying the calculations in § 429.700(b) and (c) are subject to the suggestion of error process)). Therefore, we believe it is not necessary to further specify in regulatory text the calculations for which the suggestion of error process will be available. Consistent with our response to similar comments in the Negotiation Program Guidance, submissions related to statutorily required criteria or the policies adopted in Negotiation Program guidance or in this final rule are outside the scope of the suggestion of error process.

Final Decision: After consideration of public comments received, we are finalizing § 429.445 as proposed.

F. Negotiation Process (§§ 429.500 through 429.535)

1. General Rule (§ 429.500)

Section 1194 of the Act describes the process that CMS must follow when conducting negotiation and renegotiation. Specifically, section 1194(b)(2) of the Act directs CMS to use a consistent methodology and process for negotiation that aims to achieve the lowest MFP for each selected drug. Further, section 1194(e) of the Act requires CMS to consider section 1194(e)(1) factors and section 1194(e)(2) factors as the basis for determining offers and counteroffers. CMS proposed to codify these provisions at § 429.500(a). We also proposed in § 429.500(b) that to formalize an agreed-upon MFP, CMS and the Primary Manufacturer must sign an Addendum to the Negotiation Program Agreement, as described in proposed § 429.200(e) and discussed in section II.C.1. of this final rule.

With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, sections 60.3 and 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028. With respect to initial price applicability year 2029 and subsequent years, we proposed in §§ 429.500 through 429.535 to codify the negotiation process consistent with the requirements of the IRA and such prior guidance, with proposed revisions noted in these sections.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.500 as proposed.

2. Negotiation Factors (§ 429.505)

Section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining offers and counteroffers, as described at proposed § 429.505(a) and further discussed at proposed § 429.510(e) and (f) and section II.F.3. of this final rule. These factors include data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act and evidence about alternative treatments, as specified in section 1194(e)(2) of the Act. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, with respect to initial price applicability year 2028, section 50 of the Negotiation Program Guidance. With respect to initial price applicability year 2029 and subsequent years, consistent with the policies for implementation as described in section 50 of the Negotiation Program Guidance, proposed § 429.505, as described more fully in the next section, codifies our collection of data related to the factors listed at section 1194(e) of the Act, the process for such data collection, the timing of such data collection, and requirements for the Primary Manufacturer to update submitted data. This section also discusses how we proposed to consider evidence from

comparative clinical effectiveness research in accordance with section 1194(e)(2) of the Act.

a. Information Related to Section 1194(e)(1) Factors

As noted previously, section 1194(e) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining offers and counteroffers, including data submitted by the Primary Manufacturer, as specified in section 1194(e)(1) of the Act. Further, section 1194(b)(2)(A) requires that, not later than March 1 of the year of the selected drug publication date, with respect to the selected drug, the Primary Manufacturer shall submit the information described in section 1193(a)(4) of the Act, including but not limited to, information required to carry out the negotiation or renegotiation process. Accordingly, in accordance with the requirements of its Negotiation Program Agreement (proposed in subpart C and described in section II.C.3. of this final rule) and in accordance with sections 1193(a)(4) and 1194(b)(2)(A) of the Act, we proposed to codify at § 429.505(b) that the Primary Manufacturer of a selected drug is required to submit, among other information, information required to carry out the Negotiation Program, including but not limited to, information related to the factors listed in section 1194(e)(1) of the Act, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, by 11:59 p.m. PST on March 1 of the year of the selected drug publication date (described in proposed § 429.100(c) and section II.B.1. of this final rule). We proposed that such information would be submitted through the Drug Price Negotiation ICR.

Specifically, in accordance with sections 1193(a)(4), 1194(b)(2)(A), and 1194(e)(1) of the Act, we proposed at § 429.505(b)(1) to codify that a Primary Manufacturer is required to submit the following information with respect to its selected drug, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, by 11:59 p.m. PST on March 1 of the year of the selected drug publication date: (1) R&D costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs; (2) current unit costs of production and distribution of the selected drug; (3) prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug; (4) data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the selected drug; and (5) market data and revenue and sales volume data for the selected drug in the United States.

When determining what information we require to carry out the statutory obligation to consider the section 1194(e)(1) factors, we considered the operational and financial burden to the Primary Manufacturer alongside the importance of collecting sufficient information to inform determination of offers and counteroffers, including development of the initial offer. Specifically for the section 1194(e)(1) factors, we do not believe that we are able to obtain this information from sources other than the Primary Manufacturer of the selected drug per statute regardless of whether alternative sources for this information may exist, whether publicly available or available within CMS. Likewise, in accordance with section 1194(e)(1) of the Act, the Primary Manufacturer will be required to submit information for the section 1194(e)(1) factors for renegotiation, as proposed in § 429.615(b)(1) and discussed further in II.G.4 of this final rule.

In accordance with a Primary Manufacturer's responsibility under section 1193(a)(5) of the Act and under the Negotiation Program Agreement (set forth in proposed § 429.200(b)), we proposed in § 429.505(c) that a Primary Manufacturer has an ongoing obligation to report any updates to the information provided in proposed § 429.505(b) if the Primary Manufacturer becomes aware that any of such information has changed or is otherwise inaccurate. CMS will provide the Primary Manufacturer with a method to report any updates to the information provided in proposed § 429.505(b). For example, under proposed § 429.505(c), Primary Manufacturers must submit updates to the Primary Manufacturer's data submitted under proposed § 429.505(b) if the data was restated due to requirements of the Federal government entity that initially receives and oversees processing of such data. For example, under the Medicaid program, manufacturers must report revisions to best price under § 447.510. The Primary Manufacturer must timely notify CMS if any such updates are applicable to the selected drug. This ongoing obligation to update the Primary Manufacturer's original data submissions is separate both from any voluntary submission of data from a Primary Manufacturer of a selected drug to inform renegotiation eligibility and selection (described at proposed § 429.615(a) and section II.G.4. of this final rule) and the required submission of data related to section 1194(e)(1) factors to CMS for drugs selected for renegotiation (described at proposed § 429.615(b)(1) and section II.G.4. of this final rule), which cover different reporting periods. As discussed further in section II.G.4.a. of this final rule, we may consider the Primary Manufacturer's prior data submission(s) under proposed § 429.505(b), including any updates to such information, to inform renegotiation eligibility and selection, and may use such information during renegotiation if a drug is selected for renegotiation.

b. Information Related to Section 1194(e)(2) Factors

Section 1194(e)(2) of the Act directs CMS, for purposes of negotiating the MFP for a selected drug with the Primary Manufacturer, to consider certain factors, as applicable to the selected drug, as the basis for determining its offers. These factors, listed at sections 1194(e)(2)(A) through (D) of the Act, include: (1) the extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives; (2) FDA-approved prescribing information for the selected drug and its therapeutic alternatives; (3) comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations as described in section 1194(e)(2)(C) of the Act); and (4) the extent to which the selected drug and the therapeutic alternatives to the selected drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy. Section 1194(e)(2) of the Act does not require the information listed to come from any specific source. As such, we considered various options for obtaining information related to the factors listed in section 1194(e)(2) of the Act, including an internal CMS analysis, obtaining the information from the Primary Manufacturer, obtaining information from the public, or some combination of these options. We believe that obtaining input from multiple perspectives, including but not

limited to manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties will provide the most comprehensive understanding of the selected drug and its therapeutic alternatives.

For section 1194(e)(2) factors, we proposed to take a two-pronged approach consistent with policies for implementation for initial price applicability year 2028 as described in section 50.2 of Negotiation Program Guidance. In this approach, we would evaluate existing literature and real-world evidence, conduct internal analytics, and consult subject matter experts and clinicians, whether within CMS or external to CMS, when considering available evidence about alternative treatments to the selected drug (consistent with the process proposed at § 429.510(b) and (c) and described in section II.F.3.c. of this final rule for the purposes of the initial offer). We also intend to provide for a voluntary submission of information related to section 1194(e)(2) factors from manufacturers and the public through the Drug Price Negotiation ICR. Accordingly, consistent with policies for implementation for initial price applicability year 2028 as described in section 50.2 of the Negotiation Program Guidance, we proposed at § 429.505(d) to codify that the submission of information related to section 1194(e)(2) of the Act will be open to the public and voluntary. We proposed at § 429.505(d)(1) that any interested party, including the Primary Manufacturer of a selected drug, may submit information on selected drugs and their therapeutic alternatives (consistent with policies for implementation for initial price applicability year 2028 as described in section 60.3 of Negotiation Program Guidance) including information on the extent to which the selected drug represents a therapeutic advance compared to its therapeutic alternative(s), prescribing information for the selected drug and its therapeutic alternative(s), comparative effectiveness data for the selected drug and its therapeutic alternative(s) including information about the impact of the selected drug and its therapeutic alternative(s) on specific populations, and, information on the extent to which the selected drug and therapeutic alternatives address unmet medical need, or any combination thereof, as described in section 1194(e)(2) of the Act.

In accordance with section 1196(a)(4) of the Act, we also proposed at § 429.505(d)(2) that the deadline for submission of information related to the factors listed in section 1194(e)(2) of the Act be the same date and time as the deadline for the Primary Manufacturer to submit non-FAMP and information related to factors listed in section 1194(e)(1) of the Act, that is by 11:59 p.m. PST on March 1 of the year of the selected drug publication date for the selected drug (described in proposed § 429.100(c) and section II.B.1. of this final rule). This serves to enable CMS to consider all submitted evidence in totality and meet the statutory deadline for the initial offer.

Section 1194(e)(2) of the Act also requires that CMS not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Accordingly, consistent with policies for implementation for initial price applicability year 2028 as described in section 50.2 of the Negotiation Program Guidance, we proposed to codify at § 429.505(e), that we will not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

Specifically, we proposed to codify at § 429.505(e)(1) that we will review cost-effectiveness measures used in studies relevant to a selected drug to determine whether the use of the measure is permitted in accordance with section 1194(e)(2) of the Act as described at § 429.505(e), well as section 1182(e) of the Act and other applicable law, including section 504 of the Rehabilitation Act. We also proposed at § 429.505(e)(2) that we may use content in a study that uses a cost-effectiveness measure if we determine that the cost-effectiveness measure used is permitted in accordance with section 1194(e)(2) of the Act as described at proposed § 429.505 (e), as well as section 1182(e) of the Act and other applicable law, including section 504 of the Rehabilitation Act. In proposed § 429.505(e)(2), we proposed that in instances where some, but not all, content in a study is excluded, we may still consider content that is relevant and allowable (for example, clinical effectiveness, risks, harms) under section 1194(e)(2) of the Act and section 1182(e) of the Act.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested that CMS establish a minimum threshold for the requirement under § 429.505(c) to update the data submitted under § 429.505(b) (described in section II.F.2.a. of the proposed rule (91 FR 36287)) to avoid added manufacturer burden, without clear benefit to CMS. A commenter requested that CMS allow manufacturers to reopen the HPMS portal to submit required data updates rather than having to request that CMS open the HPMS portal on their behalf. A commenter requested that CMS limit the requirements at § 429.505(c) to only require updated information if such information was inaccurate at the time of submission. A commenter stated that APA requirements for notice-and-comment preclude CMS from including open-ended standards in regulation, such as indicating that information ''will be collected in a form and manner specified by CMS'', for example as in § 429.505(c) and § 429.505(d)(1).

Response: We thank these commenters for their feedback on the data update requirements set forth at § 429.505(c). Consistent with our response to similar comments in the Negotiation Program Guidance and as described in section II.F.2.a. of the proposed rule (91 FR 36287), the requirement proposed at § 429.505(c) is intended to capture instances in which the Primary Manufacturer becomes aware that the information reported for the time period covered by the submission required under § 429.505(b) has changed (for instance because the Primary Manufacturer has received updated data) or is otherwise inaccurate (for instance because the Primary Manufacturer identifies errors in its calculations). We believe that these data update requirements are aligned with statute and important for informing offers, counteroffers, and renegotiation eligibility and selection, as applicable. We therefore decline to establish minimum thresholds for the update requirements for the factors described at section 1194(e) of the Act.

We appreciate the commenter's suggestion regarding the need for CMS to reopen the CMS HPMS portal for a Primary Manufacturer to make updates to submitted data. We will consider this suggestion for future updates. However, to continue to meet statutory timing requirements and due to limitations of the system at this time, it will remain necessary for CMS to reopen the CMS HPMS portal for manufacturer data updates.

Regarding the comment that suggests that APA requirements preclude CMS from stating in regulation that

information ''will be collected in a form and manner specified by CMS'', we disagree with the commenter. This language is commonly used in proposed and final rules, for example in several instances in the CY 2026 Physician Fee Schedule final rule (90 FR 49266), to provide flexibility for submission processes to evolve over time. Further, we issued a proposed rule, including the reporting requirements at § 429.505, for public comment and are now finalizing the rule in a manner fully consistent with the requirements of the APA.

Comment: A few commenters stated that the submission process for information related to section 1194(e)(2) factors, specifically the Patient and Caregiver Focused Input questions, is difficult for patients, caregivers, and other members of the public to navigate and requested that CMS make the submission process clearer and more accessible. A few commenters suggested that interested parties should be provided a later deadline to section 1194(e) data, stating that providing the information in 30 days is not feasible. A commenter suggested that CMS publish a list of organizations and respondent categories that responded to ICRs for the Negotiation Program for each selected drug, similar to how public dockets identify commenters for rulemaking.

Response: We thank the commenters for their input. As noted in our previous response to commenters suggesting options to streamline the submission for information related to section 1194(e)(1) factors, we are also open to streamlining the information collection related to section 1194(e)(2) factors. We appreciate commenters' concern about the 30-day submission timeframe for information related to section 1194(e)(2) factors. We note that the information provided through the Drug Price Negotiation Program ICR is considered when developing the initial offer for a selected drug along with CMS analyses and assessments of evidence as described in § 429.510. Consistent with our response to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, it is not feasible to extend the timeframe for the submission of information under section 1194(e)(2) of the Act due to the statutory timeline of the negotiation period, including the requirement under section 1194(b)(2)(B) of the Act for CMS to issue an initial offer by June 1 after publication of the selected drug list. As described in § 429.515, interested parties have an opportunity to provide additional section 1194(e)(2) information after the March 1 ICR deadline. With regard to the suggestion to publish a list of organizations and respondent categories that respond to ICRs, we appreciate the suggestion, but we believe the publication of redacted copies of the section 1194(e)(2) factors submitted by interested parties alongside the MFP explanation for each selected drug provides sufficient information and transparency for the public to review. We decline to adopt the commenter's suggestion.

Comment: Some commenters supported CMS' decision not to use Quality-Adjusted Life Years (QALYs) when assessing section 1194(e)(2) factors. Some commenters requested that CMS also exclude the use of other measures of cost effectiveness in addition to QALYs, such as the Equal Value of Life-Years Gained (evLYG). A few commenters opposed CMS' consideration of studies that have content relevant to the negotiation process even if the study uses QALYs and one of these commenters requested additional insight into how CMS considers cost-effectiveness measures other than QALYs. A commenter stated CMS should continue to exclude QALYs from the negotiation process while recognizing that some utilization-and-expenditure analyses would not violate the limitations in section 1194(e)(2) of the Act, section 1182(e) of the Act, and as proposed at § 429.505(e)(1) and (e)(2).

Response: We appreciate these commenters' feedback on cost effectiveness measures. Consistent with our responses in the final guidance for initial price applicability year 2027 and the Negotiation Program Guidance, we reaffirm that QALYs will not be used in the Negotiation Program. We will consider studies that use QALYs only when they contain other content that is relevant and permitted under applicable law, including section 1194(e)(2) of the Act and section 1182(e) of Title XI of the Act and Section 504 of the Rehabilitation Act. We also state in § 429.505(e)(1) that we will review cost-effectiveness measures and studies that use such measures to determine whether the measure may be considered in accordance with section 1194(e)(2) of the Act. However, while such measures are reviewed, they will not be used to adjust the initial offer if the measures do not provide information related to the negotiation factors described in section 1194(e) of the Act or are prohibited under section 1194(e)(2) or under section 1182(e) of the Act. We also note that the explanation of the MFP described at § 429.705(b) will include an explanation of CMS' use of the section 1194(e)(2) factors submitted and redacted copies of the section 1194(e)(2) factors submitted by interested parties.

Comment: A commenter stated that CMS does not need to limit information provided under section 1194(e)(1)(A) through (D) of the Act to data from the United States and could collect international data for these section 1194(e)(1) factors. A commenter stated that CMS should consider evidence on drug prices paid in comparable high-income countries within the bounds of statute.

Response: We appreciate the commenter's suggestion to collect information outside the United States in the submission of information related to factors specified at section 1194(e)(1)(A) through (D) of the Act and to consider certain information about prices paid in comparable high-income countries for therapeutic alternatives within the bounds of statute, which we assume the commenter to be referring to the factor listed at section 1194(e)(2)(A) of the Act. We believe the data submission requirements specified at § 429.505(b), CMS' consideration of the data submitted pursuant to these requirements in the Drug Price Negotiation ICR, and CMS' consideration of evidence about the selected drug and therapeutic alternatives under § 429.505(d)(3) will provide a robust information base for the exchange of offers and counteroffers with the Primary Manufacturer consistent with section 1194(e) of the Act. These requirements reflect the success of negotiating MFPs in prior cycles and lessons learned to date. Based on the information we have to date, we decline to revise the scope of information we proposed to collect and consider under section 1194(e) of the Act in the proposed rule.

Comment: A few commenters recommended that CMS work with external stakeholders to facilitate evidence development to inform the Negotiation Program in the future.

Response: We appreciate this suggestion but note it is out of scope for this final rule.

Final Decision: After consideration of public comments, we are finalizing § 429.505 as proposed with a technical correction to add a missing parenthetical to § 429.505(b)(2)(iv).

3. Methodology for Developing the Initial Offer (§ 429.510)

Section 1194(e) of the Act directs CMS to consider certain factors related to manufacturer-specific data and available evidence about therapeutic alternative(s) as the basis for determining offers and counteroffers in the negotiation process. Further, section

1194(b)(2)(B) of the Act requires CMS to provide the manufacturer of a selected drug with a written initial offer and a concise justification based on the factors described in section 1194(e) of the Act that were used in developing the offer. However, the statute does not specify how and to what degree each factor should be considered, thereby providing CMS with the discretion to determine how each factor is considered.

Consistent with section 1194(e) of the Act and with policies for implementation as described in section 60.3 of Negotiation Program Guidance, we proposed in § 429.510 that for purposes of determining the initial offer, we would: (1) identify conditions for which the selected drug is used, as described in proposed § 429.510(a); (2) identify the therapeutic alternative(s), if any, for the selected drug, as described in proposed § 429.510(b) and (c) and consistent with policies for implementation as described in section 60.3.1 of Negotiation Program Guidance; (3) determine the starting point for the initial offer based on the price(s) of the therapeutic alternative(s) for the selected drug, if any, or an alternative price if there is no therapeutic alternative, as described in § 429.510(d) and consistent with policies for implementation as described in section 60.3.2 of Negotiation Program Guidance; (4) consistent with policies for implementation as described in section 60.3.3 of Negotiation Program Guidance and as proposed at § 429.510(e), evaluate the selected drug, including compared to its therapeutic alternative(s), for the purposes of adjusting the starting point using the negotiation factors outlined in section 1194(e)(2) of the Act, which would result in the preliminary price as defined at proposed § 429.20; and (5) adjust the preliminary price based on the negotiation factors outlined in section 1194(e)(1) of the Act and consistent with policies for implementation as described in section 60.3.4 of Negotiation Program Guidance as described in proposed § 429.510(f) to determine the initial offer price. In accordance with section 1194(b)(1) of the Act, this process will be conducted with the aim of achieving the lowest MFP for each selected drug.

In accordance with section 1194(b)(2)(F) of the Act we would not make any offers or accept any counteroffers for the MFP that are above the statutorily defined ceiling as indicated in proposed § 429.410 nor below the Temporary Floor for Small Biotech Drugs, if applicable, as indicated in § 429.440.

a. Identifying Conditions for Which the Selected Drug Is Used (§ 429.510(a))

To identify conditions for which the selected drug is used, we proposed at § 429.510(a)(1) to identify the FDA-approved indication(s) of the selected drug covered under Part D, payable under Part B, or both using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act and consistent with policies for implementation as described in section 60.3.1 of Negotiation Program Guidance. In § 429.510(a)(2), we proposed to consider off-label use to identify conditions for which the selected drug is used, if such use is included in evidence-based clinical practice guidelines and the off-label use is a medically accepted indication, as defined in section 1927(k)(6) of the Act, payable under Part B, covered under Part D, or both, taking into consideration the major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination thereof.

In proposed § 429.510(a)(3), we proposed to exclude from our analysis for development of the initial offer any FDA-approved indication(s) or off-label uses for which we believe that utilization of the selected drug within such indication(s) and for such uses is intended solely for use in a setting in which the selected drug is not payable under Part B and not covered under Part D. Since the MFP resulting from a negotiation may only be applied for drugs payable under Part B, covered under Part D, or both, it is consistent for CMS to exclude from its analysis these FDA-approved indications or off-label uses. The MFP would not be applied unless payable under Part B or covered under Part D, so excluding such FDA-approved indications or off-label uses from CMS' analysis provides the opportunity to focus on indications for which the MFP would be applied when developing the initial offer. For example, we may not include an FDA-approved indication or off-label use in our analysis for the initial offer if such indication or off-label use is recommended for use in clinical practice guidelines only in inpatient hospital settings. We note that a Primary Manufacturer may suggest in its response to the initial offer that use within an FDA-approved indication or an off-label use that was not included in the initial offer is relevant for negotiating an MFP for the selected drug, in which case we may include such indication or off-label use in our consideration of any counteroffers or revised offers.

b. Identifying Therapeutic Alternatives for Each Condition (§ 429.510(b) and (c))

For each condition for which the selected drug is used, we would use the information identified in proposed § 429.510(b) and would follow the steps defined in proposed § 429.510(c) and consistent with policies for implementation as described in section 60.3.1 of Negotiation Program Guidance to identify a pharmaceutical therapeutic alternative(s), if any, for purposes of developing the initial offer. To identify potential therapeutic alternatives for the condition(s) for which a selected drug is used, we proposed in § 429.510(b)(1) to use data submitted by the Primary Manufacturer and the public, prescribing information approved by the FDA, drug classification systems commonly used in the public and private sector for formulary development, major drug compendia, widely accepted clinical practice guidelines, evidence identified through the CMS-led literature review, published drug or drug class reviews, peer-reviewed studies, and Medicare claims or other data sets. In addition to brand name drugs and biological products, we proposed to consider generic drugs and biosimilars, including specific formulations or dosage forms and strengths of a brand name drug, brand name biological product, generic drug, or biosimilar, as applicable, when identifying a potential therapeutic alternative(s) to a selected drug as described in proposed § 429.510(b)(2).

We considered evaluating non-pharmaceutical interventions as potential therapeutic alternatives to the selected drug, including requesting public comment on the use of health care services during the 45-day public comment period on the draft guidance for initial price applicability year 2028 and manufacturer effectuation of the MFP in 2026, 2027, and 2028. Considering non-pharmaceutical interventions as a therapeutic alternative poses several challenges. First, from a clinical perspective, non-pharmaceutical interventions are not exclusively used as alternatives to drugs, or vice versa. For example, non-pharmaceutical interventions may serve as a complementary component of treatment provided at the same time as treatment with a drug. In other situations, such as cancer care, the standard of care may recommend the sequential use of non-pharmaceutical interventions and drugs, with the non-pharmaceutical intervention (for example, surgery) provided as a first-

line treatment and then a drug that is used as the second-line treatment (for example, oral chemotherapy) or vice versa. It may also be difficult to assess the comparative effectiveness of a non-pharmaceutical intervention and a drug. As a result of these considerations, we are not proposing to use non-pharmaceutical interventions as a therapeutic alternative for selected drugs in this final rule. As we continue to gain experience with the Negotiation Program, we may continue to evaluate approaches to the identification of therapeutic alternatives.

Section 1194(e)(2)(A) of the Act directs CMS to consider ''[t]he extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.'' As such, we also considered how to understand this directive from statute if non-pharmaceutical interventions were included as therapeutic alternatives, including how to consider differential pricing between drugs and non-pharmaceutical interventions. Pricing and payment for drugs and services often differ substantially, not only within Medicare but also across other payer types, and non-pharmaceutical interventions may not have similar periodicity or frequency of administration as drugs, which could make comparisons challenging. If CMS were to consider non-pharmaceutical interventions as therapeutic alternatives, we would be required to adopt or create a methodology for determining the 30-day equivalent supply of a non-pharmaceutical intervention, which could include or exclude many components of a service. For example, if physical therapy could potentially serve as a therapeutic alternative to the use of a selected drug, we would need to determine how many and what types of physical therapy services and what duration of those services should be compared to the selected drug and over what time frame. Also, if a type of surgery could potentially serve as a therapeutic alternative to the use of the selected drug, we would need to determine what bundle of services from that surgery would be included in the therapeutic alternative. We believe that general rules would likely be insufficient to capture the heterogeneity of possible non-pharmaceutical interventions available and that specific analyses would be needed in each case. Therefore, we do not believe this is feasible at this time given the statutory timelines provided for negotiation and renegotiation.

Given these challenges, we believe that pharmaceutical therapeutic alternatives would be the most analogous alternative to the selected drug. By comparing a selected drug to a pharmaceutical therapeutic alternative, we would be able to consider the treatment effect and costs as directed by the statute in section 1194(e) of the Act while also operating within statutorily determined timeframes for the negotiation and renegotiation periods. We proposed at § 429.510(c)(1) that we may consult with FDA to obtain information regarding other therapies with FDA-approved indications for the same condition. We may also consult with clinicians, patients or patient organizations, researchers, or any combination thereof to ensure that appropriate therapeutic alternatives are identified. We proposed in § 429.510(c)(2)(i) to consider off-label use when identifying conditions for therapeutic alternatives if such use is included in evidence-based clinical practice guidelines and the off-label use is a medically accepted indication payable under Part B or covered under Part D or both, taking into consideration the major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination thereof, as defined in proposed § 429.20.

We proposed at § 429.510(c)(2)(ii) to identify potential therapeutic alternatives within the same pharmacologic class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action and also proposed at § 429.510(c)(2)(iii) to consider potential therapeutic alternatives in different pharmacologic classes based on our evaluation of the sources noted previously and in proposed § 429.510(b)(1). Where appropriate, only certain formulations or dosage forms and strengths of a brand name drug, brand name biological product, generic drug, or biosimilar (as described in § 429.510(b)(2)) would be identified as the therapeutic alternative to the selected drug as specified in proposed § 429.510(c)(2)(iv), for example, when one formulation of a drug meets the criteria for a therapeutic alternative, but other formulations do not.

In proposed § 429.510(c)(3), we proposed that, in cases where there are many potential therapeutic alternatives for a given condition for which the selected drug is used, we may focus on a subset of therapeutic alternatives that are clinically comparable to the selected drug for the purpose of developing the initial offer. We note that when referencing a ''therapeutic alternative'' this may refer to one or more therapeutic alternative(s) or a subset of therapeutic alternatives that are clinically comparable. For example, for a potential therapeutic alternative, we may consider the place in therapy based on evidence-based clinical practice guidelines, pharmacologic and therapeutic characteristics, utilization in the Medicare population, and the availability of direct and indirect comparative evidence relative to the selected drug. In § 429.510(c)(4), we proposed to prioritize clinical appropriateness in the selection of therapeutic alternatives.

c. Developing a Starting Point for the Initial Offer (§ 429.510(d))

To fulfill the statutory requirement to develop the initial offer per section 1194(b)(2)(B) of the Act in accordance with section 1194(e) of the Act, we proposed at § 429.510(d) to determine a numerical starting point that would be adjusted based on the section 1194(e)(2) factors to determine a preliminary price (as described in § 429.510(e) and section II.F.3.d.1. of this final rule) which would then be adjusted based on the section 1194(e)(1) factors (as described in § 429.510(f) and section II.F.3.d.2. of this final rule). We considered several options for what price should be used as the starting point for developing the initial offer. Options considered included the use of the Part D net price(s), the ASP/WAC(s) of therapeutic alternative(s) for drugs covered under Part D or payable under Part B, respectively, or both; the unit cost of production and distribution for the selected drug; the ceiling for the selected drug (as described in proposed § 429.440(a)); a domestic reference price for the selected drug (for example, the Federal Supply Schedule [84] (FSS) price); a ''fair profit'' price for the selected drug based on whether R&D costs have been recouped and margin on unit cost of production and distribution; Net Part D Plan Payment and Beneficiary Liability for drugs covered under Part D; the MFP, if available; a starting point between: (a) the Part B ASP/WACs, the Net Part D Plan Payment and Beneficiary Liability, or the combined Part B and D amount discussed previously for the therapeutic alternatives; and (b) the statutory ceiling; or considering a starting point

[84] The Federal Supply Schedule (FSS) represents long-term government-wide contracts with commercial companies that provide access to millions of commercial products and services to the government. See: *https://www.gsa.gov/buy-through-us/purchasing-programs/gsa-multiple-award-schedule.*

between (a) the Part B ASPs/WACs, the Net Part D Plan Payment and Beneficiary Liability, or the combined Part B and Part D amount discussed previously for therapeutic alternatives and (b) unit cost of production and distribution of the selected drug; or some combination thereof. Under any of these options, CMS would not make any offers or accept any counteroffers that are above the statutory ceiling as required by section 1194(c) of the Act and proposed at § 429.410(b) nor below the Temporary Floor for Small Biotech Drugs, if applicable, as indicated in § 429.440.

After considering these options and based on experience from implementation of the Negotiation Program for initial price applicability years 2026 through 2028, in accordance with section 1194(e)(2)(A) of the Act, which directs CMS to consider the cost of therapeutic alternative(s), we proposed at § 429.510(d)(1) to use the price of the therapeutic alternative(s) to determine the starting point for developing the initial offer. We proposed at § 429.510(d)(1)(i) that the price of a therapeutic alternative covered under Part D would be the lower of: the Net Part D Plan Payment and Beneficiary Liability, WAC, or the MFP for a selected drug negotiated for a prior initial price applicability year (regardless of whether the agreed-upon MFP for such selected drug has become effective). We proposed at § 429.510(d)(1)(ii) that the price of a therapeutic alternative payable under Part B would be the lower of: ASP, the MFP for a selected drug negotiated for a prior initial price applicability year (regardless of whether the agreed-upon MFP for such selected drug has become effective), or WAC. We proposed at § 429.510(d)(1)(iii) that for a therapeutic alternative that is both payable under Part B and covered under Part D, the price would be equal to a combined amount based on the price of the therapeutic alternative under Part D and the price under Part B (as determined under proposed § 429.510(d)(1)(i) and (ii)). We proposed that the combined amount would be determined using an approach similar to the methodology used to combine the sum of the plan-specific enrollment weighted amounts and the payment amount under section 1847A(b)(4) of the Act; this single combined amount would be weighted by utilization of the drug across Part B and Part D.

For a selected drug with no therapeutic alternative or for a selected drug where the price(s) of the therapeutic alternative(s) determined under proposed § 429.510(d)(1) are above the ceiling, we proposed at § 429.510(d)(3) to use an alternative price equal to the lower of: the pharmaceutical price for the selected drug as included in the FSS as managed by the Department of Veterans Affairs per 48 CFR part 38 as most recently submitted by the Primary Manufacturer under § 429.505(b); the maximum price a manufacturer can charge for the selected drug under 38 U.S.C. 8126 as most recently submitted by the Primary Manufacturer under § 429.505(b); or the ceiling for the selected drug as determined in § 429.410(b).

When determining the Net Part D Plan Payment and Beneficiary Liability of a therapeutic alternative, as defined in § 429.20, we would exclude PDE records for which a compound code indicates the PDE record is for a compounded drug as described in section II.B.5.a. of this final rule. We also believe it is important to reduce the total gross covered prescription drug costs by both DIR and Manufacturer Discount Program payments to permit an appropriate accounting of the price paid by the plan and beneficiary net of price concessions received by Part D plan or pharmacy benefit managers on behalf of a Part D plan. When assessing a therapeutic alternative(s) payable under Part B to determine a starting point for the initial offer, we believe using the lesser of ASP or WAC aligns with the payment amount under section 1847A(b)(4) of the Act, including in circumstances where the WAC of a therapeutic alternative is lower than its ASP. We also believe that considering the agreed-upon MFP for a selected drug that is payable under Part B, covered under Part D, or both, is also appropriate since the agreed-upon MFP may be the lowest available pricing metric for certain drugs.

In proposing this approach, we acknowledge that the therapeutic alternative(s) may not be priced to reflect the clinical benefit of the selected drug; however, using existing prices for therapeutic alternatives, including Net Part D Plan Payment and Beneficiary Liability, MFP, or WAC for a drug covered under Part D, or ASP, MFP, or WAC for a drug payable under Part B, enables CMS to start developing the initial offer within the context of the cost and clinical benefit of one or more drugs that treat the same disease or condition. By using the price(s) of the selected drug's therapeutic alternative(s), we would be able to focus the adjustments on section 1194(e)(2) factors by adjusting this starting point (as described in proposed § 429.510(e)(4)) based on the overall evidence of benefits and harms offered by the selected drug as compared with its therapeutic alternative(s). The other options considered do not provide a starting point that reflects the cost of therapeutic alternatives in the current market, which is an important factor when considering the overall benefit that a treatment brings to Medicare beneficiaries relative to the other drug(s) available to treat the patient's disease or condition.

We proposed at § 429.510(d)(2) that the prices determined under § 429.510(d)(1) and the starting point would be expressed as a 30-day equivalent supply. We proposed at § 429.510(d)(2)(i) to use the same methodology described in proposed § 429.410(b)(1) to calculate the 30-day equivalent supply for drugs covered under Part D, as appropriate, unless we determine it is appropriate to apply an alternative methodology as further described later in this section. We proposed at § 429.510(d)(2)(ii) to use the same methodology described in proposed § 429.410(b)(2) to calculate the 30-day equivalent supply for drugs payable under Part B, as appropriate, unless we determine it is appropriate to apply an alternative methodology as further described later in this section. We proposed at § 429.510(d)(2)(iii) to calculate the 30-day equivalent supply of a therapeutic alternative that is both covered under Part D and payable under Part B separately (as determined in proposed § 429.510(d)(1)(i) and (ii)), unless we determine it is appropriate to apply an alternative methodology as discussed later in this section. We also proposed in § 429.510(d)(2)(iii) that we would determine the 30-day equivalent supply for the price of the therapeutic alternative that is payable under Part B and, separately determine the 30-day equivalent supply for the therapeutic alternative that is covered under Part D prior to combining these amounts using the methodology described in proposed § 429.510(d)(1)(iii) to result in a single combined price expressed as a 30-day equivalent supply.

In certain circumstances it may be necessary to use an alternative methodology to calculate a 30-day equivalent supply, for example, if a therapeutic alternative for a condition is typically prescribed for a period meaningfully shorter than 30 days (for example, for a 2-week period, meaning that one fill would be defined as a 30-day equivalent supply despite lasting only 2 weeks), and the selected drug does not have a similar prescribing pattern, we may use an alternative methodology to calculate 30-day equivalent supply for the therapeutic alternative to ensure that its price is

expressed on comparable terms to a 30-day equivalent supply. In circumstances such as these, we proposed at § 429.510(d)(4)(iv) to use a tailored alternative methodology to calculate the 30-day equivalent supply for therapeutic alternative(s) covered under Part D, payable under Part B, or both, when appropriate. The tailored methodology would promote comparability between the therapeutic alternative(s) and the selected drug.

We proposed in § 429.510(d)(3) to use the price(s) identified under proposed § 429.510(d)(1) to determine the starting point for developing the initial offer. We proposed at § 429.510(d)(3)(i) that if there is no therapeutic alternative for a selected drug or there is no price of the therapeutic alternative(s) determined under proposed § 429.510(d)(1)(i) through (iii) that are below the ceiling, then the starting point for developing the initial offer is the lower of the prices listed at proposed § 429.510(d)(3)(i)(A) through (C). That is, we proposed to use the lower of the maximum price a manufacturer can charge under 38 U.S.C. 8126 as most recently submitted by the Primary Manufacturer, the pharmaceutical price for the selected drug as included in the FSS as managed by the Department of Veterans Affairs per 48 CFR part 38 (hereinafter the ''FSS price'') as most recently submitted by the Primary Manufacturer, or the ceiling.

If there are multiple therapeutic alternatives and at least one therapeutic alternative price identified is below the ceiling, we proposed at § 429.510(d)(3)(ii) to determine a starting point for developing the initial offer within a range based on the lower of the prices of the therapeutic alternatives determined under § 429.510(d)(1) and the ceiling. In implementing this approach, we may weigh prices used to determine the range based on utilization, for example, by the utilization of therapeutic alternatives within and across multiple conditions or other patterns of use for the therapeutic alternatives or the selected drug. When determining the starting point within this range, we may consider the therapeutic alternative prices for each condition if such prices are available and if such prices are different across conditions.

Finally, we proposed at § 429.510(d)(3)(iii) that if there is one therapeutic alternative for the selected drug with a price that is below the ceiling, the price of such therapeutic alternative is the starting point. In all cases, the starting point would not exceed the statutory ceiling and would be subject to adjustments as described further in proposed § 429.510(e) and section II.F.3.d. of this final rule.

d. Adjusting the Starting Point and Preliminary Price Based on the Factors Listed at Section 1194(e) of the Act (§ 429.510(e) and (f))

Section 1194(e) of the Act directs CMS to consider the factors listed at section 1194(e)(1) and 1194(e)(2) of the Act as the basis for any offers and counteroffers and, in accordance with section 1194(b)(1) of the Act, CMS must develop and use a consistent methodology and process for negotiations to achieve the lowest MFP for each selected drug. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, sections 60.3.3 and 60.3.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028. With respect to initial price applicability year 2029 and subsequent years, and consistent with policies for implementation as described in sections 60.3.3 and 60.3.4 of the Negotiation Program Guidance, we proposed at § 429.510(e) to adjust the starting point determined under proposed § 429.510(d), based on the section 1194(e)(2) factors to determine the preliminary price and then adjusting the preliminary price based on the section 1194(e)(1) factors, as described in § 429.510(f), to determine the initial offer. This approach ensures that we consider each section 1194(e) factor while also providing a consistent methodology for doing so.

(1) Adjusting the Starting Point Based on Section 1194(e)(2) Factors (§ 429.510(e))

To evaluate the section 1194(e)(2) factors, including the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), we proposed at § 429.510(e)(1) to use a qualitative approach to broadly evaluate the body of available evidence, including information received from the public and the Primary Manufacturer as described in proposed §§ 429.505(b), 429.505(d), and 429.515(b), evidence identified through a CMS-led literature review, Medicare claims or other datasets, potentially including evidence related to health care resource utilization and usage patterns of the selected drug versus its therapeutic alternative(s), clinical data, or other information relevant to the selected drug and its therapeutic alternative(s). We also proposed at § 429.510(e)(2) that we may consult with clinicians, patients or patient organizations, researchers, and/or FDA. This review would be complementary to additional engagement opportunities for interested parties—specifically, meetings with the Primary Manufacturer and public events as proposed in § 429.515 and described in section II.F.4.b. of this final rule—after the March 1 deadline described at proposed § 429.505(d)(2) for submission of section 1194(e)(2) data.

As a complement to the public submission of information on section 1194(e)(2) factors and consistent with policies for implementation as described in section 50.2 of Negotiation Program Guidance, we proposed at § 429.510(e)(1) to additionally evaluate existing literature and real-world evidence, conduct internal analytics, and consult subject matter experts and clinicians on these topics when considering available evidence about alternative treatments to the selected drug. When evaluating the literature from the public and manufacturer submissions as well as literature from CMS' review, we intend to consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons, generalizability, study population, and relevance to the negotiation factors listed in section 1194(e)(2) of the Act to ensure the integrity of the contributing data within the negotiation process. We also proposed to prioritize research, including both observational research and research based on randomized samples, that is methodologically rigorous, appropriately powered (that is, has sufficient sample size) to answer the primary question of the research, and structured to avoid potential false positive findings due to multiple subgroup analyses. We proposed to consider research and real-world evidence relating to Medicare populations, including individuals with disabilities, patients with end-stage renal disease, and Medicare-aged populations, as particularly important. In considering impact on specific populations and patients with unmet medical needs, we intend to prioritize research specifically designed to focus on these populations over studies that include outcomes for these populations but for which these populations were not the primary focus.

This approach would provide a pathway for CMS to consider the multitude of information expected from public input, including but not limited to peer-reviewed research, expert reports or white papers, clinician

expertise, real-world evidence, and patient experience. This approach also would provide us with the flexibility to consider a variety of aspects in our evaluation of comparative effectiveness, including patient experiences, disease severity, treatment complexity, and/or other unique considerations related to use of the selected drug or therapeutic alternatives.

To consider comparative effectiveness of a selected drug and its therapeutic alternative(s) as required by section 1194(e)(2)(C) of the Act, we proposed at § 429.510(e)(3) to identify outcomes to evaluate for each identified condition for which the selected drug is used. Outcomes of interest may include direct clinical outcomes (for example, cure, mortality) or validated or reasonably likely surrogate endpoints (for example, serum hemoglobin A1c) or both. In determining outcomes of interest, we would consider patient-reported outcomes and outcomes of importance to patients, if available. We would consider the identified outcomes of interest, including patient-centered outcomes, and patient experience data, when evaluating the clinical benefit of the selected drug and its therapeutic alternative(s) for those conditions. In addition, we proposed at § 429.510(e)(3)(i)(C) that outcomes and contextual factors such as health-related quality of life or patient and caregiver preferences would also be considered to the extent these outcomes and factors correspond with benefits or harms to the individuals taking the selected drug or therapeutic alternative(s) and are appropriately measurable and quantifiable.

We proposed at § 429.505(e) that when evaluating such information, we would not, per section 1194(e)(2) of the Act, use evidence in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill, and would not, per section 1182(e) of the Act, use QALYs. In proposed § 429.510(e)(3)(i)(D), we proposed to also consider the caregiver perspective to the extent that it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug. As described in proposed § 429.510(e)(3)(ii), relevant outcomes would be identified using the CMS-led literature review and information submitted by manufacturers and the public, including patients and caregivers, as well as in the events described in proposed § 429.515(b).

In all cases, we proposed to consider applicable evidence and other input collectively, within the context of the course of care for each condition for which the selected drug is used. As noted previously, we believe this approach would provide flexibility to consider a variety of aspects in our evaluation of comparative effectiveness, including patient experiences, disease severity, treatment complexity, and/or other unique considerations related to the use of the selected drug or its therapeutic alternative(s) for a given condition.

Once the starting point for the initial offer has been established and evidence on section 1194(e)(2) factors has been considered, we would consider the information regarding the four factors outlined in section 1194(e)(2) of the Act collectively and within the context of the course of care for each condition for which the selected drug is used as described at proposed § 429.510(e)(4) and apply an upward adjustment, downward adjustment, or no adjustment to the starting point to determine the preliminary price as described at proposed § 429.510(e)(5). In accordance with section 1194(b)(1) of the Act, consideration and adjustment for the section 1194(e) factors will be made with the aim of achieving the lowest MFP for each selected drug. We considered employing both a qualitative approach (for example, adjusting the starting point upward or downward relative to the section 1194(e)(2) factors offered by the selected drug compared to its therapeutic alternative(s)) and a more thoroughly pre-specified quantitative approach. Consistent with the first three cycles of negotiation, we proposed to use a qualitative approach to consider nuanced differences between drugs, for example, interactions with other treatments commonly prescribed simultaneously for a condition or disease, and other factors that might not be captured in a more thoroughly pre-specified quantitative approach.

(a) Analysis for Selected Drugs With Therapeutic Alternative(s)

For each condition for which we identify a therapeutic alternative, we proposed to consider the information regarding the four factors outlined in section 1194(e)(2) of the Act collectively. As described at proposed § 429.510(e)(4)(i), we proposed that such review would include, but is not limited to, examining improvements (as described at proposed § 429.510(e)(4)(i)) in outcomes (as determined in proposed § 429.510(e)(3)) to determine the extent to which a selected drug represents a therapeutic advance (as defined at proposed § 429.20) as compared to its therapeutic alternative(s) (as defined at proposed § 429.20) (for example, if selected drug is curative versus a therapeutic alternative that delays progression) and would consider the costs of the selected drug and its therapeutic alternative(s) as described at proposed § 429.510(e)(4)(i)(A).

We proposed at § 429.510(e)(4)(i)(B) to consider the magnitude of differences in outcomes of interest conferred by the selected drug compared to the selected drug's therapeutic alternative(s) for each condition in which we identify a therapeutic alternative, when determining the extent to which a selected drug represents a therapeutic advance. We understand that a selected drug can be first in class.[85] However, other drugs may have become available since the selected drug's initial approval and therefore we proposed in the definition of ''therapeutic advance'' at proposed § 429.20 to consider the extent to which a selected drug represents a therapeutic advance for a condition at the time of consideration based on all available information at such time of consideration. In accordance with section 1194(e)(2)(A) of the Act, we proposed to review the analyses detailed previously for each identified condition of the selected drug and its therapeutic alternative(s) to determine the extent to which the selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) as described in proposed § 429.510(e)(4)(i). For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS proposed to consider the extent to which the drug represents a therapeutic advance at the time of consideration based on all available information at such time of consideration.

In accordance with section 1194(e)(2)(C) of the Act, we would also consider the effects of the selected drug and its therapeutic alternative(s) on specific populations, such as individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations. To do so, we proposed to identify studies, if available, focused on the conditions for which each selected drug is used and the impact of the selected drug and its therapeutic alternative(s) on such specific populations. Further, per section 1194(e)(2)(D) of the Act, for each

[85] For purposes of this discussion, first in class drugs are those that have a new mechanism of action, defined by the National Cancer Institute as ''a term used to describe how a drug or other substance produces an effect in the body.'' See: *https://www.cancer.gov/publications/dictionaries/cancer-terms/def/mechanism-of-action.*

condition in which CMS has identified a therapeutic alternative, we would consider the extent to which the selected drug and its therapeutic alternative(s) address an unmet medical need for each condition for which the selected drug is used. For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS would consider the extent to which the drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration. When considering unmet medical need (see proposed § 429.20), we proposed to consider the selected drug, its therapeutic alternative(s), if any, and any existing treatment options, which may include pharmacologic or non-pharmacologic treatments. We may consider the nonbinding recommendations in the FDA's ''Guidance for Industry Expedited Programs for Serious Conditions—Drugs and Biologics,'' [86] as well as any updates that may be issued by FDA in the future, when determining the extent to which a selected drug addresses an unmet medical need for a condition.

(b) Analysis for Conditions of Selected Drugs Without Therapeutic Alternatives

For conditions of selected drugs without therapeutic alternatives, we would consider the information regarding the four factors outlined in section 1194(e)(2) of the Act collectively. We proposed at § 429.510(e)(4)(ii) certain parameters for our review of conditions of selected drugs where we need to account for the lack of therapeutic alternatives for such conditions. Specifically, we proposed at § 429.510(e)(4)(ii)(A) that for each condition for which a selected drug is used but does not have a therapeutic alternative, we would consider the totality of available information relevant to the section 1194(e)(2) factors as detailed previously and in proposed § 429.510(e)(1), including information received from Primary Manufacturers and the public as described in proposed § 429.505(d), and evidence identified through a CMS-led literature review. We also proposed at § 429.510(e)(4)(ii)(B) to consider the selected drug and any existing treatment options, which may include pharmacologic or non-pharmacologic treatments, to determine the extent to which the selected drug addresses an unmet medical need (as defined in § 429.20) at the condition level. For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS would consider the extent to which the selected drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration. We would consider unmet medical need in the same manner as discussed in section II.F.3.a. of this final rule. At proposed § 429.20, we proposed to define unmet medical need as a circumstance in which the relevant condition is one for which no treatment options exist, or existing treatments do not adequately address the condition. As noted previously, we may consider the nonbinding recommendations in the FDA ''Guidance for Industry Expedited Programs for Serious Conditions—Drugs and Biologics,'' as well as any updates that may be issued by FDA in the future, when considering the extent to which a selected drug addresses an unmet medical need for the purpose of the Negotiation Program.

Finally, as described at proposed § 429.510(e)(4)(ii)(C), we proposed to examine improvements in outcomes, such as the magnitude of differences in outcomes of interest conferred by the selected drug, for a condition wherein CMS has not identified a therapeutic alternative to determine the extent to which a selected drug represents a therapeutic advance. For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS would consider the extent to which the selected drug represents a therapeutic advance at the time of consideration based on all available information at such time of consideration

(c) Preliminary Price

As noted in section II.F.3.d.1.a. of this final rule, we proposed to take a qualitative approach to adjusting the starting point based on the unique characteristics of the drug and its therapeutic alternative(s), if any, as well as the patient population(s) taking the selected drug. For each selected drug, we proposed to adjust the applicable starting point (as determined in proposed § 429.510(d)) upward or downward or to not adjust (as described in proposed § 429.510(e)(5)) based on the totality of the relevant information and evidence submitted and gathered through our analysis based on section 1194(e)(2) factors. We may adjust the starting point based on how the section 1194(e)(2) factors apply with respect to individual condition(s) in cases where there are notable differences relative to the therapeutic alternative(s).

After the starting point is adjusted, if applicable, as described in proposed § 429.510(e)(4), as appropriate, based on section 1194(e)(2) factors, evaluated using data submitted by the Primary Manufacturer and the public through the Drug Price Negotiation ICR and gathered through our analyses and literature review, the resulting price is referred to as ''the preliminary price'' (defined in proposed § 429.20).

We proposed to adjust the preliminary price, as appropriate, based on data submitted by the Primary Manufacturer in accordance with section 1194(e)(1) of the Act, as described in detail in section II.F.3.d.(2). of this final rule and proposed at § 429.510(f).

(2) Adjusting the Preliminary Price Based on Consideration of Section 1194(e)(1) Factors

Section 1194(e)(1) of the Act directs CMS to consider certain factors, which must be reported by each Primary Manufacturer, when determining offers and counteroffers. To fulfill this requirement, we proposed at § 429.510(f) to adjust the preliminary price based on the factors listed at section 1194(e)(1) of the Act. The preliminary price may be adjusted upward, adjusted downward, or not adjusted to account for these manufacturer-specific data elements. In accordance with section 1194(b)(1) of the Act, this process would be conducted with the aim of achieving the lowest MFP for each selected drug. The section 1194(e)(1) factors are listed at proposed § 429.505(b)(2) and include: (1) R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs; (2) current unit costs of production and distribution of the drug; (3) prior Federal financial support for novel therapeutic discovery and development with respect to the drug; (4) data on pending and approved patent applications or exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act for the drug; and (5) market data and revenue and sales volume data for the drug in the United States.

We proposed to consider the five factors outlined in section 1194(e)(1) of the Act in totality at proposed § 429.510(f)(1) and apply an upward adjustment, downward adjustment, or no adjustment to the preliminary price as described at proposed § 429.510(f)(2). We provide illustrative examples of how we might adjust, or not adjust, the preliminary price based on evaluation of a manufacturer-specific data element

[86] FDA Guidance for Industry Expedited Programs for Serious Conditions—Drugs and Biologics, May 2014. See: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics.*

later in this section. However, the overall adjustment, inclusive of all five elements taken together, may differ from the example adjustment for any single element viewed in isolation.

Section 1194(e)(1)(A) of the Act requires CMS to consider the extent to which the Primary Manufacturer has recouped its R&D costs. As an example of how we could approach this consideration, CMS could compare the R&D costs with the global and U.S. net revenue for the selected drug reported by the Primary Manufacturer to determine the extent to which the Primary Manufacturer has recouped its R&D costs. For example, if a Primary Manufacturer has not recouped its R&D costs, we may consider adjusting the preliminary price upward. Conversely, if a Primary Manufacturer has recouped its R&D costs, we may consider adjusting the preliminary price downward or apply no adjustment. We may use the R&D costs reported by the Primary Manufacturer and the calculated recouped costs, including the assumptions and calculations in the accompanying narrative text, and/or other factors as described in proposed § 429.505(b)(2) to adjust the preliminary price.

As an example for how we may consider the relationship between the preliminary price and the unit costs of production and distribution (the factor listed at section 1194(e)(1)(B) of the Act), we may consider adjusting the preliminary price downward if the unit costs of production and distribution are lower than the preliminary price, or upward if the unit costs of production and distribution are greater than the preliminary price. Again, we may consider the assumptions and calculations in the accompanying narrative text submitted by the Primary Manufacturer of the selected drug as described in proposed § 429.505(b) to determine if an adjustment is appropriate.

As an example of how we may consider the extent to which the Primary Manufacturer benefited from Federal financial support with respect to the selected drug (the factor listed at section 1194(e)(1)(C) of the Act), we may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.

We would also review the patents and exclusivities reported as we develop our initial offer, consistent with section 1194(e)(1)(D) of the Act. We believe that this information would support CMS' consideration of the factors listed at section 1194(e) of the Act and in proposed § 429.505(b)(2) and (d)(3). For instance, patents and exclusivities may inform our understanding of therapeutic alternatives and other available therapy for the purposes of adjusting for clinical benefit, including consideration of the extent to which the selected drug represents a therapeutic advance or the extent to which the selected drug addresses an unmet medical need. More specifically, in light of exclusivities, there may be no other available therapy aside from the selected drug that adequately addresses treatment or diagnosis of a disease or condition, and consideration of such information would be relevant to our consideration of the extent to which the selected drug addresses an unmet medical need for that disease or condition.

Finally, we would consider how the market data and revenue and sales volume data compare to the preliminary price in accordance with section 1194(e)(1)(E) of the Act. For example, if the average commercial net price is lower than the preliminary price, we may consider adjusting the preliminary price downward. If the average commercial net price is greater than the preliminary price, we may consider adjusting the preliminary price upward.

We proposed in § 429.510(f)(3) that after any adjustments to the preliminary price are made as described in paragraphs (f)(1) and (f)(2), the result is the initial offer unless paragraph (f)(3)(i) applies. As proposed in § 429.510(f)(3)(i), if the resulting amount is above the ceiling (as determined in § 429.410), then the initial offer will be equal to the ceiling, and if the amount is below the Temporary Floor for Small Biotech Drugs (as determined in proposed § 429.440), if applicable, then the initial offer will be equal to the Temporary Floor for Small Biotech Drugs.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters stated that while they support clinical practice guidelines as a component of the evidence that CMS considers during the negotiation process, they indicated that guidelines offer the standards of care for a disease based on the information available at the time of publication and may not reflect the current evidence base or advancements in treatments; that is, clinically accepted uses can emerge before guidelines and compendia are updated and CMS should consider guidelines alongside other evidence.

Response: We thank these commenters for their input and agree that clinical practice guidelines, like other forms of evidence, may have limitations and biases. We believe clinical practice guidelines, when available, are an important component of understanding how a drug contributes to the course of care for a condition. As we stated in section II.F.3.d.1. of the proposed rule (91 FR 36292), we will use a qualitative approach to broadly evaluate the body of available evidence, which includes clinical guidelines and other forms of evidence including information received from the public and the Primary Manufacturer, evidence identified through a CMS-led literature review, Medicare claims or other datasets, potentially including evidence related to health care resource utilization and usage patterns of the selected drug versus its therapeutic alternative(s), clinical data, or other information relevant to the selected drug and its therapeutic alternative(s). We also proposed at § 429.510(e)(2) that we may consult with clinicians, patients or patient organizations, researchers, FDA, or some combination thereof. We also note that the Primary Manufacturer can provide additional context or information on clinical guidelines, including whether there may be a change in clinical approach, throughout the negotiation period. We believe the combined approach of discussions with the Primary Manufacturer, reviewing the most recent guidelines, and consulting with clinicians, patients or patient organizations, researchers, FDA, or some combination thereof, as needed, provides CMS with a robust and up-to-date understanding of clinical guidelines and where recommendations may evolve.

Comment: A few commenters stated CMS should provide more transparency in how the section 1194(e)(1) factors are used and weighted during development of the initial offer and counteroffers. A commenter suggested that CMS should adjust the initial offer downward if R&D costs have been recouped for the selected drug. A commenter recommended that CMS place minimal weight on R&D recoupment. A commenter cautioned that CMS should not use prior Federal financial support, the factor listed at section 1194(e)(1)(C) of the Act, to adjust the preliminary price downward because it may discourage future innovation. A few commenters suggested that CMS should provide an upward adjustment for the factor listed at section 1194(e)(1)(D) of the Act (particularly, data on pending and approved patents and exclusivities) to indicate CMS' recognition of the innovation of the selected drug. A few

commenters stated that CMS should review patents and exclusivities for a selected drug to determine if such patents and exclusivities are indicative of innovation or if they indicate efforts to extend monopolies without associated clinical benefit. As a component of the factor listed at section 1194(e)(1)(A) of the Act, a commenter suggested that CMS increase the weighting of post-approval research that results in new indications or addresses an unmet medical need and also increase the weighting for active development of an additional indication. A commenter stated CMS should ''pay for the marginal cost of production and distribution'' for drugs used by Medicare beneficiaries. A commenter requested that CMS state how it considers the gross-to-net relationship of the price of a selected drug when developing the preliminary price. A commenter stated that CMS has not affirmed that section 1194(e)(1) factors may result in an upward adjustment to the preliminary price. A commenter supported the proposal to consider section 1194(e)(1) factors in totality.

Response: We thank these commenters for their input. Consistent with our response to similar comments in the final guidance for initial price applicability year 2027 and the Negotiation Program Guidance, we believe it is important to maintain flexibility when considering how each negotiation factor contributes to the initial offer and subsequent offers and counteroffers, as applicable, which may be impacted by the unique characteristics of each selected drug, the populations each selected drug is intended to treat, and information that may emerge from meaningful discussions with manufacturers, patients, and patient representatives. Therefore, we decline to adopt the commenters' suggestions to apply specific positive or negative adjustments to specific section 1194(e)(1) or (e)(2) factors. With regard to suggestions that CMS provide more information on how a factor is weighted when developing the initial offer, we note that, as proposed at § 429.505(e), we consider all factors listed in section 1194(e) of the Act in the development of the initial offer. All applicable negotiation factors will be considered in totality for each selected drug, as proposed at § 429.510(f)(1). We also note that as proposed at § 429.510(f)(2), the preliminary price may be adjusted upward, downward, or not adjusted based on CMS' consideration of the section 1194(e)(1) factors.

Comment: A couple of commenters provided input on how CMS should consider clinical benefit for a selected drug that includes a fixed combination drug subject to the proposed policy described in section II.B.6.a.1. of the proposed rule (91 FR 36260) and at proposed § 429.125(b)(4)(i). One of these commenters recommended that CMS keep separate approaches for identification of potential qualifying single source drugs at proposed § 429.125(b) and valuation of selected drugs during negotiation at proposed § 429.510(e), stating that CMS may properly aggregate two products into the same qualifying single source drug to circumvent program integrity concerns while still recognizing during the negotiation process that each product provides distinct value. A couple of commenters recommended that CMS clarify in the final rule that when a selected drug subject to the negotiation process includes a fixed combination drug in accordance with proposed § 429.125(b)(4)(i), CMS will still consider formulation-specific clinical evidence under § 429.510(e) during the negotiation process.

Response: We appreciate the input from these commenters. As we stated in the Negotiation Program proposed rule at section II.B.6.a.1. (91 FR 36260) and as proposed at § 429.125(b)(4)(i), we clarified how CMS would comply with sections 1192(d)(3)(B) and 1196(a)(2) of the Act for fixed combination drugs that include an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s), when identifying qualifying single source drugs for purposes of drug selection. We agree with the commenter that the process for identification of potential qualifying single source drugs is separate from our review of the factors listed at section 1194(e) of the Act, which we will consider as the basis for developing offers and counteroffers. We will follow the process described at § 429.510, including considering clinical and other evidence, for all drugs selected for negotiation for which the Primary Manufacturer has signed a Negotiation Program Agreement.

Comment: Many commenters recommended that CMS provide more detailed information on the framework used to develop the initial offer to promote transparency and consistency. Specifically, many commenters recommended that CMS assign greater weight to section 1194(e)(2) factors because these factors reflect the benefit a selected drug provides to patients, caregivers, society, and the health care system; some commenters also suggested that CMS should place less weight on section 1194(e)(1) factors as placing too much weight on such factors might undervalue innovation and overemphasize manufacturer costs and other manufacturer-submitted data. Some commenters requested that CMS consider factors not mentioned in the proposed rule, including the impact of a selected drug on the health system, costs to the patient, the societal value of a selected drug, cost offsets (such as avoiding ineffective or harmful treatment options and reducing downstream costs to the health care system), adherence, the value of multi-indication drugs, the value of companion diagnostics, and the mental and social wellbeing of patients and caregivers. A few commenters encouraged CMS to consider the full range of patient outcomes including but not limited to patient preferences, caregiver burden, and quality of life. A few commenters recommended applying greater weight to unmet medical need when adjusting for section 1194(e)(2) factors. A commenter suggested that when considering whether a selected drug represents a therapeutic advance, CMS should consider cost and outcomes metrics including patient and caregiver perspectives, reduced treatment burden, reduced hospitalizations, decreased reliance on adjunct therapies, and improved care coordination. A commenter suggested that the safety profile of a drug should be weighted when considering section 1194(e)(2) factors. A commenter recommended that CMS adopt an approach like the one used in Germany by the Institute for Quality and Efficiency in Health Care (IQWiG) to categorize therapeutic benefit. A couple of commenters recommended using the European Society for Medical Oncology (ESMO) Magnitude of Clinical Benefit Scale (ESMO–MCBS)[87] in the assessment of section 1194(e)(2) factors. A commenter requested that CMS consider the full range of patient outcomes when considering evidence related to section 1194(e)(2) factors, including outliers and subpopulations that may benefit from a selected drug more than the mean. A commenter requested that CMS acknowledge the difference between evidence indicating that a drug offers no

[87] Cherney NI, Oosting SF, Dafni U, et al. ESMO-Magnitude of Clinical Benefit Scale version 2.0 (ESMO–MCBS v2.0). Annals of Oncology. 2025: *https://www.annalsofoncology.org/article/S0923-7534(25)00166-8/fulltext.*

additional benefit versus evidence that indicates uncertainty of additional benefit. A commenter suggested that CMS should treat each factor listed at section 1194(e) of the Act independently rather than conducting a holistic inquiry.

Response: We thank commenters for their feedback on the adjustments related to the factors listed at section 1194(e) of the Act. As we stated in the Negotiation Program Guidance, section 1196(a)(4) of the Act provides the Secretary with the authority to establish a negotiation and renegotiation process in accordance with section 1194 of the Act. This section directs the Secretary to establish a consistent methodology and process for negotiation (section 1194(b)(1) of the Act) and to consider the section 1194(e) factors as the basis for determining the offers and counteroffers (section 1194(e) of the Act) but does not dictate the manner in which those factors must be considered. Consistent with our response to similar comments in the Negotiation Program Guidance and the previously provided response related specifically to section 1194(e)(1) factors, we believe that flexibility in determining which section 1194(e) factors to emphasize over others will depend on the unique considerations related to each selected drug, the populations each selected drug is intended to treat, and information that may emerge from meaningful discussions with manufacturers, patients, and patient representatives. Considerations for how evidence will be prioritized are proposed at § 429.505(d) and (e) and section II.D.1. of the proposed rule (91 FR 36292); these considerations are also applicable to renegotiation as proposed at § 429.620(d) and section II.G.5.c. of the proposed rule (91 FR 36308). All applicable negotiation factors will be considered in totality for each selected drug.

We appreciate the suggestion to use the ESMO–MCBS to assess section 1194(e)(2) factors and the approach used by IQWiG to categorize therapeutic benefit. As noted in our response to similar suggestions in the Negotiation Program Guidance, we consider whether the general approaches used in these frameworks may be informative for evaluating evidence in the context of the Negotiation Program and whether their use would be consistent with statutory requirements. We also note that the ESMO–MCBS is a tool specifically developed to assess cancer therapies and is not broadly applicable to all selected drugs. In situations where an interested party provides an ESMO–MCBS score for a particular selected drug or therapeutic alternative, we may consider such information in the context of the section 1194(e)(2) factors.

Comment: A few commenters supported CMS' approach described in section II.F.3.d. of the proposed rule (91 FR 36292) to consider source, rigor, and risk of bias, among other factors, when evaluating evidence. A commenter stated that CMS has not articulated an evidence review protocol. A couple of commenters recommended that CMS prioritize high quality, robust real-world evidence (RWE) while a commenter requested additional guidance on how CMS assesses RWE. A commenter suggested prioritizing evidence provided by clinicians and manufacturers given their expertise in the selected drug; a commenter suggested prioritizing evidence submitted by patients and clinicians. A commenter stated the CMS should recognize that while rigorous evidence is important, conventional evidence standards may not be appropriate to apply to rare diseases, small clinical populations, heterogenous conditions, or underrepresented patient populations. A couple of commenters stated that CMS should leverage claims and other datasets to understand utilization and usage patterns for a selected drug and its therapeutic alternative(s), if any.

Response: We appreciate commenters' support and their feedback regarding how we will consider evidence and how we will prioritize such evidence. Consistent with our response to similar comments in the Negotiation Program Guidance and as described in section II.F.3.d. of the proposed rule (91 FR 36292), when reviewing the data submissions from the public and manufacturer (including the previous examples of data) as well as literature from CMS' review, we intend to consider the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons, generalizability, study population, and relevance to the negotiation factors listed in section 1194(e)(2) of the Act to ensure the integrity of the contributing data within the negotiation process. We will prioritize research, including both observational research and research based on randomized samples, that is methodologically rigorous, appropriately powered (that is, has sufficient sample size) to answer the primary question of the research, and structured to avoid potential false positive findings due to multiple subgroup analyses. We believe this approach will ensure the integrity of data within the negotiation process.

Comment: Some commenters urged CMS to provide more information on how the information provided by the public, particularly patients, is used in the development of the initial offer. Suggestions included publication of a plain language summary of the major patient and caregiver themes received for each selected drug and an explanation of how those themes informed the negotiation process, publishing decisions throughout the negotiation process, and leveraging the National Health Council Patient-Centered Value Assessment Rubric and Rubric to Capture the Patient Voice to create a public framework for how evidence is considered and included in the negotiation process. A commenter suggested leveraging FDA Voice of the Patient Reports when available for selected drugs. A couple of commenters indicated express support for inclusion of patient and caregiver perspectives in the negotiation process, including related data such as patient-centered outcomes and patient experience data.

Response: We thank commenters for their suggestions. Consistent with the response provided to similar comments in the final guidance for initial price applicability year 2027 and the Negotiation Program Guidance, we agree that considerations related to the patient and caregiver experience are important and relevant for consideration of the section 1194(e)(2) factors. We direct commenters to the provision proposed at § 429.510 and responses to comments about this section, which concern how we will use the section 1194(e) data, including patient and caregiver perspectives and experiences (such as through FDA Voice of the Patient Reports, as applicable), in developing an initial offer and, if any, counteroffers. We also believe the information provided in the explanation of the MFP as described in II.H.2. of the proposed rule (91 FR 36311), which we will make available to the public per the provision proposed at § 429.705(b), serves to provide sufficient information regarding use of the section 1194(e)(2) factors submitted and redacted copies of the section 1194(e)(2) factors submitted by interested parties that we considered during the negotiation process.

Comment: A commenter stated that CMS should share with the Primary Manufacturer whether CMS used the standard or alternative 30-day equivalent supply methodology described at § 429.510(d)(2)(iv) prior to or within the concise justification for

the initial offer. A commenter suggested that CMS should weight therapeutic alternative utilization such that utilization reflects the populations and uses for which the selected drug is prescribed in cases where aggregate utilization does not reflect the populations and uses for which the selected drug is prescribed. A commenter requested that CMS commit to a process that assesses and weights therapeutic alternatives by utilization across conditions, to avoid devaluing products that have shown benefit across multiple indications. A commenter requested that CMS clarify how it weights net prices across multiple indications and therapeutic alternatives. A commenter recommended that CMS calculate indication-level therapeutic alternative starting points and weight those starting points based on the Medicare utilization of the therapeutic alternatives relative to the selected drug in the same population.

Response: We thank these commenters for their suggestions. Although we do not include a detailed methodology of therapeutic alternative calculations in the concise justification for an initial offer, we welcome specific methodology questions related to how we calculated the starting point using the prices of therapeutic alternatives from the Primary Manufacturer during the optional negotiation meetings. We believe this approach appropriately balances transparency with the Primary Manufacturer while protecting proprietary information related to a therapeutic alternative.

Comment: A few commenters opposed CMS' consideration of off-label use for the purpose of determining indications and therapeutic alternatives to the selected drug stating that this conflicts with section 1194(e)(2)(B) of the Act. A commenter requested clarity on the ''threshold for inclusion'' of an off-label use and a commenter stated CMS should apply the same evidentiary rigor when reviewing off-label use as is applied to review of FDA-approved indications. A commenter suggested that CMS only consider off-label use for negotiation if it is voluntarily submitted by the Primary Manufacturer by adopting the provision for renegotiation eligibility as was proposed at § 429.605(c)(1)(ii). A commenter stated that Primary Manufacturers should not be responsible for submitting information on off-label use. A commenter stated that CMS should ensure that therapeutic alternatives are grounded in clinically appropriate FDA-approved indications and distinguish between approved uses and other off-label uses.

Response: We thank commenters for their feedback on consideration of off-label use of the selected drug when determining conditions for which the selected drug is used (as proposed at § 429.510(a)(2)) and therapeutic alternatives for the selected drug (as proposed at § 429.510(c)(2)(i)). Regarding the comments indicating that section 1194(e)(2)(B) of the Act directs CMS to consider prescribing information approved by FDA for such drug and therapeutic alternatives as the basis for determining offers and counteroffers, we affirm that we consider such information as described at § 429.510(e)(1) in the adjustment to the starting point based on section 1194(e)(2) factors. We also clarified in this final rule that we consider FDA prescribing information when determining therapeutic alternatives, if any, by revising proposed § 429.510(c)(2) to include a new paragraph (ii) indicating that CMS will consider prescribing information as approved by FDA. As other commenters have noted, particularly for rare diseases or small subpopulations or in situations where clinical evidence is not yet published, off-label use is an important component of patient care. Further, the Medicare program recognizes the importance of evidence-based off-label use of certain drugs by making such drugs payable under Part B, covered under Part D, or both for such uses. It is for this reason we define ''off-label use'' as described at § 429.20 as the use of a drug that is ''included in evidence-based clinical practice guidelines and is a medically accepted indication payable under Part B or covered under Part D or both, taking into consideration major drug compendia, authoritative medical literature, and accepted standards of medical practice, or some combination thereof.'' Under this definition, not all off-label uses are considered.

For these reasons, we believe that consideration of off-label use for the purposes of identifying conditions for which the selected drug is used and identifying therapeutic alternatives for those conditions, as applicable, is appropriately grounded in evidence and statute. We also believe that it is not necessary to solely consider off-label use if voluntarily submitted by a Primary Manufacturer for the purposes of identifying conditions for which the selected drug is used and identifying therapeutic alternatives for those conditions. When we are undergoing these processes, a drug has already been selected for negotiation or renegotiation and we are fulfilling our statutory directive to achieve the lowest MFP for the selected drug under section 1194(b)(1) of the Act. These are fundamentally different processes from determining renegotiation eligibility. We also note that neither in negotiation nor renegotiation is a Primary Manufacturer required to submit information on off-label use; in both cases submission of such information is optional.

Comment: A couple of commenters stated that CMS should not use generics, biosimilars and reference products as therapeutic alternatives in the development of the initial offer, as reliance on these products as therapeutic alternatives is not authorized by the statute. A few commenters stated that CMS should select therapeutic alternatives based on clinical appropriateness and solicit input from relevant stakeholders, including clinicians, patients, caregivers, and manufacturers, when evaluating clinical appropriateness. A few commenters suggested that CMS seek input from clinicians with expertise in treating the indications of the selected drug when selecting therapeutic alternatives, as well as seek input from patients, caregivers, manufacturers, and other stakeholders. A commenter stated that therapeutic alternatives should be based on clinical appropriateness and not based on least costly alternatives. A commenter stated that CMS should not rely on off-label use when comparing costs of therapeutic alternatives, absent robust evidence for the relevant condition. A commenter recommended that CMS account for variation in site-of-care practices and explain data and assumptions for determining that use of a drug occurs solely outside of Part B and Part D.

Response: We appreciate commenters' feedback regarding the identification of a therapeutic alternative(s) for the selected drug. Consistent with our response to similar comments in the Negotiation Program Guidance and final guidance for initial price applicability year 2027, we will identify the therapeutic alternative(s) for the indications of a selected drug by using data submitted by the Primary Manufacturer and the public, prescribing information approved by the FDA, drug classification systems commonly used in the public and private sector for formulary development, major drug compendia, widely accepted clinical guidelines, evidence identified through the CMS-led literature review, published drug or drug class reviews, peer-reviewed studies, and Medicare claims or other data sets. We believe the framework

described in the proposed rule allows us to select appropriate therapeutic alternatives for the indications of current and future selected drugs, if such alternatives exist. We disagree with the commenters that state the statute does not authorize CMS to consider generics, biosimilars, or reference products as therapeutic alternatives in the development of the initial offer. Section 1194(e)(2) of the Act directs CMS to consider various evidence regarding therapeutic alternatives of the selected drug and does not limit the scope of therapeutic alternatives to exclude such products. However, if a Primary Manufacturer disagrees with CMS' identification of appropriate therapeutic alternatives to the selected drug, including any biosimilars or generic drugs, the Primary Manufacturer will have multiple opportunities to share that feedback with CMS, as described in § 429.515 and section II.F.4.a. of this final rule.

We agree with commenters that robust public input can provide important information on the selected drug and its therapeutic alternatives. As described at § 429.510(c), we may consult with FDA to obtain information regarding other therapies with FDA-approved indications for the same condition. We may also consult with clinicians, patients or patient organizations, and/or researchers, to ensure that appropriate therapeutic alternatives are identified. As such, we encourage members of the public, including manufacturers, Medicare beneficiaries, researchers, clinicians, caregivers, and other interested parties, to provide information about the selected drug and its therapeutic alternative(s), if any, through the Drug Price Negotiation ICR. We will consider information submitted through the Drug Price Negotiation ICR when developing the initial offer and throughout the negotiation process.

Regarding consideration of off-label use for therapeutic alternatives and their associated costs, we note that our policy includes the criteria that must be met for CMS to consider an off-label use of a selected drug as described at § 429.20. That is, we may consider off-label use when identifying indications if such use is included in evidence-based clinical practice guidelines and the off-label use is a medically accepted indication payable under Part B or covered under Part D, taking into consideration the major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination thereof. In addition to consideration of public input and consultation when considering therapeutic alternatives, we also note that consistent with the policies in the Negotiation Program Guidance, the negotiation process policies described at § 429.515 include an opportunity for the Primary Manufacturer to meet with CMS regarding the data submission for the factors listed at section 1194(e) of the Act prior to CMS sending the initial offer. This initial meeting, as well as the negotiation process, including offer and counteroffer exchanges and negotiation meetings, provide additional opportunities for the Primary Manufacturer to discuss off-label use(s) and therapeutic alternatives with CMS.

Comment: A commenter recommended that CMS not treat within-class drugs as necessarily interchangeable therapeutic alternatives. A commenter suggested CMS limit selection of therapeutic alternatives to products in the same category and class that share a common clinical use. A commenter recommended that CMS limit therapeutic alternatives to pharmaceutical products that share the same mechanism of action as the selected drug, an overlapping indication, and occupy a comparable position in the treatment pathway for the same population. A commenter recommended that CMS identify therapeutic alternatives separately by each indication or line of therapy, or role of the drug in a multi-agent regimen. A commenter recommended that CMS not identify products as therapeutic alternatives that fail a clinical study for use in a condition in which a selected drug is approved. A commenter recommended CMS consider how FDA defines indicated populations and treatment settings, clinical guidelines, how clinician input addresses sequencing, contraindications, and Medicare utilization when considering therapeutic alternatives.

Response: We appreciate commenters' feedback regarding the identification of a therapeutic alternative(s) for the selected drug. Consistent with the response provided to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, as well as the previous comment response, we will identify the therapeutic alternative(s) for the indications of a selected drug by using data submitted by the Primary Manufacturer and the public, prescribing information approved by the FDA, drug classification systems commonly used in the public and private sector for formulary development, major drug compendia, widely accepted clinical guidelines, evidence identified through the CMS-led literature review, published drug or drug class reviews, peer-reviewed studies, and Medicare claims or other data sets. We believe the framework provided at § 429.510(b) allows us to select appropriate therapeutic alternatives for the indications of current and future selected drugs, if such alternatives exist. As described at § 429.510(c)(1) we may consult with FDA to obtain information regarding other therapies with FDA-approved indications for the same condition and may also consult with clinicians, patients or patient organizations, researchers, or some combination thereof to ensure that appropriate therapeutic alternatives are identified.

Comment: A commenter recommended CMS leverage several resources when reviewing evidence related to therapeutic alternatives, including the National Pharmaceutical Council's Guiding Practices for Patient-Centered Value Assessment; The Myth of Average: Why Individual Patient Differences Matter, published by the National Pharmaceutical Council; ISPOR—The Professional Society for Health Economics and Outcomes Research and the International Society for Pharmacoepidemiology (ISPE) practices for real-world data studies of comparative effectiveness; and National Health Council (NHC) resources on patient-centeredness in value assessment. A commenter suggested that CMS adopt best practices from the Agency for Healthcare Research and Quality's (AHRQ) Effective Health Care Program guidance for therapeutic alternative selection.

Response: Consistent with our response in the Negotiation Program Guidance, we appreciate the suggested resources for best practices in observational comparative effectiveness research, real-world data studies of comparative effectiveness, and patient-centeredness in value assessments. We believe the methods and approach to therapeutic alternative selection and review of evidence related to therapeutic alternatives appropriately include similar elements and is aligned with the requirements of section 1194(e)(2) of the Act.

Comment: Some commenters recommended that CMS provide clarity on and adopt a consistent, transparent process for evaluation and selection of therapeutic alternatives. A commenter requested that CMS clarify how appropriate comparators are identified. A few commenters suggested that CMS provide detail on the data sources used to inform identification of therapeutic alternatives. A few commenters suggested that CMS provide

justifications for selections of therapeutic alternatives. A few commenters recommended that CMS disclose to the Primary Manufacturer the list of drugs it considers to be therapeutic alternatives and supporting evidence for those determinations early in the negotiation process. A few commenters recommended that CMS provide more transparency on how CMS distinguishes between clinically meaningful differences in therapeutic alternatives and how the agency selects therapeutic alternatives. A commenter recommended that CMS allow the Primary Manufacturer to object to the determination of a therapeutic alternative and for CMS to consider such objection before making a final determination. A commenter recommended offering Primary Manufacturers the opportunity to submit comparative effectiveness evidence after CMS has identified indications and therapeutic alternatives and seek input from manufacturers and other stakeholders on these alternatives, then using the prioritized alternatives for comparative effectiveness analysis.

Response: We thank these commenters for their input. As discussed in previous responses in this final rule, as well as consistent with our response to similar comments in the Negotiation Program Guidance, we believe the framework provided at § 429.510 allows us to select appropriate therapeutic alternatives for the indications of current and future selected drugs, if such alternatives exist. We also note that the Primary Manufacturer is provided with information about the therapeutic alternative(s) selected per this process, if any, in the concise justification accompanying the initial offer proposed at § 429.520(b). In addition to consideration of public input and consultation when considering therapeutic alternatives, we also noted in a previous response that, consistent with the policies in the Negotiation Program Guidance, the negotiation process policies at § 429.515 include an opportunity for the Primary Manufacturer to meet with CMS regarding the data submission related to the factors listed at section 1194(e) of the Act prior to provision of the initial offer. This initial meeting, as well as the negotiation process, including offer and counteroffer exchanges and negotiation meetings, provide additional opportunities for the Primary Manufacturer to discuss therapeutic alternatives with CMS, including the opportunity to provide additional information or context, as suggested by a commenter. We believe this provides sufficient opportunity for discussions with the Primary Manufacturer while also adhering to the statutory timeline provided in section 1194(b)(2) of the Act.

Comment: A commenter recommended that CMS publish the list of potential therapeutic alternatives when selected drugs are announced and allow for stakeholder comment, while also allowing the Primary Manufacturer to see the list of therapeutic alternatives before submitting data.

Response: We appreciate commenters' feedback. Currently, the selected drug list is published no later than the selected drug publication date as defined in § 429.20 with respect to such initial price applicability year per § 429.100(b). We do not believe it is feasible to review drugs for selection for negotiation and renegotiation by the selected drug publication date and also determine potential therapeutic alternatives, if any, for such drugs. Further, such a process would preclude CMS' ability to review the information submitted by the Primary Manufacturer and interested parties under § 429.505 to inform selection of therapeutic alternatives, including engagement opportunities described at § 429.515(b). We also reiterate that the negotiation process policies at § 429.515 include an opportunity for the Primary Manufacturer to meet with CMS regarding the data submission related to the factors listed at section 1194(e) of the Act prior to provision of the initial offer and that we provide information about therapeutic alternatives in the concise justification accompanying the initial offer proposed at § 429.520(b).

Comment: A commenter supported CMS' approach for adjusting the starting point of the initial offer but stated that the prices of therapeutic alternatives should not be used as the starting point, as this approach would entrench high prices into the negotiation process. A few commenters opposed CMS' proposals for developing a starting point. A commenter stated that the starting point is extra-statutory. A couple of commenters stated that CMS should anchor its initial offer to the statutory ceiling and evaluate section 1194(e) factors independently from that ceiling. A commenter stated that CMS should not use not-yet-effective MFPs of therapeutic alternatives as the basis for setting a starting point, as the not-yet-effective MFP is not a price that presently exists in the marketplace. A commenter stated that CMS should not build the starting point for a drug in one monopoly status on the price of a drug in a different monopoly status. A commenter stated that CMS should not consider starting points based on reference prices, costs of production or distribution, or other factors that do not provide clinical value to Medicare beneficiaries. A commenter recommended that CMS base an initial offer on risk-adjusted research and development costs; the extent to which those costs have been recouped by the manufacturer; federal investment; and section 1194(e)(2) factors. The commenter also recommended that once an initial offer is determined, CMS should compare the price of the selected drug to therapeutic alternatives and offer an MFP that is no higher than the lowest price of a therapeutic alternative that has a comparable safety and efficacy profile.

Response: We thank commenters for their feedback on determining a starting point for developing the initial offer. We disagree that the approach to determining a starting point for development of the initial offer is not grounded in statute. As described earlier, section 1194(e)(2)(A) of the Act directs CMS to consider both the extent to which a selected drug represents a therapeutic advance compared to its therapeutic alternative(s) and the cost of such existing therapeutic alternative(s). We previously considered several alternative options for what price should be used as the starting point for developing the initial offer, including the unit cost of production and distribution for the selected drug, the ceiling, a domestic reference price (for example, the FSS price), or a ''fair profit'' price based on whether R&D costs have been recouped, and margin on unit cost of production and distribution. We determined using Net Part D Plan Payment and Beneficiary Liability, ASP, WAC, or MFP of therapeutic alternatives is consistent with the Act and provides a point at which to start developing the initial offer within the context of the cost and clinical benefit of one or more drugs that treat the same disease or condition, if available, and then make adjustments based on the factors listed at section 1194(e) of the Act. The other options considered do not provide a starting point that reflects the cost of therapeutic alternatives in the current market, which is an important factor when considering the overall benefit that a treatment brings to Medicare beneficiaries relative to the other drug(s) available to treat the patient's disease or condition.

Consistent with our response to similar comments in the Negotiation Program Guidance, we believe the negotiation process described in subpart

F, and the renegotiation process described in subpart G, results in an MFP for a selected drug that reflects each selected drug's circumstances and is based on the factors outlined in section 1194(e) of the Act, which we are required to consider. We believe this includes situations where the starting point is another selected drug's MFP (in cases where there is one therapeutic alternative) or includes an MFP (in cases where there are multiple therapeutic alternatives and only one or some of the therapeutic alternatives are selected drugs). Consistent with the Negotiation Program Guidance, the policy to use the MFP as the starting point in cases where the therapeutic alternative was itself a selected drug and the MFP is lower than the Net Part D Payment and Beneficiary Liability is aligned with the statutory directive in section 1194(e)(2)(A) of the Act to consider the costs of therapeutic alternatives, which may include selected drugs with an agreed-upon MFP, including situations where there is an agreed-upon MFP but such MFP has not taken effect. And, consistent with our response to similar comments in the Negotiation Program Guidance, offering the ceiling without a more thorough review of section 1194(e)(1) factors, including manufacturer-submitted data, may not achieve that objective and is inconsistent with the statutory directive at section 1194(e) of the Act. Regarding the comment that once an initial offer is determined, CMS should compare the price of the selected drug to therapeutic alternatives and offer an MFP that is no higher than the lowest price of a therapeutic alternative that has a comparable safety and efficacy profile if the initial offer is not already below such price, we believe such an approach might overweight the factors listed at section 1194(e)(2)(A) and (C) (and further overweight a single therapeutic alternative, if multiple therapeutic alternatives are identified), as those would be the only factors reflected in an initial offer when such an offer was made, in contrast to the proposed approach in which all factors listed at section 1194(e) of the Act may impact the development of the initial offer. Upon consideration of these comments, we decline to adopt these alternative approaches to establishing a starting point for developing the initial offer to preserve agency flexibility in making adjustments to the price based on section 1194(e) factors.

Comment: A few commenters recommended CMS develop and implement a clear, consistent and transparent methodology for developing a starting point for the initial offer. A commenter offered support for CMS' proposed approach to consider patient-centered outcomes, patient experience data, and patient and caregiver preferences in the framework for evaluation of the initial offer. The commenter also suggested CMS consider whether negotiated prices could correspond with measurable, real-world outcomes, such as medication persistence and reduction in treatment interruptions, while ensuring that these outcomes are examined across patient populations. A commenter stated that CMS does not provide a transparent methodology or information on how factors in CMS' valuation framework are applied and recommended that CMS provide an explanation to manufacturers on how it applies its valuation methodology to each selected drug. A commenter stated that CMS does not articulate how it operationalizes definitions of unmet medical need and therapeutic alternatives, and that Primary Manufacturers are unaware of how such data is weighted, or if a selected drug satisfies either definition. The commenter recommended that CMS specify reference points governing in-scope evidence and describe the process by which such evidence is evaluated. A commenter recommended CMS apply a transparent two-stage qualitative framework that assesses the relevance and credibility of appropriate analyses and then synthesizes the body of work writ large to determine relevance across comparative direction, economic materiality, certainty and Medicare applicability. A couple of commenters recommended that CMS provide transparency on the types of evidence used to evaluate therapeutic advance, unmet need, and effects of the selected drug on specific populations. A commenter requested that CMS disclose the methodology and assumptions used when calculating prices for therapeutic alternatives. A commenter requested that CMS commit to a holistic review of evidence when developing the initial offer, including real world evidence, benefits to subpopulations, patient preferences and treatment of conditions with limited alternatives. A commenter requested CMS specify how it will value unmet medical need when a selected drug is used in combination with a therapeutic alternative. The commenter also requested CMS clarify how the cost of a therapeutic alternative will impact the assessment of a therapeutic advance. A commenter recommended that CMS pursue the lowest MFP permitted by law and give substantial weight to evidence demonstrative what constitutes a reasonable price. A commenter stated that the proposed value assessment framework does not effectively account for viral suppression, adherence outcomes or public health costs of averted HIV transmissions. The commenter recommended that injectable forms of long-acting HIV therapies receive appropriate consideration as therapeutic alternatives, as well as off-label utilization.

Response: We appreciate commenters' feedback and recognize the importance of balancing transparency and confidentiality in the negotiation process. Consistent with our response to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, we reiterate that we believe it is important to maintain flexibility when considering how each negotiation factor contributes to the initial offer and subsequent offers and counteroffers, as applicable, which may be impacted by the unique characteristics of each selected drug, the populations each selected drug is intended to treat, and information that may emerge from meaningful discussions with manufacturers, patients, and patient representatives.

Section II.D.1. of the proposed rule (91 FR 36292) describes how CMS will prioritize evidence related to the section 1194(e) factors; these considerations are also applicable to renegotiation as discussed at section II.G.5.c. of the proposed rule (91 FR 36308). All applicable negotiation factors will be considered in totality for each selected drug.

Consistent with our response to similar comments in the Negotiation Program Guidance, we will evaluate the extent to which a selected drug addresses an unmet medical need or represents a therapeutic advance at the time of consideration based on all available information at such time of consideration.

Regarding the commenter's suggestion that we pursue the lowest MFP permitted by law, we refer the commenter to section II.D. of the proposed rule (91 FR 36292) where we introduce our methodology and process as developed in accordance with section 1194(b) of the Act, which requires CMS to aim to achieve the lowest MFP possible. We believe the framework outlined in the proposed rule and adopted by this final rule achieves this statutory directive and decline to adopt commenters' recommendations.

Final Decision: After consideration of public comments, we are finalizing § 429.510(a), (b), and (f) as proposed.

We are finalizing § 429.510(c) as proposed but with a modification to § 429.510(c)(2) to include a new paragraph (ii) indicating that we consider FDA approved prescribing information when determining therapeutic alternatives, if any. We also are adding ''all of the following'' to § 429.510(c)(2) and are deleting ''and'' in the re-numbered § 429.510(c)(2)(iv).

We are finalizing § 429.510(d) as proposed but with the following technical changes: we are adding ''the following'' to § 429.510(d)(1)(i); we are deleting ''or'' in § 429.510(d)(1)(i)(B); we are adding ''the following'' to § 429.510(d)(1)(ii); we are deleting ''or'' in § 429.510(d)(1)(ii)(B); we are adding ''the following'' to § 429.510(d)(3)(i); and we are deleting ''or'' in § 429.510(d)(3)(i)(B).

We are finalizing § 429.510(e) as proposed but with the following technical changes: we are adding ''all of the following'' to § 429.510(e)(3)(i); we are deleting ''and'' at § 429.510(e)(3)(i)(C); we are adding ''both of the following'' to § 429.510(e)(3)(ii); we are deleting ''and'' at § 429.510(e)(3)(ii)(A); we are adding ''both of the following'' to § 429.510(e)(4)(i); we are deleting ''and'' at § 429.510(e)(4)(i)(A); we are adding ''all of the following'' to § 429.510(e)(4)(ii); and we are deleting ''and'' at § 429.510(e)(4)(ii)(B).

4. Engagement With Primary Manufacturers and Interested Parties (§ 429.515)

a. Engagement With Primary Manufacturers

Consistent with policies for implementation as described in section 60.4 of the Negotiation Program Guidance, we proposed in § 429.515 to hold up to four, optional meetings in a form and manner specified by CMS with Primary Manufacturers of selected drugs that have submitted the information set forth in proposed § 429.505. As proposed in § 429.515(a)(1), the first meeting that we would offer Primary Manufacturers to attend would be intended for the Primary Manufacturer to provide additional context on their data submission of the section 1194(e)(1) factors and section 1194(e)(2) factors described in proposed § 429.505(b)(2) and (d)(3), respectively, as we begin evaluating the data submission and developing an initial offer as described in proposed § 429.510. We would also offer Primary Manufacturers the opportunity to attend up to three optional meetings that would focus on the section 1194(e)(1) factors and section 1194(e)(2) factors, and other topics aimed at working toward an agreement on an MFP. During these meetings, discussion of disputes and program policies regarding the negotiation process would be considered out of scope. As proposed in § 429.515(a)(2), meetings would be attended solely by representatives of the Primary Manufacturer and of CMS. The number of attendees would be limited as specified by CMS via future communications with the Primary Manufacturer specific to each initial price applicability year. For example, as described in section 60.4.4 of the Negotiation Program Guidance, CMS and the Primary Manufacturer were permitted to bring up to eight meeting attendees and both parties would share their participant lists ahead of each meeting. We determined this meeting attendee number after considering the roles from each party that would be critical to the conversation while ensuring that the meeting is sized appropriately to encourage active discussion. Given these considerations, we proposed at § 429.515(a)(2) to continue to limit the number of meeting attendees.

We proposed at § 429.515(a)(3)(i) that Primary Manufacturers may share new information on section 1194(e)(2) factors during meetings. We also proposed that the Primary Manufacturer may bring materials to facilitate discussion which must comply with limits on the amount and format of such materials as specified by CMS, and we may request that the Primary Manufacturer provide copies of any presented or discussed materials after the meeting in which they are presented or discussed, as proposed in § 429.515(a)(3)(ii). For example, for initial price applicability year 2028, if a Primary Manufacturer is interested in sharing materials at a negotiation meeting, such materials are limited to 15 pages (or a combination of pages, slides, and/or charts and graphs totaling 15 pages) and no more than 30 citations, to focus the discussion on issues that can reasonably be discussed within the scope of the meeting. We would specify the limits on the amount and format of materials specific to each initial price applicability year via future communications with the Primary Manufacturer. We proposed at § 429.515(a)(1)(ii) that new data related to section 1194(e)(1) factors, as described in proposed § 429.505(b), would not be considered. Rather, we proposed that any information shared during these meetings and materials shared afterwards should only contextualize the Primary Manufacturer's submission of data related to section 1194(e)(1) factors specified in proposed § 429.505(b).

We proposed at § 429.515(a)(4) for the first optional meeting that CMS would offer to Primary Manufacturers to attend would occur, at a time to be specified by CMS, after the data submission deadline specified in section II.F.2. of this final rule and in proposed § 429.505(b)(1) and (d)(2) and before the provision of CMS' initial offer, as set forth in proposed § 429.520. We would offer up to three additional optional meetings to occur after the provision of CMS' initial offer. If accepted by the Primary Manufacturer, such meeting(s) would occur, at a time to be specified by CMS, after the provision of CMS' initial offer as set forth in proposed § 429.520 and before the provision of CMS' final offer, if applicable, as specified in proposed § 429.535. A written record of these meetings would be developed and retained by CMS in compliance with applicable Federal laws, including the Federal Managers' Financial Integrity Act and the Federal Records Act, and would be subject to the confidentiality policy described in section II.D.1. of this final rule and in proposed § 429.300. The Primary Manufacturer may also develop and retain its own written record. As proposed in § 429.515(a)(5), audio or video recording of the meetings would not be permitted.

As described in section II.D.1. of this final rule regarding proposed § 429.300, we would not publicly discuss ongoing negotiations with a Primary Manufacturer, including details of the negotiation meetings. A Primary Manufacturer may publicly disclose information regarding ongoing negotiations with CMS at their discretion. If a Primary Manufacturer discloses information regarding any aspects of the negotiation process prior to the explanation for the MFP being released by CMS, we reserve the right to publicly discuss the specifics of the negotiation process regarding that Primary Manufacturer.

Final Decision: We did not receive public comments on this provision. We are finalizing § 429.515(a) with a technical modification to add ''and'' to § 429.515(a)(3)(i)(A) and (B). We also are making a modification to § 429.515(a)(3)(ii) to clarify that CMS may request that the Primary Manufacturer provide copies of any presented or discussed materials before the meeting in which they are presented or discussed. This modification aligns with current operational practices in

which CMS requests materials prior to a meeting.

b. Engagement With Interested Parties

At proposed § 429.515(b), we proposed to codify the policy as described in section 60.4.1 of the Negotiation Program Guidance to hold events in a form and manner and at times to be specified by CMS with interested parties to seek input from patients and other interested parties about selected drugs and therapeutic alternatives. These public engagement events are intended to bring together patient-focused interested parties to share feedback with us on patient experiences with the conditions or diseases treated by the selected drug, as well as with the selected drugs and therapeutic alternatives to the selected drugs, and other information as we review data related to section 1194(e)(2) factors and develop an initial offer for each selected drug. These public engagement events allow us to hear from patients and other stakeholders close to the patient experience—directly and in their own words—about patients' personal experiences and perspectives on their condition(s) and about the drug(s) used to treat those conditions. This type of information helps inform CMS' understanding of what matters to patients. We would use the information shared during these patient-focused events to better understand patients' experiences with the conditions and diseases treated by the selected drug and their experiences with the selected drugs themselves, as well as to inform CMS' identification of therapeutic alternatives, key outcomes, and adjustment of the starting point to develop the initial offer. These events would be held annually in the Spring.

Public engagement events for each initial price applicability year may include, for example, patient-focused roundtable events that would be open to patients, patient advocacy organizations, and caregivers and would allow for discussion among speakers. These patient-focused roundtable events may focus on one selected drug or group selected drugs by condition when appropriate as determined by CMS.

The public engagement events also may include one town hall meeting for all selected drugs that would be focused on the clinical considerations related to the selected drugs and would be open to practicing clinicians and researchers, as well as other interested parties. This town hall meeting may be divided into multiple sessions and may be held across multiple days. We may have the opportunity to ask follow-up questions of participants at the town hall meeting.

Lastly, we may incorporate drugs selected for renegotiation into the public engagement events for drugs selected for negotiation or we may hold separate events specifically for drugs selected for renegotiation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed appreciation for CMS codifying public engagement events in regulation and supported CMS' continued efforts to engage patients and interested parties in the negotiation process. However, some commenters noted their disappointment that CMS did not establish minimum requirements and standards around public engagement events through rulemaking, such as committing to multiple public meetings for each selected drug. They encouraged CMS to do so. A few of these commenters acknowledged CMS' preference to preserve flexibility but they expressed concern that without clear requirements, CMS falls short of supporting meaningful stakeholder engagement.

Response: We appreciate the commenters' input. By codifying public engagement events in regulation, we are establishing a minimum requirement—that is, we are committing to holding these events for future initial price applicability years. We believe it is important to maintain flexibility when holding these events because of the potential for an increase in the number of selected drugs covered under Part D and/or payable under Part B in future cycles of negotiations. We disagree that maintaining flexibility indicates that these events inadequately support meaningful stakeholder engagement. As stated in the Negotiation Program proposed rule (91 FR 36296), the public engagement events allow us to hear from patients and other stakeholders—directly and in their own words—about patient's personal experiences and perspectives on their condition(s) and about the drug(s) used to treat those conditions.

Comment: Many commenters provided feedback on and recommendations for CMS to improve upon public engagement events held for initial price applicability year 2028. Recommendations included: simplifying the event registration process; publishing CMS' speaker selection criteria; providing a list of discussion questions in advance of the events; providing more time for participants to prepare for the events; broadening the information asked of patients to more holistically address how they value medications and treatment; expanding outreach efforts; expanding the public engagement events to include more participants; providing more accessibility accommodation such as translated materials and interpretation services; expanding conflict of interest disclosure and reporting by CMS; publishing thematic event summaries in addition to event transcripts; providing greater transparency in explaining how information gathered via public engagement events is used in negotiations.

Response: We appreciate commenters providing specific feedback about the public engagement events held for initial price applicability year 2028 and offering recommendations for improvement and refinement. We will consider these recommendations as we plan the events for future negotiation cycles.

Comment: Many commenters recommended that CMS expand the methods for patients and other interested parties to provide information to CMS beyond participating in public engagement events, including offering opportunities for ongoing input. Examples cited include asynchronous input such as written comments, audio submissions, or recorded video statements.

Response: We appreciate these suggestions about increasing the ways interested parties share information with us. We recognize the importance of patients having access to multiple methods for sharing information about their experiences. We hosted such events in a non-livestreamed venue that included only patients, patient advocacy organizations, and caregivers for initial price applicability years 2027 and 2028. Additionally, patients, patient advocacy organizations, caregivers, and others such as clinicians, researchers, and the public at large, may submit written comments via the Drug Price Negotiation ICR. We intend to submit this final ICR for OMB approval upon publication of the final rule. Once approved, patients and others will have the opportunity to submit their information in early 2027 for initial price applicability year 2029. At this time, we are unable to accept recorded comments or audio submissions for the Negotiation Program. However, we broadly welcome input from interested parties and the public by email at: *IRARebateandNegotiation@cms.hhs.gov.* We review and respond to inquiries received via the IRA mailbox.

Final Decision: After consideration of public comments, we are finalizing § 429.515(b) as proposed.

5. Provision of CMS' Initial Offer and Concise Justification (§ 429.520)

Section 1194(b)(2)(B) of the Act requires that, not later than June 1 following the selected drug publication date with respect to the initial price applicability year, CMS shall provide the Primary Manufacturer of the selected drug with a written initial offer that contains the proposal for the MFP of the drug and a concise justification based on the factors described in section 1194(e) that were used in developing such offer. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with policies for implementation as described in section 60.4 of the Negotiation Program Guidance, we proposed in § 429.520(a) that the written initial offer from CMS would be provided to the Primary Manufacturer no later than June 1 following the selected drug publication date as defined in proposed § 429.20. We proposed at § 429.520(a)(1) that this written initial offer would be accompanied by an Addendum to the Negotiation Program Agreement populated with the proposal for the MFP for CMS and the Primary Manufacturer to formalize agreement upon the MFP if such agreement is reached at this stage. Consistent with proposed § 429.410(a), no written initial offer can exceed the statutorily determined ceiling as defined in section 1194(c) of the Act and described in section II.E.3. of this final rule and in proposed § 429.410(b). Consistent with proposed § 429.440(b), no written initial offer can be less than the Temporary Floor for Small Biotech Drugs, if final, as defined in section 1194(d) of the Act and described in section II.E.9. of this final rule.

With respect to initial price applicability year 2029 and subsequent years, we proposed in § 429.520(b) that CMS would include a concise justification for the written initial offer based on the data set forth in proposed § 429.505. Consistent with proposed § 429.505(a), CMS considers the Primary Manufacturer-required data specified in § 429.505(b)(2) and evidence about the selected drug and therapeutic alternatives specified in § 429.505(d)(3), as applicable to the drug, as the basis for determining the offers and counteroffers for the selected drug. As proposed in § 429.520(b)(1), the concise justification would include a qualitative description of the factors from section 1194(e) of the Act as proposed in § 429.505(b) and (d) and a description of the methodology that CMS used to develop the written initial offer as described in section II.F.3. of this final rule and under proposed subpart F. As proposed in § 429.520(b)(2), the information contained in the concise justification would provide the Primary Manufacturer with information on the range of evidence and other information considered under section 1194(e) of the Act that CMS found compelling during the development of the written initial offer and may include information obtained through events with interested parties as proposed in § 429.520(b)(3). We believe the information in the concise justification would provide the Primary Manufacturer with information to build a statutory written counteroffer if the Primary Manufacturer decides to reject the written initial offer.

The written initial offer and concise justification would not include information that we determine to be third-party proprietary pricing information, information that could lead to the calculation of a third-party's proprietary pricing information, PHI/PII, other information that is protected from disclosure under other applicable law in accordance with the confidentiality policies described in section II.D.1. of this final rule and in proposed § 429.300, or the starting point.

We received public comments on these proposals. The following is a summary of the comments we received and our responses. Given that commenters combined feedback on these proposals regarding the initial offer and concise justification with feedback on the proposal for counteroffers at § 429.525, we include the comments received on counteroffers and proposed § 429.525 in this section.

Comment: A commenter recommended CMS provide a meaningful justification for the initial offer and provide manufacturers with the opportunity to comment on CMS' response to any counteroffers. Another commenter stated that without a meaningful justification from CMS in the initial offer, manufacturers cannot provide a meaningful justification in a statutory written counteroffer. A few commenters suggested that the concise justification and CMS' response to any counteroffer should detail specific information, such as the sources CMS referenced, evidence considered, section 1194(e) data considered and how they were weighted, therapeutic alternatives considered, interested parties consulted, and benefits and impacts of the drugs considered. Another commenter recommended CMS' concise justification should have a consistent documented structure containing certain elements relevant to the proposal for the MFP.

Response: We thank these commenters for their feedback. Consistent with our response to similar comments in Negotiation Program Guidance and the final guidance for initial price applicability year 2027, section 1194(b)(2)(B) of the Act directs CMS to provide a concise justification to the Primary Manufacturer when the initial offer is made. CMS implements the requirement to provide an initial offer and concise justification to a Primary Manufacturer in a consistent manner across all Primary Manufacturers, as required by section 1194(b)(1) of the Act. We will include information regarding the range of evidence and other information submitted pursuant to section 1194(e) of the Act that CMS found compelling in developing its initial offer, which includes the identification of therapeutic alternatives. Because this information will be shared with the Primary Manufacturer, we believe the concise justification will be meaningful and will provide the Primary Manufacturer with information to build a statutory written counteroffer if the Primary Manufacturer decides to reject the initial offer. While any statutory written counteroffer should respond to the justification provided in CMS' written initial offer, a Primary Manufacturer is not limited by the information provided in CMS' written initial offer when developing a statutory written counteroffer. As described in § 429.515(a)(1), the first meeting that we will offer Primary Manufacturers to attend will be intended for the Primary Manufacturer to provide additional context on their data submission of the section 1194(e)(1) factors and section 1194(e)(2) factors described in § 429.505(b)(2) and (d)(3), respectively, as we begin evaluating the data submission and developing an initial offer as described in § 429.510. We will also offer Primary Manufacturers the opportunity to attend up to three optional meetings that would focus on the section 1194(e)(1) factors and section 1194(e)(2) factors, and other topics aimed at working toward an agreement on an MFP. These meetings also provide a Primary Manufacturer with an opportunity to comment on CMS' response to any counteroffer.

Additionally, as described in § 429.530, the additional price exchange opportunities enable CMS and Primary Manufacturers to initiate additional written offers and counteroffers via the CMS HPMS, and this functionality includes an optional text field to enable the offering or counteroffering party to include additional contextual information for the offer or counteroffer.

Final Decision: After consideration of public comments, we are finalizing § 429.520 as proposed but with a technical modification to add ''and'' to § 429.520(b)(1).

6. Statutory Written Counteroffers (§ 429.525)

Section 1194(b)(2)(C) of the Act requires that the Primary Manufacturer shall either accept the written initial offer under section 1194(b)(2)(B) of the Act, or propose a counteroffer, within 30 days of receipt of the written initial offer. If a Primary Manufacturer proposed a counteroffer, such counteroffer shall be in writing and shall be justified based on the factors described in section 1194(e) of the Act. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with policies for implementation as described in section 60.4 of the Negotiation Program Guidance, we proposed in § 429.525(a) that the Primary Manufacturer would have no more than 30 days from receipt of the written initial offer from CMS to respond in writing by either accepting the initial offer for the selected drug or making a statutory written counteroffer and providing a justification for such counteroffer based on the data described in proposed § 429.505(b) and (d). As proposed in § 429.525(b)(1)(ii), any statutory written counteroffer must respond to the concise justification provided in CMS' written initial offer, and the Primary Manufacturer's response must focus on the factors described in section 1194(e) of the Act, as set forth in proposed § 429.505(b) and (d). We proposed at § 429.525(b)(1)(iii) that the statutory written counteroffer justification must indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the section 1194(e)(1) factors or section (e)(2) factors, or other available data related to the selected drug and its therapeutic alternative(s), as described in section 1194(e)(2) of the Act, supports the Primary Manufacturer's statutory written counteroffer or otherwise does not support CMS' written initial offer. Primary Manufacturers may also include in their statutory written counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) of the Act that supports the counteroffer.

We proposed at § 429.525(b)(1)(i) that the Primary Manufacturer must provide a proposal for the MFP for the selected drug in its statutory written counteroffer. The proposal for the MFP must be a single price for the selected drug per 30-day equivalent supply, weighted across dosage forms and strengths. For a statutory written counteroffer to be considered complete, we proposed at § 429.525(b)(2) that a Primary Manufacturer must complete an Addendum to the Negotiation Program Agreement, as described in section II.C.1. of this final rule and in proposed § 429.200(e), in the CMS HPMS and must submit the statutory written counteroffer in a form and manner specified by CMS as part of the Drug Price Negotiation ICR. A completed Addendum to the Negotiation Program Agreement would include, but is not limited to, the proposal for the MFP the Primary Manufacturer is counteroffering and a signature by an authorized representative.

Section 1194(b)(2)(D) of the Act requires that, after receiving a counteroffer under section 1194(b)(2)(C) of the Act, CMS must respond in writing to such counteroffer. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, we proposed in § 429.525(c) that we would respond in writing to a statutory written counteroffer made by the Primary Manufacturer. Although the statute does not specify a timeframe for CMS' response to the Primary Manufacturer's statutory written counteroffer, in accordance with section 1194(b)(2)(E) of the Act and as proposed in § 429.535(b), negotiations must end prior to November 1 following the selected drug publication date to avoid potential excise tax liability under 26 U.S.C. 5000D(b)(2).

As proposed in § 429.525(c)(1), in the case CMS' written initial offer is not accepted and the Primary Manufacturer submits a statutory written counteroffer, we would consider the statutory written counteroffer and either accept or reject it in writing within 30 days of receipt of the statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later. When considering a statutory written counteroffer, we would evaluate whether accepting the counteroffer is consistent with the statutory directive to aim to arrive at an agreement that achieves the lowest possible MFP for the selected drug.

Section 1194(b)(2)(F) of the Act requires that CMS cannot offer a proposal for the MFP or agree to a Primary Manufacturer's proposal for the MFP for a selected drug, with respect to the initial price applicability year for the selected drug, that exceeds the ceiling determined under section 1194(c) for the selected drug and year. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, consistent with proposed § 429.410(a), CMS cannot accept a statutory written counteroffer from a manufacturer that exceeds the statutorily determined ceiling as defined in section 1194(c) of the Act and described in section II.E.3. of this final rule and in proposed § 429.410(b). Consistent with proposed § 429.440(b), CMS cannot agree to any Primary Manufacturer proposal for the MFP that is less than the Temporary Floor for Small Biotech Drugs, if applicable, as defined in section 1194(d) of the Act and described in section II.E.9. of this final rule.

We received public comments on these proposals. The summary of the comments we received and our responses are included in section II.F.5. of this final rule.

Final Decision: After consideration of public comments, we are finalizing § 429.525 with modifications at § 429.525(b)(1) to clarify any statutory written counteroffer must ''do all of the following'' in § 429.525(b)(1)(i) through (iii). We also are making a technical modification to remove ''and'' from § 429.525(b)(1)(ii).

7. Additional Price Exchange Opportunities (§ 429.530)

Consistent with policies for implementation in section 60.4 of Negotiation Program Guidance, we proposed in § 429.530(a) to provide additional price exchange opportunities

through which CMS and Primary Manufacturers can initiate additional written offers and counteroffers via the CMS HPMS during the period between CMS' rejection of the Primary Manufacturer's statutory written counteroffer, if applicable, and the parties reaching an agreement on the MFP, or at least 8 business days before the deadline by which CMS must issue the final offer, whichever is earlier. We believe this functionality would enable both parties to have additional flexibility to extend and consider offers and counteroffers during this time period.

We proposed at § 429.530(a)(1) that the functionality for additional price exchange opportunities in the CMS HPMS would allow for the optional upload of materials which must comply with limits on the amount and format of such materials as specified by CMS and include an optional text field to enable the offering or counteroffering party to include additional contextual information for the offer or counteroffer. As proposed in § 429.530(a)(2), only one offer or counteroffer per selected drug may be active at a time in the CMS HPMS as part of the functionality for additional price exchange opportunities. Proposed § 429.530(a)(3) states an offering/counteroffering party may revise its offer/counteroffer in the period before the other party accepts or rejects it but not afterwards. We proposed at § 429.530(a)(4) that parties would not need to alternate making offers and counteroffers. Consistent with proposed § 429.410(a), CMS cannot propose an MFP or agree to any Primary Manufacturer proposal for the MFP that exceeds the statutorily determined ceiling as defined in section 1194(c) of the Act and as set forth in section II.E.3. of this final rule and in proposed § 429.410(b). Consistent with proposed § 429.440(b), CMS cannot propose an MFP or agree to any Primary Manufacturer proposal for the MFP that is less than the Temporary Floor for Small Biotech Drugs, if applicable, as defined in section 1194(d) of the Act and described in section II.E.9. of this final rule. Lastly, as proposed in § 429.530(a)(5), to formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in section II.C.1. of this final rule and in proposed § 429.200(e) that sets forth the agreed-upon MFP.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.530 as proposed.

8. Notification of Final Offer and Conclusion of Negotiations (§ 429.535)

Section 1194(b)(2)(E) of the Act requires that all negotiations between CMS and the Primary Manufacturer of the selected drug shall end prior to November 1 following the selected drug publication date, with respect to the initial price applicability year. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.4 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with policies for implementation as described in section 60.4 of the Negotiation Program Guidance, we proposed in § 429.535(b) that all negotiations between CMS and the Primary Manufacturer of the selected drug must end prior to November 1 following the selected drug publication date, with respect to the initial price applicability year, to avoid potential excise tax liability. As proposed in § 429.535(a), in the event neither CMS' initial offer nor the Primary Manufacturer's statutory written counteroffer were accepted, and an MFP was not agreed to during the negotiation meetings or via the additional price exchange functionality, we would send the Primary Manufacturer a ''Notification of Final Maximum Fair Price Offer'' and an Addendum with the final offer MFP by September 30 following the selected drug publication date defined in proposed § 429.20. This would serve as the final offer to the Primary Manufacturer for the MFP for the selected drug. This final offer would be sent only if, by September 30 following the selected drug publication date neither CMS nor the Primary Manufacturer has accepted the latest offer or counteroffer made in writing or agreed upon an MFP during the negotiation meeting process or via the additional price exchange functionality. We proposed at § 429.535(a)(1), that if a final offer is sent, the Primary Manufacturer must respond in writing to this final offer by either accepting or rejecting the final offer by October 31 following the selected drug publication date.

As proposed at § 429.535(a)(2), to formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in section II.C.1. of this final rule and in proposed § 429.200(e) that sets forth the agreed-upon MFP. For example, when CMS prepares a written offer, we would also populate an Addendum to the Negotiation Program Agreement with the offered MFP and send that Addendum to the Negotiation Program Agreement with the written offer to the Primary Manufacturer via the CMS HPMS. If the Primary Manufacturer accepts the written offer, it would sign the Addendum to the Negotiation Program Agreement after which CMS would countersign the Addendum to the Negotiation Program Agreement.

If CMS and the Primary Manufacturer do not agree to an MFP by the deadline set forth in paragraph (b) of this section, the Primary Manufacturer would enter a period during which the excise tax may be imposed on certain sales of the selected drug. As described in 26 U.S.C. 5000D(b)(2) and 5000D(c), the Primary Manufacturer can end the period during which the excise tax may apply by agreeing to an MFP; meeting the statutory criteria for the suspension of tax; or terminating its Negotiation Program Agreement in the manner described in section II.C.2. of this final rule and in proposed § 429.205.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.535 as proposed.

G. Renegotiation of an MFP (§§ 429.600 Through 429.620)

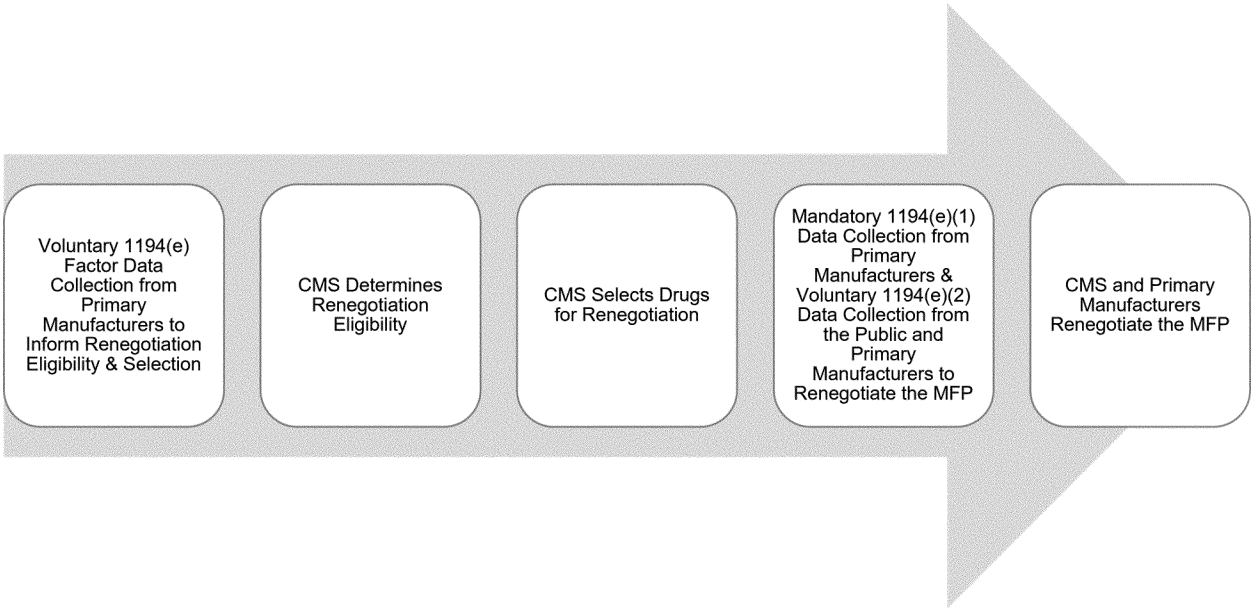
1. General Rule (§ 429.600)

Section 1194(f) of the Act establishes the requirements governing the identification of renegotiation-eligible drugs, the selection of drugs for renegotiation, and the renegotiation process. With respect to initial price applicability year 2028, the first year in which renegotiation could occur per section 1194(f) of the Act, we implemented policies for renegotiation in section 130 of the Negotiation Program Guidance. With respect to initial price applicability year 2029 and subsequent years, and consistent with the policies described in section 130 of the Negotiation Program Guidance, we proposed to identify renegotiation-eligible drugs in accordance with section 1194(f)(2) of the Act, as described proposed § 429.605. Next, we would select certain renegotiation-eligible drugs for renegotiation in accordance with section 1194(f)(3) of the Act, as described in proposed § 429.610. Finally, we would renegotiate MFPs for such drugs selected for renegotiation, in accordance with section 1194(f)(4) of the Act, as described in proposed § 429.620. Figure

2 depicts an overview of this proposed process.

We note that renegotiation is a component of the Negotiation Program. A Primary Manufacturer that has a Negotiation Program Agreement in effect, as discussed in proposed subpart C and section II.C. of this final rule, would be required to adhere to the process and deadlines described throughout this final rule. For example, the policies described in proposed subparts F and H (described in sections II.F. and II.H. of this final rule) are applicable to renegotiation unless otherwise specified herein. The renegotiation process would conclude with an agreed-upon MFP, unless the Primary Manufacturer chooses not to participate or chooses not to agree upon a new MFP (or CMS determines that a generic drug is approved or a biosimilar is licensed for the selected drug is subject to Bona Fide Marketing during the renegotiation period consistent with proposed § 429.130(c)(5), in which case it will no longer be subject to the renegotiation process in accordance with section 1194(f)(5) of the Act and proposed § 429.135(c)(2)). To meet their MFP effectuation obligations, Primary Manufacturers must make any agreed-upon MFP available as set forth in proposed § 429.200(b)(4).

FIGURE 2: OVERVIEW OF RENEGOTIATION PROCESS STEPS



If the Primary Manufacturer and CMS agree upon an MFP through the renegotiation process set forth under § 429.620, we proposed at § 429.600(b)(1) that the renegotiated MFP would apply starting January 1 of the initial price applicability year for which the drug was selected for renegotiation. We also proposed at § 429.600(b)(3) and consistent with the requirement in proposed § 429.200(b)(4), that to meet their MFP effectuation obligations, Primary Manufacturers of a selected drug with a renegotiated MFP must provide access to the selected drug's initial agreed-upon MFP in accordance with subpart I for all dispenses, administrations, and furnishings of the selected drug prior to such effective date for the renegotiated MFP. Additionally, we proposed at § 429.600(b)(2) that the MFP that is agreed upon following renegotiation would apply to all formulations across dosage forms and strengths of the selected drug by applying the methodology set forth at proposed § 429.700. Information on MFP effectuation for 2029 and subsequent years will be included in future rulemaking.

Finally, we proposed at § 429.600(c) that we would publish the list of drugs selected for renegotiation no later than the selected drug publication date (consistent with § 429.100(b)(2)).

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.600 as proposed with technical modifications. Specifically, we are deleting ''proposed'' at §§ 429.600(b)(1) and (b)(2) to reflect that this is a final regulation. We also are adding ''of the Act'' to § 429.600(b)(3) to clarify that the reference is to section 1193(a)(3) of the Social Security Act.

2. Eligibility of Drugs for Renegotiation (§ 429.605)

Section 1194(f)(2) of the Act establishes the definition of a ''renegotiation-eligible drug'' as a selected drug for which (1) a new indication is added to the drug; (2) the drug monopoly status was not that of an extended-monopoly or a long-monopoly drug and changes to that of an extended-monopoly drug; (3) the drug monopoly status was not that of a long-monopoly drug; and changes to that of a long-monopoly drug; or (4) the Secretary determines there has been a material change to any section 1194(e)(1) or (e)(2) factor.

In accordance with section 1194(f)(1) of the Act, we proposed to identify renegotiation-eligible drugs from selected drugs negotiated, or renegotiated, if applicable, with respect to prior initial price applicability years. We interpret section 1194(f)(1) of the Act to mean that the Secretary must

provide for a process of renegotiation for years during the selected drug's price applicability period. For example, because calendar year 2029 will be a year within the price applicability period for drugs selected for initial price applicability years 2026, 2027, and 2028, these selected drugs may be eligible for renegotiation with respect to initial price applicability year 2029 (which would involve a renegotiation taking place in calendar year 2027) if these drugs meet any of the eligibility criteria set forth in section 1194(f)(2) of the Act and proposed § 429.605.

As a matter of operations, first, we proposed in § 429.605(a) that the scope of selected drugs that would be considered for renegotiation eligibility and selection with respect to initial price applicability years beginning with initial price applicability year 2029 would include any selected drugs with an agreed-upon MFP from a prior initial price applicability year, which would include a selected drug that has an agreed-upon MFP from a prior renegotiation. A selected drug would not be subject to renegotiation if CMS determines prior to the selected drug publication date for the relevant initial price applicability year that the manufacturer of any generic drug or biosimilar, as applicable, of the selected drug is engaging in Bona Fide Marketing of such generic drug or biosimilar, based on CMS' consideration of the information set forth at proposed § 429.130(a). That is, for any selected drugs with an agreed-upon MFP from a prior initial price applicability year where CMS has not yet determined that Bona Fide Marketing exists, we would proceed to review such drugs for renegotiation eligibility. If CMS determines based on consideration of the information set forth at proposed § 429.130(a) in accordance with the timing in proposed § 429.135(b)(2) and section II.B.6.d. of this final rule, that one or more manufacturers of an approved generic drug or licensed biosimilar, as applicable, of the selected drug, including a drug selected for renegotiation, is engaging in Bona Fide Marketing of such generic drug or biosimilar then the selected drug ceases to be subject to the renegotiation process.

Among such selected drugs, we proposed to identify selected drugs which are renegotiation-eligible drugs due to a change in monopoly status as described in proposed § 429.605(b). Then, we proposed to review the remaining selected drugs and identify those which are renegotiation-eligible drugs due to the addition of a new indication as described in proposed § 429.605(c) or due to a material change in any section 1194(e) factor as described in proposed § 429.605(d).

Selected drugs negotiated in initial price applicability years 2026 and 2027 were limited to those covered under Part D per section 1192(d)(2)(A) of the Act. In proposed § 429.605(a)(1), we proposed to consider any selected drugs from initial price applicability years 2026 and 2027, including those with Part B utilization, for renegotiation eligibility under section 1194(f)(2) of the Act. If such drugs meet the eligibility criteria described in proposed § 429.605, they may be selected for renegotiation under section 1194(f)(3) of the Act and as described in proposed § 429.610; and may have an agreed-upon MFP after renegotiation. For such renegotiation-eligible drugs that are selected for renegotiation and for which a renegotiated MFP is agreed upon, the renegotiated MFP would apply as described in proposed § 429.600(b) and would apply to claims payable under Part B and dispenses covered under Part D, as applicable. The MFP that is agreed upon following the renegotiation process would apply to all formulations across dosage forms and strengths of the selected drug as specified in proposed § 429.600(b)(2), which would include when the selected drug is payable under Part B only, covered under Part D only, and when the drug is payable under Part B and covered under Part D. Proposed § 429.600(b)(3) would require the Primary Manufacturer of a selected drug with a renegotiated MFP to make the prior agreed-upon MFP available as set forth in proposed subpart I for all dispenses, administrations, and furnishings of the selected drug prior to the effective date of the renegotiated MFP as specified in proposed § 429.600(b)(1).

a. Selected Drugs for Which There Is a Change in Status to an Extended-Monopoly Drug

To meet the definition of an extended-monopoly drug proposed in § 429.20, the initial approval date under section 505(c) of the FD&C Act or the initial licensure date under section 351(a) of the PHS Act, as applicable, associated with the earliest-approved FDA application containing the active moiety/active ingredient (or in the case of a potential qualifying single source drug identified under proposed § 429.125(b)(4), the distinct combination of active moieties/active ingredients) [88] must be on or before January 1 of the year 12 years prior but no more than 16 years prior. In accordance with section 1194(f)(2)(C) of the Act, we proposed in § 429.605(b)(1) that a selected drug that meets the definition of an extended-monopoly drug with respect to initial price applicability years beginning with initial price applicability year 2029, and that did not qualify as an extended-monopoly drug when the drug was selected for negotiation or a prior renegotiation would be determined to be renegotiation-eligible due to a change in status to an extended-monopoly drug.[89]

b. Selected Drugs for Which There Is a Change in Status to a Long-Monopoly Drug

To meet the definition of a long-monopoly drug, the initial approval date under section 505(c) of the FD&C Act or the initial licensure date under section 351(a) of the PHS Act, as applicable, associated with the earliest-approved FDA application containing the active moiety/active ingredient (or in the case of a potential qualifying single source drug identified under proposed § 429.125(b)(4), the distinct combination of active moieties/active ingredients) [90] must be on or before January 1 of the year 16 years prior. In accordance with section 1194(f)(2)(C) of the Act and the existing policy established in section 130.1.2 of the Negotiation Program Guidance, we proposed at § 429.605(b)(2) that a selected drug that meets the definition of a long-monopoly drug (as proposed in § 429.20) and that did not qualify as a long-monopoly drug when the drug was selected for negotiation or a prior renegotiation would be determined to be

[88] For biological products with approved applications under section 505 of the FD&C Act as of March 23, 2020, that were deemed to be approved BLAs under section 351 of the PHS Act, effective March 23, 2020, under section 7002(e)(4)(A) of BPCI Act, and that are currently licensed and marketed under section 351 of the PHS Act, CMS will consider March 23, 2020 to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B) of the Act.

[89] As we proposed to codify in § 429.20, section 1194(c)(4)(B)(ii) of the Act expressly excludes a selected drug for which a Primary Manufacturer has entered into a Negotiation Program Agreement with CMS with respect to an initial price applicability year that is before 2030 from the definition of an ''extended-monopoly drug''. Therefore, the proposal at § 429.605(b)(1) would apply to drugs selected for negotiation in initial price applicability year 2030 or later.

[90] For biological products with approved applications under section 505 of the FD&C Act as of March 23, 2020, that were deemed to be approved BLAs under section 351 of the PHS Act, effective March 23, 2020, under section 7002(e)(4)(A) of BPCI Act, and that are currently licensed and marketed under section 351 of the PHS Act, CMS will consider March 23, 2020 to be the licensure date for purposes of identifying the time since licensure under section 1192(e)(1)(B) of the Act.

renegotiation-eligible due to a change in status to a long-monopoly drug.

c. Selected Drugs for Which a New Indication Is Added

Section 1194(f)(2)(A) of the Act identifies a selected drug for which a new indication is added as a renegotiation-eligible drug. As described in proposed § 429.615(a), we proposed to collect voluntary information submissions from Primary Manufacturers of selected drugs to inform renegotiation drug eligibility and selection.

To identify whether a new indication has been added to the FDA-approved labeling [91] for a selected drug, we proposed at § 429.605(c) to use a number of sources, for example the Drugs@FDA database.[92] We also proposed at § 429.605(c)(2)(ii) to review voluntary submissions from Primary Manufacturers if any are submitted. We proposed at § 429.605(c)(2)(ii)(A) that we may review off-label use for the purpose of determining whether such off-label use is a new indication for renegotiation eligibility determinations only if voluntarily submitted by the Primary Manufacturer. At § 429.605(c)(1), we proposed that we would determine a drug to be renegotiation-eligible based on the addition of a new indication if the FDA-approved labeling has been updated to include treatment or prevention of a new disease or condition. In the renegotiation context, ''new'' means not considered in the previous negotiation process or renegotiation process. For example, we would not determine a selected drug to be renegotiation-eligible under section 1194(f)(2)(A) of the Act based on FDA labeling updates within a previously indicated disease or condition.

In proposed § 429.605(c)(2)(ii)(A), we proposed that if the Primary Manufacturer of a selected drug submits the off-label use through the voluntary information submission process then CMS may review off-label uses when identifying new indications for renegotiation eligibility. We would apply the definition proposed at § 429.20 when reviewing an off-label use submitted by a Primary Manufacturer for consideration as a new indication for the purpose of renegotiation eligibility. Voluntary submissions from a Primary Manufacturer of an off-label use for a selected drug would not be regarded as a ''new indication'' for renegotiation eligibility under section 1194(f)(2)(A) of the Act if such off-label use is for a previously indicated disease or condition. For example, in the event we previously considered an off-label use during negotiation and the Primary Manufacturer later received FDA approval for that off-label use, we would not consider the new on-label use to be a new indication in accordance with section 1194(f)(2)(A) of the Act. We may consider such off-label use that is for a previously considered disease or condition as part of the evaluation of section 1194(e) factors for material change for purposes of renegotiation eligibility under section 1194(f)(2)(D) of the Act, as described in proposed § 429.605(d).

To ensure we have appropriate time to consider applicable data, we proposed at § 429.605(c)(3) that the new indication must be added to the FDA-approved labeling for the selected drug on or before a time specified by CMS and any information regarding off-label use must be voluntarily submitted under § 429.615(a). We are making a technical correction to § 429.605(c)(3). This correction indicates that, in the absence of a voluntary data submission from the Primary Manufacturer, a new indication must be added to the FDA-approved labeling on or before a time specified by CMS, which will be September 30 of the year before the selected drug publication date for which the drug would be selected for renegotiation. The Primary Manufacturer may voluntarily submit data on a new indication, including an indication added to the FDA label or an off-label use, through the due date of the Drug Selection ICR (CMS–10844, OMB 0938–1443) to be specified by CMS upon approval of the Drug Selection ICR by the OMB and prior to the selected drug publication date for which the drug would be selected for renegotiation. If a Primary Manufacturer chooses to submit information on a new indication, we may incorporate the Primary Manufacturer's submission in determining whether a new indication has been added for a selected drug such that it is renegotiation-eligible. We expect that there would be a low likelihood of new indications being available for selected drugs whose negotiation or renegotiation period ends on November 1 immediately prior to the Primary Manufacturer submission deadline for the Drug Selection ICR.

d. Selected Drugs for Which There is a Material Change in a Section 1194(e) Factor

Section 1194(f)(2)(D) of the Act directs CMS to identify a selected drug for which there has been a material change to any factor listed in section 1194(e) as a renegotiation-eligible drug and provides CMS with the discretion to determine what constitutes a ''material change.''

We proposed to consider a change(s) to a section 1194(e) factor for a selected drug to be material if the change(s) to the factor would reasonably be expected to meaningfully alter our consideration of that factor within the context of renegotiation offers and counteroffers, including the initial offer as determined in proposed subpart F, as compared with our consideration of that factor within the context of offers, including the initial offer and, if applicable, counteroffers, during the most recent prior negotiation or renegotiation process for the selected drug. For purposes of determining whether a selected drug is renegotiation-eligible under section 1194(f)(2)(D) of the Act, we would evaluate available information pertaining to section 1194(e) factors (as listed in proposed § 429.505(b) and (d) and section II.F.2.b. of this final rule) to determine if there is a material change. We also proposed to consider voluntary submissions by a Primary Manufacturer of the information discussed in proposed § 429.615(a) to inform our determination.

This approach complements our review of new indications described in § 429.605(c) and discussed in section II.G.2.c. of this final rule as we would consider prescribing information (see section 1194(e)(2)(B) of the Act) as part of this material change evaluation. As part of that inquiry, we would review the FDA-approved labeling for a material change in prescribing information as described in proposed § 429.605(d)(1) and, in doing so, would also capture the impact of labeling updates within a previously indicated disease or condition during such review (for example, expansion of an existing indication to include an additional age group(s)). That is, labeling updates within a previously considered disease or condition would not be regarded as a ''new indication'' for renegotiation eligibility under section 1194(f)(2)(A) of the Act but would be considered as part of the review of section 1194(e) factors for material change for purposes of renegotiation eligibility under section 1194(f)(2)(D) of the Act.

[91] Such additions to the FDA approved labeling include new indications approved in both new NDAs/BLAs and supplements to previously approved NDAs/BLAs.

[92] Available at *www.fda.gov/drugsatfda, https://www.fda.gov/vaccines-blood-biologics/cber-regulated-products-supporting-documents.*

To provide sufficient time to consider the applicable information to determine whether a change in a factor listed in section 1194(e) of the Act is material, we would consider the applicable information that is available on or before September 30 of the calendar year before the selected drug publication date for which the drug would be selected for renegotiation. Our review of information that is available on or before September 30 would not be inclusive of information submitted by the Primary Manufacturer through a voluntary submission through the Drug Selection ICR. Should the Primary Manufacturer choose to submit data through the voluntary submission described in proposed § 429.615(a), then we may update our review of material change(s) with new applicable information.

Table II.F1 provides a few illustrative examples of this approach to determining a material change(s) to a section 1194(e) factor for the purpose of determining renegotiation eligibility. We reiterate that these are illustrative examples and the potential results may vary in all cases depending on the fact patterns of a given drug.

TABLE II.F1: ILLUSTRATIVE EXAMPLE SCENARIOS AND POTENTIAL RESULT IN DETERMINATION OF MATERIAL CHANGE

Example Scenario	Potential Result for Changes in Section 1194(e) Factor
New clinical data is released showing increased clinical value for a greater number or new group of individuals who are prescribed a selected drug.	CMS may determine that in this scenario this new data would likely meaningfully impact CMS' consideration of section 1194(e)(2)(C) of the Act in the context of offers and counteroffers. Therefore, this change may be considered a material change.
Unit cost of production and distribution increases from $1.00 per unit to $1.50 per unit.	CMS may determine that in this scenario this change would not likely meaningfully impact CMS' consideration of section 1194(e)(1)(B) of the Act in the context of offers and counteroffers. Therefore, this change alone may not be considered a material change.
A therapeutic alternative is now generic, the price for the therapeutic alternative drops significantly, and utilization of the therapeutic alternative increases significantly.	CMS may determine that in this scenario this new data would likely meaningfully impact CMS' consideration of section 1194(e)(2)(A) in the context of offers and counteroffers. Therefore, this change may be considered a material change.
New clinical data is released showing increased clinical efficacy of the selected drug for one of its indications; a new black box warning indicates additional safety concerns for the selected drug, limiting its use.	CMS may determine that in this scenario the net impact of these changes would not meaningfully impact CMS' consideration of section 1194(e)(2)(C) of the Act in the context of offers and counteroffers. Therefore, these changes alone may not be considered a material change.
An indication for a selected drug was not covered under Part D or payable under Part B at the time the drug was previously negotiated. The indication is now covered under Part D and/or payable under Part B and there are no alternative treatments available for that indication.	CMS may determine that in this scenario the newly covered indication for which there are no alternative treatments to the selected drug would meaningfully impact CMS' consideration of section 1194(e)(2)(D) of the Act in the context of offers and counteroffers. Therefore, this change may be considered a material change.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters recommended that a drug should not be selected for renegotiation until at least one year has passed since its last negotiation or renegotiation period concluded. A commenter recommended that CMS not select drugs for renegotiation that have had an MFP established in the last 2 to 3 years, absent a change in monopoly status or manufacturer request. A commenter requested that CMS not exclude drugs from selection for renegotiation in cases where the MFP might only apply briefly, since even a single year of the MFP could have a substantial impact on beneficiaries and the program.

Response: We appreciate the perspectives offered by these commenters and acknowledge that it is possible under the statute that a selected drug with an agreed-upon MFP could be renegotiated relatively soon after the conclusion of a prior negotiation or renegotiation. However, consistent with our response to similar comments in the Negotiation Program Guidance and as discussed in section II.G.2. of the proposed rule (91 FR 36299), we interpret section 1194(f)(1) of the Act to mean that the Secretary must provide for a process of renegotiation for years during the selected drug's price applicability period. We provided the following example: because calendar year 2029 will be a year within the price applicability period for drugs selected for initial price applicability years 2026, 2027, and 2028, these selected drugs may be eligible for renegotiation with respect to initial price applicability year 2029 (which would involve a renegotiation taking place in calendar year 2027) if these drugs meet any of the eligibility criteria set forth in section 1194(f)(2) of the Act and described at § 429.605. Sections 1194(f)(2) and (f)(3) of the Act clearly describe the circumstances under which CMS considers renegotiation eligibility and subsequently selects a renegotiation-eligible drug for renegotiation. We believe it is possible that a selected drug could have a change in monopoly status, a material change to a factor

described at section 1194(e) of the Act, or a new indication as described at § 429.605(b) through (d) since its last negotiation or renegotiation period concluded, even if less than one year has passed since that negotiation period or renegotiation period concluded. The statute does not provide for exceptions or delay in selection for renegotiation for any specific category of renegotiation-eligible drugs.

Comment: A commenter requested that CMS clarify that changes in a drug's monopoly status to or from extended monopoly status would not result in such drug becoming eligible for renegotiation under proposed § 429.605(b) before initial price applicability year 2030.

Response: We direct this commenter to footnote 60 in section II.G.2.a. of the proposed rule (91 FR 36300) and to the definition of ''extended-monopoly drug'' proposed at § 429.20 where we indicate that the definition of ''extended-monopoly drug'' excludes a selected drug for which a Primary Manufacturer has entered into a Negotiation Program Agreement with CMS with respect to an initial price applicability year that is before 2030 per section 1194(c)(4)(B)(ii) of the Act.

Comment: A couple of commenters opposed CMS' consideration of off-label use when determining if there is a new indication for the purpose of renegotiation eligibility under proposed § 429.605(c); a commenter supported this policy. A few commenters supported the inclusion of off-label use when considering new indications for renegotiation eligibility but requested that CMS expand consideration beyond voluntary manufacturer submissions of off- label use information to avoid a situation where a new off-label use emerged but a manufacturer chose not to submit such use for CMS' consideration.

Response: We appreciate the feedback from these commenters. We believe that the consideration of off-label use when determining whether a selected drug is eligible for renegotiation under § 429.605(b) is appropriate as the statutory text at section 1194(f)(2)(A) of the Act does not make specific reference to the FDA, licensures, or approvals as can be seen elsewhere in the Act, therefore CMS is not limited to only consideration of on-label use. Further, the statutory reference to ''new indication'' at section 1194(f)(2)(A) of the Act is best read as including off-label use for consistency with longstanding Medicare program policy to permit coverage and payment of drugs that are supported by evidence-based clinical practice guidelines and the off-label use is a medically accepted indication payable under Part B or covered under Part D and for consistency with the negotiation process.

We note that renegotiation eligibility and selection is a distinct process from selection for negotiation as proposed at § 429.105, which specifically indicates that CMS reviews negotiation-eligible drugs to determine that such drug is approved or licensed under section 505(j) of the FD&C Act or under section 351(k) of the PHS Act. Additionally, the consideration of off-label use for the purpose of renegotiation eligibility is aligned with the negotiation process, specifically, CMS considers off-label use when determining the conditions for which the selected drug is used (as proposed at § 429.510(a)(2)) and when determining therapeutic alternatives for the selected drug (as proposed at § 429.510(c)(2)(i)). Renegotiation eligibility is determined based on changes to the monopoly status of a drug, the addition of a new indication to the drug, or a material change to a factor listed at section 1194(e) of the Act. We believe that off-label use is an appropriate element to consider in the context of renegotiation eligibility, specifically with respect to renegotiation eligibility based on the addition of a new indication to the drug since off-label use is relevant for determining the conditions for which a selected drug is used, and with respect to eligibility based on a material change to a factor listed at section 1194(e) of the Act since off-label use within a previously considered disease or condition could demonstrate a material change to a factor listed at section 1194(e) of the Act.

We considered what sources of information CMS should review for consideration of new off-label uses that might be considered for renegotiation eligibility. When considering off-label use for the purpose of renegotiation eligibility under section 1194(f)(2)(D) of the Act, we believe that the Primary Manufacturer is well-positioned to provide information regarding off-label uses that may be considered to be a new indication as the Primary Manufacturer often has complete information about use of the selected drug, including updates on how the drug might be used off-label, as well as the extent to which CMS and the Primary Manufacturer already engaged on a given potential off-label use during a previous negotiation or renegotiation. We also note that should a new off-label use emerge, in the event it is not submitted to CMS by the manufacturer for CMS' consideration, there would likely be downstream impacts on other factors listed at section 1194(e) of the Act that could lead to consideration for renegotiation eligibility as a material change. In accordance with § 429.605(d)(2), we will review several sources as listed in § 429.510(f) when reviewing whether there has been a material change to a factor listed at section 1194(e) of the Act for a selected drug. For example, a new off-label use could increase utilization of a selected drug and therefore result in changes to the factor listed at section 1194(e)(1)(E) of the Act. Another example is if a new off-label use could meet an unmet medical need per the factor listed at section 1194(e)(2)(D) of the Act and therefore be considered as a potential material change for renegotiation eligibility.

Comment: A few commenters requested that CMS clarify what constitutes a material change within the factors listed at section 1194(e) of the Act. A commenter urged CMS not to finalize the proposed policy at § 429.605(d) and instead requested a narrower and more specific framework for determining what constitutes a material change. A commenter also stated that the proposed rule does not explain how materiality calculations can be made prior to a manufacturer's data submission. A commenter provided a list of changes to each factor listed under section 1194(e) of the Act and recommended that CMS consider such changes material under proposed § 429.605(d). These changes included for the factors listed at section 1194(e)(1)(A) through (D) of the Act: the recoupment of R&D costs if such costs had not been recouped at the time of its initial negotiation; a significant increase or decrease in the manufacturer's unit costs of production and distribution; if primary patents or exclusivities recognized by FDA expire or are invalidated and no generic or biosimilar competition has emerged; if the selected drug no longer represents a therapeutic advance as compared to existing therapeutic alternatives due to new drug or indication approvals or, alternatively, if the costs of existing therapeutic alternatives change or if an existing therapeutic alternative is selected for negotiation and the MFP is lower than its previous price; if prescribing information changes meaningfully; if additional comparative effectiveness evidence becomes available that adds to the existing body of evidence; and if the selected drug is no longer fulfilling an unmet medical need. A commenter stated that the proposed rule did not specify what constitutes the time of

consideration for the purpose of determining whether there has been a material change. A commenter suggested that CMS consider revision in ESMO–MCBS scoring or other clinical benefit frameworks applicable to a selected drug as a circumstance that would represent a potential material change. A commenter also recommended that CMS not allow multiple material changes to cancel one another out, if there would still likely be an impact on the MFP when considered holistically. A commenter recommended that CMS consider whether a Primary Manufacturer has secured longer monopoly protection due to ''patent thicketing'' or other similar strategies.

Response: We thank these commenters for their feedback. Section II.G.2.d. of the proposed rule (91 FR 36301) describes an approach to determine what constitutes a material change to a factor listed at section 1194(e) of the Act, which includes a change(s) that would reasonably be expected to meaningfully alter the consideration of the factor within the context of renegotiation offers and counteroffers compared to offers and counteroffers during the most recent prior negotiation or renegotiation for the selected drug. As stated in the proposed rule, section 1194(f)(2)(D) of the Act provides CMS with the discretion to determine what constitutes a material change. Regarding commenters' concern about material changes effectively ''canceling'' one another out, we note that for the purpose of renegotiation eligibility we consider changes within each factor holistically when considering whether there has been a material change for a given factor for the purpose of renegotiation eligibility. When considering whether a renegotiation-eligible drug that is eligible due to the addition of a new indication or a material change to a factor listed at section 1194(e) of the Act must be selected for renegotiation because CMS expects renegotiation is likely to result in a significant change in the MFP otherwise negotiated, we consider the new indication(s) and material change(s) to factors listed at section 1194(e) of the Act holistically when evaluating the likelihood that the new indication(s) and material change(s) would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP and whether such a change in MFP would have a significant impact on the Medicare program. Material changes within different factors would not ''cancel'' each other out for purpose of renegotiation eligibility; however, for selection, CMS would consider the likely impact of the changes to the factors listed at section 1194(e) of the Act holistically. Similar to our approach to considering evidence related to the factors listed at section 1194(e) of the Act (proposed at § 429.510(e) and (f)), we believe a holistic approach is necessary to consider the unique characteristics of each selected drug. Further, due to the unique characteristics of each selected drug and the population and conditions treated by such drug, it is not feasible to provide a list of specific changes that would qualify as a material change for the purpose of renegotiation eligibility. We also note that consideration of data on pending and approved patents may be considered within this holistic framework as part of our consideration of the factor listed at section 1194(e)(1)(D) of the Act. We appreciate commenters' request for additional clarity, and believe the illustrative examples provided in Table II.F1 of the proposed rule (91 FR 36302) help readers understand how we may consider material change in different circumstances and that determining renegotiation eligibility will be drug specific.

Regarding when we will consider material change relative to when information is submitted for the factors listed at section 1194(e) of the Act, we direct commenters to section II.G.2.d. of the proposed rule (91 FR 36301) where we indicated that we will consider the applicable information that is available on or before September 30 of the calendar year before the selected drug publication date for which the drug would be selected for renegotiation and, should the Primary Manufacturer chose to submit information through the voluntary Drug Selection ICR of that same calendar year, we may update our review of material change(s) with new applicable information. This comment prompted us to make a clarification to when we would consider a new indication for the purpose of renegotiation eligibility as discussed in section II.G.2.c. of the proposed rule (91 FR 36300) where we state that a ''new indication must be added to the FDA-approved labeling for the selected drug on or before March 1 of the year of the selected drug publication date for the initial price applicability year for which the drug would be selected for renegotiation''. We clarify in this response that we will consider a new indication that is added to the FDA-approved labeling for the selected drug for renegotiation eligibility if such indication is added on or before September 30 of the year prior to the selected drug publication date for the initial price applicability year for which the drug would be selected for renegotiation or, as discussed in section II.G.2.d. of the proposed rule (91 FR 36301), should the Primary Manufacturer choose to submit data through the voluntary submission proposed at § 429.615(a), then we may consider such information in our review of new indication(s).

Regarding the suggestion to consider a revision to the ESMO–MCBS or another clinical framework as a material change for the purpose of determining renegotiation eligibility, we note that should such a change be submitted through the Drug Selection ICR, we may consider such information when determining renegotiation eligibility. A revision in scoring to the ESMO–MCBS or another clinical framework may or may not be indicative of a material change under section 1194(f)(2)(D) of the Act. We believe the criteria under § 429.605(d) provides a clear and appropriate framework for how we will consider information, including changes in scoring for selected drugs within clinical frameworks such as the ESMO–MCBS, for the purpose of renegotiation eligibility.

Comment: A few commenters opposed or requested the removal of the last example in Table II.F1 of the proposed rule (91 FR 36302) regarding how CMS may view an indication for a selected drug that was not covered under Part D or payable under Part B at the time the drug was previously negotiated. A couple of commenters requested that CMS clarify that Part B utilization of a selected drug with an existing MFP would not, alone, constitute a material change. A couple of commenters opposed the notion that a change in coverage status would constitute a material change. A commenter appreciated the example provided in Table II.F1 (91 FR 36302).

Response: We thank these commenters for their feedback on the example included in Table II.F1 of the proposed rule (91 FR 36302) and the interpretation of this example. We assume the commenters requesting that we clarify that Part B utilization alone would not constitute a material change are specifically referring to a situation where a drug was selected for negotiation in initial price applicability year 2026 or 2027 when such selection and negotiation was for coverage under Part D only. In this context, we agree that the existence of Part B utilization of a selected drug would not, alone, constitute a material change. However,

per section 1194(f)(2)(D) of the Act, we would consider changes to the factor listed at section 1194(e)(1)(E) of the Act (''market data and revenue and sales volume data for the drug in the United States''), which could be impacted by the inclusion of, or a change in, Part B utilization for a selected drug. In addition, should a situation arise where a selected drug was either not previously payable under Part B or covered under Part D when it first became a selected drug but later becomes payable under either Part B and covered under Part D, or both, this could be indicative of a change in a factor listed at section 1194(e) of the Act. For example, a coverage change could indicate that there is a new off-label use being added to clinical guidelines or compendia, or could address an unmet medical need, among other possibilities. In such cases, if there were a corresponding change in a factor listed at section 1194(e) of the Act, we would consider such change and determine if the change is material under § 429.605(d)(1). This is explained in the column titled ''Potential Result for Changes in Section 1194(e) Factor'' in Table II.F1 (91 FR 36302). To clarify the last example listed in Table II.F1 (91 FR 36302), the Example Scenario is intended to describe a situation where an indication for a selected drug was either not covered under Part D, not payable under Part B, or both, at the time the drug was previously negotiated but is now payable under Part B, covered under Part D, or both and, as a result, Medicare beneficiaries now have a covered treatment option for an indication for which treatment was previously not addressed adequately by available therapy. A potential result for this illustrative scenario could be that we may determine the selected drug now addresses an unmet medical need for Medicare beneficiaries as an available treatment for the newly covered indication, and this could meaningfully impact CMS' consideration of section 1194(e)(2)(D) of the Act in the context of offers and counteroffers; therefore, this change may be considered a material change.

Comment: A commenter requested that CMS provide the Primary Manufacturer with the analysis used to determine that the drug was eligible for renegotiation by February 1st of the initial price applicability year.

Response: We thank this commenter for their suggestion. We intend to follow the same process and timeline for publishing the selected drug list for renegotiation as for negotiation. This provides consistency for interested external parties, is operationally feasible for CMS, and aligns the negotiation and renegotiation process timelines. Consistent with our response to similar requests in the Negotiation Program Guidance, we do not believe providing the Primary Manufacturer with additional information prior to the February 1 publication deadline is operationally feasible based on the timelines prescribed in section 1194(b) of the Act, which apply consistently to the renegotiation process to the extent practicable by section 1194(f)(4)(B) of the Act.

Final Decision: After consideration of public comments, we are finalizing § 429.605 as proposed with technical changes. At § 429.605(c)(1), we are revising ''previously indicated condition'' to ''previously considered disease or condition'' to clarify that this refers to a disease or condition as discussed at section III.G.2.c. of this final rule. At § 429.605(c)(2)(ii), (c)(2)(ii)(A), and (c)(3), we are removing ''§ 429.615(b)'' and replace with ''§ 429.615(a)'' such that these cross references appropriately refer to the voluntary submission of information under § 429.615(a) to inform renegotiation eligibility and selection.

In section II.G.c. of this final rule, we make a technical correction to revise the cross reference to § 429.615(b) to refer to § 429.615(a). As discussed in this final rule, a new indication must be added to the FDA-approved labeling for the selected drug information to inform renegotiation eligibility and selection (as proposed at § 429.615(a)) by a time specified by CMS. In section II.G.c. of this final rule, we indicate that such time will be on or before September 30 of the year prior to the selected drug publication date for the initial price applicability year for which the drug would be selected for renegotiation. The technical corrections regarding references to the voluntary submission of information under § 429.615(a) ensures that the submission of information on a new indication from a Primary Manufacturer is aligned with the time during which CMS will be reviewing selected drugs for renegotiation eligibility and selection such that CMS can review the submitted information and consider it accordingly. In alignment with this clarification, we also revised cross references in § 429.605(c)(2)(ii), (c)(2)(ii)(A), and (c)(3) in this final rule to correct the cross reference from § 429.615(b) (which refers to data collection from interested parties to inform renegotiation) to § 429.615(a) (which refers to the voluntary submission of data by the Primary Manufacturer to inform renegotiation eligibility and selection).

We are revising § 429.605(d)(2) to add a cross reference to § 429.505(b)(2), which corrects an inadvertent omission.

3. Selection of Drugs for Renegotiation (§ 429.610)

Section 1194(f)(3) of the Act directs CMS to select drugs for renegotiation from the identified renegotiation-eligible drugs (described in proposed § 429.605). Sections 1194(f)(3)(A) and (B) of the Act require all such drugs eligible for renegotiation due to a change in monopoly status to either an extended-monopoly drug or a long-monopoly drug, as specified in proposed § 429.610(b), be selected for renegotiation. Section 1194(f)(3)(C) of the Act states that among the remaining renegotiation-eligible drugs (that is, selected drugs that are determined to be renegotiation-eligible due to a new indication or a material change in a section 1194(e) factor), CMS shall select renegotiation-eligible drugs for which CMS expects renegotiation is likely to result in a significant change in the previously agreed-upon MFP. Section 1194(f)(3)(C) of the Act provides CMS with the discretion to make determinations on when a renegotiation is ''likely to result in a significant change'' in the MFP.

a. Selecting Drugs for Renegotiation Among Renegotiation-Eligible Drugs Due to a Change in Monopoly Status

In accordance with section 1194(f)(3)(A) and (B) of the Act and consistent with the existing policies established in section 130.2 of the Negotiation Program Guidance, we proposed at § 429.610(a) to select for renegotiation all drugs that are determined to be renegotiation-eligible due to a change in monopoly status to either an extended-monopoly drug or a long-monopoly drug as set forth in proposed § 429.605(b).

b. Selecting Drugs for Renegotiation Among Renegotiation-Eligible Drugs Due to a New Indication or a Material Change in a Section 1194(e) Factor

In accordance with section 1194(f)(3)(C) of the Act and consistent with the existing policies established in section 130.2.1 of the Negotiation Program Guidance, we proposed to select remaining renegotiation-eligible drugs (that is, selected drugs that are determined to be renegotiation-eligible due to a new indication or a material change in a section 1194(e) factor), for renegotiation if we expect renegotiation is likely to result in a significant change in the MFP.

To inform our determination of whether renegotiation is likely to result

in a significant change in the MFP, we proposed to consider two criteria to effectuate this statutory standard, as discussed in greater detail in this section. We proposed that the evaluation of these two criteria would be a holistic inquiry based on the totality of the information available and the circumstances of the remaining renegotiation-eligible drug(s). The first criterion that we proposed in § 429.610(b)(1)(i) is that we would consider whether a new indication(s) or material change(s) would be likely to result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP upon engaging in renegotiation with the Primary Manufacturer. The second proposed criterion in § 429.610(b)(1)(ii) is to consider whether such a change in the MFP for the remaining renegotiation-eligible drug(s) would have a significant impact on the Medicare Program. We believe these criteria are important to consider holistically to understand the circumstances for each selected drug.

Our evaluation for these two criteria would be a holistic inquiry based on the totality of the information available and the circumstances of the remaining renegotiation-eligible drug(s), including nonfinancial information, such as the expiration of an exclusivity period under the FD&C Act or the PHS Act, and would support our determination of whether renegotiation is likely to result in a significant change, whether an increase or decrease, to the MFP for the remaining renegotiation-eligible drug(s). The scope of information considered may extend beyond the scope of information evaluated for renegotiation eligibility to include a CMS-led review of the information sources discussed in proposed § 429.510(b) (described in section II.F.2. of this final rule) and the evaluation of such sources as discussed in proposed § 429.510(c), (e), and (f) (described in section II.F.3.d. of this final rule) pertaining to section 1194(e)(1) and section 1194(e)(2) factors. We proposed to consider these information sources and others to inform whether a renegotiation-eligible drug would be selected for renegotiation because these sources may inform a potential future renegotiation process, including the potential development of the initial offer and subsequent offers, as well as our consideration of potential counteroffers.

We proposed that when a remaining renegotiation-eligible drug is subject to this evaluation, we will only select such drug for renegotiation if that renegotiation-eligible drug meets both of these criteria. We believe each of these criteria are of equal importance when considering whether renegotiation is likely to result in a significant change in the MFP otherwise negotiated. We believe that when considering drug selection for renegotiation from among renegotiation-eligible drugs, described previously, the evaluation of the proposed criteria would indicate that renegotiation is both likely to change the MFP and that the change in MFP would be significant, in accordance with the directive under section 1194(f)(3)(C) of the Act to select remaining renegotiation-eligible drugs when CMS ''expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated.'' We interpret section 1194(f)(3)(C) of the Act to require that for a drug that is eligible for renegotiation based on a new indication or material change to a factor listed at section 1194(e) of the Act, we must expect that renegotiation would likely result in a change to the MFP, but also that such change must be considered significant, such that the magnitude of change is meaningful and that such change would be significant for CMS. We believe that evaluating the proposed criteria provides transparency into how we intend to implement section 1194(f)(3)(C) of the Act. As a matter of process and for additional clarity, if a remaining renegotiation-eligible drug(s) were to fail to meet either criterion, we would not proceed to examine the other criterion given that a remaining renegotiation-eligible drug(s) must meet both criteria to be selected for renegotiation.

In establishing the first criterion (the likelihood that the new indication or material change would result in a renegotiated MFP that would likely represent a 15 percent or greater change relative to the current MFP) we reviewed sections 1194(c)(3)(A) through (C) of the Act, which provide the applicable percentage of non-FAMP used to establish a ceiling during negotiation. The applicable percentages are 75 percent for short-monopoly drugs and vaccines, 65 percent for extended-monopoly drugs, and 40 percent for long-monopoly drugs (as described further in proposed § 429.410). Given that, under sections 1194(c)(3)(A) through (C) of the Act, a change in monopoly status is associated with a percent reduction in the ceiling for negotiation and that such change in monopoly status of a selected drug results in eligibility and selection for renegotiation per sections 1194(f)(2)(B) and (C) of the Act and sections 1194(f)(3)(A) and (B) of the Act, we believe this range of percent change is informative for interpreting what the term ''significant change'' means in the context of the statute.

We calculated the percent change in the applicable percentage for a drug that had a change in monopoly status from a short-monopoly drug (75 percent) to a long-monopoly drug (40 percent), which is approximately 46.7 percent change; this represents the maximum percent change in the applicable percentage that would correspond with a selected drug becoming renegotiation-eligible and selected for renegotiation. We also calculated the percent change in the applicable percentage for a drug that had a change in monopoly status from a short-monopoly drug (75 percent) to an extended-monopoly drug (65 percent), which is approximately 13.3 percent change; this represents the minimum percent change in the applicable percentage that would correspond with a selected drug becoming renegotiation-eligible and selected for renegotiation. We rounded these percent changes to the nearest 5 percent, resulting in a range of percent change from 15 to 45 percent that we believe represent an informative range for interpreting what a ''significant change'' means in the context of the statute, as discussed previously. We believe that a potential change in the MFP between 15 and 45 percent would be significant for the Medicare program and Medicare beneficiaries. We proposed to use minimum percent change that corresponds with a selected drug becoming renegotiation-eligible and selected for renegotiation, that is 15 percent change, so as to not preclude the benefits that could come from a change in the MFP that is at least 15 percent. The agency also considered the resources invested in renegotiation. We believe that the resources invested for both CMS and the Primary Manufacturer in a renegotiation process that would likely result in a change to the MFP of 15 percent or greater is an appropriate investment for the potential resulting change.

We also considered the option of evaluating the likelihood that a new indication or material change would result in a 35 percent or greater change to the MFP. In connection with the public comment period for the Negotiation Program Guidance, a few commenters noted that the difference between the applicable percentage for short-monopoly drugs and vaccines (75 percent) and long-monopoly drugs (40 percent) is 35 percent and therefore they recommended we adopt an expected change to the MFP of 35 percent as the first criterion indicating a potential

change to the MFP is significant. We note that a 35 percent change would fall in the range calculated based on the percent change in the applicable percentages as described previously. However, we believe using the minimum percent change in the applicable percentage that corresponds with a selected drug becoming renegotiation-eligible and selected for renegotiation provides CMS with the best opportunity to both clearly define what constitutes a ''significant change to the MFP'' and to meet our statutory obligation per section 1194(b)(1) of the Act to establish a process that aims to achieve the lowest MFP for each selected drug. Additionally, we believe using a range based on the *percent change* in the applicable percentage is more aligned with section 1194(f)(3)(C) of the Act that specifies that CMS should select drugs for renegotiation that are likely to have a significant *change* in the MFP [emphasis added]. The suggested approach from commenters represents looking at the arithmetic difference in applicable percentages, rather than the change in applicable percentages. Use of percent change rather than the difference in the applicable percentages has practical importance in that our language more closely aligns with statute, meaning that a renegotiation would result in a change in the MFP. Given the variance in expected percent change in the MFP, a numerical value of 15 percent establishes the minimum amount that may have a meaningful effect for beneficiaries and the Medicare program and allows CMS to potentially consider more renegotiation-eligible drugs for renegotiation selection, whereas a higher number, like 35 percent, may normalize that any change less than 35 does not have a meaningful effect and may result in the selection of fewer renegotiation-eligible drugs for renegotiation. A 15 percent or greater change is consistent with the range of percent reductions in the ceiling that is statutorily defined for drugs eligible and selected for renegotiation due to monopoly status changes.

We also believe this criterion serves to promote transparency and consistency in the approach to selecting drugs for renegotiation in accordance with section 1194(f)(3)(C) of the Act. Therefore, in an effort to promote transparency and consistency, we proposed to include this criterion of considering the likelihood that the new indication(s) and/or material change(s) to a section 1194(e) factor would result in a renegotiated MFP that would represent a 15 percent or greater change relative to the current MFP, which can help provide clarity for interested parties and the public on when we may select remaining renegotiation-eligible drugs in accordance with section 1194(f)(3)(C) of the Act.

We recognize that there may be other circumstances related to the renegotiation-eligible drug that may make selecting the drug for renegotiation less reasonable, for example the impending entry of a generic or biosimilar to market. As such, we proposed the complementary criterion of evaluating whether such a change would have a significant impact to the Medicare program. For the second proposed criterion for determining whether renegotiation is likely to result in a significant change in the MFP, we proposed at § 429.610(b)(1)(ii) to consider the impact on the Medicare program of such a change in the renegotiated MFP. For example, if we determine there was a likelihood that the new indication(s) or material change(s) could result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP, we would consider the financial impact to the Medicare program and Medicare beneficiaries by reviewing associated changes in expenditures and beneficiary cost-sharing. In doing so, we seek to incorporate consideration of whether such change in MFP warrants the time and resource investment by the Primary Manufacturers and CMS in the renegotiation process. As an example, consider a scenario where a selected drug becomes renegotiation-eligible and there was a likelihood that the percentage change in the MFP would be greater than 15 percent. However, in this example scenario, patents on the selected drug will have expired before a renegotiated MFP would take effect, and we determine that this patent expiration will likely result in the introduction of robust generic competition. In this example scenario, we believe that: (1) it is likely there will be a substantial price drop in the market price for the selected drug unrelated to a renegotiated MFP; and (2) the drug will no longer be a selected drug on January 1 of the initial price applicability year because such drug has an approved generic drug that is subject to Bona Fide Marketing. As such, we may not select this hypothetical selected drug for renegotiation since the impact to the Medicare program might be minimal and does not warrant the considerable investment of time and resources by the Primary Manufacturer or CMS.

We proposed to consider the totality of other available information to determine whether renegotiation is likely to result in a change in MFP of 15 percent or greater and that such a change would have a significant impact on the Medicare program. This would include an initial evaluation of the evidence available for a renegotiation-eligible drug. This holistic consideration of the available information and circumstances for renegotiation drug selection provides for the consideration of drug- and fact-specific circumstances. This approach would also maintain consistency with the process for developing the initial offer, which considers the totality of available evidence as described in proposed §§ 429.510 and 429.620(f).

In making this determination, we do not presume that the result of a renegotiation would reflect these estimations, rather, these criteria would serve to support our selection determination in alignment with the requirements set forth in section 1194(f)(3)(C) of the Act and to help provide clarity for interested parties and the public. We note that no criteria to select drugs for renegotiation can predict the actual outcome of a renegotiation. A determination by CMS that renegotiation is likely to result in a significant change in MFP does not restrict the possibilities for the outcome of renegotiation. Any given renegotiation, informed by data on section 1194(e) factors available during the renegotiation period, could result in an increase in MFP, decrease in MFP, or no change in MFP. Further, the magnitude of the change in MFP could be higher or lower than 15 percent. Similarly, we do not presume that the result of a renegotiation will reflect these approximations, for example, with respect to the impact of an agreed upon MFP following the renegotiation process on the Medicare program.

We considered reviewing the remaining renegotiation-eligible drugs solely based on the criterion related to the impact on the Medicare program. We believe this criterion is an important component of defining, as a procedural matter, what constitutes a ''significant change to the MFP otherwise negotiated'', that is, we believe it is necessary when paired with some expectation of a change in the actual MFP but not sufficient to define a ''significant change''.

We also acknowledge that for renegotiation eligibility and selection of selected drugs that are negotiated or renegotiated for the initial price applicability years 2 years prior and immediately before the initial price applicability year for which eligibility and selection for renegotiation is being conducted, the time between agreeing

upon an MFP (through negotiation or renegotiation), and the review for renegotiation eligibility for the applicable initial price applicability year may be relatively short. The relatively short period between the negotiation or renegotiation of an MFP and our subsequent review of such drug for renegotiation may make it less likely that recently negotiated or renegotiated drugs would meet the material change criteria proposed at § 429.610(b) and described in section II.G.3.b. of this final rule.

Table II.F2 provides illustrative examples of how we may consider these criteria to determine whether a renegotiation-eligible drug would be selected for renegotiation.

TABLE II.F2: ILLUSTRATIVE EXAMPLE SCENARIOS AND POTENTIAL RESULT FOR SELECTION OF RENEGOTIATION-ELIGIBLE DRUGS DUE TO A NEW INDICATION OR CHANGE IN A SECTION 1194(e) FACTOR

Example Scenario	Potential Result
New comparative clinical effectiveness data has become available that is favorable for the selected drug compared to therapeutic alternatives (for example, studies are published showing the selected drug has a greater positive effect on clinical outcomes relative to therapeutic alternatives), but the ceiling* represents a <15% increase in the MFP.	It is not possible for renegotiation to result in a 15% increase in the MFP (because the ceiling* is less than 15% higher than current MFP), so the selected drug would not be selected for renegotiation.
New comparative clinical effectiveness data has become available that is **unfavorable** for the selected drug compared to its therapeutic alternatives (for example, studies are published showing the therapeutic alternative has a greater positive effect on clinical outcomes relative to the selected drug) and the MFP is much higher than competitors' prices. If such data were used during renegotiation with the Primary Manufacturer, the renegotiated MFP would likely **decrease** by 15% or more compared to the original MFP.	The selected drug would be selected for renegotiation if consideration of the other criterion supports the determination that renegotiation is likely to result in a significant change to the MFP.
New comparative clinical effectiveness data has become available that is **favorable** for the selected drug compared to therapeutic alternatives (for example, studies are published showing the selected drug has a greater positive effect on clinical outcomes relative to the therapeutic alternatives, and the ceiling represents a >15% increase in the MFP.) Upon renegotiating with the Primary Manufacturer, the renegotiated MFP would likely **increase** by 15% or more compared to the original MFP.	

*See § 429.620(b) for additional detail on the ceiling that would be used for renegotiation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters recommended that CMS select only drugs that are eligible for renegotiation based on a change in the monopoly status.

Response: We thank these commenters for their input. Section 1194(f)(3) of the Act describes the circumstances under which CMS shall select a renegotiation-eligible drug for renegotiation. The statute does not provide for exceptions or delay in selection for renegotiation for any specific category of renegotiation-eligible drugs and as such we decline to adopt these commenters' recommendation.

Comment: A few commenters recommended that CMS reconsider the criterion that renegotiation should be expected to result in at least a 15 percent or greater change in the MFP. A few commenters supported CMS' codification of the proposed renegotiation process and two-part test for selecting renegotiation-eligible drugs, with a commenter also supporting CMS' consideration of factors beyond spending. A commenter stated that when determining whether a material change could have a significant impact on the Medicare program, that CMS consider whether the underlying material change or new indication reflects greater clinical value for patients, how providers and pharmacies dispensing the product might be impacted, and how the marketplace and development of new therapies might be impacted. A commenter requested that CMS decrease the MFP through renegotiation when evidence indicates that a lower MFP is necessary. A couple of commenters recommended that CMS establish a standard and reproducible methodology for selecting drugs for renegotiation based on a significant change with objective, externally verifiable criteria to determine whether renegotiation is likely to result in a significant change to MFP, and stated that the 15 percent change criterion is discretionary and not reproducible. A couple of commenters requested that CMS provide greater transparency regarding selection criteria, with a commenter suggesting that CMS establish what a ''significant'' change would be and provide illustrative examples of circumstances that would fit this criterion. Among these commenters, one commenter recommended that CMS' analysis of whether a material change is likely to result in at least a 15 percent change to the MFP should include new indications, patient populations evaluated, projected Medicare utilization, the projected range of MFPs, and the calculation of the resulting Medicare expenditures.

Response: We thank these commenters for their input. Consistent with our response to similar comments

in the Negotiation Program Guidance, we reiterate that we developed the criteria related to a significant change to the MFP to serve to support CMS in making a selection determination in alignment with the requirements set forth in section 1194(f)(3)(C) of the Act for drugs eligible for renegotiation because a new indication is added or for which the Secretary determines there has been a material change to a section 1194(e) factor. While statute does not explicitly require any specific criterion to select these drugs for renegotiation in section 1194(f)(3)(C) of the Act, we set forth these criteria to provide transparency for the benefit of interested parties and the public into how the agency would approach determining what constitutes a significant change to the MFP. Our review of the two criteria—(1) the likelihood that the new indication or material change would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP and (2) whether such a change in the MFP would have a significant impact on the Medicare program—will be a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug, including nonfinancial information, such as the expiration of an exclusivity period under the FD&C Act or the PHS Act as discussed in section II.G.3.b. of the proposed rule (91 FR 36302). The scope of information considered may include a CMS-led review of the information sources discussed in section II.F.2. and II.F.3. of the proposed rule (91 FR 36286 through 36290) pertaining to section 1194(e)(1) and section 1194(e)(2) factors. We note that no criteria to select drugs for renegotiation can predict the actual outcome of a renegotiation. A determination that renegotiation is likely to result in a significant change in MFP does not restrict the possibilities for the outcome of renegotiation and any given renegotiation, informed by data on section 1194(e) factors available during the renegotiation period, could result in an increase in the MFP, decrease in the MFP, or no change in the MFP. Further, the magnitude of the change in the MFP could be higher or lower than 15 percent.

We also note that adopting a more rigid framework for selecting drugs for renegotiation could result in circumstances that neglect the fact- and drug-specific information that we are able to consider as part of a holistic consideration of information. For example, a methodology that does not offer discretion in drug selection could require selection for renegotiation every time a new indication was added for a selected drug without consideration of information about imminent entry of a biosimilar or generic drug that would result in a renegotiated MFP likely not becoming applicable. Similarly, a more rigid methodology for when CMS determines if a renegotiation-eligible drug is likely to result in a 15 percent change to the MFP is likely to neglect fact- and drug-specific information that is relevant to the consideration of this criterion. For example, the addition of a particular indication for one selected drug could indicate that renegotiation is likely to result in at least a 15 percent change to the MFP, but the addition of the same indication to a different selected drug that serves a different clinical population within Medicare could result in a finding that renegotiation is not likely to result in at least a 15 percent change to the MFP. For these reasons, we decline to adopt a more rigid methodology that would neglect the drug-specific and fact-specific circumstances of each selected drug.

Regarding the comment that CMS should consider clinical value to patients, impact on providers and pharmacies dispensing the product, and impact on the marketplace and development of new therapies when determining the impact on the Medicare program under § 429.610(b)(1)(ii), we may consider certain changes reflecting ''clinical value for patients'', including, for example, the selected drug addressing an unmet medical need that it had not previously addressed, in our holistic inquiry for determining the likelihood that the new indication(s) or material change(s) would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP and (2) whether such a change in the MFP would have a significant impact on the Medicare program. The commenter also requested that we consider effects on providers and pharmacies dispensing the product and the impact on the marketplace and development of new therapies. We appreciate the commenters' suggestion, and to the degree that these effects would impact the financial impact to the Medicare program and Medicare beneficiaries, such effects would be considered when we review associated changes in expenditures and beneficiary cost-sharing as described in section G.3.b. of the proposed rule (91 FR 36304). Otherwise, these considerations would be considered out of scope.

Comment: A few commenters recommended that CMS should increase the criterion from 15 percent change to at least 35 percent, and if not adopting a higher threshold, explain why 15 percent is appropriate. A commenter recommended that CMS decrease the criterion to below 15 percent change as potentially significant. A commenter stated that they oppose the criterion that renegotiation should be expected to result in at least a 15 percent or greater change to the MFP as it is arbitrary and capricious and self-validating and that the statutory mechanism CMS uses to justify the 15 percent change criterion is not applicable and that CMS picked the floor of the possible range.

Response: We appreciate commenters' input. As discussed in the Negotiation Program Guidance and section II.G.3.b. of the proposed rule (91 FR 36302 through 36304), we considered a range of percent changes to the MFP that might be appropriate based on percent change to the applicable percentage of non-FAMP used to establish a ceiling during negotiation, including a percent change that is less than 15 percent, and options for a percent change that is higher than 15 percent (including the option of evaluating the likelihood that a new indication or material change would result in a 35 percent or greater change to the MFP) as we believe this range of percent change is informative for interpreting what the term ''significant change'' means in the context of the statute. This is because under sections 1194(c)(3)(A) through (C) of the Act, a change in monopoly status is associated with a percent reduction in the ceiling for negotiation and such change in monopoly status of a selected drug results in eligibility and selection for renegotiation per sections 1194(f)(2)(B) and (C) of the Act and sections 1194(f)(3)(A) and (B) of the Act. As noted in section II.G.3.b. of the proposed rule (91 FR 36302), the range that we considered is based on the percent change in the applicable percentage for non-FAMP when determining the ceiling was between 15 and 45 percent. We proposed to use a percent change that corresponds with the lower end of this range, that is 15 percent change, so as to not preclude the benefits that could come from a likely change in the MFP that is at least 15 percent (while considering the second criterion that such change in MFP would have a significant impact on the Medicare program). We balanced considerations about the resources invested in renegotiation in determining what constitutes a significant change. Additionally, while statute does not explicitly require any specific criterion to select these drugs for renegotiation in section 1194(f)(3)(C) of the Act, we set

forth these criteria to provide transparency for the benefit of interested parties and the public into how the agency would approach determining what constitutes a significant change to the MFP. Our review of the two criteria—(1) the likelihood that the new indication or material change would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP and (2) whether such a change in the MFP would have a significant impact on the Medicare program—will be a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug, including nonfinancial information, such as the expiration of an exclusivity period under the FD&C Act or the PHS Act as discussed in section II.G.3.b. of the proposed rule (91 FR 36302 through 36305).

We disagree with the comment that the first criterion (the likelihood that a new indication or material change would result in a renegotiated MFP that represents a 15 percent or greater change relative to the current MFP) is arbitrary and capricious. As discussed earlier in this response, we arrived at this criterion as informed by numerical values in the statute. Given that, under sections 1194(c)(3)(A) through (C) of the Act, a change in monopoly status is associated with a percent reduction in the ceiling for negotiation and that such change in monopoly status of a selected drug results in eligibility and selection for renegotiation per sections 1194(f)(2)(B) and (C) of the Act and sections 1194(f)(3)(A) and (B) of the Act, we believe this range of percent change is informative for interpreting what the term ''significant change'' means in the context of the statute. As previously discussed, we proposed to use a percent change at the lower end of this range so as to not preclude the benefits that could come from a likely change in the MFP that is at least 15 percent while considering the second criterion. In arriving at the first criterion, we balanced considerations about the resources invested in renegotiation in determining what constitutes a significant change. We also disagree with the commenter's assertion that this criterion is ''self-validating''. We refer the commenter to section II.G.3.b. of the proposed rule (91 FR 36304) which states that a determination that renegotiation is likely to result in a significant change in MFP does not restrict the possibilities for the outcome of renegotiation and any given renegotiation, informed by data on section 1194(e) factors available during the renegotiation period, could result in an increase in the MFP, decrease in the MFP, or no change in the MFP. Further, the magnitude of the change in the MFP could be higher or lower than 15 percent. Consistent with our response to similar comments in the Negotiation Program Guidance, we also recognize that there may be other circumstances related to the renegotiation-eligible drug that may make selecting the drug for renegotiation less reasonable, for example the impending entry of a generic or biosimilar to market. As such, we proposed the complementary criterion of evaluating whether renegotiation would likely have a significant impact to the Medicare program. We decline to revise the criterion that renegotiation should be expected to result in at least a 15 percent or greater change.

Comment: A few commenters recommended that CMS permit manufacturers of drugs expected to be selected for renegotiation an opportunity to submit information and respond to any factual or methodological errors before selection.

Response: We thank these commenters for their suggestion. We do not believe the commenters' proposal would be operationally feasible to ensure that the selected drug list for both renegotiation and negotiation would be published by February 1. We intend to follow a similar process and timeline that is used for negotiation for renegotiation. We do not believe providing the Primary Manufacturer with additional time to provide more information after the submission of information through the Drug Selection ICR is operationally feasible based on the timelines prescribed in section 1194(b) of the Act. We also note that there is no statutory requirement to provide an opportunity for manufacturers to dispute selection for renegotiation.

Comment: A commenter requested CMS provide examples, such as impact on the ceiling and evidence that CMS would consider, that indicate circumstances where added value would result in an increase in the MFP, such that manufacturers do not view renegotiation as a penalty on indication expansion.

Response: We thank this commenter for their input. Consistent with section II.G.3.b. of the proposed rule (91 FR 36304), any given renegotiation, informed by data on section 1194(e) factors available during the renegotiation period, could result in an increase in MFP, decrease in MFP, or no change in MFP. Further, the magnitude of the change in MFP could be higher or lower than 15 percent. We also refer the commenter to Table II.F2 in the proposed rule (91 FR 36302) for example scenarios for renegotiation selection. We also reiterate that the result of a negotiation or renegotiation is not pre-determined and that we will consider evidence related to section 1194(e)(1) and (e)(2) factors in totality, alongside engagement with the Primary Manufacturer, as described in subpart F.

Final Decision: After consideration of public comments, we are finalizing § 429.610 as proposed with one technical correction. At § 429.610(b)(2)(i), we are revising ''section 1194(e) factors'' to ''the factors listed at section 1194(e) of the Act'' for precision.

4. Data Collection To Inform Renegotiation Eligibility, Selection, and Renegotiation of the MFP for a Selected Drug (§ 429.615)

Section 1194(f)(1) of the Act directs CMS to provide for a process to renegotiate the MFP for selected drugs that are determined to be renegotiation-eligible under section 1194(f)(2) of the Act and selected in accordance with section 1194(f)(3) of the Act. With respect to initial price applicability year 2028, we implemented these requirements through guidance, including section 130.3 of the Negotiation Program Guidance. With respect to initial price applicability year 2029 and subsequent years, consistent with the policies for implementation as described in section 130.3 of Negotiation Program Guidance, we proposed two data collections in § 429.615 for purposes of informing renegotiation eligibility, selection, and renegotiation of the MFP for a selected drug. The first data collection as described in § 429.615(a) would inform renegotiation eligibility and selection; the second data collection as described in § 429.615(b) would inform the renegotiation process for drugs selected for renegotiation. We will issue these ICRs alongside this final rule. The ICRs include more details regarding how manufacturers can submit data, including the format for data submission. The associated burdens for these ICRs are also discussed in section IV. of this final rule.

a. Voluntary Information Submission From Primary Manufacturers To Inform Renegotiation Eligibility and Selection for Selected Drugs

Sections 1194(f)(2) and 1194(f)(3) of the Act do not identify any specific source for the information used to inform renegotiation eligibility and selection. We believe that the

information necessary to determine renegotiation eligibility and selection for drugs with an agreed upon MFP is available without submission by the Primary Manufacturer or other interested parties. The sources of information we intend to use for renegotiation eligibility are listed in proposed § 429.605(c)(2), (d)(2), and (d)(3) and further discussed in sections II.G.2.c. and II.G.2.d. of this final rule. The sources of information we intend to use to select drugs for renegotiation from among those that are determined to be renegotiation-eligible are listed in proposed § 429.610(b)(2) and further discussed in section II.G.3.b. of this final rule. However, we believe input from the Primary Manufacturer on new indications, including off-label uses, and material changes to any factor listed at section 1194(e) of the Act, if applicable, could provide additional information or further validate our review. To minimize burden on the Primary Manufacturer, we proposed to make this data submission voluntary. We do not intend to review information submitted by a Primary Manufacturer if its selected drug is renegotiation-eligible due to a change in monopoly status as described at proposed § 429.605(b) as sections 1194(f)(3)(A) and (B) of the Act require CMS to select all drugs with a change in monopoly status described at proposed § 429.605(b) regardless of whether the drug has a new indication or a material change to a factor listed at section 1194(e) of the Act; no additional information would be required to make such a determination. We may consider the Primary Manufacturer's past data submissions, including any updates to such information, to inform renegotiation eligibility and selection, and to use such information during renegotiation if a drug is selected for renegotiation.

We also proposed at § 429.605(c)(2)(ii)(A) that we would only review off-label uses as a new indication for the purpose of determining renegotiation eligibility if the off-label use meets the definition proposed in § 429.20 and is submitted by the Primary Manufacturer in this voluntary submission. We believe that the review of off-label use is discretionary and not explicitly mandated in section 1194(f)(2)(A) of the Act. Further, there is no single reliable directory or source of information regarding off-label use of FDA-approved drugs. Therefore, consideration of off-label use would be based on the evidence available for a given selected drug. Should a Primary Manufacturer of a selected drug decide to submit information about off-label use of the selected drug through this process, the Primary Manufacturer should indicate in their submission if the referenced off-label use meets the definition of off-label use as proposed in § 429.20.

Consistent with the policies for implementation provided in section 130.3.1 of the Negotiation Program Guidance, we proposed at § 429.615(a) to provide each Primary Manufacturer of a selected drug the opportunity to submit information on new indications, including new off-label use, and new or updated information on the factors listed in section 1194(e) of the Act to inform renegotiation eligibility (as described in proposed § 429.605(c) and (d)) and selection (as described in proposed § 429.610(b)). We intend to collect this information through the Drug Selection ICR (CMS–10844, OMB 0938–1443) which would include revisions to collect such information to inform renegotiation eligibility and selection. We would deem this voluntary submission to be proprietary information from the Primary Manufacturer that is protected from disclosure in accordance with the confidentiality policies described in section II.D.1. of this final rule and in proposed § 429.300.

b. Data Collection From Primary Manufacturers and Other Interested Parties for Renegotiation of the MFP

In accordance with a Primary Manufacturer's responsibility under section 1193(a)(5) of the Act and under the Negotiation Program Agreement (set forth in proposed § 429.200(b)) and consistent with the policies for implementation provided in section 130.3.2 of Negotiation Program Guidance, we solicited comment on these proposed policies for data collection in the context of renegotiation of the MFP, including whether it may be preferable to more expressly establish CMS' intent to align with data collection in the context of the original negotiation process by replacing the text in proposed § 429.615(b) with text that parallels that used in § 429.505(a).

Specifically, we proposed at § 429.615(b)(1)(i) that the Primary Manufacturer of a drug selected for renegotiation would be required to submit information regarding the section 1194(e)(1) factors for the selected drug to CMS, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, as occurs following selection for negotiation. We also proposed at § 429.615(b)(1)(ii) that if the drug selected for renegotiation was originally selected for negotiation for initial price applicability year 2026 or 2027 and has not previously been selected for renegotiation for initial price applicability year 2028 or thereafter, the Primary Manufacturer would be required to submit, if available, non-FAMP, unit type, and total unit volume for all NDC–11s of the selected drug payable under Part B, not covered under Part D, and for which the Primary Manufacturer did not report such information with the Primary Manufacturer's data submission for the initial price applicability year for which the selected drug was first selected for negotiation, for the same calendar years for which non-FAMP data was reported in the Primary Manufacturer's data submission for the initial price applicability year for which the selected drug was first selected for negotiation. Such data, if applicable, will be used to update the non-FAMP used in the renegotiation ceiling calculation described at proposed § 429.620(b) and further discussed in section II.G.5.a. of this final rule. The submission of information described at proposed § 429.615(b)(1) would be due at the same time the submission described at § 429.505(a) is due for drugs selected for negotiation for the same initial price applicability year, that is by 11:59 p.m. PST on March 1 of the year of the selected drug publication date for the initial price applicability year for which the drug was selected for negotiation or renegotiation, as applicable. This information would be submitted through the Drug Price Negotiation ICR (CMS–10849, OMB 0938–1452).

Similar to the proposal in § 429.505(c) and discussed in section III.F.2. of the proposed rule, we proposed at § 429.615(b)(2) that, in accordance with a Primary Manufacturer's responsibility under section 1193(a)(5) of the Act and under the Negotiation Program Agreement (set forth in proposed § 429.200(b)), a Primary Manufacturer has an ongoing obligation to report any updates to the information provided in proposed § 429.615(b)(1) if the Primary Manufacturer becomes aware that any of such information has changed or is otherwise inaccurate. CMS will provide the Primary Manufacturer with a method to report any updates to the information provided in proposed § 429.615(b)(1). For example, under proposed § 429.505(c), Primary Manufacturers must submit updates to the Primary Manufacturer's data submitted under proposed § 429.615(b)(2) if the data was restated due to requirements of the Federal government entity that initially receives

and oversees processing of such data. For example, under the Medicaid program, manufacturers must report revisions to best price under § 447.510. The Primary Manufacturer must timely notify CMS if any such updates are applicable to the selected drug. This ongoing obligation to update the Primary Manufacturer's original data submissions is separate both from any voluntary submission of data from a Primary Manufacturer of a selected drug to inform renegotiation eligibility and selection (described at proposed § 429.615(a) and section II.G.4. of this final rule) and the required submission of data related to section 1194(e)(1) factors to CMS for drugs selected for negotiation (described at proposed § 429.505(b) and section II.F.2. of this final rule), which cover different reporting periods. As discussed further in section II.G.4.a. of this final rule, we may consider the Primary Manufacturer's prior data submission(s) under proposed § 429.505(b), including any updates to such information, to inform renegotiation eligibility and selection, and may use such information during renegotiation if a drug is selected for renegotiation.

We also proposed at § 429.615(b)(3) to provide any interested party with the opportunity to submit information related to section 1194(e)(2) factors, as occurs for negotiation. We proposed at § 429.615(b) that the submission of section 1194(e)(2) information would be due at the same time such information is due for drugs selected for negotiation for the same initial price applicability year, that is 11:59 p.m. PST on March 1 of the year of the selected drug publication date for the initial price applicability year for which the drug is selected for renegotiation. We intend to collect this information through the Drug Price Negotiation ICR (CMS–10849, OMB 0938–1452) which will include revisions to collect the optional information regarding the section 1194(e)(2) factors (set forth in proposed in § 429.505(d)(3)) to inform renegotiation of selected drugs). To minimize burden on Primary Manufacturers, we proposed that this information collection be a streamlined version of that used for negotiation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters requested that we streamline the Drug Negotiation Process ICR for drugs selected for renegotiation to reduce manufacturer burden. A few of these commenters suggested that a full submission of information related to the section 1194(e) factors is not necessary for drugs selected for renegotiation and, instead, the Primary Manufacturer should be able to limit its submission to include only information that has changed since the last negotiation or renegotiation and allow the Primary Manufacturer to attest that the information previously submitted is still up to date. A commenter suggested that the Primary Manufacturer only be required to submit information on the section 1194(e) factors for drugs selected for renegotiation if the information was not previously submitted or is not otherwise accessible to CMS. A commenter recommended that CMS only require resubmission of information related to the factors listed at section 1194(e) of the Act if the information provided to CMS was inaccurate at the time of submission.

Response: We appreciate these commenters' suggestions and, as noted previously, we appreciate and continue to consider efforts to minimize manufacturer reporting burden within the Negotiation Program. We note that for both negotiation and renegotiation, information submission related to section 1194(e)(2) factors remains optional for all interested parties, including the Primary Manufacturer. CMS considers the 1194(e)(1) factors for renegotiation pursuant to section 1194(f)(4)(B) of the Act, which directs CMS to adopt a process for renegotiation that is to the extent practicable consistent with the process established for negotiation. We interpret section 1194(e)(1) of the Act as requiring information related to section 1194(e)(1) factors to be submitted by the Primary Manufacturer of a selected drug to CMS for consideration in the negotiation and renegotiation process. We also note that any selected drug with an MFP is considered for renegotiation eligibility under section 1194(f)(2) of the Act and the time between selection for negotiation and renegotiation, if applicable, or renegotiation and a subsequent renegotiation, if applicable, may vary significantly by drug. That is, it may be a relatively short period of time before a drug is selected for renegotiation or it may be multiple years, if ever. We believe that it is important for the same information to be submitted for the section 1194(e)(1) factors for every drug selected for negotiation and renegotiation, if applicable, in a given initial price applicability year. This helps ensure the application of a consistent process and methodology as required by section 1194(b)(1) of the Act. We continue to encourage feedback on ways to streamline reporting requirements for the Negotiation Program, including for renegotiation.

Final Decision: After consideration of public comments, we are finalizing § 429.615 as proposed with modification for clarity. At § 429.615(b), we are adding ''information as specified in (b)(1) and (b)(3) of this section must be submitted to CMS,'' to clarify that this data collection is for the factors listed at section 1194(e) of the Act for use in the renegotiation process. We also are adding text to section II.G.4.b.of this final rule to provide information on the data update requirement listed at § 429.615(b)(2). In addition, we are deleting ''and (B)'' at § 429.615(b)(1)(ii)(B) as it was included in error.

5. Renegotiation Process (§ 429.620)

In accordance with section 1194(f)(4)(B) of the Act, we intend, to the extent practicable, for the renegotiation process to be consistent with the methodology and process established under section 1194(b) of the Act. We proposed to implement policies consistent with the policies for implementation set forth in section 130.4 of the Negotiation Program Guidance, with revisions discussed later in this section based on implementation experience.

a. Determining the Ceiling

Section 1194(f)(4)(B) of the Act requires that the process specified for renegotiation must, to the extent practicable, be consistent with the methodology and process established under section 1194(b) of the Act and in accordance with sections 1194(c), (d), and (e) of the Act. Section 1194(f)(4)(B) of the Act further provides that for purposes of applying sections 1194(c)(1)(A) and 1194(d) of the Act, the reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the MFP established pursuant to such renegotiation applies, including for applying section 1194(c)(3)(B) of the Act in the case of renegotiation-eligible drugs described in section 1194(c)(3)(A) of the Act and section 1194(c)(3)(C) of the Act in the case of renegotiation-eligible drugs described in section 1194(c)(3)(B) of the Act.

Consistent with section 1194(b)(2)(F)(i) of the Act, in renegotiating the MFP of a selected drug, we proposed at § 429.620(b) that CMS would not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling determined under

section 1194(c) of the Act, as adjusted, if applicable, as described in this section II.G.5.a. of this final rule. Additionally, consistent with the policies for implementation set forth in section 130.4.1 of the Negotiation Program Guidance, we proposed at § 429.620(a) to use the same methodology to calculate the ceiling amounts under section 1194(c) of the Act for renegotiation as is used for negotiation (described in proposed § 429.410) with limited revisions to reflect the updates required by statute.

For the purposes of calculating the ceiling amount under section 1194(c) of the Act, we interpret section 1194(f)(4)(B) of the Act as permitting limited updates to the ceiling applied during negotiation when a drug is first selected. We interpret section 1194(f)(4)(B) of the Act as directing CMS to update the applicable percents applied to selected drugs determined to be renegotiation-eligible due to a change in monopoly status under sections 1194(f)(3)(A) and 1194(f)(3)(C) of the Act, in accordance with the applicable percent for such monopoly statuses described in sections 1194(c)(3)(B) and 1194(c)(3)(C) of the Act. In contrast, section 1194(f)(4)(B) of the Act does not specify that the agency should otherwise recalculate the ceiling amounts described under sections 1194(c)(1)(B) and 1194(c)(1)(C) of the Act, including any redeterminations of the time periods used to calculate such amounts. We interpret the absence of such language in statute, in the context of the more specific instructions to update the applicable percents applied with respect to certain renegotiation-eligible drugs, to provide that CMS largely may not recalculate the ceiling amounts determined with respect to the negotiation for which the drug was first selected. We believe that a contrary interpretation, under which we recalculate the ceiling amounts described under sections 1194(c)(1)(B) and 1194(c)(1)(C) of the Act using the most recent data available with respect to the initial price applicability year for which a drug is selected for renegotiation, would likely result in a renegotiation ceiling that, over time, exclusively decreases. Such an interpretation would effectively preclude the possibility of renegotiating a higher MFP for the selected drug, and such a limitation is not set forth in the statute, including in the criteria for renegotiation selection described under section 1194(f)(3)(C) of the Act. We do not believe such an interpretation is the best reading of the statutory text set forth in section 1194(f) of the Act.

In accordance with this interpretation, and consistent with the policies for implementation set forth in section 130.4.1 of the Negotiation Program Guidance, we proposed to determine the ceiling applicable to renegotiation using the ceiling amounts determined with respect to the negotiation for which a drug is first selected, with limited updates discussed later in this section, including to account for the statutory directive to update the applicable percent for certain renegotiation-eligible drugs.

We proposed at § 429.620(b)(1) to update the ceiling amounts under section 1194(c) of the Act to incorporate NDC–11s that are payable under Part B if a drug that was originally selected for initial price applicability year 2026 or 2027 is selected for renegotiation and has such NDC–11s. In accordance with section 1192(d)(1) of the Act, initial price applicability years 2026 and 2027 were the only years in which CMS was directed to limit drug selection to drugs covered under Part D and as such, the ceiling amount under section 1194(c) of the Act did not include NDC–11s payable under Part B, if any, since such NDCs were not considered negotiation-eligible at that time. This approach would address the fact that the Negotiation Program is no longer limited to drugs covered under Part D. Because renegotiation under this final rule applies to initial price applicability year 2029 and beyond, any NDC–11s of a selected drug that are on the HCPCS–NDC crosswalks would be included in the negotiation process, including for renegotiation, and thus any such NDC–11s should be incorporated into the ceiling used for such renegotiation. Not doing so would mean applying a ceiling amount under section 1194(c) of the Act that is based only on NDC–11s covered under Part D of the selected drug, despite the renegotiation process and the MFP that may result from such renegotiation applying to all NDC–11s covered under Part D and/or payable under Part B.

We proposed at § 429.620(b)(2) to update the applicable percent under section 1194(c)(3)(C) of the Act for purposes of calculating the non-FAMP ceiling under section 1194(c)(1)(C) of the Act for drugs selected for renegotiation due to a change in monopoly status. Consistent with § 429.435(a)(4)(vi), the applicable percent would be based on the initial approval date associated with the earliest-approved FDA application belonging to the NDA holder or BLA holder, as described in section II.B.6. of this final rule, for the selected drug and the initial price applicability year for which the drug is selected for renegotiation.

Finally, for all drugs selected for renegotiation, we proposed at § 429.620(b)(3) to adjust the amounts considered for the ceiling described under section 1194(c) of the Act and proposed at § 429.410 by the percent increase in the CPI–U from July of the calendar year that is 2 years prior to the initial price applicability year of the most recent agreed upon MFP through July of the calendar year prior to the calendar year in which the drug is selected for renegotiation. This approach is consistent with sections 1194(f)(4) and 1195(b)(1)(A) of the Act and proposed § 429.705 under which we would publish an updated MFP increased by the annual percentage increase in the CPI–U. That is, for each year subsequent to the first initial price applicability year of the price applicability period for the selected drug with an agreed-upon MFP, the annual percentage increase in the CPI–U would be based on the 12-month period ending with the July immediately preceding November 30 of the year that is 2 years prior to such subsequent year. For example, if a drug was selected for negotiation for initial price applicability year 2026, CMS and the Primary Manufacturer agreed upon an MFP, and the drug was selected for renegotiation for initial price applicability year 2029, we would increase the amounts considered for the ceiling that were applicable to the initial price applicability year 2026 negotiation (incorporating any Part B data as applicable) by the increase in CPI–U from July 2024 through July 2026. This increase represents the cumulative inflation adjustment that we would have applied to the initial price applicability year 2026 MFP through the most recent published MFP files at the time that the drug is selected for renegotiation (which would be the files for MFPs effective January 1, 2029, published in November 2026). If we did not similarly increase the amounts considered for the ceiling by the same inflation adjustment that we apply to the MFP under section 1195(b)(1)(A) of the Act, the inflation-adjusted MFP could, over time, approach and eventually exceed the original ceiling amount. This could preclude our ability to select a drug for renegotiation and renegotiate the MFP for such drug that may otherwise be renegotiation-eligible and selected in accordance with sections 1194(f)(2) and 1194(f)(3) of the Act and under the criteria proposed in §§ 429.605 and 429.610, respectively. This potential limitation on CMS' ability to renegotiate

increased MFPs would be inconsistent with section 1194(f)(3)(C) of the Act, which does not limit selection for renegotiation to instances exclusively in which renegotiation would likely result in a decrease in the MFP and thus contemplates that renegotiation may be appropriate where we expect renegotiation would be likely to result in an increased MFP.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.620(a) through (b) as proposed, but with a technical modification to add the word ''and'' between § 429.620(b)(1)(i) and (ii) to clarify that both steps will be performed.

b. Negotiation Factors

Section 1194(f)(4)(B) of the Act requires that the renegotiation process shall be consistent with the methodology and process for negotiation, to the extent practicable. As such, we proposed at § 429.620(c) to consider the negotiation factors listed at sections 1194(e)(1) and (e)(2) of the Act inclusive of information submitted or shared about the factors listed at sections 1194(e)(1) and (e)(2) of the Act in any prior negotiation or renegotiation(s) as described in proposed § 429.505 and discussed in II.F.2. of this final rule consistent with the policies for implementation at section 130.4.2 of Negotiation Program Guidance.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.620(c) as proposed.

c. Methodology for Developing an Initial Offer

Consistent with policies for implementation as described in section 130.4.2 of Negotiation Program Guidance, we proposed at § 429.620(d) that the methodology for developing the initial offer for all drugs selected for renegotiation be the same process and timeline set forth for development of the initial offer for the negotiation process under proposed § 429.510. This would apply the process described in proposed § 429.510 including the review of information related to the section 1194(e)(1) and 1194(e)(2) factors described in proposed § 429.505. By uniformly adopting the initial offer process described in proposed § 429.510 for the purpose of the development of all initial offers in the context of renegotiation this aspect of renegotiation process would be fully aligned with the negotiation process consistent with the requirement at section 1194(f)(4)(B) of the Act. We note that we would apply the ceiling calculated for renegotiation per proposed § 429.615(b) when adopting the process described in proposed § 429.510 where applicable. As part of this proposed policy, we intend to require the Primary Manufacturer to submit the most recent agreed upon MFP as part of the data submission requirement described in proposed § 429.615(b)(1) through the Drug Price Negotiation ICR (OMB 0938–1452) discussed in section II.G.4.b. of this final rule. We believe that considering the MFP during the development of the initial offer would better allow us to incorporate the impact of the offer and counteroffer process from the prior negotiation or renegotiation into the initial offer for the current renegotiation.

Submission of the MFP would be a new collection requirement within the existing data submission. All drugs selected for renegotiation will have an agreed upon MFP and adding collection of the MFP as a data point in this submission requirement would be standard for all such selected drugs. We believe the MFP is an important data point to consider as part of our consideration of ''market data and revenue and sales volume data for the drug in the United States'' (the factor listed at section 1194(e)(1)(E) of the Act) as it is a Medicare-specific price that, per section 1193(a) of the Act, Primary Manufacturers are required to make available to MFP-eligible individuals (as defined at section 1191(c)(2) of the Act). We also believe that considering the MFP under the factor listed at section 1194(e)(1)(E) of the Act and therefore as a part of the totality of data submitted related to section 1194(e)(1) factors is consistent with the process used to develop the initial offer for negotiation as described at proposed § 429.510, and more specifically the adjustment described at proposed § 429.510(f). By collecting the MFP as part of the data submission requirement described at proposed § 429.615(b)(1), we may then consider the MFP as a component of the factor listed at section 1194(e)(1)(E) of the Act and the adjustment to the preliminary price described at proposed § 429.510(f)(2). We note that while the MFP is a publicly available price updated regularly by CMS, section 1194(e)(1) of the Act requires information related to the section 1194(e)(1) factors to be submitted by the Primary Manufacturer for consideration in offer development and during consideration of counteroffers, if applicable (as discussed in section II.F.2.a. of this final rule). Thus, collecting the MFP through the Drug Price Negotiation ICR (OMB 0938–1452) would allow us to consider the MFP within the context of the section 1194(e)(1) adjustment as discussed in proposed § 429.510(f)(2).

As an alternative to the proposal at § 429.620(d), we considered applying the policy set forth in the Negotiation Program Guidance. In this option we would not include the MFP as a component of the factor listed at section 1194(e)(1)(E) of the Act and therefore the MFP would not be considered within the section 1194(e)(1) adjustment described at § 429.510(f). With this alternative, we would also not collect the MFP through the Drug Price Negotiation ICR as the data would not be required for offer development or counteroffer consideration. We did not propose this option as we believe that the MFP is an important data point to consider within the context of renegotiation, as discussed previously.

As another alternative, we considered applying a third and separate adjustment based on the prior agreed upon MFP after the adjustment based on the section 1194(e)(1) factors is applied to the preliminary price as described at proposed § 429.510(f)(2). We believe this alternative would also be consistent with the methodology and process for the negotiation process to the extent practicable, but which would incorporate additional adjustments for the renegotiation context to afford distinct weight to the prior negotiation. In this approach, the MFP would be collected through the data submission requirement described at proposed § 429.615(b)(1) but considered separately from other information collected related to the section 1194(e)(1) factors. For example, for drugs selected for negotiation for initial price applicability year 2028, the Primary Manufacturer and CMS may have conducted up to three negotiation meetings following CMS' provision of the initial offer. During those meetings, the Primary Manufacturer may have, for example, presented additional evidence or otherwise raised a point not previously considered that contributes to our determination to accept a counteroffer or provide a subsequent offer that is different than the initial offer. If we were to follow the initial offer development process as described in proposed § 429.510 without considering the information that may have been exchanged over the course of the negotiation (or prior renegotiation, if applicable), then there may be circumstances where the initial offer is similar to the initial offer from the previous negotiation or renegotiation, and does not account for the additional

discussions and information that contributed to the agreed upon MFP. By adjusting the amount determined after the section 1194(e)(1) adjustment described at proposed § 429.510(f)(2) by the MFP, we would be able to consider such negotiation meeting discussions and provide an initial offer that is informed by the prior negotiation or renegotiation process. We acknowledge that this approach would consider the MFP separately from the other section 1194(e)(1) factors. However, we believe this alternative approach would be consistent with the negotiation process to the extent practicable per sections 1194(f)(4)(B) and 1194(b)(1) of the Act as the initial offer development process would otherwise remain the same except for the single MFP adjustment.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested that CMS should state that the prior agreed-upon MFP is one factor among section 1194(e)(1) factors and would not be weighted more than other such factors. The commenter also requested that CMS not use the prior MFP as the starting point for developing the initial offer as this could result in a situation where renegotiation offer development starts from a starting point based on the preceding negotiation or renegotiation cycle while the ceiling does not reset.

Response: We appreciate this commenter's feedback on the proposals to consider a previously agreed-upon MFP for the selected drug as part of the factor listed at section 1194(e)(1)(E) of the Act and the alternative proposal to consider the agreed-upon MFP as a separate adjustment. As we stated in section II.G.5.c. of the proposed rule (91 FR 36308), we believe that the MFP is an important data point to consider within the context of renegotiation. We also stated that we believe that considering the MFP under the factor listed at section 1194(e)(1)(E) of the Act and therefore as a part of the totality of data submitted related to section 1194(e)(1) factors is consistent with the process used to develop the initial offer for negotiation as proposed at § 429.510, and more specifically the adjustment as proposed at § 429.510(f). By considering the previously agreed-upon MFP as part of the adjustment for section 1194(e) factors, the MFP would be one data element considered among many within the various section 1194(e) factors. We also clarify that consideration of the MFP for the selected drug that is being renegotiated is different from the consideration of MFPs for a therapeutic alternative(s), if any, of the selected drug for the purpose of determining a starting point for the initial offer. As described at § 429.620(d), we will adopt the process for developing the initial offer as described at § 429.510. In this process, we consider the cost of therapeutic alternatives, if any, as the starting point, not the MFP of the selected drug itself.

Comment: A commenter supported the use of the same framework for developing the initial offer for renegotiation as is used for negotiation. A couple of commenters recommended CMS create a transparent, predictable, and clear standard for the renegotiation framework.

Response: We thank this commenter for their support of the proposal to adopt the negotiation process for drugs selected for renegotiation. Regarding the framework used for the renegotiation process, we proposed at § 429.620(d) that the methodology for developing the initial offer for all drugs selected for renegotiation be the same process and timeline set forth for development of the initial offer for the negotiation process proposed at § 429.510. As stated in similar comment responses in section II.F.3. of this final rule, we believe the process proposed at § 429.510 and adopted for renegotiation as proposed at § 429.620(d) appropriately balances transparency and confidentiality in the negotiation and renegotiation processes and we decline to revise these policies. We refer commenters to similar comments and responses under section II.F.3. of this final rule for more information.

Comment: A commenter suggested that CMS should recognize off-label use, particularly in oncology, consistent with Medicare coverage policy when considering clinical evidence during renegotiation. A commenter proposed that CMS should create a renegotiation pathway wherein if a drug is selected for renegotiation due to a new indication that addresses an unmet medical need or other ''significant'' need, CMS would increase the renegotiated MFP for such drug.

Response: We appreciate the feedback provided by these commenters on the evidence considered and weighting of the factors listed at section 1194(e) of the Act for the purpose of developing the initial offer. We believe that the definition of off-label use proposed at § 429.20 is aligned with Medicare coverage policy as off-label use must be included in evidence-based clinical practice guidelines and is a medically accepted indication payable under Part B or covered under Part D or both, taking into consideration major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination thereof.

Regarding the suggestion to increase the MFP for drugs selected for renegotiation due to a new indication that addresses an unmet medical need or other ''significant'' need, we agree that, subject to the ceiling, a drug that meets a previously unmet medical need or other ''significant'' need for patients could be renegotiated and that renegotiation could result in an increase to the previous MFP. However, the outcome of any renegotiation, including offers and consideration of counteroffers, will be subject to consideration of the evidence related to the factors listed at section 1194(e) of the Act, which include but are not limited to unmet medical needs and other clinical factors as part of the adjustment of section 1194(e)(2) factors described at § 429.510(e).

Comment: One commenter stated that CMS should provide a clear explanation as to how data are weighted in the renegotiation process and stated that they believe a lack of transparency limits the ability of a Primary Manufacturer to prepare for renegotiation.

Response: We refer this commenter to our response to similar comments in section II.F.3. of this final rule.

Final Decision: After consideration of public comments, we are finalizing § 429.620(d) as proposed.

d. Engagement With Primary Manufacturers and Interested Parties

We proposed at § 429.620(e) through (l) that the renegotiation process would conform to the same procedures, structure, and timeline set forth for the negotiation process to the extent practicable. We note that we would apply the ceiling calculated for renegotiation per proposed § 429.620(b) when adopting these processes where applicable. We may incorporate drugs selected for renegotiation into the public engagement events for drugs selected for negotiation or host separate events specifically for drugs selected for renegotiation, as described in § 429.620(e).

If the Primary Manufacturer is delayed in meeting one or more deadlines in proposed §§ 429.525 through 429.535, such as submitting the renegotiation written counteroffer, we would continue to engage in the renegotiation process and would complete the established process as described in section II.C.6. of this final rule and as proposed subpart F. In the circumstance that CMS and the Primary Manufacturer do not agree to an MFP by the deadline set forth in proposed

§ 429.535, we refer to the discussion and proposal in subpart K, as described in section II.C.7. of this final rule. Additionally, if the failure to meet a deadline results in the failure of CMS and the Primary Manufacturer to reach an MFP following renegotiation, this may result in certain sales of the selected drug being subject to a potential excise tax (see 26 U.S.C. 5000D(b)(3)).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple commenters supported incorporating public engagement events as part of the renegotiation process. One of these commenters recommended the public engagement events for a drug selected for renegotiation focus on the factors that contributed to the drug being selected for renegotiation.

Response: We appreciate commenters' support and recommendations to improve the public engagement events for renegotiation. As stated in the Negotiation Program proposed rule, the public engagement events allow us to hear from patients and other stakeholders—directly and in their own words—about patient's personal experiences and perspectives on their condition(s) and about the drug(s) used to treat those conditions. We do not believe narrowing the scope of the information shared during the public engagement events for drugs selected for renegotiation supports CMS' holistic approach to renegotiation.

Final Decision: After consideration of public comments, we are finalizing § 429.620(e) through (j) and (l) as proposed.

e. Publication of the MFP

For a selected drug for which CMS and a Primary Manufacturer agree upon an MFP through the renegotiation process, we proposed at § 429.620(k) to publish and update the renegotiated MFP and related information as proposed in § 429.705 and as described in section II.H.2. of this final rule.

We do not intend to include redacted information from any voluntary information submitted by a Primary Manufacturer in response to the Drug Selection ICR in the MFP explanation if the selected drug of the Primary Manufacturer is selected for renegotiation and there is an agreement upon a renegotiated MFP. If the selected drug is then selected for renegotiation and the Primary Manufacturer submits the same information the Primary Manufacturer provided in response to the Drug Selection ICR also provided in response to the Drug Price Negotiation ICR, as described in section II.G.4. of this final rule and in proposed § 429.615, we may redact and include information provided in response to the Drug Price Negotiation ICR in the MFP explanation of a renegotiated MFP as described in section II.H.2. of this final rule and § 429.705(b) and in accordance with section II.H.2. of this final rule and proposed § 429.705(c) and the confidentiality policy described in section II.D.1. of this final rule and in proposed § 429.300.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter recommended CMS share specific information in the MFP explanation for drugs selected for renegotiation, such as the new changes and evidence considered since the prior negotiation and how these factors influenced the new MFP.

Response: We thank this commenter for their suggestions to include specific information in the MFP explanations. Consistent with our response to similar comments in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, the MFP explanation, as described at § 429.705, will include a narrative explanation of the MFP, redacted information regarding the negotiation meetings, as applicable, including exchanges of offers and counteroffers, as applicable, and the redacted information submitted by a Primary Manufacturer, as described at § 429.505(b)(2) or § 429.615(b)(1), as applicable, and the redacted information submitted by interested parties, as described at § 429.505(d)(3) or § 429.615(b)(3), as applicable, and in alignment with the confidentiality policy described at § 429.300.

Final Decision: After consideration of public comments, we are finalizing § 429.620(k) as proposed.

H. Implementation of the MFP (§§ 429.700 Through 429.710)

1. Application of the MFP Across Dosage Forms and Strengths (§ 429.700)

Section 1196(a)(2) of the Act states an administrative duty in which we must establish procedures to compute and apply the MFP across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 60.5 of the Negotiation Program Guidance with respect to initial price applicability year 2028. We proposed at § 429.700 to codify the administrative duty requirement and that once the MFP has been agreed upon for a selected drug, we would compute and apply the MFP across different dosage forms and strengths of a selected drug. We proposed at § 429.700 the methodology that we would use to apply the single agreed-upon MFP (which, as proposed at § 429.415 and section II.E.4. of this final rule, would be an average price per 30-day equivalent supply for the selected drug across all formulations of the selected drug) across NDC–9s and HCPCS codes, as applicable, and calculate an MFP-per-billing unit price for each billing unit and payment code associated with the selected drug, as applicable, as contemplated under section 1196(a)(2) of the Act and described at § 429.700(b)(4). CMS proposed to use a methodology that scales the MFP per unit and the MFP per billing unit based on price differentials across different dosage forms and strengths of the selected drug to ensure that the MFP is made available to MFP-eligible individuals at the point of sale (and to dispensing entities and Part B providers), we would publish the MFP per NCPDP unit (for example, tablet) for each NDC–9 and per billing unit for each HCPCS code, as applicable, associated with the selected drug based on the list of NDCs and HCPCS codes determined as described at § 429.100(c). We advise supply chain entities to use the NDC–9 MFP per unit price when effectuating the MFP for a selected drug with a formulation covered under Part D to ensure accuracy (for example, in the event of partial package dispense).

As proposed at § 429.700(b), we describe the proposed procedures to compute and apply the MFP across dosage forms and strengths of the selected drug using the WAC of the selected drug as reported by Primary Manufacturer in the CMS HPMS (as described in proposed § 429.20). This proposed process would apply the MFP to any NDCs of the selected drug, to include NDCs of a self-administered drug, assigned to the Primary Manufacturer and/or Secondary Manufacturer(s) where such NDCs do not represent sample packages and where the Primary Manufacturer reported a non-zero WAC for at least one calendar quarter of the calendar year 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation. (The proposed process for

applying the MFP to NDCs of the selected drug with insufficient data is set forth in proposed § 429.700(c) as described later in this section.) For NDCs of selected drugs covered under Part D, we would use PDE records from the calendar year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation where the PDE record is associated with a prescription filled between January 1st of that year and December 31st of that year, and meets the inclusion criteria proposed at § 429.120(a)(2) through (a)(5) (as discussed in section II.B.5.a. of this final rule). With respect to NDCs of selected drugs payable under Part B, we would use OM Part B claims data and/or MA encounter data for Part B items and services from the calendar year 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation where the claim and/or record is associated with a service date between January 1st of that year and December 31st of that year, and meets the inclusion criteria proposed at § 429.120(b)(1)(ii) through (b)(1)(vi) (as discussed in section II.B.5.b. of this final rule). We proposed to use the calendar year 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation for purposes of the calculations set forth in § 429.700(b) because it will be the most recent period of data available.

We proposed at § 429.700(b)(1)(i), for each NDC–11 and calendar quarter, to calculate the quarterly WAC per unit by dividing the WAC quarterly units by the total WAC annual units (from the manufacturer-submitted data) and multiply this quotient by the quarterly WAC per unit. At § 429.700(b)(1), we proposed to use the WAC unit cost for the period beginning on January 1 and ending December 31 for the year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation. We proposed at § 429.700(b)(1)(ii), for each NDC–11, to sum the results determined under § 429.700(b)(1)(i) and to calculate the annual WAC per-unit cost for each of the NDC–11s for the selected drug (including NDC–11s payable under Part B, which are assigned to HCPCS codes in NDC–HCPCS code crosswalk files published by CMS, as well as NDC–11s covered under Part D) from the manufacturer-submitted quarterly WAC per unit and unit volume data to account for potential variation in unit volume across quarters.

We proposed at § 429.700(b)(2) to convert the annual WAC per unit for each NDC–11 into an amount for a 30-day equivalent supply (using the methodology described § 423.104(d)(2)(iv)(A)(2) for Part D and at § 429.415(a)(2)(v) for Part B), so that the WAC will be comparable to the negotiated single MFP. We proposed in § 429.700(b)(2)(i) to determine total units for the purpose of this calculation as the sum of the total quantity dispensed for NDC–11s present only in PDE data and the NDC–11 NCPDP unit equivalent conversion of the total Part B billing units administered for NDC–11s associated with HCPCS codes present in Part B data.

We proposed at § 429.700(b)(3)(i) through (b)(3)(v), to then aggregate the WAC per 30-day equivalent supply for each NDC–11 into a WAC per 30-day supply for each NDC–9 of the selected drug. The WAC per 30-day equivalent supply for each NDC–9 would then be used to calculate a WAC price ratio for each NDC–9 of the selected drug as proposed in § 429.700(b)(3)(vi). The WAC price ratio derived from the WAC per 30-day equivalent supply for each NDC–9 would then be multiplied by the single MFP for the selected drug to calculate the MFP for a 30-day equivalent supply of each NDC–9 of the selected drug as proposed in § 429.700(b)(4)(A).

Lastly, we proposed at § 429.700(b)(4)(i)(B), we would convert from an MFP for a 30-day equivalent supply to an MFP per NCPDP unit based on the average number of NCPDP units in a 30-day equivalent supply to determine the per NCPDP unit MFP for an NDC–9. We proposed at § 429.700(b)(4)(ii), that for selected drugs payable under Part B, we would further convert the MFP per NCPDP unit of each NDC–9 into an MFP per billing unit by converting the per-NCPDP unit amount into an amount per billing unit as necessary to account for any differences in the NDC–9 unit versus the billing unit. This conversion would require us to convert the NDC–9 MFP per NCPDP unit to an NDC–11 MFP per package (by multiplying the NDC–9 MFP per NCPDP unit by the NDC–11 NCPDP package quantity), and then divide this product by the HCPCS billing units per NDC–11 package to arrive at an NDC–11 MFP per billing unit. We would then take an average of the NDC–11 MFP per billing unit across all NDC–11s associated with a HCPCS code for the selected drug, weighted by the ASP units reported by manufacturers for each NDC–11 under section 1847A of the Act.

We would include the MFP per billing unit, calculated at § 429.700(b)(4)(ii)(E), and the MFP per NCPDP unit price for each NDC–9 of the selected drug, calculated at § 429.700(b)(4)(i)(B) in the publication of MFPs as proposed in § 429.705. We recognize there may be other ways to apply the MFP to dosage forms and strengths and intend to monitor this policy. We proposed to codify the approach taken in policies for implementation as described in section 60.5 of Negotiation Program Guidance to list in the public pricing file only the NDC–9 MFP-per-unit price (rounded to 6 decimals) rather than also including the NDC–11 MFP-per-package price. The NDC–11 MFP-per-package price was removed due to the potential for confusion arising from differences between the NDC–11 MFP-per-package price as published by CMS (calculated without rounding any values in interim steps) and the NDC–11 MFP-per-package price that would result if another entity were to take the product of the published NDC–9 MFP-per-unit price (rounded to 6 decimals) and the package size. The application of the MFP is not inclusive of NDCs of the selected drug that are not manufactured, marketed, controlled, or sold by the Primary Manufacturer or a Secondary Manufacturer, or NDC–11s to which the MFP would not apply, such as sample packages, inner packages, and discontinued products.

Consistent with policies for implementation as described in section 60.5.1 of Negotiation Program Guidance, we proposed at § 429.700(c), the process by which we would apply the MFP to NDCs associated with new NDAs/BLAs, NDCs, or HCPCS codes, including those added during the negotiation period or after agreeing upon an MFP, and to NDCs and HCPCS codes with insufficient PDE, Part B data, or WAC data in calendar year 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation to apply the MFP across those dosage forms and strengths. We proposed at § 429.700(c)(1), the process for how we would apply the MFP to NDCs associated with new NDAs or BLAs and we proposed at § 429.700(c)(2), the process for how we would apply the MFP to NDCs associated with HCPCS codes of new NDAs or BLAs. We proposed at § 429.700(c)(3), the process for how we would apply the MFP to NDCs and HCPCS codes with insufficient data, which would be considered if there was no data available to calculate a sum of the plan-specific enrollment weighted amount in the applicable calendar year, no payment amount under section 1847A(b)(4) of the Act, and no average

non-FAMP data (when it has not yet been a full year following the market entry for such drug) are determined to have insufficient data. As proposed at § 429.700(c)(4)(i), we would determine whether there is an existing NDC that is comparable to the new NDC and has sufficient data for the MFP application calculations proposed § 429.700(b). We would base our review of a comparable NDC using the FDA-approved labeling of the selected drug and other relevant sources. We would evaluate whether an existing NDC is comparable to a new NDC if it shares the same NDC–9, has a different NDC–9 but has the same dosage form and strength, has a different NDC–9 but has a similar dosage form and strength, or has the same active moiety/active ingredient. We proposed at § 429.700(c)(3)(i)(A) and (B), respectively, the process that we would use if an existing, comparable NDC exists and the process if a comparable NDC does not exist.

We proposed at § 429.700(c)(3)(ii), the process for which we would adjust the MFP application. Specifically, for the NDCs and HCPCS codes described in § 429.700(c)(3)(ii), we would monitor total quantity dispensed or administered and 30-day equivalent supply from PDE data and Part B data over time, beginning when these NDCs and/or HCPCS codes are first added to our computation of how we will apply a single MFP across dosage forms and strengths of the selected drug. We would update the total quantity dispensed and 30-day equivalent supply values and recompute the application of the single MFP across dosage forms and strengths for these NDCs and/or HCPCS codes (but only for such NDCs and/or HCPCS codes, not for all NDCs and/or HCPCS codes of the selected drug) based on which of the following situations occurs first: (1) a year has elapsed since the NDCs first appeared in PDE records or the HCPCS codes associated with the NDCs appeared in Part B data; or (2) the NDC or HCPCS code has accrued the same number of units dispensed/administered as the NDC–11 that had the fewest units dispensed/administered at the time that the WAC ratios were originally calculated. We included a third condition in section 60.5.1 of the Negotiation Program Guidance: CMS determines the variation in average total quantity dispensed and 30-day equivalent supply is stable over time. We proposed to remove this condition due to its subjectivity and lack of predictability compared to the other two conditions and codify proposed § 429.700(c). We proposed at § 429.700(c)(3)(iii), the process we would apply if a new NDC is assigned to a HCPCS code for which we have already calculated an MFP per billing unit.

We proposed at § 429.700(d), that after we recompute the application of the single MFP across dosage forms and strengths for the new NDC–11 as proposed in § 429.700(c)(4)(i)(B)(1), to provide Primary Manufacturers with the calculations described at proposed § 429.700(b) and (c) and if the Primary Manufacturer believes in good faith that we made an error, a Suggestion of Error may be submitted, as set forth in § 429.445(c), in a form and manner as specified by CMS, as set forth in § 429.445(d), as described in section II.E.11. of this final rule. We solicited comments on our proposed approaches for the application of the MFP across dosage forms and strengths.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter noted that the application of a single MFP across all dosage forms and formulations may fail to capture meaningful differences in a pharmacy's acquisition costs, storage and handling requirements, dispensing complexity, and associated administrative expenses.

Response: We thank this commenter for their feedback. We interpret section 1194 of the Act to establish a single MFP, updated pursuant to section 1195(b) of the Act, for a selected drug with respect to its price applicability period. While MFP effectuation policies are outside the scope of this final rule, under section 1193(a)(3)(a) of the Act, the Primary Manufacturer must provide access to the MFP to the MFP-eligible individual and to the pharmacy, mail order service, or other dispensing entity with respect to such MFP-eligible individual who is dispensed a selected drug. This means the Primary Manufacturer is responsible for ensuring the dispensing entity's acquisition cost for a selected drug that is dispensed to an MFP-eligible individual does not exceed the MFP, which includes considering differences in acquisition cost across NDCs in order to determine the amount necessary to effectuate the MFP with respect to a particular dispense.

Final Decision: After consideration of public comments, we are finalizing § 429.700 with technical modifications. Specifically, we are updating a cross-reference in § 429.700(c)(1) to reflect that we are finalizing the general fixed combination drug policy at § 429.125(b)(4)(i) (rather than at § 429.125(b)(4), as we proposed). In addition, at § 429.700(c)(4)(i)(B), we are updating the term ''FDA-approved label'' to ''FDA-approved labeling'' for consistency and clarity.

2. Publication of the MFP (§ 429.705)

Section 1195(a)(1) of the Act requires that with respect to an initial price applicability year and a selected drug with respect to such year, not later than November 30 of the year that is 2 years prior to such initial price applicability year, CMS shall publish the MFP for such drug negotiated with the manufacturer of such drug. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.6 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with section 60.6 of the Negotiation Program Guidance, we proposed at § 429.705(a) that we would publish by November 30 of the year that is 2 years prior to the initial price applicability year, the MFP for each selected drug for which CMS and the Primary Manufacturer have reached an agreement on an MFP. For example, we would publish the MFP for each selected drug for which CMS and the Primary Manufacturer have reached an agreement on an MFP no earlier than November 1, 2027 and no later than November 30, 2027 for initial price applicability year 2029. Related to this requirement, we proposed at § 429.705(a)(1) to publish the following on the CMS website: the selected drug; the initial price applicability year; and the MFP file. The MFP file [93] would contain the single MFP for a 30-day equivalent supply of the selected drug, NDC–9 MFP-per-unit price and HCPCS code dosage price and would be updated annually to show the inflation-adjusted MFP for the selected drug. We would also update the file as needed if any NDC–9s or HCPCS codes are added or removed for the selected drug, or if the NDC–9 MFP per-unit price or HCPCS code dosage price is updated as a result of additional data.

Further, as proposed at § 429.705(a)(1)(iv), we would publish on

[93] The Maximum Fair Price Layout file would display the NDC–9 MFP per-unit price to 6 decimal places. Publishing an NDC–9 MFP per-unit price rounded to the sixth decimal point place aligns with how CMS publishes other prices. Furthermore, publishing an NDC–9 MFP per-unit price rounded to the sixth decimal place would also result in the same agreed-upon MFP per 30-day equivalent when reversing the application of the single MFP across dosage forms and strengths calculations.

the CMS website whether an MFP between a Primary Manufacturer and CMS is not agreed upon. As proposed at § 429.705(a)(1)(v), we would also publish on the CMS website whether a drug is no longer a selected drug and the reason for that change. In accordance with section 1192(c) of the Act, a selected drug with an agreed-upon MFP would cease to be a selected drug and no longer be subject to an MFP in accordance with the timeline described in section II.B.6.d. of this final rule and in proposed subpart B if we determine that a generic drug or a biosimilar for the selected drug is approved or licensed by the FDA and—as proposed under subpart B—is subject to Bona Fide Marketing. We further recognize that, in accordance with section 1194(f) of the Act, the MFP for a selected drug may also change due to renegotiation beginning in initial price applicability year 2028 (in the case of a renegotiation-eligible drug selected by the Secretary under section 1194(f)(3) of the Act), as described in section II.G. of this final rule and in proposed subpart G.

Section 1195(b)(1)(A) of the Act requires that, for a selected drug for each year subsequent to the first initial price applicability year of the price applicability period with respect to such drug, with respect to which an agreement for such drug is in effect under section 1193 of the Act, not later than November 30 of the year that is 2 years prior to such subsequent year, CMS shall publish the MFP applicable to such drug and year, which shall be the amount equal to the MFP published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with the July immediately preceding such November 30. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.6 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with section 60.6 of the Negotiation Program Guidance, we proposed in § 429.705(a)(2) that for each selected drug, for each year subsequent to the first initial price applicability year of the price applicability period (unless renegotiation occurs as set forth in section II.G. of this final rule and under proposed subpart G), we would publish an updated MFP no later than November 30 of the year that is 2 years prior to such subsequent year. We proposed at § 429.705(a)(2)(i) that the updated MFP for each selected drug would be equal to the MFP that was published for such drug for the previous year, increased by the annual percentage increase in the CPI–U for the 12-month period ending with the July immediately preceding such November 30. For example, no later than November 30, 2028, we would publish on the CMS website updated amounts for any MFPs for initial price applicability year 2029 selected drugs for which a manufacturer agreement is in effect. Those updated MFPs would take effect in 2030 and would be equal to the initial price applicability year 2029 MFP for the selected drug increased by the percent increase in CPI–U from July 2027 to July 2028.

Section 1195(b)(2) of the Act requires that, in the case of a selected drug with respect to an initial price applicability year for which the MFP is determined after the date of publication under section 1195(a) of the Act, CMS shall publish such MFP by not later than 30 days after the date such MFP is so determined. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.6 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with section 60.6 of the Negotiation Program Guidance, we proposed in § 429.705(a)(3) that in the case of a selected drug with respect to an initial price applicability year for which the MFP is determined after the MFPs are published for other selected drugs, such as due to the circumstances described in proposed § 429.710, we would publish the MFP no later than 30 days after the date such MFP is so determined.

Section 1195(a)(2) of the Act requires that with respect to an initial price applicability year and a selected drug with respect to such year, not later than March 1 of the year prior to such initial price applicability year, the Secretary shall publish, subject to section 1193(c) of the Act, the explanation for the MFP with respect to the factors as applied under section 1194(e) of the Act for such drug. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, section 60.6 of the Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, and consistent with section 60.6 of the Negotiation Program Guidance, we proposed in § 429.705(b) that we would publish explanations for the MFPs no later than March 1 of the year prior to the initial price applicability year. We proposed in § 429.705(b)(1) to develop and publish the explanations for the MFPs for each selected drug, or drug selected for renegotiation, subject to the requirements for treatment of confidential and proprietary information in proposed § 429.300 and described in section II.D.1. of this final rule. The explanation for the MFP includes: the narrative explanation of the MFP; redacted information regarding the negotiation meetings, as applicable, including exchanges of offers and counteroffers, as applicable; and the redacted information submitted by a Primary Manufacturer in proposed § 429.505(b)(2) or § 429.615(b)(1) (as described in section II.F.2. or section II.G.4. of this final rule), as applicable, and the redacted information submitted by interested parties in proposed § 429.505(d)(3) or § 429.615(b)(3), as applicable.

Within the explanation of the MFP, we may also make public, high-level comments about the sections 1194(e)(1) and 1194(e)(2) data submitted to CMS that are determined to be proprietary, without sharing any PHI/PII or any proprietary information reported to CMS under section 1193(a)(4) of the Act for purposes of the negotiation. Similar to the approach taken for publication of the public MFP explanations for initial price applicability year 2026 and 2027, for each drug, we would make available on the CMS website redacted versions of section 1194(e)(2) data that are determined to be nonproprietary and will not disclose any PHI, PII, or information that is protected from disclosure under other applicable law.

If an agreement for an MFP is reached for a selected drug and CMS makes a determination before the end of the negotiation period (as set forth in proposed § 429.535) that an approved generic drug or licensed biosimilar for the selected drug is subject to Bona Fide Marketing (consistent with proposed § 429.130(a)), we would neither publish an MFP nor publish an MFP explanation because the selected drug ceases to be subject to the negotiation, pursuant to section 1192(c)(2) of the Act and as described in proposed § 429.135(b)(1) (see further discussion in section II.B.6.d. of this final rule).

If an agreement for an MFP is not reached for a selected drug, we would neither publish an MFP nor publish an MFP explanation, as proposed at § 429.705(b)(2). Instead, we would

indicate on the CMS website that an MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters requested that CMS detail specific information in the explanations of MFP. These elements include information such as the starting point for the initial offer, how therapeutic alternatives were selected, specific data and evidence used, benefits and impacts considered, Federal funding, stakeholders consulted and how their input was used, sources for information used in negotiation, specific offers and counteroffers, NDC per unit and per package price, and details on how information influenced the MFP. One of these commenters recommended CMS commit to a schedule for public release of information such as specific offers and counteroffers. A commenter supported CMS' proposal to publish whether an MFP was not agreed upon for a selected drug and the reason a drug ceases to be a selected drug. Some commenters requested CMS discuss in the MFP explanations more information about how stakeholder input was used in negotiations. A commenter supported that CMS publishes the MFPs before the initial price applicability year.

Response: We thank these commenters for their suggestions to include specific information in the MFP explanations. Consistent with our response to similar comments in the Negotiation Program Guidance, as required under section 1195(a)(1) of the Act, we will publish the MFP explanations for all selected drugs where there is an agreed-upon MFP no later than March 1 of the year prior to the initial price applicability year. The MFP explanation, as described at § 429.705, will include a narrative explanation of the MFP, redacted information regarding the negotiation meetings, as applicable, including exchanges of offers and counteroffers, as applicable, and the redacted information submitted by a Primary Manufacturer, as described at § 429.505(b)(2) or § 429.615(b)(1), as applicable, and the redacted information submitted by interested parties, as described at § 429.505(d)(3) or § 429.615(b)(3), as applicable, and in alignment with the confidentiality policy described at § 429.300. We will also strive to share the section 1194(e)(2) data submitted by the public with the Primary Manufacturer of a selected drug during the negotiation period. This data will be redacted in accordance with the confidentiality standards described at § 429.300 and will not include proprietary information, PHI/PII, or other information that is protected from disclosure under other applicable law. We also thank commenters for their recommendation to include more detail in the MFP explanations, including regarding how stakeholder input was used in negotiations. We refer interested parties to the MFP explanations published on the CMS website for more information about the negotiation process for initial price applicability years 2026 and 2027 through which CMS and Primary Manufacturers reached agreement on an MFP. Additionally, as discussed in section II.F.4. of the proposed rule (91 FR 36296), we used information shared during the patient-focused events to better understand patients' experiences with the conditions and diseases treated by the selected drug and their experiences with the selected drugs themselves, as well as to inform the identification of therapeutic alternatives, key outcomes, and adjustment of the starting point to develop the initial offer.

Comment: A commenter expressed appreciation for CMS' stated goals of protecting proprietary information while avoiding treating non-qualifying information as proprietary and urged CMS to continue refining its approach to transparency and to lean toward disclosure to the maximum extent possible when the statute is silent. Another commenter stated CMS could promote transparency by providing additional detail not included in the MFP explanation directly to the affected manufacturer. A commenter recommended MFP explanations provide information in accordance with the confidentiality policy set forth in § 429.300.

Response: We thank these commenters for their support and suggestions. Consistent with our response in the Negotiation Program Guidance and the final guidance for initial price applicability year 2027, and as described at § 429.705, the MFP explanation, subject to the requirements for treatment of confidential and proprietary information as described at § 429.300, will include a narrative explanation of the MFP, redacted information regarding the negotiation meetings, as applicable, including exchanges of offers and counteroffers, as applicable, and the redacted information submitted by a Primary Manufacturer, as described at § 429.505(b)(2) or § 429.615(b)(1), as applicable, and the redacted information submitted by interested parties, as described at § 429.505(d)(3) or § 429.615(b)(3), as applicable. We believe that engagement with Primary Manufacturers throughout the negotiation and renegotiation process, as applicable, such as through discussion during the optional meetings and exchange of offer(s) and counteroffer(s), provides Primary Manufacturers with multiple opportunities to receive detailed information from CMS regarding the negotiation and renegotiation process, as applicable, and reaching agreement upon an MFP. CMS therefore declines to provide additional detail not included in the MFP explanation directly to a Primary Manufacturer beyond the information made available during the negotiation and renegotiation process, as applicable.

Final Decision: After consideration of public comments, we are finalizing § 429.705 as proposed.

3. Establishment of MFPs After the Negotiation Deadline (§ 429.710)

Section 1194(b)(2) of the Act contemplates that agreement upon an MFP must be reached prior to November 1 following the selected drug publication date, with respect to the initial price applicability year, to avoid potential imposition of an excise tax. If negotiations have not ended by this date, the Primary Manufacturer may be subject to an excise tax under 26 U.S.C. 5000D. As a general matter, if the Primary Manufacturer is delayed in meeting one or more deadlines related to the negotiation process, we would continue to engage in the negotiation process described in section II.F. of this final rule and under proposed subpart F.

Certain actions or delays by the Primary Manufacturer may delay the process such that the MFP may be agreed to after the end of the negotiation period as described in proposed § 429.535(b). Section 1194(b)(1) of the Act requires that the Secretary shall develop and use a consistent methodology and process, in accordance with section 1194(b)(2) of the Act, for negotiations under section 1194(a) of the Act that aims to achieve the lowest MFP for each selected drug. With respect to initial price applicability years 2026 through 2028, we implemented this requirement through guidance, including, for example, Negotiation Program Guidance with respect to initial price applicability year 2028.

With respect to initial price applicability year 2029 and subsequent years, we proposed in § 429.710 that, in

the event of a delay by the Primary Manufacturer such that the MFP may be agreed to after the end of the negotiation period described in the proposed § 429.535(b), we would follow timelines consistent with the negotiation process established in section II.F. of this final rule and under proposed subpart F and take the time to complete the established process so described as appropriate for the selected drug. Certain actions by the Primary Manufacturer may delay the negotiation process to such an extent that a selected drug has a change in status that is material to CMS' statutory obligations under the negotiation process. If this occurs, as proposed at § 429.710(a), when CMS initiates or resumes the negotiation process, we would apply the consistent methodology and process with respect to the selected drug based on its status at the time the negotiation process occurs, including with respect to renegotiation, as applicable, as described in subpart G.

If the manufacturer and CMS complete each step of the negotiation process as described in section II.F. of this final rule and under subpart F, including CMS' issuance of a final offer in accordance with § 429.535(a), and then, after the statutory end of the negotiation period, the Primary Manufacturer of a selected drug wishes to agree to an MFP, the Primary Manufacturer must notify CMS in writing that it would like to accept the final offer from CMS, as proposed at § 429.710(b).

In accordance with section 1195(b)(2) of the Act and as proposed at § 429.705(a)(3), in the case of a selected drug with respect to an initial price applicability year for which the MFP is determined after the MFPs are published for other selected drugs, we would publish the MFP no later than 30 days after the date such MFP is so determined. For such a drug, in accordance with §§ 429.705(b) and 429.710, we would follow timelines consistent with the established process for publishing the explanation of the MFP and would not expedite our timeline due to late action from the Primary Manufacturer.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.710 as proposed.

I. Manufacturer Compliance and Oversight (§ 429.900)

Section 1196(b) of the Act requires that CMS monitor compliance by a Primary Manufacturer with the terms of the Negotiation Program Agreement and establish a mechanism through which violations of such terms shall be reported. With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 90.1 of the Negotiation Program Guidance with respect to initial price applicability year 2028. With respect to initial price applicability year 2029 and subsequent years, we proposed to codify our policies for effectuating the compliance monitoring required by section 1196(b) of the Act, consistent with those policies described in section 90.1 of the Negotiation Program Guidance, in proposed subpart J. Section 429.900 codifies sections 90 through 90.1 of the Negotiation Program Guidance.

1. Monitoring Manufacturer Compliance (§ 429.900)

Proposed § 429.900 establishes CMS' approach to monitoring and assessment of Primary Manufacturer compliance with the terms of the Negotiation Program Agreement as described in proposed § 429.200, the Primary Manufacturer's obligation to cooperate with CMS' compliance monitoring activities, and actions CMS may take to address Primary Manufacturer noncompliance.

In accordance with section 1193(a)(5) of the Act, section 429.900(a) proposed that CMS may monitor and assess Primary Manufacturer compliance with the Negotiation Program Agreement, including compliance with all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including part 429, implementing those provisions and any changes to the Act that affect the Negotiation Program. We will closely monitor the Primary Manufacturer's compliance with the terms of the Negotiation Program Agreement, including the requirements for Primary Manufacturers of selected drugs as described in part 429. Following the publication of selected drugs for negotiation and renegotiation for each initial price applicability year, as described in proposed § 429.100, we may provide information about the negotiation or renegotiation process, as applicable, to the Primary Manufacturer of each selected drug. We anticipate this information would include operational and statutory timelines, procedural requirements, systems instructions, IRA resources, and contact information. During the negotiation and renegotiation periods and in accordance with proposed § 429.900(a), we would track and monitor progress during all steps of the process. CMS compliance monitoring will continue beyond the negotiation period and extend to all aspects of Primary Manufacturer participation in the Negotiation Program. For example, during the negotiation period and after it has closed, we may require additional information from the Primary Manufacturer to administer or monitor compliance with the Negotiation Program in accordance with section 1193(a)(5) of the Act and as proposed in § 429.900(b). This may include requiring recurring reporting (for example, providing evidence that the MFP is being made available), or making specific ad hoc requests to the Primary Manufacturer for information related to targeted monitoring, auditing, or investigation efforts. Methods CMS may use to monitor and assess compliance, during the negotiation and renegotiation periods or otherwise, include but are not limited to: evaluation of complaints made by individuals and entities to CMS; CMS' engagement in direct communications with the Primary Manufacturer; and CMS audits and comprehensive reviews.

As described in proposed § 429.900(b), Primary Manufacturers must cooperate with CMS compliance monitoring activities. This includes providing complete, accurate, and relevant responses to CMS requests for clarifications, corrections, and additional information and complying fully with requests for corrective action during the compliance monitoring process and when noncompliance is identified. For example, we proposed that Primary Manufacturers must submit complete, accurate, and relevant responses, in the form and manner and on the timeline specified by CMS, in response to written requests CMS provides to the Primary Manufacturer in the course of our compliance monitoring activities when we deem appropriate. We are committed to providing Primary Manufacturers with reasonable timeframes to accommodate these information requests; Primary Manufacturers have the burden of establishing why an extension of any deadline to submit information should be considered by CMS. As stated in the proposed rule, if a Primary Manufacturer articulates a reasonable basis for seeking an extension for a reasonable duration of time, and the request is submitted at a reasonable point in time before the deadline (for example, 3 calendar days prior to the initial deadline), then CMS may grant an extension of a limited duration to the extent consistent with statutory

timelines and other operational considerations.

Likewise, we proposed in § 429.900(b) that a Primary Manufacturer must comply fully with corrective action requests that we provide to the Primary Manufacturer when we deem it appropriate; for example, including but not limited to, in the event that a Primary Manufacturer fails to submit data as described in proposed §§ 429.100 and 429.505 of this final rule. We recognize the substantial role that manufacturer-submitted information will play in the negotiation and renegotiation processes and the need for complete and accurate information. Should CMS determine that a submission is incomplete or contains inaccurate information, CMS may provide a written request to the Primary Manufacturer to clarify the submission, correct the inaccuracy, or provide the necessary information, with a deadline by which the Primary Manufacturer must respond. The written corrective action request would outline the needed action and establish a deadline for the Primary Manufacturer to correct the submission and/or provide additional information to validate the accuracy and completeness of the original submission. We intend to be available to engage with the Primary Manufacturer about the specifics of a corrective action request and to answer questions and provide clarification.

The information outlined in the proposed rule is necessary for CMS to administer and monitor the Negotiation Program in accordance with section 1193(a)(5) of the Act. As such, as proposed at § 429.900(b), failure to provide complete and accurate information, initially or in response to CMS' initial questions or corrective action requests, may result in the Primary Manufacturer being subject to a CMP as authorized under section 1197(c) of the Act and as described in proposed § 429.1005.

In proposed § 429.900(c), we proposed to establish the actions CMS may take if we conclude that a Primary Manufacturer is noncompliant with one or more requirements of the Negotiation Program Agreement, including all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including part 429, implementing those provisions and any changes to the Act that affect the Negotiation Program. Upon identifying a violation, CMS may take one or more of the following actions: (1) CMS may provide a written notice to the Primary Manufacturer of the violation; (2) CMS may request the Primary Manufacturer to take specific corrective action to address the noncompliance; or (3) CMS may impose a CMP on the Primary Manufacturer as set forth in subpart K. In instances in which CMS provides a written notice to the Primary Manufacturer of the violation and/or requests specific corrective action, the agency may offer the Primary Manufacturer the opportunity, by a specified deadline, to provide information regarding the circumstances of violation, evidence seeking to refute the finding of violation, proof of mitigation of noncompliance, and other factors for CMS' consideration. CMS proposed to consider such information if timely submitted when determining whether to pursue further enforcement action such as imposition of CMPs.

We received public comments on the proposed provisions to establish the actions CMS may take if the agency concludes that a Primary Manufacturer is noncompliant with one or more requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including part 429, implementing those provisions and any changes to the Act that affect the Negotiation Program. The following is a summary of the comments we received and our responses.

Comment: A commenter requested protection from enforcement in instances where 340B covered entities refuse to share data needed for 340B claim deduplication.

Response: We appreciate the feedback provided by this commenter. First, as this comment addresses a process related to MFP effectuation, it is considered outside the scope of this final rule. However, broadly, in the final rule, we decline to designate any specific compliance safe harbors under the Negotiation Program, including related to instances where 340B covered entities refuse to share data related to the 340B eligibility of a claim. CMS reiterates the policy established in Negotiation Program Guidance describing a Primary Manufacturer's obligation to transmit payment of an amount that provides access to the MFP of a selected drug to the dispensing entity within the 14-day prompt MFP payment window and applicability of section 1193(d)(1) of the Act only if: (1) the claim for the selected drug is a 340B-eligible claim; and (2) the 340B ceiling price is lower than the MFP for the selected drug. As described in sections 40.4.3.1 and 40.4.4.2 of the Negotiation Program Guidance, in cases where a Primary Manufacturer receives claim-level data elements for a selected drug that it reasonably believes is subject to the exception under section 1193(d)(1) of the Act, the Primary Manufacturer would indicate so when reporting claim-level payment elements to the MTF and declining to transmit payment in an amount that provides access to the MFP within the 14-day prompt MFP payment window. In this scenario, the Primary Manufacturer would be required to provide documentation demonstrating the claim was 340B-eligible and the 340B ceiling price was lower than the MFP upon request from CMS as described in section 90.2 of the Negotiation Program Guidance.

In the course of its monitoring and oversight functions, CMS may investigate Primary Manufacturer compliance with MFP effectuation requirements, including to assess whether an MFP refund was owed rather than the exception in section 1193(d)(1) of the Act applying. As part of such investigations, CMS will review the extent to which the Primary Manufacturer reasonably believed that the exception in section 1193(d)(1) of the Act applied and the role that any operational barriers played in the Primary Manufacturer being able to take timely action to meet its statutory obligation to make MFP available, as applicable, with respect to these claims. Consistent with enforcement policies described later in this section, in instances where CMS finds noncompliance with Negotiation Program requirements, CMS intends to exercise the authority to impose CMPs for instances of noncompliance that substantively obstruct Negotiation Program processes and/or availability of the MFP.

Comment: A few commenters raised concerns that Primary Manufacturers may be subject to enforcement actions despite acting in good faith to fulfill their compliance obligations under the Negotiation Program. A couple of commenters mentioned that a Primary Manufacturer may reasonably misinterpret an information request for which CMS may deem a response to be incomplete or inaccurate. When addressing noncompliance and imposing CMPs, a commenter felt that CMS was departing from HHS' general practices by penalizing Primary Manufacturers without assessing good faith effort. Another commenter mentioned that there are a number of ways that a Primary Manufacturer could unintentionally omit reporting data when responding to CMS. Another commenter remarked that the proposed changes deviate from principles of good faith and timely resolution of issues related to data integrity. A commenter

suggested that CMS define what constitutes as a good faith compliance effort.

Response: We thank these commenters for their feedback. As discussed in section II.J.1. of this final rule, CMS intends to exercise the authority to impose CMPs in instances of noncompliance that substantively obstruct administration of the Negotiation Program. We are establishing a structure for enforcement actions that, among other things, is not punitive in response to immaterial noncompliance or other instances of noncompliance that are not substantive. Consistent with policy established in the Negotiation Program Guidance, we provide in § 429.900(b) that Primary Manufacturers must cooperate with CMS compliance monitoring and evaluation activities, including providing complete and accurate responses to CMS requests for clarifications, corrections, and additional information, and complying fully with all requests for corrective action. These monitoring efforts reflect CMS' intent to continue to engage in Negotiation Program compliance monitoring and oversight activities in accordance with HHS' established practices for managing noncompliance by offering, when warranted and at CMS' discretion, opportunities for correction, including clarification. The determination of whether to exercise enforcement discretion with respect to identified noncompliance is based on the facts, circumstances, and totality of evidence available to CMS for each specific case. Primary Manufacturers are expected to make good faith efforts to resolve compliance issues and maintain open communication with CMS. CMS recommends that Primary Manufacturers maintain documentation evidencing their good faith efforts to comply with Negotiation Program obligations. CMS may request or consider such documentation when considering whether to impose CMPs with respect to identified noncompliance. We intend to offer opportunities for Primary Manufacturers to undertake corrective action when appropriate and at CMS' discretion. Regarding the request for CMS to define what constitutes a ''good faith compliance effort'', we emphasize that every instance of noncompliance is assessed on a case-by-case basis. In all instances, we encourage communication, cooperation, and timely attempts to rectify compliance issues. Where a Primary Manufacturer can demonstrate that it has made reasonable, good faith efforts to fulfill its obligations, or that compliance was impeded by circumstances outside its control, this will be considered in our assessment of whether to impose CMPs.

Comment: A few commenters requested more specificity in proposed § 429.900(c) where CMS outlines the enforcement actions the agency may take in response to Primary Manufacturer noncompliance. To address noncompliance, the proposed language states that CMS may take one or more of the following actions: provide notice of violation, request corrective action, and/or impose a CMP. These commenters expressed that the language is too vague and open-ended. These commenters recommended that CMS provide clarity on the applicable guidance and requirements for the respective enforcement actions. Particularly, commenters are unclear as to which requirements would trigger a CMP response.

Response: We thank these commenters for their feedback regarding enforcement actions CMS may take if we conclude a Primary Manufacturer is noncompliant with one or more of the requirements of the Negotiation Program Agreement, including all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations. Our primary goal is to successfully administer all aspects of the Negotiation Program; we intend to exercise the authority to impose CMPs in instances of noncompliance that substantively obstruct Negotiation Program processes. In evaluating whether to impose CMPs in instances of identified noncompliance, we will consider the circumstances of each case, taking into account the severity and frequency of noncompliance. As described in section II.J.1. of this final rule, instances of noncompliance that may warrant the imposition of CMPs include, but are not limited to, egregious or knowing violations of Negotiation Program requirements or repeated violations of the Negotiation Program Agreement or other Negotiation Program requirements. Examples of substantive violations for which CMPs may be appropriate can be found in Table 4—Examples of Substantive Violations of this final rule. Note that the examples in Table 4 are not an exhaustive list of violations that may warrant CMPs. As appropriate and upon determination of an instance of noncompliance, we may issue a written notice to the Primary Manufacturer of the violation(s), request the Primary Manufacturer to take specific corrective action to address the noncompliance, and/or impose a CMP. If we make a determination to assess a CMP, we will follow the procedures outlined in section II.J.4. of this final rule.

Comment: A few commenters encouraged CMS to have robust mechanisms in place for compliance oversight to ensure manufacturers fulfill program obligations. A commenter stressed the need for increased enforcement. Another commenter supported CMS' proposed compliance and enforcement efforts, including broad monitoring authority.

Response: We appreciate the feedback provided by commenters regarding the monitoring and enforcement efforts related to Primary Manufacturer compliance with the Negotiation Program Agreement. We recognize the importance of effective oversight mechanisms to ensure that Primary Manufacturers meet their obligations under the Negotiation Program Agreement. Our approach is to maintain a robust monitoring and oversight program intended to foster transparency, accountability, and adherence to established guidelines throughout the operation of the Negotiation Program.

Comment: A commenter encouraged CMS to be cognizant of the administrative burden on downstream entities as the agency continues to develop policies related to compliance monitoring and other procedures. The commenter expressed concern that providing flexibility for manufacturers adopting manufacturer-specific approaches to MFP effectuation could result in inconsistency across different products and markets, resulting in heightened administrative burden in navigating the program for downstream entities.

Response: We appreciate the feedback provided by this commenter. We remain committed to considering stakeholder burden across Negotiation Program operations, including program monitoring, oversight, and enforcement activities; we routinely aim to minimize burden on manufacturers, dispensing entities, and other downstream entities related to compliance activities while balancing the need to operate robust monitoring and oversight as we implement the Negotiation Program. For example, we conduct extensive monitoring and oversight exercises internally at CMS, such as conducting ongoing analysis using program and industry data. With respect to the comment regarding ''manufacturer-specific'' approaches to MFP effectuation, we note that MFP effectuation policies are outside the scope of this final rule. However, we note generally that public input is

considered when designing operational processes, including agency compliance monitoring and oversight processes. CMS works to gather such input both through informal channels (for example, monthly stakeholder technical meetings) and formal channels (for example, public comment periods on program policy and various Information Collection Requests). These collective efforts allow stakeholders to provide insight into real-world perspectives, stakeholder data, and emerging issues to inform agency decision-making to support our goal of streamlining operations and reducing burden. Importantly, we have designed compliance and oversight processes that are applied consistently across manufacturers and intend to continue to operate in a consistent manner.

Final Decision: After consideration of public comments, we are finalizing § 429.900 as proposed.

J. Civil Monetary Penalties (§§ 429.1005 Through 429.1020)

1. Civil Monetary Penalties

Section 1197 of the Act provides for the imposition of CMPs on manufacturers for: (1) failure to provide access to a price that is less than or equal to the maximum fair price for a drug; (2) failure to pay the rebate amount for a biological product inclusion of which on the selected drug list was delayed but has since undergone negotiation, as described in section 1192(f)(4) of the Act; (3) violation of certain terms of the Negotiation Program Agreement; and (4) the provision of false information as described in section 1197(d) of the Act.

With respect to initial price applicability years 2026 through 2028, we implemented these requirements through guidance, including, for example, section 100 of the Negotiation Program Guidance with respect to initial price applicability year 2028. With respect to initial price applicability year 2029 and subsequent years, with the exception of our authority pursuant to section 1197(a) of the Act as described later in this section, we proposed to codify our policies for implementation of our CMP authorities as set forth in section 1197 of the Act, consistent with those policies described in section 100 of the Negotiation Program Guidance, in proposed subpart K.

In future rulemaking, we will codify our policies for implementation of section 1197(a) of the Act, under which manufacturers may be subject to a CMP for failure to provide access to a price less than or equal to the MFP, for 2029 and subsequent years. Consistent with the statutory directive to use program instruction or other forms of program guidance to implement sections 1191 through 1198 of the Act for 2026, 2027, and 2028, a Primary Manufacturer's compliance obligations with respect to its obligation to provide access to a price less than or equal to the MFP for 2026, 2027, and 2028 are established in the applicable program guidance, and we are reserving codifying the CMP associated with violation of this obligation, including the process, calculation, and substantive compliance obligations, for 2029 and subsequent years, for future rulemaking.

In proposed § 429.1005, we address potential imposition of CMPs for a Primary Manufacturer's violation of a requirement determined by CMS to be necessary for the purposes of administering and monitoring compliance with the Negotiation Program, including without limitation, the requirement to submit information pursuant to section 1193(a)(4) of the Act, in accordance with section 1197(c) of the Act. In proposed § 429.1010, we address potential imposition of CMPs for provision of false information for use in applying the eligibility rules at sections 1192(d)(2)(B) and (f)(1)(C) of the Act, in accordance with section 1197(d) of the Act. In proposed § 429.1015, we address potential imposition of CMP for failure to pay a rebate as required by section 1192(f)(4) of the Act, in accordance with section 1197(b) of the Act. In proposed § 429.1020, we address details about the process for imposition of CMPs. Separate from CMS imposition of CMPs, per 26 U.S.C. 5000D, failure of a Primary Manufacturer to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program may result in potential excise tax liability.

Our primary goal is to successfully administer all aspects of the Negotiation Program; we intend to exercise the authority to impose CMPs in instances of noncompliance that substantively obstruct Negotiation Program processes. Such instances may include, but are not limited to, the examples shown in Table II.F3, such as failure to provide timely, complete, and accurate information that is necessary to execute the negotiation process or other administrative or monitoring functions of the Negotiation Program; repeated violations of the Negotiation Program Agreement or other Negotiation Program requirements determined by CMS to be necessary for the purposes of administering and monitoring compliance with the Negotiation Program; or egregious or knowing violations of Negotiation Program requirements. Note that these examples are not an exhaustive list of violations that could warrant CMPs. We reserve the authority to issue CMPs for other violations as required to effectively administer and monitor the Negotiation Program.

TABLE II.F.3: EXAMPLES OF SUBSTANTIVE VIOLATIONS*

Category	Example
Violations of the Negotiation Program Agreement	• Failure to submit data required under §§ 429.100(d), 429.405(a), 429.505(b), and 429.615(b) including failure to engage in requested corrective action to mitigate such failures. • Omission or inaccuracy of manufacturer-submitted information described in §§ 429.100(d), 429.405(a), 429.505(b), and 429.615(b) (for example, non-FAMP data from the Primary Manufacturer, including non-FAMP data for a selected drug manufactured, marketed, controlled, or sold by any Secondary Manufacturer(s), required for ceiling calculation) or other violations that impede CMS efforts to administer or monitor the Negotiation Program (for example, failure to report new NDC-11s, failure to provide information requested during an audit) as well as failure to engage in requested corrective action to mitigate such omissions, inaccuracies or other violations. • Submission of false information that interferes with the negotiation process (for example, submission of false data on unit costs of production or research and development costs). • Failure to provide information requested by CMS in accordance with CMS' oversight responsibilities under section 1196(b) of the Act and described in subpart J.
Other Violations	• Knowing provision of false information to CMS for use in applying the aggregation rule described at § 429.110(b)(1)(iv)(A). • Knowing provision of false information to CMS for use in applying the test to determine if a selected drug or drug selected for renegotiation is eligible for the Temporary Floor for Small Biotech Drugs as described in proposed § 429.440(b)(2). • Failure to pay a biosimilar delay rebate by the deadline established in proposed § 429.110(h).

*This table does not address violations related to a Primary Manufacturer's failure to make MFP available.

Broadly, we proposed to establish a structure for enforcement actions that: (1) is within CMS' statutory authority; (2) is not punitive in response to immaterial noncompliance, or other instances of noncompliance that are not substantive; (3) can be applied consistently across applicable instances of Primary Manufacturer noncompliance; and (4) facilitates the ability to successfully engage in all components of the negotiation process within the established timeframes.

2. Violations of the Negotiation Program Agreement (§ 429.1005)

In accordance with section 1197(c) of the Act, any Primary Manufacturer of a selected drug that has entered into a Negotiation Program Agreement with CMS as set forth in proposed § 429.200 that fails to comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, including failure to provide information required under section 1193(a)(4) of the Act, including information required to be submitted under proposed § 429.405(a) and (b), may be subject to statutorily-specified CMPs for each day of such violation. The statutorily specified amount of $1,000,000 a day is updated yearly per the Federal Civil Penalties Inflation Adjustments Improvements Act of 2015. In applying CMPs for Primary Manufacturer violations of the Negotiation Program Agreement, we intend to use discretion such that CMPs are reserved for instances of substantive noncompliance.

Effective oversight of the Negotiation Program requires that CMS receive complete and accurate data from Primary Manufacturers. We view the authority to impose CMPs as established in section 1197(c) of the Act as a tool to ensure that a Primary Manufacturer is participating in the Negotiation Program consistent with its signed Negotiation Program Agreement, including, but not limited to, providing complete and accurate information CMS deems necessary for administering and monitoring compliance with the Negotiation Program and promptly responding to any communications from CMS regarding the Negotiation Program, including requests for clarification, correction, additional information, or specific corrective actions.

In the proposed rule, we proposed to consolidate and clarify our approach to monitoring and enforcement in the context of data reporting. Specifically, we did not propose to codify the policies previously stated in section 40.2.3 of the Negotiation Program Guidance but rather we proposed to pursue a consolidated approach to monitoring and enforcement that is consistent with the policies regarding data reporting obligations stated in sections 90 and 100 of the Negotiation Program Guidance. For example, we may impose a CMP for violation of a requirement of the Negotiation Program Agreement if a Primary Manufacturer fails to provide data required under the Drug Price Negotiation ICR Forms, such as information on non-FAMP for each applicable quarter, as described in proposed § 429.405 of this final rule, for each NDC–11 of the selected drug for the applicable period, by the deadline established at proposed § 429.505(b)(1). In this scenario, upon identifying the missing data, we may take a variety of actions. For one, in accordance with proposed § 429.900(c), we may send the Primary Manufacturer a request for corrective action to address the noncompliance, such as a request that

the Primary Manufacturer provide a complete and accurate production of the outstanding non-FAMP data by a specified date. If the Primary Manufacturer complies with the request for corrective action by timely providing complete and accurate non-FAMP data, we may exercise discretion and determine not to impose a CMP for the Primary Manufacturer's initial failure to provide complete and accurate non-FAMP data by the specified deadline. Or, depending on the circumstances, in accordance with enforcement priorities, we may determine that, even if a Primary Manufacturer complies with a request for corrective action, it remains appropriate to issue a violation notice and impose a CMP for the initial violation. Alternatively, in accordance with proposed § 429.900(c), we may not issue a request for corrective action and instead send a notice of violation to the Primary Manufacturer and impose a CMP in accordance with subpart K. Finally, if we send the Primary Manufacturer a request for corrective action and the Primary Manufacturer does not comply with such request, in accordance with proposed § 429.900(c), we may issue a violation notice and impose a CMP for the failure to comply with CMS' corrective action request, which would be separate from any violation notice and CMP imposition addressing the violation that arose from the Primary Manufacturer's initial failure to provide complete and accurate non-FAMP data by the specified deadline.

In a case where a CMP is pursued, we stated that we intended to send a written CMP notification, as described in proposed § 429.1005(d), that reflects the start date of the penalty accrual, the end date of the penalty accrual, and the total amount of the penalty assessed, as described in proposed § 429.1020(a). As described at proposed § 429.1005(c), the state date of the penalty accrual is the first day of the violation as set forth in proposed § 429.1005(a). In the earlier example, the start date of the penalty accrual would be the day after the applicable submission deadline. As described at proposed § 429.1005(c), the CMP shall accrue until the Primary Manufacturer has provided the necessary information or otherwise taken any corrective action determined by CMS to be necessary to address the violation, including, as applicable, providing documentation to evidence that the Primary Manufacturer has provided all past due information, or the Negotiation Program Agreement is terminated. In the earlier example, in the event the Primary Manufacturer never provides the required information, the daily CMP would continue to accrue until the Negotiation Program Agreement was terminated as described in proposed § 429.205. We plan to adopt the same approach to enforcement in a circumstance where a Primary Manufacturer failed to provide data for a drug selected for renegotiation, with a violation accruing each day after the deadline established for provision of the data in proposed § 429.615 until the Primary Manufacturer provided the data. In the event the Primary Manufacturer never provides the required data, the CMP will continue to accrue until the Negotiation Program Agreement is terminated as described in proposed § 429.205. The imposition of a CMP related to failure to provide required data for the renegotiation process does not negate the Primary Manufacturer's ongoing obligation to provide access to the previously negotiated MFP. Primary Manufacturers continue to have the obligation to make the previously negotiated MFP available.

Another example of when CMS may impose a CMP for violation of the Negotiation Program Agreement is if the Primary Manufacturer submits information that is required under the Negotiation Program Agreement and CMS determines the information is false. In this example, the Primary Manufacturer would be determined to be noncompliant with the requirement to submit information and may be subject to a CMP. In instances of a Primary Manufacturer submitting false information that is required under the Negotiation Program Agreement, in accordance with proposed § 429.1005, a CMP would begin to accrue on the day after the established deadline for submission of information under the Negotiation Program Agreement and would continue to accrue until the Primary Manufacturer provides a complete and accurate submission of the required information to CMS or the Negotiation Program Agreement is terminated as described in § 429.205. The start and end date of CMP accrual as well as the total amount accrued will be noted on the CMP notification sent by CMS, following the process established in proposed § 429.1020.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters opposed the policy proposed at § 429.1005 because they stated it bypasses the opportunity for corrective action in certain instances of identified noncompliance. These commenters noted that section 40.2.3 of the Negotiation Program guidance governing initial price applicability years 2026, 2027, and 2028 explicitly afforded a 5-business day window to respond to corrective action requests and provided the opportunity to rectify any issues related to submission of information required under section 1193(a)(4) of the Act and that this 5-day window was not included in the proposed rule. A few commenters advocated for CMPs to be imposed only for repeated and severe violations. A commenter stated that the proposed rule is a ''more aggressive approach to enforcement,'' and advocated for warning notices to be issued prior to potential applicability of excise taxes. A few commenters stated that CMS did not provide an explanation as to why the proposed rule no longer includes a 5-day window for rectifying issues regarding noncompliance related to submission of information required under section 1193(a)(4) of the Act and stated that the Supreme Court has held that agencies must provide a reasoned explanation when making new policy changes. A commenter requested that CMS maintain the current oversight and enforcement methods and reserve any process changes for future rulemaking opportunities. A couple of commenters recommended that CMS establish a corrective action process as a mandatory step prior to CMP issuance, rather than limiting corrective action opportunities specifically to circumstances in which CMS determines such opportunities are warranted.

Response: We thank the commenters for their input. In implementing § 429.1005, we reiterate that we intend to exercise the authority to impose CMPs in instances of noncompliance that substantively obstruct the processes of the Negotiation Program. We remain committed to providing opportunities for corrective action in situations where we deem it appropriate and intend to maintain our operational approach of providing Primary Manufacturers reasonable time periods to fulfill requests for information and/or corrective action and considering requests for extensions as warranted. For example, if we determine that a submission from a Primary Manufacturer is incomplete or contains inaccurate information, we may issue a written request to the Primary Manufacturer to clarify the submission, correct the inaccuracy, or provide the missing information. This written request will specify a deadline by which the Primary Manufacturer must respond. If the Primary Manufacturer

complies with the request for corrective action by timely providing complete and accurate information, we may exercise enforcement discretion and determine not to impose a CMP for the Primary Manufacturer's initial failure to provide complete and accurate information by the specified deadline. Alternatively, in accordance with§ 429.900(c), we may not issue a request for corrective action and instead send a notice of violation to the Primary Manufacturer and impose a CMP in accordance with subpart K. In evaluating whether to impose CMPs in instances of identified noncompliance, we will consider the circumstances of each case, including but not limited to taking into account the severity and frequency of noncompliance. The enforcement framework outlined in the final rule is designed to ensure that penalties are not imposed in a punitive manner for immaterial or non-substantive instances of noncompliance. In section II.J.2. of the proposed rule (91 FR 36314 through 15), we outlined scenarios demonstrating how outcomes may vary, including situations where corrective action may or may not be pursued.

We intend to be available to engage with Primary Manufacturers about the specifics of a corrective action request and to answer questions and provide clarifications. Additionally, we intend to provide Primary Manufacturers with reasonable deadlines to respond to requests for information requests and/or corrective action. This approach is designed to facilitate timely and effective resolution of compliance issues.

In response to requests for further explanation regarding the absence of the specified 5-day response time to corrective action requests in response to noncompliance related to submission of information required under section 1193(a)(4) of the Act, we note that the policy in the proposed rule, which we are finalizing herein, is not a significant change to the approach previously described in section 40.2.3 of the Negotiation Program Guidance. By consolidating and clarifying the policies described in the Negotiation Program Guidance, we seek to ensure that stakeholders understand the agency's enforcement processes and how they will be applied within the Negotiation Program. The monitoring and enforcement policies adopted in this final rule aim to provide the guidance and support necessary to facilitate consistent, good faith compliance. Operationally, CMS intends to continue to provide Primary Manufacturers with opportunities to correct information submissions or to provide additional information with reasonable timeframes to respond to such actions or both. However, offering these opportunities is not a required precursor to potential enforcement actions for any failure to meet these obligations.

We decline to explicitly establish that a corrective action process will be required as the initial step prior to CMP issuance in every instance under the final rule. We may choose to pursue corrective action, impose a CMP, or both depending on the nature of the violation and its potential effects on program operations. Regarding the comment on potential applicability of excise taxes, we refer this commenter to 26 U.S.C. 5000D for additional information. We note that the Internal Revenue Service (IRS) is responsible for administering and enforcing the excise tax, not CMS.

Comment: Commenters recommended that CMS add to § 429.200(b), which specifies requirements and conditions to which a Primary Manufacturer agrees when executing a Negotiation Program Agreement, a specific reference to a Primary Manufacturer's obligation to timely report updates to the NDC–11 information of the selected drug as described in § 429.100(e), to more explicitly warn manufacturers of a potential CMP for failure to report NDC updates as provided in § 429.100(e) and to further support adherence to program compliance.

Response: We thank these commenters for their feedback. Consistent with the policy described at § 429.1005, failure of a Primary Manufacturer that has entered into a Negotiation Program Agreement to comply with certain Negotiation Program deadlines and other requirements of the Negotiation Program, including failure to provide updated NDC–11 information to CMS as described in the proposed rule under § 429.100(e), which we are finalizing herein, may result in CMPs. The specific regulatory sections identified in § 429.200(b) are illustrative and not exhaustive of the Negotiation Program requirements for which a violation may give rise to the imposition of CMPs. As mentioned in previous responses, we intend to use our authority to impose CMPs for substantive noncompliance that obstructs Negotiation Program processes, while remaining committed to offering corrective action opportunities when appropriate. We will provide Primary Manufacturers reasonable timeframes to meet requests for information or corrective action and will consider extension requests as warranted.

Comment: A few commenters raised concerns about the potential for CMS to impose concurrent CMPs for a Primary Manufacturer's failure to provide complete and accurate information. For example, a CMP could be imposed for the initial failure to provide complete and accurate information followed by an additional CMP due to failure to comply with a CMS corrective action request. A few commenters indicated that because of the complexity and extent of the information collection requests for the negotiation process Primary Manufacturers may inadvertently provide inaccurate or incomplete information. A few commenters requested that CMS clarify its intent and recommended the elimination of duplicative CMPs stemming from the same underlying violation.

Response: We appreciate the feedback provided by commenters regarding enforcement actions for program violations. We emphasize that CMS retains the authority to address separate and distinct violations of the Negotiation Program even where such violations may be related or run concurrently. However, CMS is not establishing a policy that more than one CMP would be issued for the same underlying violation. Enforcement actions may be applied separately to each applicable case of noncompliance, ensuring that the response aligns with the specific nature and impact of the violation.

We are establishing an enforcement framework that operates within our statutory authority and provides clear and consistent procedures for addressing noncompliance within the Negotiation Program. Further, we reiterate that the enforcement framework is designed to ensure that penalties are not imposed in a punitive manner for immaterial or non-substantive instances of noncompliance.

Final Decision: After consideration of public comments, we are finalizing § 429.1005 as proposed.

3. Provision of False Information Related to the Biosimilar Delay and Temporary Floor for Small Biotech Drugs (§ 429.1010)

In accordance with section 1197(d) of the Act, we proposed at § 429.1010 two circumstances where CMS may impose a CMP due to provision of false information: (1) CMS proposed we may impose a statutorily specified CMP on a Biosimilar Manufacturer for each item of false information the Biosimilar Manufacturer knowingly provides to CMS for use in applying the aggregation rule described at proposed § 429.110(b)(1)(iv)(A); and (2) CMS

proposed that we may impose a statutorily specified CMP on a Primary Manufacturer for each item of false information the Primary Manufacturer knowingly provides to CMS for use in applying the test to determine if a selected drug or drug selected for renegotiation is eligible for the Temporary Floor for Small Biotech Drugs described at proposed § 429.440(b)(2). Section 1197(d) of the Act provides for imposition of a CMP in the amount of $100,000,000 per item of false information. This amount will be updated yearly per the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015.

CMS proposed to adopt a standard for ''knowingly'' that conforms with the Office of Inspector General definition at § 1003.110 in the application of CMPs. Knowingly means that a manufacturer: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. Upon identifying instances of knowing submission of false information under this provision, CMS intends to provide the Biosimilar Manufacturer or Primary Manufacturer, as applicable, with a CMP notification following the process established in proposed § 429.1020.

Final Decision: We did not receive public comments on this provision, and therefore, we are finalizing § 429.1010 as proposed.

4. Failure To Pay a Biosimilar Delay Rebate (§ 429.1015)

In accordance with section 1197(b) of the Act, where a Reference Manufacturer fails to comply with the rebate requirements under section 1192(f)(4) of the Act as described at proposed § 429.110(i) and section II.B.3. of this final rule, CMS proposed at § 429.1015 that the Reference Manufacturer may be subject to a CMP equal to 10 times the amount of the rebate the Reference Manufacturer failed to pay. When CMS makes a determination to assess a CMP under section 1197(b) of the Act, CMS intends to follow the procedures established in proposed § 429.1020.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested that, in situations where a Primary Manufacturer does not fulfill its obligation to pay the biosimilar delay rebate, CMS should promptly initiate enforcement actions; these actions would be triggered immediately upon non-payment. Furthermore, the commenter proposed that CMS should refer such cases to the Federal Trade Commission for antitrust evaluation.

Response: We thank this commenter for their feedback. We affirm our commitment to engaging in robust oversight, monitoring, and enforcement activities, in support of successful and effective administration of all aspects of the Negotiation Program. Continuous oversight helps CMS oversee and evaluate adherence, allowing for prompt detection and resolution of compliance issues. We also acknowledge the recommendation to refer cases to the Federal Trade Commission and will take this into consideration.

Final Decision: After consideration of public comments, we are finalizing § 429.1015 as proposed.

5. Notice and Appeal Procedures (§ 429.1020)

Under section 1197(e) of the Act, CMPs imposed in accordance with sections 1197(a) through (d) of the Act are subject to the provisions of section 1128A of the Act (other than subsections (a) and (b)). Accordingly, when CMS makes a determination to assess a CMP, we intend to provide a written CMP notification that the manufacturer has engaged in one or more violations as described at proposed §§ 429.1005 through 429.1015 and is subject to a CMP. We proposed at § 429.1020(a) that the CMP notification would include the following:

- A description of the basis for the determination.
- The basis for the penalty,
- The start date of the penalty (if applicable).
- The end date of the penalty (if applicable).
- The total amount of the penalty assessed.
- The date the penalty is due.
- The manufacturer's right to a hearing.
- Information about where to file the request for a hearing.

In the case of violations associated with CMPs with daily accruals as described in proposed § 429.1005, we intend to send the CMP notification after the accrual has ended to reflect both the start date, end date, and total amount of penalty assessed within the notice. We have considered an alternative policy in which CMP notification letters would be issued during the period that the daily penalty amounts are still actively accruing. Such an approach would result in assessment of interim CMPs on Primary Manufacturers, each for the dollar amount that had accrued as of the date we issue each applicable interim CMP notice. We would issue such interim notices at set time intervals (for example, every 14 days) throughout the period in which the penalty continues to accrue as described in proposed § 429.1005. CMS solicited comment on this alternative option.

Per section 1128A of the Act, CMPs are due 60 calendar days after the receipt of the CMP notification, unless the manufacturer chooses to initiate an appeal. At the conclusion of any appeal process initiated by the manufacturer, where there is still a CMP amount owed, the civil monetary penalty is due within 60 calendar days of the appeal decision.

To operationalize the CMP appeal process in the Negotiation Program, we proposed adopting the existing procedures as codified in 42 CFR part 423 subpart T: Appeal Procedures for Civil Money Penalties (see 42 CFR 423.1000 through 423.1094) that currently apply to Part D sponsors and to manufacturers under the Manufacturer Discount Program. In accordance with this appeals process, the manufacturer would have 60 calendar days after receipt of the CMP notification to request a hearing (42 CFR 423.1020). If the manufacturer requests a hearing, the procedures outlined in section 1128A of the Act and operationalized by part 423, subpart T would apply. As set forth in section 1128A(f) of the Act, if the manufacturer does not pay the CMP timely, the CMP amount may be deducted from any sum then or later owing by the United States. CMP funds would be deposited in accordance with section 1128A(f) of the Act.

As described in proposed § 429.1020(e), in the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code and fails to pay either the full rebate amount of a Biosimilar Delay rebate owed or the total sum of CMPs imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid rebate amount and/or CMPs owed by the manufacturer. Filing a proof of claim does not waive any other rights of the United States to recover such amounts or to assert priority status as permitted under applicable law. CMS may exercise its offset authority under section 1128A(f) of the Act independently of, and in addition to, other available collection remedies permitted under Federal law.

We received public comments on these proposals. The following is a

summary of the comments we received and our responses.

Comment: Some commenters stated the need for advanced notice prior to any CMP accrual noting that in proposed § 429.1020, CMS proposed to send CMP notification after the accrual has ended to reflect both the start date, end date, and total amount of penalty assessed within the notice. These commenters were concerned that CMPs could accrue daily prior to written notice and requested due process in addressing program violations to mitigate the risk of the CMP appeal process and to avoid unnecessary accrual. Commenters stated that adequate due process should involve a warning notice with the opportunity to cure prior to the issuance and accrual of a CMP. A commenter supported interim notices while a CMP is actively accruing.

Response: We reiterate the established procedures for CMPs, which are consistent with the policies described in the Negotiation Program Guidance. We will issue notice of a CMP to a Primary Manufacturer once the accrual period for the CMP has ended and we have assessed the penalty amount. However, we may also issue earlier notices regarding noncompliant conduct such as a notice of violation or request for corrective action to alert the party that a CMP may be accruing or both. We will take the recommendation to issue interim notices while a CMP is actively accruing into consideration; we anticipate any such interim notice would communicate the amount of the potential CMP accrued to date in the event a violation is ongoing, but these notices would not change the start or end date of CMP accrual. We disagree with commenters' assertion that due process requires advance notice or an opportunity to engage in corrective action prior to CMP accrual.

The CMP determination notification process offers a Primary Manufacturer the opportunity to appeal the penalty. We proposed to adopt § 429.1020(c) providing that the existing procedures codified in part 423 subpart T: Appeal Procedures for Civil Money Penalties (see §§ 423.1000 through 423.1094) will govern any appeal of a CMP imposed pursuant to §§ 429.1005 through 429.1015. These regulations provide an opportunity for Primary Manufacturers to appeal a determination to impose a CMP. The notice of the determination to impose a CMP will include detailed information regarding the appeal process and instructions for filing an appeal.

Comment: A couple of commenters advocated for more transparency and recommended that CMS publicly disclose written violation notices, corrective actions, CMP determinations (including final dispositions), or aggregated information on trending compliance issues. A commenter stated that increased transparency would lead to increased accountability.

Response: We thank commenters for their suggestions related to greater transparency surrounding program oversight and monitoring activities. We will take these recommendations into consideration.

Final Decision: After consideration of public comments, we are finalizing § 429.1020 as proposed.

K. Application of Medicare Part B and Part D Drug Inflation Rebate Programs to Selected Drugs

Section 1847A(i) of the Act requires that manufacturers of Part B rebatable drugs pay inflation rebates to Medicare for certain Part B rebatable drugs based on specific requirements and formulas. Section 1860D–14B of the Act requires that manufacturers of Part D rebatable drugs pay inflation rebates to Medicare for certain Part D rebatable drugs based on specific requirements and formulas.

As described in section 120 of the Negotiation Program Guidance, whether a drug is a selected drug will have no bearing as to whether the drug is also subject to the Medicare Part B and Part D Drug Inflation Rebate Program. However, when a selected drug is no longer considered to be a selected drug, certain components of the applicable rebate amount formula are recalculated. As such, in the CY 2025 PFS final rule (89 FR 98582 through 98583), at § 427.303(c)(5) and (e)(5), we codified the identification of the payment amount benchmark quarter and the identification of the benchmark period CPI–U, respectively, in the case when a Part B rebatable drug is no longer considered to be a selected drug. Additionally, in the CY 2025 PFS final rule (89 FR 98591 through 98592), at § 428.202(c)(5) and (e)(5), we codified the identification of the payment amount benchmark period and the identification of the benchmark period CPI–U, respectively, in the case when a Part D rebatable drug is no longer considered to be a selected drug.

Final Decision: We did not receive public comments on this provision of the proposed rule.

III. Implementation of Inflation Reduction Act Provisions for the Medicare Prescription Drug Benefit Program

A. Part D Formulary Inclusion of Selected Drugs

1. Background

Sections 11001 and 11002 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) created Part E under Title XI of the Act (sections 1191 through 1198) which established the Negotiation Program to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products.

Section 11001(b) of the IRA added section 1860D–4(b)(3)(I)(i) of Act, which requires that, starting in 2026 and for each subsequent year, Part D plan sponsors include on their formularies each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP (as defined in section 1191(c)(3) of the Act) is in effect with respect to the year. Section 11001(b) of the IRA also added section 1860D–4(b)(3)(I)(ii) of the Act, which clarifies that nothing in clause (i) shall be construed as prohibiting Part D plan sponsors from removing from their formularies such a selected drug if such removal would be permitted under § 423.120(b)(5)(iv) or any successor regulation.

Section 11001(c) of the IRA directed the Secretary to implement the provisions in section 11001 of the IRA, including amendments made by such section, for 2026, 2027, and 2028, by program instruction or other forms of program guidance. In accordance with the law, CMS has issued several guidance documents for implementing the Negotiation Program, including the requirement that Part D plan sponsors include on their formularies selected drugs for which an MFP is in effect, starting in 2026.

CMS issued revised or final guidance on June 30, 2023, October 2, 2024, and September 30, 2025 for implementation of the Negotiation Program for initial price applicability years 2026, 2027, and 2028, respectively.[94] In these guidance documents, CMS described the requirement for Part D plan sponsors to include on their formularies each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP (as defined in section

[94] *https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf; https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf; https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.*

1191(c)(3) of the Act) is in effect with respect to the year as well as the exception that allows Part D plan sponsors to remove a selected drug from their formulary if such removal meets the requirements specified in § 423.120(b)(5)(iv) or any successor regulation. As discussed in section I.A.2, in this final rule, unless otherwise specified, references hereinafter to ''the Negotiation Program Guidance'' are to the most recent program guidance published by CMS, which is the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of sections 1191—1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 that was published on September 30, 2025.

On April 7, 2025, CMS issued the Final CY 2026 Part D Redesign Program Instructions which described certain changes under the IRA to the Part D benefit for CY 2026.[95] In section 90 of these program instructions, CMS identified § 423.120(e)(2)(i), and the corresponding notice requirements at § 423.120(f)(2) through (4), as the successor regulation for purposes of implementing section 1860D–4(b)(3)(I)(ii) of the Act, as added by section 11001(b) of the IRA. In section 110.1 of the Negotiation Program Guidance, CMS incorporated section 90 of the Final CY 2026 Part D Redesign Program Instructions with respect to the successor regulation exception and extended the policies therein to 2027 and 2028.

In the Negotiation Program proposed rule, we proposed to codify at new § 423.120(b)(2)(vii) and (viii) the requirement that Part D plan sponsors include each Part D drug that is a selected drug with an MFP in effect on their formularies and the exception that permits Part D plan sponsors to remove such a selected drug if the removal would be permitted under the successor regulation that we proposed to identify as § 423.120(e)(2)(i), (f)(2), (3), and (4). In alignment with these changes, we also proposed to codify a conforming change to the definition of corresponding drug at § 423.100.

2. Part D Formulary Inclusion of Selected Drugs (§ 423.120)

Section 11001(b) of the IRA added section 1860D–4(b)(3)(I)(i) of the Act to require that for 2026 and each subsequent year, Part D plans include each covered Part D drug that is a selected drug under section 1192 of the Act on Part D formularies if an MFP is in effect for that drug with respect to that year. For 2026, 2027, and 2028, we have implemented this requirement through guidance.[96] With the expiration of the IRA program instruction requirement for the Negotiation Program at the end of 2028, we proposed to codify this requirement at new § 423.120(b)(2)(vii) with respect to selected drugs for which an MFP is in effect in 2029 and subsequent years.

While section 1860D–4(b)(3)(I)(i) of the Act specifies that Part D plans must include on their Part D formularies covered Part D drugs that are selected drugs for which an MFP is in effect with respect to the year, it does not otherwise specify formulary requirements for tier placement or utilization management. CMS received comments[97] expressing concerns that plans may hinder beneficiary access to selected drugs (for example, by applying utilization management requirements that are not based on medical appropriateness or placing selected drugs on less favorable tiers compared to non-selected drugs). In response to these comments, we stated[98] that CMS agrees on the importance of ensuring meaningful beneficiary access to selected drugs and their MFPs and ensuring that plans do not engage in behavior that hinders access to selected drugs or non-selected drugs when medically appropriate. However, CMS also understands that not all selected drugs and drug classes will present Part D plan sponsors and their Pharmacy and Therapeutics Committees with the same formulary considerations, and the same formulary placement might not be warranted in all situations. In order to ensure meaningful beneficiary access to selected drugs and their MFPs, CMS would continue to use its comprehensive formulary review process to assess any practices that may undermine beneficiary access to selected drugs and ensure that Part D plan sponsors comply with existing statutory and regulatory restrictions on formulary design.

Sections 1860D–2(b)(2)(B) and 1860D–4(c)(1)(A) of the Act permit Part D plan sponsors to use formularies and tiered cost sharing in their benefit design, subject to certain limitations, and require them to have a cost-effective drug utilization management program that includes incentives to reduce costs when medically appropriate. Under section 1860D–11(e)(2)(D)(i) of the Act, CMS may approve a prescription drug plan only if the agency does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. In addition, § 423.272(b)(2)(i) requires that CMS not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan. Further, § 423.120(b)(2)(iii) requires each Part D plan formulary to ''include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines''. Finally, § 423.120(b)(1)(v) requires that in making decisions about formulary design, the entity designing the formulary must ''base clinical decisions on the strength of scientific evidence and standards of practice''. CMS maintains a robust clinical formulary review process to ensure that all Medicare Part D plans meet these and other applicable requirements. CMS reviews all formularies annually to ensure that each formulary meets the agency's clinical review criteria, which include comprehensive evaluation of tier placement and all utilization management restrictions and criteria.

Consistent with section 110 of the Negotiation Program Guidance, given CMS' statutory obligation to monitor Medicare Part D plans' compliance with all applicable formulary requirements, we would continue to use our formulary review process to assess: (1) any instances where Part D plan sponsors place selected drugs on non-preferred tiers; (2) any instances where a selected drug is placed on a higher cost-sharing tier than non-selected brand drugs in the same class; (3) any instances where Part D plan sponsors require utilization of an alternative non-selected brand drug prior to a selected drug (that is, step therapy); or (4) any instances where

[95] *https://www.cms.gov/files/document/final-cy-2026-part-d-redesign-program-instruction.pdf.*

[96] Section 110, Negotiation Program Guidance. *https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf; https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf; https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.*

[97] *https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf; https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf; https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.*

[98] *https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf, https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf, https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.*

Part D plan sponsors impose more restrictive utilization management (for example, step therapy and prior authorization) for a selected drug compared to a non-selected brand drug in the same class.

For this review, we would consider, consistent with section 110 of the Negotiation Program Guidance, class to mean the FDA Established Pharmacologic Class or other source that groups like drugs with similar mechanisms of action and similar indications. Specifically, CMS would expect Part D plan sponsors to provide a reasonable justification to support their submitted plan benefit design and formulary design that includes any of the practices noted previously during the annual bid review process. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements (for example, the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). CMS would evaluate these justifications for compliance with applicable statutory and regulatory requirements and would approve a Part D plan bid submitted by a Part D plan sponsor only if the plan benefit design and formulary design complies with those requirements.

As discussed in the Negotiation Program Guidance, CMS also is aware that there are concerns that Part D plan sponsors could broadly shift access with respect to a drug selected for negotiation after the drug has been announced as a selected drug, that is, in the contract year prior to the selected drug's MFP taking effect. To address these concerns, CMS would continue to monitor trends in formulary placement for selected drugs beginning after drugs are selected for an initial price applicability year. We believe this approach would continue to provide Part D plan sponsors with the flexibility to continue to manage costs through utilization management in a clinically appropriate manner, while allowing us to monitor practices that may undermine beneficiary access to selected drugs and potentially inform new requirements for future contract years.

Finally, because a selected drug includes all dosage forms and strengths to which the MFP applies, section 1860D–4(b)(3)(I)(i) of the Act requires that formularies include all such dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect. Thus, consistent with section 110 of the Negotiation Program Guidance, we proposed that Part D plan sponsors would continue to be required to include all such dosage forms and strengths of the selected drug that constitute a Part D drug and for which the MFP is in effect on their formularies.

In summary, in alignment with section 1860D–4(b)(3)(I)(i) of the Act, as added by section 11001(b) of the IRA, we proposed to codify at new § 423.120(b)(2)(vii) the requirement that, for 2026 and each subsequent year, Part D plan sponsors include each Part D drug that is a selected drug under section 1192 of the Act for which a maximum fair price (as defined in section 1191(c)(3) of the Act) is in effect with respect to the year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to codify the requirement that Part D plan sponsors include each Part D drug that is a selected drug on their formularies if an MFP is in effect with respect to that year.

Response: We thank the commenters for their support.

Comment: Many commenters who supported codifying the selected drug formulary inclusion requirement also argued that formulary inclusion alone does not ensure meaningful, timely, or affordable beneficiary access to selected drugs. Several commenters stated that a selected drug may technically remain on a formulary while being placed on an unfavorable tier, subjected to prior authorization or step therapy, or restricted through a narrow pharmacy network, and that these practices can undermine the practical value of an MFP and can result in delayed treatment, treatment switching, or interruption of established therapy or lead beneficiaries to abandon treatment altogether. A commenter argued that the MFPs under the Negotiation Program alter the underlying economics for selected drugs, for example, by replacing existing rebate arrangements and creating altered incentives that favor cost management strategies over clinically appropriate access decisions. Other commenters raised a related concern that, because Part D plans have historically preferred higher-priced drugs that generate larger rebates, the lower point-of-sale prices resulting from MFPs may lead plan sponsors and their PBMs to favor higher-cost competing therapies in the same class, including non-selected drug alternatives that carry a higher net cost to Medicare and beneficiaries, in order to capture greater rebate revenue, and to steer patients toward those products through less favorable tier placement or utilization management requirements on selected drugs.

Several commenters urged CMS to go beyond formulary inclusion and establish stronger protections, including requiring that selected drugs be placed on a tier no less favorable than coverage for competing therapies and that utilization management for selected drugs be clinically grounded and no more restrictive than what is applied to therapeutic alternatives in the same class. A few commenters urged CMS to prohibit step therapy that is not supported by scientific and clinical evidence, and to implement continuity-of-care protections so that patients already stabilized on a selected drug are not subjected to new utilization management requirements, less favorable cost sharing, or non-medical switching driven by MFP implementation rather than clinical need.

Response: We appreciate the commenters' support of our proposal to codify the formulary inclusion requirement. We are committed to ensuring that beneficiaries can meaningfully access selected drugs.

We appreciate commenters' concerns. However, as we explained in section III.A.2 of the proposed rule (91 FR 36318), section 1860D–4(b)(3)(I)(i) of the Act requires that Part D plan sponsors include on their formularies each covered Part D drug that is a selected drug for which an MFP is in effect. We do not believe additional regulatory requirements beyond the formulary inclusion requirement that we are finalizing in this rule are needed at this time. We do not believe it is necessary to impose tier placement or utilization management requirements specific to selected drugs because Part D regulations already require oversight of tier placement and utilization management. Our existing requirements for Part D plan sponsor Pharmacy and Therapeutics Committees require that these determinations be grounded in clinical evidence. Under § 423.120(b)(1), a Part D plan sponsor's formulary must be developed and reviewed by a Pharmacy and Therapeutics Committee and this committee must, among other requirements, base clinical decisions on the strength of scientific evidence and standards of practice, consider whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy, review policies that

guide exceptions and other utilization management processes, and review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug. Therefore, the additional requirements the commenters recommend would duplicate requirements that already apply to Part D formulary and utilization management decisions, including those affecting selected drugs.

We are committed to using our existing authorities to monitor and address plan practices that may undermine meaningful beneficiary access to selected drugs and the respective MFPs. As stated in the Negotiation Program proposed rule (91 FR 36318), and consistent with section 110 of the Negotiation Program Guidance, we will continue to use our formulary review process to assess: (1) any instances where Part D plan sponsors place selected drugs on non-preferred tiers; (2) any instances where a selected drug is placed on a higher cost-sharing tier than non-selected brand drugs in the same class; (3) any instances where Part D plan sponsors require utilization of an alternative non-selected brand drug prior to a selected drug (that is, step therapy); or (4) any instances where Part D plan sponsors impose more restrictive utilization management (for example, step therapy and prior authorization) for a selected drug compared to a non-selected brand drug in the same class. We will expect Part D plan sponsors to provide a reasonable clinical justification to support any such formulary design during the annual bid review process, and we will evaluate those justifications for compliance with applicable statutory and regulatory requirements. We will approve a Part D plan bid only if the plan benefit design and formulary design comply with those requirements.

Comment: Several commenters noted that selected drug status is a pricing designation under the Negotiation Program and not a determination of clinical superiority. However, not all these commenters drew the same conclusions from that shared premise. A few commenters recommended that CMS should clearly state that selection of a drug for negotiation or the establishment of an MFP does not, standing alone, provide a clinical rationale for plans to impose more restrictive utilization management requirements on selected drugs. Other commenters argued that selected drug status should not be treated as a presumption of clinical appropriateness that limits a plan's ability to apply otherwise permissible formulary and utilization management requirements on the selected drug.

Response: We thank the commenters for their feedback. As described in section 1192 of the Act and proposed and finalized at §§ 429.105 through 429.125, CMS selects a negotiation-eligible drug based on certain statutory eligibility criteria and total expenditures under Part B and Part D. A selected drug, as defined at § 429.20, is, in part, a qualifying single source drug that ranks among the highest in total expenditures under Part B and Part D and is selected from the ranked list of negotiation-eligible drugs. Selection therefore reflects a drug's total expenditures and eligibility profile under those statutory criteria and is not a determination that the drug is clinically superior or inferior to therapeutic alternatives.

Further, as proposed and finalized at § 423.120(b)(1)(v), a Part D plan sponsor's Pharmacy and Therapeutics Committee must base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate. As described in the Negotiation Program proposed rule (91 FR 36318), we also expect Part D plan sponsors to provide a reasonable justification to support their submitted plan benefit design and formulary design that includes any of the practices identified in that section of the final rule during the annual bid review process. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements (for example, the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). We evaluate these justifications for compliance with applicable statutory and regulatory requirements and will approve a Part D plan bid submitted by a Part D plan sponsor only if the plan benefit design and formulary design complies with those requirements.

Comment: Several commenters expressed concerns specifically about access to selected drugs within the six protected classes. A commenter urged CMS to ensure beneficiary access to selected drugs within the six protected classes is not restricted compared to non-selected drugs within the protected classes. This commenter noted that this is particularly crucial, arguing that there have been widespread and significant reductions in beneficiary access since the passage of the IRA. A commenter urged CMS to confirm that nothing in this rule creates a loophole around existing protections for protected class drugs.

Response: We thank the commenters for their input. Consistent with section 1860D–4(b)(3)(G) of the Act and § 423.120(b)(2)(v), Part D plan sponsors are required to include in their formularies all covered Part D drugs in the classes and categories of clinical concern identified by the Secretary, with limited exceptions, as described in § 423.120(b)(2)(vi) and Chapter 6, Section 30.2.5, of the Medicare Prescription Drug Benefit Manual.[99] Part D plan sponsors remain subject to all applicable requirements with respect to protected class drugs, including selected drugs that fall within a protected class, and this final rule does not change that. Our formulary review process will continue to assess compliance with those existing requirements. With respect to the commenter's assertion that there have been reductions in beneficiary access to protected class drugs since the passage of the IRA, based on our review of available data, we have not seen evidence to support this claim.

Comment: Several commenters raised concerns that the Negotiation Program alters the incentive structure for Part D plan sponsors in a way that may affect beneficiary access not only to selected drugs but also to non-selected drugs in the same therapeutic class. A few commenters noted that when prices for selected drugs decrease to reflect the MFP, plans and their PBMs may have financial incentives to favor non-selected drugs in the same class that continue to generate higher rebates and administrative fees. A few commenters also stated that plans may place selected drugs on less favorable tiers or impose more burdensome utilization management requirements than non-selected drugs to encourage patients to prefer higher-cost non-selected alternatives.

Response: We appreciate the commenters sharing their concerns about the potential effects of the Negotiation Program on beneficiary access to selected drugs and non-selected drugs in the same therapeutic class. We recognize that by significantly altering the Part D benefit design and implementing the Medicare Drug Price

[99] *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.*

Negotiation Program, the IRA changed the structure of liabilities for Part D plan sponsors and may create incentives for plans to alter their formulary and utilization management decisions not only with respect to selected drugs but also with respect to non-selected drugs in the same class. As discussed in our response above, our formulary review process assesses whether Part D plan sponsors place selected drugs on higher cost-sharing tiers than non-selected brand drugs in the same class and whether plans impose more restrictive utilization management for a selected drug compared to non-selected brand drugs in the same class. We will continue to monitor formulary and utilization management trends at the class level and will use our existing authorities to address plan practices that are inconsistent with applicable statutory and regulatory requirements.

Comment: Several commenters who supported codification of the selected drug formulary inclusion requirement also noted that they oppose the imposition of additional tier placement, utilization management, or other special formulary requirements for selected drugs. Most of these commenters argued that the statute does not require preferred formulary placement for selected drugs, exemption from utilization management, or treatment that is more favorable than other covered Part D drugs and that the IRA established a formulary inclusion requirement, not a formulary preference requirement for selected drugs. A commenter emphasized that Part D plan sponsors and their P&T Committees must retain the ability to evaluate selected drugs alongside therapeutic alternatives based on clinical evidence, safety, effectiveness, utilization, and net cost, with a couple of other commenters noting that many selected drugs may be older while newer, non-selected drugs may represent the preferred standard of care for new patient initiation. A commenter urged CMS to maintain its existing case-by-case formulary review process for assessing formulary management decisions involving selected drugs. A couple of other commenters urged CMS to review selected drugs under the same formulary standards applied to non-selected drugs, rather than subjecting selected drugs to a higher standard of review.

Several commenters also noted that if CMS were to create additional formulary requirements, they would have concerns about the downstream effects on plan leverage and drug costs, arguing that mandatory preferred placement would significantly diminish the effectiveness of formularies as a key tool to promote competition, inhibit plans' ability to negotiate price concessions on therapeutically similar non-selected products, and could unduly impact formulary, rebate, and other negotiations for non-selected drugs.

A few commenters urged CMS to confirm that its monitoring is intended to assess compliance with the statutory inclusion requirement and existing Part D requirements, rather than establish an implicit expectation regarding tier placement, cost sharing, or utilization-management design, and to avoid using formulary placement trends as a basis for imposing additional requirements not established by statute or regulation. A couple of commenters expressed concern that CMS has begun applying selected drug formulary expectations before the year in which an MFP is in effect and recommended that CMS clarify that such expectations apply only in years an MFP is in effect.

Response: We thank the commenters for their support of our proposal. At this time, we are not imposing tier placement, utilization management, or other special formulary requirements for selected drugs. As discussed in the Negotiation Program proposed rule (91 FR 36318), we believe our current approach provides Part D plan sponsors with the flexibility to continue to manage costs through utilization management in a clinically appropriate manner, while allowing us to monitor practices that may undermine beneficiary access to selected drugs and potentially inform new requirements for future contract years.

Our monitoring of formulary placement for selected drugs is intended to assess compliance with the statutory inclusion requirement and existing Part D requirements, while safeguarding beneficiary access at a time when the Part D benefit has undergone significant change. We will continue to use our existing formulary review process to evaluate plan formulary designs consistent with the standards described in this final rule and applicable statutory and regulatory requirements.

With respect to the commenters' concerns about the application of formulary review standards prior to MFP effectuation for a selected drug, we clarify that our formulary review process, as discussed in the Negotiation Program proposed rule (91 FR 36319), only applies in years for which an MFP is in effect for a selected drug. As discussed in this same section of this final rule, we will separately continue to monitor trends in formulary placement for selected drugs beginning after drugs are selected for an initial price applicability year, and we clarify that our monitoring during this period is intended to identify practices that may undermine beneficiary access.

Comment: Several commenters opposed additional formulary requirements for selected drugs and urged CMS to provide greater clarity and predictability in its formulary review process. A commenter stated that plan sponsors have had limited success obtaining CMS approval for non-preferred placement or utilization management of selected drugs, even when supported by clinical evidence, and urged CMS to establish clear standards identifying the formulary placement and utilization management approaches plans may apply to selected drugs.

A commenter requested that CMS provide clear reasoning and citations when a formulary placement or utilization management choice is rejected and create more windows for plans to update utilization management criteria during the plan year, noting that the current process can lack transparency and result in last-minute formulary changes that increase plan and program costs. Another commenter urged CMS to ensure that its policies encourage preferred formulary placement of lower-cost generics and biosimilars over selected drugs when appropriate and noted that current review practices discourage plans from preferring lower-cost alternatives. A commenter requested that CMS confirm in the final rule that a Part D plan sponsor can provide a reasonable justification for placing a selected drug on a less preferred tier when the plan demonstrates that a more cost-effective, clinically appropriate alternative is available.

Response: We thank the commenters for their feedback. With respect to commenters' requests for clearer standards and more specific reasoning when formulary placements or utilization management choices are rejected, we note that the standards governing our formulary review of selected drugs are described in detail in the Negotiation Program proposed rule (91 FR 36319). In response to the commenter's request to create more windows for plans to update utilization management criteria during the plan year, we note that existing regulations and guidance already provide Part D plan sponsors with meaningful opportunities to make maintenance and non-maintenance formulary changes during the plan year, consistent with § 423.120(e) and Chapter 6, Section 30.3 of the Medicare Prescription Drug

Benefit Manual. We believe our current approach appropriately balances Part D plan sponsors' need for flexibility with the importance of formulary stability for beneficiaries.

Comment: Many commenters stated that CMS' proposed approach to rely on its existing formulary review process and on monitoring formulary trends is inadequate to guarantee that beneficiaries can access their prescribed medications and urged CMS to attach enforcement consequences to its review. Many commenters expressed concern that, without consequences, plans could impose utilization management that limits beneficiary access to selected drugs, undermining the Negotiation Program's intent. A few commenters noted that because plans are facing increased financial liability under the Part D redesign, they have strong incentives to manage utilization of selected drugs through prior authorization, step therapy, and non-preferred tiering. A few commenters stated that CMS is relying too heavily on existing processes and noted that the proposed rule largely defers to the existing formulary review process. A commenter urged CMS to preemptively modernize and strengthen its formulary review standards for a post-IRA era, and another commenter urged CMS to commit additional resources to formulary reviews.

A commenter stated that annual formulary review at the bid submission stage does not constrain plan behavior during the plan year. This commenter also argued that if CMS is only considering restrictive formulary designs individually, there is a risk that broader market-wide trends of restricting access to specific selected drugs may be missed. A couple of commenters urged CMS to attach concrete consequences, such as bid disapproval under § 423.272(b)(2)(i) or a required corrective action plan, to its monitoring so that monitoring results in enforcement, not just observation.

Several commenters recommended year-round monitoring with expedited corrective action, a clearly identified process through which beneficiaries, prescribers, and patient organizations may report emerging access barriers, and routine audits of plan coverage practices for selected drugs. A commenter recommended that CMS treat a plan's use of an identified restrictive practice as presumptive evidence that a plan is impeding meaningful access and also recommended that, in these instances, CMS should require the plan to provide a drug-specific clinical justification supported by scientific evidence and accepted standards of care, noting that a generalized assertion of cost management would be insufficient to meet that standard.

Response: We appreciate the commenters sharing their concerns about CMS' formulary review process and enforcement recommendations. We are committed to ensuring that beneficiaries can meaningfully access selected drugs.

As described in the Negotiation Program proposed rule (91 FR 36318), we conduct a robust review of each Part D plan's formularies and expect Part D plan sponsors to provide a reasonable clinical justification for any formulary design that: (1) places a selected drug on a non-preferred tier; (2) places a selected drug on a higher cost-sharing tier than non-selected brand drugs in the same class; (3) requires utilization of an alternative non-selected brand drug prior to a selected drug (that is, step therapy); or (4) imposes more restrictive utilization management (for example, step therapy and prior authorization) for a selected drug compared to a non-selected brand drug in the same class. We will approve a Part D plan bid only if the plan benefit design and formulary comply with applicable requirements, and we may disapprove a bid under § 423.272(b) when a plan's formulary design does not meet those requirements. For this review, we consider, class to mean the FDA Established Pharmacologic Class or other source that groups like drugs with similar mechanisms of action and similar indications.

As stated in Chapter 6, Section 30.3.3 of the Medicare Prescription Drug Benefit Manual, both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the contract year. We believe that formulary stability is extremely important so that beneficiaries maintain access to the benefit they chose during enrollment as represented to them by the Part D plan sponsor. We note that Part D plan sponsors are subject to limitations on mid-year formulary changes under § 423.120(e). Except in limited circumstances, such as immediate substitutions under § 423.120(e)(2)(i) and market withdrawals under § 423.120(e)(2)(ii), Part D plan sponsors must submit a negative formulary change request to CMS prior to implementing any negative formulary change, and non-maintenance changes, as defined at § 423.100, may not be implemented until CMS provides approval of the change. These limitations provide an important safeguard against mid-year access disruptions for beneficiaries.

We will continue to monitor formulary and utilization management trends for selected drugs and will use the information gathered through that monitoring to inform our formulary review standards and guidance in future years and to identify any systemic trends that may warrant further action.

Finally, we note that beneficiaries may report any issues or concerns regarding access to their prescribed medications, including selected drugs, to their plan first, and also to CMS by utilizing the public-facing online portal [100] for the Negotiation Program, supported by the MTF platform, or by contacting 1–800–MEDICARE.

Comment: Many commenters urged CMS to expand the scope of its monitoring of selected drugs beyond formulary inclusion and recommended that monitoring assess not only whether a selected drug appears on the formulary but also how it is treated relative to comparable alternatives, including its formulary placement and utilization management. A commenter specifically recommended that monitoring assess whether a selected drug's placement or utilization management materially disadvantages it relative to clinically comparable non-negotiated alternatives without a sufficient clinical justification. Several commenters recommended that CMS monitor formulary tier placement and cost sharing, prior authorization, step therapy, and quantity limit requirements, approval, denial, appeal, reversal, and decision-time measures, and treatment switching and prescription abandonment. A few commenters urged CMS to evaluate the actual out-of-pocket financial impact of plan cost-sharing designs, including shifts from copayment to coinsurance, rather than relying solely on tier placement. A commenter also urged CMS to monitor the average number of medicines covered per class and ensure the number does not decrease.

Several commenters also urged CMS to evaluate access longitudinally by comparing formulary placement and utilization management before selection, after selection, and after the MFP takes effect to identify changes associated with the Negotiation Program, with a commenter noting that plans may alter formulary placement or utilization management in anticipation of future MFP implementation. A commenter urged CMS to monitor changes in comparator medications and clinical alternatives to selected drugs, noting

[100] *https://mtf.cms.gov/.*

that comparators should be defined broadly, not just by pharmacologic class, as clinical substitution can occur across classes. Another commenter recommended that CMS monitor and publish pharmacy-level access measures for selected drugs, including dispensing and reversal rates, dispensing delays, inventory-related complaints, and geographic availability, to identify access problems arising specifically from MFP effectuation at the pharmacy counter.

A commenter expressed concern about the impact on beneficiaries in long-term care and nursing facility settings and recommended that monitoring specifically account for continuity of care disruptions in those populations. A couple of commenters also noted that patients with rare diseases and cancer typically have a limited set of effective therapeutic options and that monitoring should account for rare-disease subtypes, patient-specific characteristics, and the lack of clinically interchangeable alternatives in these populations. Another commenter recommended that CMS collect plan-level data on treatment continuity within specific disease areas, such as antiretroviral therapy stability for people living with HIV.

Response: We appreciate the commenters' detailed recommendations regarding the scope of our monitoring of selected drugs and the importance of a comprehensive monitoring framework that captures a range of plan practices that may affect beneficiary access to selected drugs. As described in the Negotiation Program proposed rule (91 FR 36319), our formulary review process already assesses a range of formulary and utilization management practices for selected drugs. We will continue to use that framework as a foundation for our ongoing monitoring of selected drug access. We appreciate the commenters' recommendations and will take these recommendations into account as we continue to refine our monitoring framework in future years. We also note that public use files are available on *CMS.gov* for external researchers.[101] These files include formulary inclusion, tier placement, utilization management edits such as prior authorization, step therapy and quantity limits, as well as plan-level cost sharing and pricing data available for each contract year.

Comment: Many commenters urged CMS to publicly report the data it collects through monitoring activities, arguing that the current process remains largely opaque to beneficiaries and the patient organizations that advocate on their behalf. Several commenters urged CMS to publish the information it already collects and reviews as part of its bid review, formulary review, and Negotiation Program oversight activities so that researchers, beneficiary advocates, and policymakers can identify potential access concerns before they become widespread. A commenter noted that existing Part D reporting is aggregated and does not provide the drug- and plan-level transparency needed.

Several commenters recommended that CMS publish drug and plan-level data at the product, therapeutic area, and disease level, including formulary tier placement and cost sharing, prior authorization, step therapy, and quantity limit requirements, and approval, denial, appeal, reversal, and decision-time measures. A couple of commenters also requested CMS to publish a plain-language account of its formulary review criteria and oversight process and to provide sufficient information regarding the basis and disposition of individual formulary reviews to provide meaningful public accountability. A commenter further requested that CMS make public any specific formulary or utilization management approaches CMS will not approve, so that stakeholders have clear visibility into the standards CMS applies. Another commenter noted that formulary submissions and written criteria do not show how those policies operate in practice and urged CMS to publish operational measures rather than relying solely on plan-submitted formulary information.

Response: We appreciate the commenters' recommendations regarding public reporting on formulary placement, utilization management, and access outcomes for selected drugs. We will take these recommendations into consideration. We note that public use files are available on *CMS.gov* for external researchers.[102] These files include formulary inclusion, tier placement, utilization management edits such as prior authorization, step therapy and quantity limits, as well as plan-level cost sharing and pricing data available for each contract year. We further note that CMS does not publish the results of its formulary reviews or the clinical justifications submitted by Part D plan sponsors or publicly share such clinical justifications with any external stakeholders, including manufacturers.

Comment: Many commenters urged CMS to strengthen and streamline the appeals, exceptions, and coverage determination processes for selected drugs, arguing that the existing processes are insufficient to provide timely beneficiary relief when formulary changes or utilization management requirements interfere with access. A few commenters stated that exceptions and appeals must be clear, accessible, and timely, with expedited review available when a preferred alternative is unsuitable and urged CMS to ensure that beneficiaries and prescribers have clear, timely information concerning coverage requirements and the ability to seek an exception when a preferred alternative is not appropriate.

A few commenters recommended that CMS create a more robust step therapy exceptions process for selected drugs, requiring plans to respond within 24 to 72 hours, and a commenter recommended allowing exceptions in specified clinical circumstances, including where the patient has already tried and failed the required drug, where delayed treatment will cause irreversible consequences, where the required drug will cause harm to the patient, or where the patient is stable on their current medication. A commenter urged CMS to require rapid, clinically meaningful exceptions and appeals, with timelines appropriate to progressive, life-threatening, or irreversibly disabling conditions.

A few commenters recommended that CMS establish an expedited process through which beneficiaries, prescribers, and patient organizations can report access barriers associated with selected drugs directly to CMS. A commenter requested that CMS' monitoring include the availability of expedited review and whether beneficiaries experience interruptions while an exception or appeal is pending. Another commenter also recommended that CMS actively monitor appeals, grievances, and exception requests that beneficiaries file with their plans in order to maintain a near real-time view of emerging access issues for selected drugs and improve the underlying appeals and grievance processes.

Response: We appreciate the commenters' recommendations regarding the coverage determination, exceptions, and appeals processes for selected drugs. We note that existing Part D requirements under subpart M of part 423 (§§ 423.558 through 423.638) already provide robust due process for enrollees seeking access to selected

[101] *https://resdac.org/cms-public-use-files-for-researcher-use.*

[102] *https://resdac.org/cms-public-use-files-for-researcher-use.*

drugs, and this process applies to selected drugs in the same manner as other covered Part D drugs. With regard to the commenters' recommendations on timing, we note that § 423.568(b) already requires that when a party makes a standard request for a drug benefit, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. For an exceptions request, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the physician's or other prescriber's supporting statement. Consistent with §§ 423.570 and 423.572, an enrollee or an enrollee's prescribing physician or other prescriber may also request that a Part D plan sponsor expedite a coverage determination or exceptions request, which requires that a Part D plan sponsor make a determination no later than 24 hours after receiving the request or the physician's or other prescriber's supporting statement.

We appreciate the commenters' recommendations that CMS establish a process through which beneficiaries, prescribers, and patient organizations can report access barriers associated with selected drugs directly to CMS. Beneficiaries may report any issues or concerns regarding access to their prescribed medications, including selected drugs, to their plan first, and also to CMS by utilizing the public-facing online portal [103] for the Negotiation Program, supported by the Medicare Transaction Facilitator (MTF) platform, or by contacting 1–800–MEDICARE. Beneficiaries may also submit inquiries, complaints, grievances, appeals, and requests for information to the Medicare Beneficiary Ombudsman. Additionally, we developed the Complaint Tracking Module (CTM) in the Health Plan Management System (HPMS) to track complaints received by CMS from beneficiaries, providers, and their representatives regarding specific plans. Complaints are recorded in the CTM and assigned to the appropriate plan and, as required under the contract provisions established at §§ 422.504(a)(15) and 423.505(b)(22), plans are required to address and resolve the complaints received by CMS against them in the CTM. Plans must also adhere to the timelines to resolve complaints in compliance with §§ 422.125 and 423.129.

We also appreciate the commenters' recommendations that CMS monitor appeals, grievances, and exception requests. One way that CMS is able to monitor appeals requests is through the review of the Appeals Decision Search Tool on *CMS.gov* which provides summaries of the Qualified Independent Contractor's (QIC) decisions on Part C and Part D appeals.[104] Further, consistent with § 423.514(a), each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report information to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires. As stated in the CY 2026 Medicare Part D Reporting Requirements document, this required information includes data on grievances (section III) and coverage determinations and redeterminations, including utilization management, formulary, and tiering exceptions (section v).[105]

Additional guidance on coverage determinations, exceptions, and appeals processes is available in subpart M of part 423 and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.[106]

Comment: A few commenters requested that CMS amend the proposed regulatory text at § 423.120 to reflect the language CMS states in preamble, that: ''because a selected drug includes all dosage forms and strengths to which the MFP applies, section 1860D–4(b)(3)(I)(i) of the Act requires that formularies include all such dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect.'' Therefore, the commenters requested that the language ''include each Part D drug'' in proposed § 423.120(b)(2)(vii) be replaced with ''include all dosage forms and strengths of each Part D drug''. A commenter stated that this will clarify Part D plan sponsors' legal obligations and ensure that the regulation aligns with CMS' stated policy in the preamble.

Response: Under our proposed regulation, because a selected drug includes all dosage forms and strengths to which the MFP applies, the formulary inclusion requirement applies to all dosage forms and strengths of a selected drug for which an MFP is in effect. Our regulation at § 429.700(a), which we are finalizing in this rule, states that the MFP is computed and applied across different dosage forms and strengths of the selected drug, as defined at § 429.20. Additionally, the Part D regulations already define ''selected drug'' at § 423.100 as having the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance, which will include our regulations at part 429. As such, we do not believe it is necessary to revise our proposed regulation at § 423.120(b)(2)(vii) and are finalizing § 423.120(b)(2)(vii) as proposed.

Comment: A commenter urged CMS to adopt new actuarial equivalence tests to more accurately and quantitatively track whether plan sponsors are offering what the commenter described as sufficient coverage of drugs selected for negotiation. The commenter argued that existing formulary review processes do not provide a sufficiently rigorous or quantitative basis for assessing whether a plan's overall treatment of selected drugs—across tier placement, cost sharing, and utilization management—is equivalent to its treatment of comparable non-selected drugs, and recommended that CMS develop and apply actuarial equivalence standards as part of its formulary oversight framework for selected drugs.

Response: We thank the commenter for their feedback. As discussed in the Negotiation Program proposed rule (91 FR 36319), section 1860D–4(b)(3)(I)(i) of the Act requires that Part D plan sponsors include on their formularies each covered Part D drug that is a selected drug for which an MFP is in effect. Sections 1860D–2(b)(2)(B) and 1860D–4(c)(1)(A) of the Act continue to permit Part D plan sponsors to use formularies, tiered cost sharing, and cost-effective drug utilization management programs, subject to applicable statutory and regulatory requirements. We do not believe it is necessary at this time to implement requirements that Part D plan sponsors treat selected drugs in a manner that is equivalent to their treatment of non-selected drugs through an actuarial equivalence standard.

Comment: A commenter requested that CMS to clearly distinguish authorized generics on the Formulary Reference File (FRF) so Part D sponsors can ensure inclusion of authorized generics that are selected drugs on their formularies when their MFP takes effect and can separately administer formulary status for authorized generics and

[103] *https://mtf.cms.gov/.*

[104] *https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d.*

[105] *https://www.cms.gov/files/document/cy2026-part-d-reporting-requirements-12-01-2025.pdf.*

[106] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

ANDA generics. The commenter states that the FRF does not always distinguish authorized generics from ANDA generics through separate RXCUIs, such as when the products share the same drug name. The commenter states that as a result, Part D plans may either inadvertently fail to include an authorized generic on formulary when required or be unable to assign different formulary treatment to authorized generics and ANDA generics, including different tier placement or utilization management requirements, or to submit an immediate substitution change.

Response: We appreciate the commenter's concern regarding the ability of Part D plan sponsors to distinguish between ANDA generic products and NDA authorized generic products when NDCs for those products are associated with the same RxCUI. RxNorm generally associates NDCs for ANDA generic products and authorized generic products with the same RxCUI when the products share the same RxNorm concept. CMS relies on the RxCUI assignments established in RxNorm and therefore cannot independently assign separate RxCUIs to distinguish these products on the FRF.

We recognize that a shared RxCUI may affect Part D plan sponsors' ability to separately administer formulary status for an authorized generic and an ANDA generic associated with that RxCUI. Accordingly, we will continue to provide submission guidance to Part D plan sponsors when an ANDA generic product (of a selected drug) becomes available on the market and is assigned the same RxCUI as the authorized generic product. We provided such technical guidance to all Part D plan sponsors when ANDA dapagliflozin NDCs became available and were associated with the same RxCUI as authorized generic dapagliflozin NDCs marketed under an NDA. This guidance is intended to assist Part D plan sponsors in complying with applicable formulary requirements for selected drugs and, where applicable, appropriately reflect separate formulary treatment for ANDA generic products and authorized generic products that share the same RxCUI.

Final Decision: After consideration of public comments, we are finalizing § 423.120(b)(2) as proposed.

3. Successor Regulation Exception Permitting Formulary Substitutions of Selected Drugs

Section 11001(b) of the IRA added section 1860D–4(b)(3)(I)(ii) of the Act, which states that nothing in section 1860D–4(b)(3)(I)(i) of the Act shall be construed as prohibiting a Part D plan sponsors from removing a selected drug from a formulary if such removal would be permitted under § 423.120(b)(5)(iv) or any successor regulation.

At the time the IRA was enacted, then-current § 423.120(b)(5)(iv) permitted a plan to immediately substitute on the formulary a newly available generic drug for its brand name drug if certain notice and timing requirements were met. However, due to changes made to the regulations in the Contract Year 2025 Parts C/D Final Rule (89 FR 30448), there is no longer a § 423.120(b)(5)(iv) in the current Part D regulations. Under the current Part D regulations, the approval requirements for immediate substitutions, which were revised to provide for the substitution of additional types of products, are now codified at § 423.120(e)(2)(i), and the corresponding notice requirements for such formulary changes are now codified at § 423.120(f)(2) through (4).

Because there was no longer a § 423.120(b)(5)(iv) in the Part D regulations, CMS had to identify the successor regulation to § 423.120(b)(5)(iv) for the purposes of the exception to the formulary inclusion requirement for selected drugs in section 1860D–4(b)(3)(I)(ii) of the Act. Because section 11001(c) of the IRA directed the Secretary to implement the provisions in section 11001 of the IRA, including amendments made by such section, for 2026, 2027, and 2028, by program instruction or other forms of program guidance, CMS identified the successor regulation for such years by guidance. For 2026, CMS identified the successor regulation in section 90 of the Final CY 2026 Part D Redesign Program Instructions. For 2027 and 2028, in section 110.1 of the Negotiation Program Guidance, CMS incorporated section 90 of the Final CY 2026 Part D Redesign Program Instructions with respect to the successor regulation exception and extended the policies therein to 2027 and 2028.

With the expiration of the IRA program instruction requirement for the Negotiation Program at the end of 2028, we proposed to codify, consistent with our previously issued guidance in the Final CY 2026 Part D Redesign Program Instructions and the Negotiation Program Guidance, the section 1860D–4(b)(3)(I)(ii) of the Act exception to the formulary inclusion requirement for selected drugs at new § 423.120(b)(2)(viii). We proposed, consistent with the Final CY 2026 Part D Redesign Program Instructions and the Negotiation Program Guidance, to codify our identification of § 423.120(e)(2)(i), (f)(2), (3), and (4) as the ''successor regulation'' for the purposes of implementing section 1860D–4(b)(3)(I)(ii) of the Act, and proposed § 423.120(b)(2)(viii). In alignment with these changes, we also proposed to codify a conforming change to the definition of corresponding drug at § 423.100.

a. Exception Permitting Formulary Substitutions of Selected Drugs

As discussed in the previous section, we proposed to codify our identification of § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor regulation for purposes of implementing section 1860D–4(b)(3)(I)(ii) of the Act. Under § 423.120(e)(2)(i), a Part D plan sponsor is permitted to make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary on the same or lower cost sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval . . . because such drug was not yet available on the market, and the Part D sponsor has provided advance general notice as specified in paragraph (f)(2) of [§ 423.120].

Under § 423.120(f)(2), (3), and (4), a Part D plan sponsor making an immediate substitution under § 423.120(e)(2)(i) is required to provide advance general notice and retrospective notice to enrollees, among others, and to ensure that written notices include specified content. Specifically, the advance general notice must be provided to all current and prospective enrollees and other specified entities, must be in the Part D plan sponsor's formulary and other applicable beneficiary communication materials, and must advise that the Part D plan sponsor may make immediate negative formulary changes, consistent with the regulation, at any time. The required retrospective notice must be provided to affected enrollees as soon as possible, but no later than by the end of the month following any month in which the change takes effect. The content of these notices is specified in § 423.120(f)(4).

Under this successor regulation, nothing in section 1860D–4(b)(3)(I)(i) of the Act, and proposed § 423.120(b)(2)(vii), would be construed as prohibiting a Part D plan sponsor from removing a selected drug from its

formulary if, in accordance with § 423.120(e)(2)(i) and the notice requirements of § 423.120(f)(2), (3), and (4), the Part D plan sponsor adds to its formulary on the same or lower cost sharing tier and with the same or less restrictive PA, ST, or QL requirements a newly available corresponding drug, as defined at § 423.100, with respect to such selected drug.

We proposed to codify the current identification of § 423.120(e)(2)(i) as part of the successor regulation, we also proposed to codify that, in addition to continuing to permit Part D plan sponsors to remove a selected drug that is a brand name drug and replace it with a generic drug as an immediate substitution, we would also continue to permit Part D plan sponsors to remove a selected drug that is a reference product and replace it with an interchangeable biological product as an immediate substitution.[107]

As discussed in section 90 of the Final CY 2026 Part D Redesign Program Instructions, allowing removal of selected drugs that are reference products and replacement with interchangeable biological products as immediate substitutions under the successor regulation that was first identified for 2026 was similar in kind to and consistent with the original regulation that was identified in the statute for the exception. Our proposed codification of the successor regulation in this rule would continue to apply the same rules to interchangeable biological products as are applied to generic drugs. As we explained when we first identified the successor regulation for 2026, this promotes consistency across selected drugs because, regardless of whether a selected drug is a drug or biological product, the Part D plan sponsor is able to remove a selected drug that is a brand name drug or reference product as an immediate substitution.

CMS would continue to permit, consistent with the agency's longstanding practice, including under § 423.120(b)(5)(iv) at the time of enactment of the IRA and under the identified successor regulation for 2026, 2027, and 2028, Part D plan sponsors to immediately substitute a selected drug for which there is a generic drug or interchangeable biological product available in the same dosage form, route of administration, and strength. The exception to the selected drug formulary inclusion requirement in section 1860D–4(b)(3)(I)(ii) of the Act allows for a selected drug to be removed as permitted under § 423.120(b)(5)(iv) (or any successor regulation). Accordingly, it is consistent with the exception established under section 1860D–4(b)(3)(I)(ii) of the Act to continue to apply this longstanding policy under the Part D program to the removal of selected drugs under the proposed codification of the current successor regulation pursuant to section 1860D–4(b)(3)(I)(ii) of the Act, and proposed § 423.120(b)(2)(viii).

Consistent with § 423.120(e)(2)(i), Part D plan sponsors that implement an immediate substitution for any brand name drug or reference product that is a selected drug on their formulary in accordance with section 1860D–4(b)(3)(I)(ii) of the Act, and proposed § 423.120(b)(2)(viii), would not be required to exempt enrollees who were already taking the selected drug. An enrollee may avail themselves of the formulary exception process, in accordance with § 423.578(b), if it is medically necessary for them to remain on a selected drug that has been removed from the formulary.

As discussed in the comment responses of the Final CY 2026 Part D Redesign Program Instructions, we also note that Part D plan sponsors would not need to remove selected drugs from their formularies to add a new generic drug, interchangeable biological product, or biosimilar biological product other than an interchangeable biological product to their formularies. A Part D plan sponsor can make such an addition at any time during the plan year, while keeping the brand name drug or reference product on the formulary. In addition, we remind Part D plan sponsors that they may also make maintenance changes with respect to selected drugs other than removing them from the formulary, in accordance with § 423.120(e) and the notice requirements of § 423.120(f).

In the Draft CY 2026 Part D Redesign Program Instructions,[108] CMS solicited comments on alternative approaches to identifying the successor regulation. These proposed alternative approaches included identifying additional regulations to expand the successor regulation exception to encompass maintenance changes, in addition to immediate substitutions. While we maintain that section 1860D–4(b)(3)(I)(ii) of the Act gives CMS the authority to identify such maintenance changes as part of the successor regulation for purposes of section 1860D–4(b)(3)(I)(ii) of the Act, CMS continues to decline to do so at this time and is proposing to maintain § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor regulation. However, in the future, CMS may identify new regulations that constitute the successor regulation (for example, as the biosimilar market matures or as additional changes are made to the underlying regulations).

In summary, consistent with the Negotiation Program Guidance and the Final CY 2026 Part D Redesign Program Instructions, CMS proposed to codify the identification of § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor regulation for the purposes of section 1860D–4(b)(3)(I)(ii) of the Act and add a new paragraph at § 423.120(b)(2)(viii) that specifies that nothing shall prohibit a Part D plan sponsor from removing a selected drug from their formulary if such removal meets the requirements specified in § 423.120(e)(2)(i) and the notice requirements specified in paragraphs (f)(2), (3), and (4) of this section.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to codify our identification of § 423.120(e)(2)(i), (f)(2) through as the successor regulation for the purposes of § 423.120(b)(2)(viii).

Response: We thank the commenters for their support of our proposal.

Comment: Several commenters requested that CMS expand the scope of the successor regulation. A few commenters recommended that CMS expand the successor regulation exception to include maintenance changes. Other commenter requested that CMS expand the successor regulation exception to include substitutions of biosimilar biological products other than interchangeable biological products. A commenter stated that allowing formulary substitutions for all biosimilars, not only those designated as interchangeable, will strengthen competition, reduce beneficiary cost-sharing, and better align formulary management with the affordability goals of the Negotiation Program. Another commenter requested

[107] As noted in section 90 of the Final CY 2026 Part D Redesign Program Instructions, the section 1860D–4(b)(3)(I)(ii) exception to the IRA's formulary inclusion requirement for selected drugs addresses when a Part D plan sponsor can remove a selected drug from a formulary. Accordingly, this section of the final rule applies specifically to negative formulary changes that result in the removal of a selected drug from a formulary. This section does not affect Part D plan sponsors' ability to implement negative formulary changes other than removal where a Part D plan sponsor would continue to include a selected drug on its formulary as required by section 1860D–4(b)(3)(I)(i) of the Act (for example, moving the selected drug to a higher cost-sharing tier or adding utilization management practices) if all applicable requirements are met.

[108] *https://www.cms.gov/files/document/draft-cy-2026-part-d-redesign-program-instructions.pdf.*

that CMS clarify that the successor regulation framework can evolve as the generic and biosimilar markets mature.

Response: We appreciate the commenters' recommendation to expand the scope of the successor regulation to include maintenance changes and biosimilar biological products other than interchangeable biological products. We understand that the commenters are interested in the successor regulation expanding to accommodate a broader range of formulary substitutions and to evolve as the generic and biosimilar markets mature. However, the successor regulation we are codifying at § 423.120(b)(2)(viii) is limited to § 423.120(e)(2)(i) and (f)(2) through (4), which govern immediate substitutions of corresponding drugs, consistent with our previously issued guidance in the Final CY 2026 Part D Redesign Program Instructions and the Negotiation Program Guidance. After consideration of the comments received, we decline to expand the scope of the successor regulation exception beyond what was proposed in the proposed rule. However, in the future, we may identify new regulations that constitute the successor regulation (for example, as the biosimilar market matures or as additional changes are made to the underlying regulations).

Comment: A commenter requested that CMS explain the scope of the successor regulation exception at § 423.120(e)(2)(i) and (f)(2) through (4), including any broader alternatives considered and the reasons for rejecting them. The commenter stated that because these provisions define the only circumstances permitting removal of a selected drug, they are the sole residual source of plan leverage.

Response: We thank the commenter for their comment. As discussed in detail in section III.A.3.a of this final rule, we are finalizing the identification of § 423.120(e)(2)(i), and the associated notice requirements at § 423.120(f)(2) through (4), as the successor regulation to § 423.120(b)(5)(iv) for the purposes of section 1860D–4(b)(3)(I)(ii) of the Act and new § 423.120(b)(2)(viii), which we are finalizing in this rule. This identification is consistent with the Negotiation Program Guidance and the Final CY 2026 Part D Redesign Program Instructions.

To ensure we fully considered alternative approaches to identifying the successor regulation, we solicited input in the Draft CY 2026 Part D Redesign Program Instructions on the advantages and disadvantages of identifying as the successor regulation the regulatory provisions that encompass only immediate substitutions of generic drugs and interchangeable biological products; immediate substitutions and maintenance changes of generic drugs and interchangeable biological products; and immediate substitutions and maintenance changes of generic drugs and interchangeable biological products, as well as maintenance changes of biosimilar biological products other than interchangeable biological products. More than half of the comments received supported identifying § 423.120(e)(2)(i), and the associated notice requirements at § 423.120(f)(2), (3), and (4), as the successor regulation to § 423.120(b)(5)(iv). After consideration of the comments received, we declined to adopt an alternative approach to identifying the successor regulation.

Comment: A commenter urged CMS not to permit, under the successor regulation, immediate substitution of interchangeable biological products and to identify a successor regulation that conforms with the plain language of the statute. The commenter stated that the plain language of the IRA limits immediate substitution to generic drugs, and the authority to identify a ''successor regulation'' does not permit CMS to materially expand immediate substitution to an entirely different class of drugs (that is, interchangeable biological products). The commenter stated that if Congress intended for immediate substitution to apply to newly marketed biosimilars, it would have said so in the statute. The commenter further argued that CMS' expansion exacerbates inequities in the underlying statute, in particular, the requirement that a manufacturer continue to offer the MFP throughout the drug's price applicability period, because a selected drug could be removed from formulary yet remain subject to the MFP for nearly two years after generic or biosimilar entry. The commenter stated that this would dissuade generic and biosimilar manufacturers from entering the market and result in manufacturers bearing the economic obligations associated with the MFP even though beneficiaries could lose access to the selected drug.

Response: We disagree with the commenter's assertion that our proposed codification of the successor regulation exception is extra-statutory. The statute does not explicitly limit the exception to § 423.120(b)(5)(iv) at the time of enactment. We believe it is significant that the statute did not establish a static exception (for example, by indicating that the exception was limited to § 423.120(b)(5)(iv) at the time of enactment), but rather expressly indicated that the exception would include ''any successor regulation.'' The statute could have limited the meaning or scope of ''any successor regulation'' to apply only to the scope of § 423.120(b)(5)(iv) at the time of enactment (that is, brand name drugs and their therapeutically equivalent generic drugs), but it did not do so. Other provisions of the Part D statute make clear that when the statute limits a provision that cross-references an existing regulation to the terms of such regulation at a particular point of time, the statute expressly states that this is the case. For example, section 1860D–14A(g)(6) of the Act defines ''negotiated price'' to have ''the meaning given such term in [42 CFR 423.100] (*as in effect on March 23, 2010*)'' (emphasis added). However, section 1860D–4(b)(3)(I)(ii) of the Act does not state that the exception is limited to 42 CFR 423.120(b)(5)(iv) as codified at a specific time, but instead expressly includes the words ''or any successor regulation,'' leaving it to CMS to identify any such successor regulation as necessary.

Furthermore, the statute does not explicitly limit the exception to brand name drugs and their therapeutically equivalent generic drugs. When CMS codified § 423.120(b)(5)(iv), there were no Part D drugs that were interchangeable biological products. At the time the IRA was enacted, there were no codified requirements for immediate substitutions with interchangeable biological products, nor were there codified requirements for maintenance changes with interchangeable biological products or biosimilar biological products other than interchangeable biological products. As a result, at the time of enactment, it would not have been possible for the statute to point to specific regulations permitting formulary changes other than those related to therapeutically equivalent generic drugs. Therefore, the inclusion of interchangeable biological products reflects the evolution of the Part D regulations since the IRA was enacted and is consistent with our statutory authority to identify a successor regulation.

With respect to the commenter's concerns about patient access, we note that the immediate substitution framework includes notice and timing requirements designed to protect beneficiaries during formulary transitions, and that existing coverage determination and exception processes remain available to beneficiaries with a documented medical need to remain on a particular product.

After consideration of public comments, we are finalizing § 423.120(e)(2)(i), (f)(2) through (4) as the successor regulation for the purposes of § 423.120(b)(2)(viii) as proposed.

b. Corresponding Drugs Do Not Include Selected Drugs

Consistent with CMS' proposed codification of the current identification of § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor regulation for the purposes of section 1860D–4(b)(3)(I)(ii) of the Act, a Part D plan sponsor may remove a selected drug from its formulary if, in accordance with § 423.120(e)(2)(i) and the notice requirements of § 423.120(f)(2) through (4), the Part D plan sponsor adds to its formulary on the same or lower cost sharing tier and with the same or less restrictive PA, ST, or QL requirements a newly available corresponding drug with respect to such selected drug.

Section 423.100 currently defines ''corresponding drug'' as ''respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product.'' As discussed in section 90 of the Final CY 2026 Part D Redesign Program Instructions, when read in isolation, the current definition might incorrectly appear to suggest that a Part D plan sponsor could remove a selected drug under section 1860D–4(b)(3)(I)(ii) of the Act, if the Part D plan sponsor adds an authorized generic of the brand name drug or an unbranded biological product marketed under the same BLA as the brand name biological product.

However, such a removal would be inconsistent with the Part D plan sponsor's obligation under section 1860D–4(b)(3)(I)(i) of the Act, and proposed § 423.120(b)(2)(vii), to include on its formulary each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP is in effect with respect to the year.

As stated in section 1192(e)(2)(A) of the Act (as added by section 11001 of the IRA), and as discussed in section II.B.6 of this final rule, an authorized generic drug and the qualifying single source drug that is the listed drug or reference product of that authorized generic drug shall be treated as the same qualifying single source drug and, thus, the same selected drug. For the purposes of the Negotiation Program, an ''authorized generic drug'' is defined in section 1192(e)(2)(B) of the Act and in proposed § 429.20 as—:

- In the case of a drug product, an authorized generic drug (as such term is defined in section 505(t)(3) of the FD&C Act); and
- In the case of a biological product, a product that has been licensed under section 351(a) of the PHS Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark than the reference product.

As discussed in section II.B.6.a of this final rule, authorized generics of a brand name drug that is a selected drug and unbranded biological products marketed under the same license as a brand name biological product that is a selected drug are treated as the same selected drug as the respective listed drug or reference product.

For example, section II.B.6.a. of this final rule states that, for drug products, CMS proposed at § 429.125(b)(1) to identify a potential qualifying single source drug using all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed under different NDAs. The potential qualifying single source drug also includes all dosage forms and strengths of the drug with the same active moiety and marketed under the same NDA(s) that are authorized generic drugs (defined in section 1192(e)(2)(B)(i) of the Act and at proposed § 429.20) that are marketed under such NDA(s). Likewise, section II.B.6.a. of the final rule states that, for biological products, CMS proposed at § 429.125(b)(2) to identify a potential qualifying single source drug using all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA), inclusive of products that are marketed under different BLAs. The potential qualifying single source drug also includes all dosage forms and strengths of the biological product with the same active ingredient and marketed under the same BLA(s) that are authorized generic drugs, the definition of which at section 1192(e)(2)(B)(ii) of the Act and proposed § 429.20 includes unbranded biological products that are marketed under such BLA(s).

Because an authorized generic of a brand name drug that is a selected drug or an unbranded biological product marketed under the same BLA as a brand name biological product that is a selected drug also qualifies as the selected drug, section 1860D–4(b)(3)(I)(i) of the Act, and proposed § 423.120(b)(2)(vii), requires the Part D plan sponsor to include each such authorized generic or unbranded biological product that is a covered Part D drug for which an MFP is in effect on its formulary.

Consequently, the statute does not permit a Part D plan sponsor to remove a selected drug that is a brand name drug or brand name biological product on the basis of adding an authorized generic of the brand name drug or an unbranded biological product marketed under the same BLA as the brand name biological product.

In situations where a selected drug includes both a brand name biological product and an unbranded biological product marketed under the same BLA as the brand name biological product, a Part D plan sponsor may remove both the brand name biological product and the unbranded biological product from its formulary when making an immediate substitution under § 423.120(e)(2)(i) by adding a single interchangeable biological product to its formulary. The interchangeable biological product that is the corresponding drug for the selected drug may replace both the reference product and the unbranded biological product provided that the requirements specified in the proposed successor regulation at § 423.120(e)(2)(i), (f)(2) through (4) are met.

To ensure consistency with the IRA's formulary inclusion requirement, which we proposed to codify at § 423.120(b)(2)(vii), and avoid any potential confusion related to the identification of § 423.120(e)(2)(i) as part of the successor regulation to § 423.120(b)(5)(iv) for the purposes of section 1860D–4(b)(3)(I)(ii) of the Act, we amended the definition of ''corresponding drug'' in section 90 of the Final CY 2026 Part D Redesign Program Instructions, consistent with the statutory directive to implement section 11001 of the IRA, including amendments made by such section, by program instruction or other forms of program guidance. Specifically, section 90 of such program instructions defined ''corresponding drug'' for 2026 to ''mean, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product. A corresponding drug does not include a selected drug as defined in section 1192(c) of the Act.'' Section 110.1 of the Negotiation Program Guidance incorporated section

90 of the Final CY 2026 Part D Redesign Program Instructions with respect to the successor regulation exception and extended the policies therein, including the revised definition of ''corresponding drug,'' to 2027 and 2028.

With the expiration of the IRA program instruction requirement for the Negotiation Program at the end of 2028, CMS proposed to codify for 2029 and subsequent years the current definition set forth in guidance at § 423.100. Specifically, the definition at § 423.100 would include language stating that a corresponding drug does not include a selected drug, as defined in section 1192(c) of the Act.

We did not receive public comments on this provision, and therefore, we are finalizing the definition of corresponding drug at § 423.100 as proposed.

c. Timing of Immediate Substitutions

Section 423.120(e)(2)(i), (f)(2), (3), and (4), which we proposed to codify as the successor regulation consistent with current guidance, permit a Part D plan sponsor, provided it has met the notice requirements, to remove a selected drug that is a brand name drug or reference product from its formulary and replace it with a generic of the brand name drug or an interchangeable biological product of the reference product ''so long as the Part D sponsor previously could not have included such corresponding drug on its formulary *when it submitted its initial formulary* for CMS approval consistent with paragraph (b)(2) of this section because such drug was *not yet available on the market*'' [emphasis added]. As such, under these regulations, for Part D plan sponsors that have a selected drug for initial price applicability year 2029 on their 2028 formulary, if a generic drug or interchangeable biological product of a selected drug becomes available on the market in 2028 after the Part D plan sponsor submitted its initial 2029 formulary for CMS approval, consistent with our longstanding policy on immediate substitutions, a Part D plan sponsor could add such generic drug or interchangeable biological product and remove the selected drug from its formulary as an immediate substitution for 2028, as well as for 2029. In other words, where the Part D plan sponsor could not have included the generic drug or interchangeable biological product on either its 2028 initial formulary submission or its 2029 initial formulary submission, and such Part D plan sponsor removes the selected drug as an immediate substitution, the Part D plan sponsor can apply the removal to both the current year formulary as well as the already-submitted formulary for the following year.

A Part D plan sponsor that does not have the selected drug on its 2028 formulary, but has submitted a formulary for 2029 that includes the selected drug, in accordance with section 1860D–4(b)(3)(I)(i) of the Act, could remove the selected drug as part of an immediate substitution only with respect to its 2029 formulary. That is, if a generic drug of a brand name drug that is a selected drug or an interchangeable biological product of a reference product that is a selected drug was first available on the market after the initial submission of the 2029 formulary, the Part D plan sponsor could, in the latter part of 2028, remove that selected drug from its 2029 formulary.

This application of the immediate substitutions policy to both the 2028 and 2029 formularies with respect to a generic drug or interchangeable biological product that becomes available on the market after the Part D plan sponsor has already submitted its initial formulary to CMS is consistent with section 1860D–4(b)(3)(I) of the Act. As discussed previously, the formulary inclusion requirement in section 1860D–4(b)(3)(I) of the Act applies with respect to selected drugs starting in initial price applicability year 2026 and the only permitted exception to the requirement is the ''removal'' of ''such selected drug.'' The plain text of the statute contemplates that a selected drug will need to be included on the plan's formulary for the first initial price applicability year in which the MFP for the selected drug is in effect, regardless of whether the plan ever previously included the drug. Moreover, the only statutory exception to the formulary inclusion obligation is the ''removal'' of ''such a selected drug'' in accordance with § 423.120(b)(5)(iv) or its successor regulation, which we proposed to codify as § 423.120(e)(2)(i), (f)(2) through (4). The references to ''removal'' and ''such selected drug'' indicate that the selected drug must first be included on the formulary for the initial price applicability year under section 1860D–4(b)(3)(I)(i) of the Act and only then can be removed under section 1860D–4(b)(3)(I)(ii) of the Act.

Accordingly, as discussed previously, a Part D plan sponsor that includes a selected drug with an initial price applicability year of 2029 on its initial formulary submission for 2029 could remove the selected drug as part of an immediate substitution prior to the start of 2029 if a generic drug or interchangeable biological product of the selected drug becomes available on the market in 2028 after the initial formulary submission. In such cases, the Part D plan sponsor will have included the selected drug on the formulary with respect to the initial price applicability year in which the MFP is in effect (that is, 2029), as required by section 1860D–4(b)(3)(I)(i) of the Act, and subsequently removed the selected drug, as permitted by section 1860D–4(b)(3)(I)(ii) of the Act.

Further, we note that there may be scenarios in which a generic drug or interchangeable biological product of, for example, a selected drug with an initial price applicability year of 2029 becomes available on the market in 2028 (after the Part D plan sponsor has submitted its initial 2028 formulary in 2027) but before the Part D plan sponsor submits its 2029 initial formulary for CMS approval in 2028. Under such a scenario, a Part D plan sponsor would be permitted, assuming all requirements are met, to remove the selected drug with an initial price applicability year of 2029 (prior to its MFP taking effect) from its 2028 formulary under § 423.120(e)(2)(i), but would be required under section 1860D–4(b)(3)(I)(i) of the Act to include the selected drug with an initial price applicability year of 2029 on its 2029 formulary when the MFP takes effect.

Consistent with section 90 of the Final CY 2026 Part D Redesign Program Instructions, if there is a generic drug or interchangeable biological product for a selected drug with an initial price applicability year of 2029 and such generic drug or interchangeable biological product is available on the market before a Part D plan sponsor's 2029 initial formulary submission, such Part D plan sponsor would still need to include the selected drug on its 2029 formulary submission, regardless of whether the Part D plan sponsor had removed such selected drug from its 2028 formulary via an immediate substitution in 2028, to comply with the formulary inclusion requirement in section 1860D–4(b)(3)(I)(i) of the Act. Moreover, the Part D plan sponsor would not be permitted to remove the selected drug from the formulary for 2029 as an immediate substitution and replace it with the generic drug or interchangeable biological product that became available on the market prior to the initial formulary submission for 2029 because section 1860D–4(b)(3)(I)(ii) of the Act permits removal only in accordance with § 423.120(b)(5)(iv) or its successor regulation. As discussed previously, the successor regulation, which we proposed to codify for 2029 and subsequent years, includes § 423.120(e)(2)(i), which, like

§ 423.120(b)(5)(iv) at the time of enactment, permits an immediate substitution only if the Part D plan sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval. In this scenario, because the Part D plan sponsor could have included the generic drug or interchangeable biological product in its initial formulary submission for 2029, an immediate substitution would not be available.

Further, consistent with section 90 of the Final CY 2026 Part D Redesign Program Instructions, the regulatory language at § 423.120(e)(2)(i), that a Part D plan sponsor previously could not have included the corresponding drug on its formulary when it submitted its initial formulary for CMS approval, would continue to mean, in practice, that the corresponding drug is not included on the final formulary reference file (FRF) update that CMS releases before the bid submission deadline. Consistent with our longstanding practice, the determination of whether a new generic drug or interchangeable biological product is included on the final FRF update that CMS releases before the bid submission deadline will be based on the presence of a RxNorm Concept Unique Identifier (RxCUI) on that FRF update that represents the generic drug or interchangeable biological product.

Finally, consistent with section 110.1 of the Negotiation Program Guidance, we proposed that removals under the statutory formulary inclusion exception, which we proposed to codify at new § 423.120(b)(2)(viii), cannot be carried over to subsequent years within the price applicability period simply because a selected drug was removed in a preceding year during the price applicability period. Instead, any removal must independently meet the immediate substitution requirements for each plan year because, consistent with CMS' longstanding policy, CMS considers each plan year's formulary to be separate and distinct from the prior year. Therefore, a removal could only apply to multiple plan years in a price applicability period if it independently meets the immediate substitution requirements for each applicable plan year.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters requested that CMS allow immediate substitutions for selected drugs in one year to carry over to subsequent years in order to prevent situations where a selected drug may need to be re-added to a formulary after it has been removed under an immediate substitution. The commenters recommended that CMS allow for the removal of selected drugs from a formulary as soon as a competitor generic or interchangeable biological products becomes available on the market, regardless of whether this is before or after the initial formulary submission. A commenter argued that Congress likely intended for the exception to the formulary inclusion requirement to consistently apply once generic or biosimilar competition exists for a selected drug to promote greater competition and affordability. Another commenter expressed concern that the requirement to re-add drugs to a formulary could artificially limit effective member migration from the selected drug to its generic or biosimilar equivalent. An additional commenter stated that requiring a selected drug that has lower cost alternatives to be re-added to a formulary can reduce incentives for competition, impede the adoption of generic and biosimilar alternatives, and prevent plans from realizing the full benefits of generic and biosimilar entry.

Response: We appreciate the commenters' recommendations to allow immediate substitutions to carry over to subsequent plan years. However, we decline to adopt this recommendation as our approach is consistent with CMS' longstanding policy to consider each plan year's formulary to be separate and distinct from the prior year. In this final rule, we are maintaining that a removal could only apply to multiple plan years in a price applicability period if it independently meets the immediate substitution requirements for each applicable plan year.

Comment: A commenter requested that CMS require Part D plan sponsors to retain on formulary any selected drug for which an MFP remains in effect, regardless of whether a generic or biosimilar has entered the market. The commenter stated that this protection should apply equally to small molecule drugs and biological reference products and would help ensure that the IRA's pricing provisions continue to function in a manner that meaningfully benefits patients. The commenter shared an example of a plan using immediate substitution to remove an innovator drug as soon as an interchangeable biological product is approved, but before that interchangeable biological product is stocked and available at local pharmacies, which would leave patients without access to their prescribed therapy. The commenter also requested that CMS implement ''grandfathering'' requirements to protect patients currently stabilized on a selected drug from abrupt access disruptions when plans utilize immediate substitution, particularly when a newly approved substituting product is not yet widely available at pharmacies.

Response: We disagree with the commenter's recommendation that Part D plan sponsors be required to retain on formulary any selected drug for which an MFP remains in effect regardless of whether a corresponding generic or biosimilar has entered the market. As described in section III.A.3.a. of this final rule, section 1860D–4(b)(3)(I)(ii) of the Act expressly provides that nothing in the formulary inclusion requirement shall be construed as prohibiting a Part D plan sponsor from removing a selected drug from a formulary if such removal would be permitted under the successor regulation. The immediate substitution framework at § 423.120(e)(2)(i) and (f)(2) through (4) includes notice and timing requirements designed to protect beneficiaries during formulary transitions, and existing coverage determination and exception processes remain available to beneficiaries.

Comment: A commenter raised concerns about the operational impact of mid-year immediate substitutions in long-term care (LTC) settings and recommended that CMS establish LTC-specific safeguards for immediate substitutions, including advance notice to the dispensing LTC pharmacy, a reasonable transition period that aligns with LTC dispensing and unit-dose packaging cycles, and protections to ensure continuity of care for stabilized residents during any mid-year product transition.

Response: We appreciate the commenter's recommendations regarding LTC-specific safeguards for immediate substitutions and recognize the operational complexities that mid-year formulary changes can present in LTC settings. However, we decline to establish LTC-specific requirements for immediate substitutions. The immediate substitution framework at § 423.120(e)(2)(i) and the notice requirements at § 423.120(f)(2) through (4) apply uniformly to Part D plan sponsors and already include beneficiary protections relevant to the commenter's concerns, including the requirement that a corresponding drug be added on the same or a lower cost-sharing tier and with the same or less restrictive formulary prior authorization, step therapy, or quantity limit requirements, and advance general and retrospective notice requirements. In addition, for beneficiaries who have

a medically necessary reason to remain on a selected drug that has been removed from the formulary, they may seek continued coverage through the coverage determination and exception processes under subpart M of part 423.

Comment: A commenter supported CMS' proposal to apply the immediate substitution regulation consistently to generic and interchangeable biological products. They urged CMS to provide clear operational guidance—including when a sponsor may implement a substitution, what notice is required, and how the change should be reflected in the applicable formulary and beneficiary materials—for circumstances in which such products become available during or after the formulary development and bid submission cycles. The commenter requested that CMS ensure that the timing of these requirements does not unnecessarily delay adoption of clinically appropriate lower-cost alternatives.

Response: We appreciate the commenter's support for our proposal and agree on the importance of clear operational guidance to support Part D plan sponsors in implementing the immediate substitution framework. As discussed in section III.A.3.a. of this final rule, we are codifying § 423.120(e)(2)(i) and (f)(2) through (4) as the successor regulation for purposes of new § 423.120(b)(2)(viii). Part D plan sponsors should refer to those regulations and the preamble discussion in this final rule for guidance on when an immediate substitution may be implemented, what notice is required, and how the change should be reflected in applicable formulary and beneficiary materials.

Comment: A commenter requested that CMS clarify that plans may begin a contract year with a qualifying corresponding biosimilar on formulary in place of a selected drug when the biosimilar is already available on the market at the time of bid submission. The commenter stated that plans have reported operational challenges when attempting to do so and the practical result is that beneficiaries may face a full plan year of higher cost-sharing on a reference product before substitution can occur, even when a lower-cost biosimilar was available on the market before the plan year began.

Response: We thank the commenter for this recommendation. We interpret this comment as a request that CMS permit a Part D plan sponsor to begin a contract year with a biosimilar on its formulary in place of a selected drug that is a reference product, where the biosimilar was available on the market at the time the sponsor submitted its bid and initial formulary. As explained below, the successor regulation does not permit removal of the selected drug in that circumstance, and we decline to adopt the recommendation.

Under the successor regulation we are finalizing, § 423.120(e)(2)(i) and the notice requirements at § 423.120(f)(2) through (4), a Part D plan sponsor may remove a selected drug that is a reference product from its formulary via an immediate substitution and replace it with an interchangeable biological product only if the Part D plan sponsor previously could not have included the drug on its formulary when it submitted its initial formulary for CMS approval because such drug was not yet available on the market. In the circumstance the commenter describes where the biosimilar is already available at the time of bid and initial formulary submission, the Part D plan sponsor could have included that product on its initial formulary, and therefore the immediate substitution exception is not permitted.

In addition, we note that only an interchangeable biological product qualifies as a corresponding drug for the purpose of the successor regulation exception. Accordingly, a Part D plan sponsor must include the selected drug that is a reference product on its formulary for the year in which the MFP is in effect, consistent with section 1860D–4(b)(3)(I)(i) of the Act and new § 423.120(b)(2)(vii).

We also note that including the selected drug on its formulary does not prevent a Part D plan sponsor from also covering an available biosimilar. A Part D plan sponsor may add a biosimilar biological product to its formulary at any time during the plan year, while retaining the reference product that is a selected drug on the formulary.

Final Decision: After consideration of public comments, we are finalizing § 423.120(b)(2)(vii) and (viii) as proposed.

B. Negotiated Price for Selected Drugs

Section 1860D–2(d)(1) of the Act requires Part D sponsors to provide beneficiaries with access to negotiated prices for covered Part D drugs. Section 1860D–2(d)(1)(A) of the Act requires Part D sponsors to ''provide enrollees with access to negotiated prices used for payment for covered Part D drugs.'' Subparagraph (B) further clarifies that negotiated prices, subject to subparagraph (D), ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs, and include any dispensing fees for such drugs.''

The negotiated price is the price paid to the network pharmacy or other network dispensing provider for a covered Part D drug dispensed to a plan enrollee and reported to CMS at the point of sale by the Part D sponsor. This point-of-sale price is used to calculate beneficiary cost sharing. The negotiated price also serves as the primary basis for adjudicating the Part D benefit because it is used to determine plan, beneficiary, manufacturer, and government liability during the payment year, subject to final reconciliation after the coverage year ends.

Section 11001(b) of the IRA amended section 1860D–2(d)(1) of the Act by adding subparagraph (D). That provision requires that, in the case of a covered Part D drug that is a selected drug, with respect to a price applicability period, the negotiated price ''used for payment (as described in this subsection) shall be no greater than the [maximum fair price] for such drug . . . plus any dispensing fees for such drug.'' Section 11001(b) of the IRA also added ''subject to subparagraph (D)'' to section 1860D–2(d)(1)(B) of the Act.

Section 11001(c) of the IRA directed CMS to implement section 11001 of the IRA, including the amendments made by such section, by program instruction or other forms of program guidance for initial price applicability years 2026 through 2028. Accordingly, we applied the statutory negotiated price requirements for selected drugs through the applicable Negotiation Program guidance for 2026, 2027, and 2028. Specifically, we stated that under section 1860D–2(d)(1)(D) of the Act, the negotiated price for selected drugs ''must not exceed the applicable [maximum fair price (MFP)] plus any dispensing fees for such drug.'' We also stated that the statute requires manufacturers to provide access to the MFP for selected drugs to pharmacies, mail order services, and other dispensing entities with respect to MFP-eligible individuals who are dispensed such drugs.

With the expiration of the IRA program instruction requirement for the Negotiation Program at the end of 2028, we proposed to codify the statutory amendments to the definition of negotiated price for selected drugs in the definition of ''negotiated price'' at § 423.100 for 2029 and subsequent years. We proposed to revise paragraph (2) of the definition to state that the required elements of the negotiated price are subject to a new paragraph (4) and add a new paragraph (4) to the definition to require that, for a covered

Part D drug that is a selected drug, and for each year of a price applicability period with respect to such selected drug, the negotiated price used for payment, as described in paragraphs (1) through (3) of the negotiated price definition, must not exceed the MFP for such drug, plus any applicable dispensing fees.

In addition, to better align the definition of ''negotiated price'' at § 423.100 with our historical interpretation of this definition, we proposed to revise the required elements of the negotiated price in subparagraph (2) to add sales tax and vaccine administration fees to the definition of ''negotiated price'' without altering any existing elements of that definition. Specifically, we proposed deleting the word ''and;'' from the end of paragraph (2)(ii), redesignating paragraph (2)(iii) as 2(v), and adding new paragraph (2)(iii) to require the inclusion of sales tax and new paragraph (2)(iv) to require the inclusion of vaccine administration fees.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to codify section 1860D–2(d)(1)(D) of the Act to require that the negotiated price paid to dispensing entities for a selected drug not exceed the MFP plus applicable dispensing fees. A commenter requested that CMS confirm Part D sponsors or pharmacy benefit managers (PBMs) have the ability to negotiate rates for selected drugs that are lower than the MFP, and that the ceiling does not alter the ability of Part D sponsors or PBMs to negotiate permissible pharmacy reimbursement arrangements or other contractual terms, provided that the resulting negotiated price used for payment complies with the statutory ceiling.

Response: We thank commenters for their support and note that under section 1860D–2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the MFP plus any dispensing fees for such drug. This does not prohibit plans from negotiating rates for selected drugs that are lower than the MFP. We encourage plan sponsors to work with pharmacies to ensure adequate and fair compensation for dispensing selected drugs.

Comment: A commenter supported CMS' inclusion of sales tax and applicable vaccine administration fees in the definition of negotiated price.

Response: We thank the commenter for their support.

Comment: Several commenters expressed concerns regarding pharmacy reimbursement for selected drugs. A commenter recommended that CMS revise the program such that Part D plans and PBMs must pay pharmacies no less than the MFP plus a commensurate dispensing fee when providing selected drugs with an agreed-upon MFP, and that Part D plans and PBMs must not assess Direct and Indirect Renumeration (DIR) fees on selected drugs with an agreed-upon MFP. A couple of commenters urged CMS to ensure that dispensing fees adequately compensate pharmacies and provided recommendations, such as requiring dispensing fees and any service fees be stated as flat, service-based amounts rather than as a percentage of the MFP, requiring the provision of a minimum dispensing fee, and affirming that dispensing fees for selected drugs must reflect the actual cost of dispensing selected drugs for long-term care (LTC) pharmacies.

Response: We thank the commenters for their input. We expect plans and PBMs to engage in sustainable and fair reimbursement practices with all pharmacies to ensure access to selected drugs, consistent with their statutory obligations, for individuals with Part D. As noted in our response to a similar comment in the Negotiation Program Guidance, under section 1860D–2(d)(1)(D) of the Act, as amended by section 11001(b) of the IRA, the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the applicable MFP plus any dispensing fees for a selected drug with an agreed-upon MFP. We are not establishing requirements for dispensing fees for selected drugs but will continue to closely monitor plan reimbursement for selected drugs, including pharmacy price concessions and dispensing fees.

Final Decision: After consideration of the public comments we received, we are finalizing § 423.100 as proposed.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 through 3520), we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement (as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations) is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether a collection of information should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment (see section II. of this final rule) on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter suggested that the burden estimate should include tasks other than submission of data that are involved with the production of the requested data, including internal review, legal analysis, data extraction, documentation, certification, and correction processes.

Response: CMS thanks this commenter for their feedback. As noted in the description of the roles involved with responses to information collections, the burden estimates already include the tasks related to the preparation of submissions. For example, the burden estimate for each Primary Manufacturer to submit negotiation data elements for drugs selected for negotiation includes 200 hours for business operation specialists to gather cost data and compile required information, 600 hours for economists to perform economic analyses, 50 hours for a financial manager to review the analysis results and cost estimates, 4 hours for a lawyer to review the data submission, 142 hours for a cost estimator to compile and report the data to CMS and 4 hours for a chief executive to review the data submission and certify the submission.

Comment: A commenter stated that CMS' interpretation that CMS can only consider section 1194(e)(1) factors submitted by manufacturers is incorrect. The commenter stated that the phrase could instead be providing clarification that CMS is able to require manufacturers to submit data on the 1194(e)(1) factors but not necessarily requiring CMS to exclude publicly available information. Similarly, a couple of commenters stated that CMS should not require manufacturer submission of data that is otherwise accessible to the Agency. A commenter

requested CMS extend the timeframe for manufacturers to submit required data. A few commenters asked that CMS decrease the burden imposed by the data collection requirement at § 429.505(b)(1), and among these commenters, a few suggested options to streamline the collection of information on section 1194(e)(1) factors. A commenter stated that aligning manufacturer requirements more closely with section 1194(e)(1) of the Act would minimize manufacturer burden and, as such, stated that CMS should not expand on the factors as provided in section 1194(e)(1) of the Act—for example by requesting information on anticipated loss of exclusivity, litigation updates, payer mix by indication, or other commercial data. A commenter suggested that CMS allow manufacturers to submit information that they believe is most relevant to the section 1194(e)(1) factors and provide a justification for the submission. A few commenters suggested that CMS should allow a single response from manufacturers to attest as to whether they have recouped research and development costs as required by section 1194(e)(1)(A) of the Act. A commenter suggested that CMS invest in the CMS HPMS submission portal to support standardized formatting and streamlined document upload, which could improve the accuracy and completeness of the information CMS relies upon during negotiation, and in any dispute or during the suggestion-of-error process.

Response: We appreciate these comments and acknowledge the burden on manufacturers as described in the Drug Price Negotiation ICR and the Drug Selection ICR. We endeavor to continue to refine these ICRs to minimize burden on Primary Manufacturers and the public. Consistent with our response to similar comments in the Negotiation Program Guidance, we respectfully disagree that we can obtain the information related to the factors listed at section 1194(e)(1) of the Act from sources other than the manufacturer of a selected drug. Section 1194(e)(1) of the Act specifically refers to the list of section 1194(e)(1) factors as, ''. . . the following data, with respect to such selected drug, as submitted by the manufacturer.'' We believe this indicates that the information for section 1194(e)(1) factors must come from the manufacturer of the selected drug. Additionally, consistent with our response to similar comments received in relation to the collection of section 1194(e)(1) data for initial price applicability years 2026 and 2027, we maintain that although some of the information may be available through other sources, we may not be able to ensure that such data are complete or up to date, and, ultimately, we believe that the Primary Manufacturer is best positioned to provide the requested data.

With regards to the comments on data collected on section 1194(e)(1) factors, including more closely aligning with section 1194(e)(1) of the Act and allowing manufacturers to determine what information is most relevant to submit, based on experience thus far, we determined that the information to be collected informs our consideration of the factors listed in section 1194(e)(1) of the Act and is needed to ensure a holistic evaluation of the selected drug. For example, payer mix is core to understanding a selected drug's market data in the United States consistent with section 1194(e)(1)(E) of the Act, which requires CMS to consider ''market data and revenue and sales volume data for the drug in the United States''. We believe this additional information is a low burden for manufacturers as this information is estimated in the ordinary course of business.

With regards to the comment on allowing an attestation for recoupment of research and development costs, at this time we believe that the full information sent and received is consistent with the statutory intent to collect ''research and development costs of the manufacturer for the drug'' as specified in section 1194(e)(1)(A) of the Act and supports a holistic evaluation of the selected drug. Based on experience to date, we do not believe that allowing solely an attestation in lieu of collecting this information would be sufficient.

With regards to the comment regarding the CMS HPMS submission portal, we continue to identify opportunities to apply lessons learned and to improve this process, including by considering respondent feedback and suggestions. We appreciate the suggestions brought forward by this commenter on potential submission options. However, in order to continue to meet statutory timing requirements, we will not adopt these suggestions at this time. We remind interested parties that we provide technical assistance throughout the ICR submission process if a Primary Manufacturer has questions about the CMS HPMS.

Comment: A few commenters expressed concern with CMS' data collection and notification processes for the Temporary Floor for Small Biotech Drugs. A commenter requested greater transparency around the deadlines for the application, notice of determination, and calculation as it relates to the Temporary Floor for Small Biotech Drugs. Some commenters suggested CMS determine eligibility for the Temporary Floor for Small Biotech Drugs using information CMS possesses.

Response: We thank commenters for raising these concerns. The Temporary Floor for Small Biotech Drugs ICR Form may be submitted to CMS no later than March 1, 2027 for initial price applicability year 2029. Primary Manufacturers that submit an application will receive a notice in writing, including eligibility and the calculation of the floor if applicable, alongside the calculation information provided as set forth in § 429.445(a). This ICR is required to accurately identify whether a given drug qualifies as a ''small biotech'' drug, consistent with section 1192(d)(2) of the Act, for purposes of determining if the drug is eligible for the Temporary Floor for Small Biotech Drugs, in accordance with section 1194(d) of the Act. CMS does not have information to determine whether manufacturers of drugs and biological products payable under Part B and/or covered under Part D were treated as a single employer with other entities under subsection (a) or (b) of section 52 of the IRC as of December 31, 2021. CMS also needs information to assess whether the Primary Manufacturer was the subject of an acquisition which would render the selected drug ineligible for the Temporary Floor for Small Biotech Drugs, per the limitation at section 1192(d)(2)(B)(ii) of the Act.

Comment: A commenter shared that the burden in completing the Drug Price Negotiation ICR is higher on individual patients and patient advocacy organizations than the burden estimates suggest. They note that the ICR instructions do not differ for manufacturers and non-manufacturers. However, the burden estimates are much higher for manufacturers. They recommend providing more time for patients and patient advocacy groups to respond, create a dedicated section of the ICR for patient advocacy organizations with questions that are more relevant and focused for that population, simplify the submission process for patients, clinicians, and organizations by accepting letters or create a direct-entry form, and publish a list of those who submitted comments.

Response: We thank this commenter for their feedback. The burden estimate is lower for non-manufacturers since they are not expected to provide responses to many of the burden-intensive questions, such as those requesting pricing and sales information

about selected drugs. Non-manufacturers are able to respond to such questions as not applicable.

Final Decision: After consideration of public comments, we are finalizing the collection of information requirements as proposed.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2025 National Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing industry, when available, to derive average labor costs for all salary estimates.[109] When industry-specific wage estimates were not available, the BLS' May 2025 Occupational Employment and Wage Statistics data was used (*https://www.bls.gov/oes/tables.htm*). In this regard, Table IV.A1 presents BLS' hourly median wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly median wage to estimate total cost is a reasonably accurate estimation method.

TABLE IV.A1: BLS' OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Hourly Median Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
All Occupations[110]	00-0000	24.51	24.51	49.02
Business Operations Specialists	13-1000	47.53	47.53	95.06
Chief Executive	11-1011	177.65	177.65	355.30
Cost Estimator	13-1051	41.41	41.41	82.82
Economist[111]	19-3011	59.96	59.96	119.92
Financial Manager	11-3031	87.99	87.99	175.98
General and Operations Managers	11-1021	82.99	82.99	165.98
General Internal Medicine Physicians[112]	29-1216	123.35	123.35	246.70
Lawyer	23-1011	142.57	142.57	285.14
Pharmacist	29-1051	66.73	66.73	133.46
Registered Nurse	29-1141	35.57	35.57	71.14

B. Information Collection Requirements (ICRs)—ICRs Regarding the Drug Price Negotiation Program Under Sections 11001 and 11002 of the Inflation Reduction Act (CMS–10844, OMB 0938–1443 and CMS–10849, OMB 1948–1452) (§§ 429.110, 429.200, 429.300, 429.405, 429.445, 429.505, and 429.600 Through 429.615)

1. Negotiation Program Drug Selection for Initial Price Applicability Year 20XX (§§ 429.110, 429.600 through 429.615)

The following was submitted to OMB for review under control number 0938–1443 (CMS–10844).[110] [111] [112]

a. Biosimilar Delay

This ICR addresses information for CMS to determine the applicability of section 1192(f)(1)(B) of the Act (which is finalized at § 429.110 of this final rule). Using information provided through this information collection in its determination, CMS may delay the inclusion of a negotiation-eligible drug that includes the reference product for a biosimilar biological product on the selected drug list for a given initial price applicability year if certain statutory requirements are met regarding the biosimilar's status of licensure and marketing (the ''Biosimilar Delay'') in accordance with section 1192(f) of the Act.

CMS estimates collecting a total of 10 requests for an Initial Delay Request (defined in proposed § 429.20 and discussed in proposed § 429.110(b)) per year. We believe that collection of these data will be a one-time cost for each Biosimilar Manufacturer (defined in proposed § 429.20) for each negotiation-eligible drug for which it is seeking the Initial Delay Request for each initial price applicability year.

Using the wage rates in Table IV.A1 of this final rule, we expect, for a Biosimilar Manufacturer, a lawyer will take 20.5 hours to gather and review the relevant ICR provisions, identify any controlled group members, identify and review any agreements between the Reference Manufacturer (defined in proposed § 429.20) and the Biosimilar Manufacturer, identify and review FDA licensure documentation and manufacturing schedule, trade agreements, and Securities and Exchange disclosures related to the Biosimilar Drug for each submission, and request technical assistance from CMS, a general and operations manager 4.5 hours to examine the gathered information, submit the form to CMS, and request technical assistance from CMS, and a chief executive 1.0 hour to review the information prior to submission and log into CMS' existing information technology system to certify the submission.

[109] See May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400—Pharmaceutical and Medicine Manufacturing. Available at: *https://www.bls.gov/oes/tables.htm.*

[110] Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000—Cross-industry. Available at: *https://www.bls.gov/oes/tables.htm.*

[111] Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000—Cross-industry. Available at: *https://www.bls.gov/oes/tables.htm.*

[112] Industry-specific wage estimate not available, see May 2025 All data (XLSX) National Industry-Specific Occupational Employment and Wage Estimates, NAICS 000000—Cross-industry. Available at: *https://www.bls.gov/oes/tables.htm.*

In aggregate, we estimated an annual burden of 260 hours (10 Biosimilar Manufacturers × 26.0 hr/response × 1 response/year) at a cost of $69,475.80 (10 responses × [(20.5 hr × $285.14/hr + (4.5 hr × $165.98/hr) + (1.0 hr × $355.30/hr)] (see Table IV.B1).

TABLE IV.B1: SUMMARY OF TOTAL ANNUAL BURDEN FOR BIOSIMILAR MANUFACTURERS TO COMPLETE AN INITIAL DELAY REQUEST ICR FORM

Requirement	Number of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Biosimilar Delay	10 Biosimilar Manufacturers	10 Biosimilar Manufacturers	26.0	260	Varies	69,475.80

b. Identification and Selection of Renegotiation-Eligible Drugs

This ICR also offers Primary Manufacturers the voluntary option to submit information to CMS to inform CMS' determinations of which selected drugs qualify as a renegotiation-eligible drug, in accordance with section 1194(f)(2) of the Act, and as finalized at § 429.605 of this final rule, and may be selected for renegotiation in accordance with section 1194(f)(3) of the Act, and as finalized at § 429.610 of this final rule. Specifically, section 1194(f)(2)(D) of the Act provides that a selected drug is eligible for renegotiation if a new indication has been added to the selected drug or if CMS determines that there has been a material change to any of the factors listed in section 1194(e) of the Act and finalized at § 429.610(b) of this final rule.

CMS estimates collecting up to 36 responses for the burden estimate base year of initial price applicability year 2029 in response to the Identification and Selection of Renegotiation-Eligible Drugs ICR Form. This estimate of potential burden incorporates assumptions that a negotiated MFP will be agreed to for all selected drugs for initial price applicability year 2028 and that, at the time of this information collection, certain previously selected drugs will no longer be considered a selected drug by CMS consistent with section 1193(c) of the Act. This would include responses from all Primary Manufacturers of selected drugs with agreed-upon MFPs for prior initial price applicability years unless the selected drug has a change in monopoly status or a previously selected drug is no longer considered a selected drug by CMS consistent with section 1193(c) of the Act. The collection of these data will be a one-time cost for each selected drug and CMS assumes each Primary Manufacturer will spend, on average, the same amount of time to collect, aggregate, analyze, and report the data for a selected drug.

Using the wage rates in Table IV.A1 of this final rule, we expect, for a Primary Manufacturer, a business operations specialist or team of business operations specialists will take 25.00 hours to gather cost data and compile required information, as specified in the data elements instructions, an economist or team of economists 75.00 hours to perform necessary economic analyses of data elements specified in the data element instructions, a financial manager 6.25 hours to review the results of all the analyses and cost estimates prior to submission to CMS, a lawyer 0.50 hours to review the compiled data submission, a cost estimator 17.75 hours to compile and report the required data to CMS, per the data element form instructions, and a chief executive 0.50 hours to review the data submission and log in to the CMS HPMS to certify the submission.

In aggregate, we estimated an annual burden of 4,500 hours (36 Primary Manufacturers × 125.00 hr/response × 1 response/year) at a cost of $513,383.40 (36 responses × [(25.00 hr × $95.06/hr + (75.00 hr × $119.92/hr) + (6.25 hr × $175.98/hr) + (0.50 hr × $285.14/hr) + (17.75 hr × $82.82/hr) + (0.50 hr × $355.30/hr)].

TABLE IV.B2: SUMMARY OF TOTAL ANNUAL BURDEN FOR IDENTIFICATION AND SELECTION OF RENEGOTIATION-ELIGIBLE DRUGS ICR FORM

Requirement	Number of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Identification and Selection of Renegotiation-Eligible Drugs	36 Primary Manufacturers	36 Primary Manufacturers	125.00	4,500	Varies	513,383.40

TABLE IV.B3: SUMMARY OF TOTAL ANNUAL BURDEN FOR NEGOTIATION PROGRAM DRUG SELECTION ICR

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	Number of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Negotiation Program Drug Selection for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act (with base year of initial price applicability year 2029)	0938-1443 (CMS-10844)	46	46	Varies	4,760	Varies	582,859.20

2. Drug Price Negotiation for Initial Price Applicability Year 20XX (§§ 429.300, 429.405, 429.445, 429.505, 429.600, and 429.615)

The following was submitted to OMB for review under control number 0938–1452 (CMS–10849).

a. Negotiation Data Elements for Selected Drugs for Negotiation From Primary Manufacturers

In accordance with section 1193(a)(4) and section 1194(b)(2)(A) of the Act and as finalized at § 429.200(b)(5) of this final rule, the Primary Manufacturer of a selected drug must submit, in a form and manner specified by CMS, information on the non-Federal average manufacturer price (''non-FAMP'') as defined in 38 U.S.C. 8126(h)(5) for the selected drug and information that CMS requires to carry out the negotiation process, including the factors outlined in section 1194(e)(1) of the Act, which, in conjunction with the available evidence on the factors outlined in section 1194(e)(2) of the Act, will serve as the basis for determining the initial offer, any offer(s) associated with negotiation meeting(s), and the final offer, if applicable. In addition, manufacturers and the public may submit information on the factors outlined in section 1194(e)(2) of the Act, which describes evidence about the selected drug and its therapeutic alternative(s). This ICR serves as a way for a Primary Manufacturer of a selected drug to submit the required 1194(e)(1) data as well as serving as one of multiple ways that CMS will collect data described in section 1194(e)(2) of the Act. Although information submission for factors outlined in section 1194(e)(2) of the Act are voluntary and open to all interested parties, this burden estimate assumes that all Primary Manufacturers would choose to submit this type of data.

CMS estimates collecting up to 20 responses for burden estimate base year initial price applicability year 2029 from Primary Manufacturers. For purposes of this collection of information, this represents one response for each selected drug, and up to 20 drugs selected for negotiation, which represents the statutory maximum. The collection of these data will be a one-time cost for each selected drug and CMS assumes each Primary Manufacturer will spend, on average, the same amount of time to collect, aggregate, analyze, and report the data for a selected drug.

Using the wage rates in Table IV.A.1of this final rule, we expect, for a Primary Manufacturer, a business operations specialist or team of business operations specialists 200 hours to gather cost data and compile required information, as specified in the data elements instructions, an economist or team of economists 600 hours to perform necessary economic analyses of data elements specified in the data element instructions, a financial manager 50 hours to review the results of all the analyses and cost estimates prior to submission to CMS, a lawyer 4 hours to review the compiled data submission, a cost estimator 142 hours to compile and report the required data to CMS, per the data element form instructions, and a chief executive 4 hours to review the data submission and log in to the CMS HPMS to certify the submission.

In aggregate, we estimated an annual burden of 20,000 hours (20 Primary Manufacturers × 1,000 hr/response × 1 response/year) at a cost of $2,281,704.00 (20 responses × [(200 hr × $95.06/hr + (600 hr × $119.92/hr) + (50 hr × $175.98/hr) + (4 hr × $285.14/hr) + (142 hr × $82.82/hr) + (4 hr × $355.30/hr)].

TABLE IV.B4: SUMMARY OF TOTAL ANNUAL BURDEN FOR COMPLETION OF NEGOTIATION DATA ELEMENTS ICR FORM FOR SELECTED DRUGS FOR NEGOTIATION BY PRIMARY MANUFACTURERS

Requirement	Number of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Negotiation Data Elements for Selected Drugs for Negotiation from Primary Manufacturers	20	20	1,000	20,000	Varies	2,281,704.00

b. Negotiation Data Elements for Selected Drugs for Renegotiation From Primary Manufacturers

In accordance with section 1194(f)(4)(B) of the Act and as finalized at § 429.615(b) of this final rule, along with definitions proposed in § 429.20, CMS will apply a similar approach regarding data collection once a drug is selected for renegotiation of the MFP, if any drugs are selected for renegotiation. Although information submission for factors outlined in section 1194(e)(2) of the Act are voluntary and open to all interested parties, this burden estimate assumes that all Primary Manufacturers will choose to submit this type of data. CMS assumes a lower burden for data submissions for drugs selected for renegotiation relative to the original submission of data for negotiation because Primary Manufacturers will need to report only new data for a short period of time.

CMS estimates collecting up to 36 responses from Primary Manufacturers of selected drugs for burden estimate base year initial price applicability year 2029 for renegotiation. CMS anticipates that fewer than 36 drugs will be selected for renegotiation, but CMS cannot provide definitive assumptions about how many drugs may be selected for renegotiation. The collection of these data will be a one-time cost for each selected drug and CMS assumes each Primary Manufacturer will spend, on average, the same amount of time to collect, aggregate, analyze, and report the data for a selected drug.

Using the wage rates in Table IV.A1 of this final rule, we expect, for a Primary Manufacturer, a business operations specialist or team of business operations specialists 150 hours to gather cost data and compile required information, as specified in the data elements instructions, an economist or team of economists 450 hours to perform necessary economic analyses of data elements specified in the data element instructions, a financial manager 37.5 hours to review the results of all the analyses and cost estimates prior to submission to CMS, a lawyer 3 hours to review the compiled data submission, a cost estimator 106.5 hours to compile and report the required data to CMS, per the data element form instructions, and a chief executive 3 hours to review the data submission and log in to the CMS HPMS to certify the submission.

In aggregate, we estimated an annual burden of 27,000 hours (36 Primary Manufacturers × 750 hr/response × 1 response/year) at a cost of $3,080,300.40 (36 responses × [(150.0 hr × $95.06/hr + (450.0 hr × $119.92/hr) + (37.5 hr × $175.98/hr) + (3.0 hr × $285.14/hr) + (106.5 hr × $82.82/hr) + (3.0 hr × $355.30/hr)].

TABLE IV.B5: SUMMARY OF TOTAL ANNUAL BURDEN COMPLETION OF NEGOTIATION DATA ELEMENTS ICR FORM FOR SELECTED DRUGS FOR RENEGOTIATION BY PRIMARY MANUFACTURERS

Requirement	Number of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Selected Drugs for Renegotiation from Primary Manufacturers	36	36	750.0	27,000	Varies	3,080,300.40

c. Negotiation Data Elements for Selected Drugs for Negotiation and Renegotiation From the General Public

To generate burden estimates for the section 1194(e)(2) data collection for burden estimate base year initial price applicability year 2029, CMS reviewed the public feedback that was received for the initial price applicability year 2028 negotiation period and adjusted accordingly due to the inclusion of selected drugs for renegotiation and the year-over-year greater awareness around the public input process for the Drug Price Negotiation Program.

CMS estimates collecting a total of 325 requests from the general public for initial price applicability year 2029. We believe that approximately 150 individual respondents and 175 organizations will respond because the proportion of individuals and organizations remained generally consistent across the first two initial price applicability years for which data has been collected thus far.

Using the wage rates in Table IV.A.1 of this final rule, we expect, for an individual respondent to spend 3 hours to review literature and submit information to CMS for a selected drug and for an organization to spend 30 hours to review literature and submit information to CMS for a selected drug.

In aggregate, we estimated an annual burden of 5,700 hours [(150 individuals × 3 hr/response × 1 response/year) + (175 organizations × 30 hr/response × 1 response/year)] at a cost of $279,414.00 [(150 responses × 3 hr × $49.02/hr) + (175 responses × 30 hr × $49.02/hr)].

TABLE IV.B6: SUMMARY OF TOTAL ANNUAL BURDEN FOR COMPLETION OF NEGOTIATION DATA ELEMENTS ICR FORM FOR SELECTED DRUGS FOR NEGOTIATION AND RENEGOTIATION BY THE GENERAL PUBLIC

Requirement	Number of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Selected Drugs for Negotiation and Renegotiation from the General Public	325	325	Varies	5,700	49.02	279,414.00

d. Temporary Floor for Small Biotech Drugs

This ICR also collects information necessary for CMS to determine eligibility of a selected drug, for negotiation or renegotiation in initial price applicability years 2029 or 2030, for the temporary floor of the maximum fair price provided to selected drugs determined by CMS to be small biotech drugs consistent with section 1194(d) of the Act and as finalized at § 429.445 (the ''Temporary Floor for Small Biotech Drugs'') of this final rule. Because eligibility for the Temporary Floor for Small Biotech Drugs relies on the same eligibility criteria specified in section 1192(d)(2) of the Act to determine if an otherwise negotiation-eligible drug was excluded from selection for initial price applicability years 2026, 2027, or 2028 because the drug met the qualifications for the exception for small biotech drugs (the ''small biotech exception'' or ''SBE''), CMS is repurposing the SBE ICR form (CMS–10844) to now collect the applicable information for the Temporary Floor for Small Biotech Drugs in this ICR (CMS–10849) for initial price applicability years 2029 and 2030.

CMS estimates up to 10 respondents will need to submit data to determine applicability of the Temporary Floor for Small Biotech Drugs per year. We believe that the collection of these data will be a one-time cost for a Primary Manufacturer for each selected drug that may be eligible for the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 or 2030.

Using the wage rates in Table IV.A1 of this final rule, we expect, for a Primary Manufacturer, a lawyer 6.50 hours to gather and review the relevant ICR provisions, identify any controlled group members, and request technical assistance from CMS, a general and operations manager 3.00 hours to examine the gathered information and submit the ICR Form for eligibility for the Temporary Floor for Small Biotech Drugs to CMS and request technical assistance from CMS, and a chief executive 0.25 hour to review the information prior to submission and to log into CMS' existing information technology system to certify the submission.

In aggregate, we estimated an annual burden of 97.5 hours (10 Primary Manufacturers × 9.75 hr/response × 1 response/year) at a cost of $24,401.75 (10 responses × [(6.50 hr × $285.14/hr + (3.00 hr × 165.98/hr) + (0.25 hr × $355.30/hr)].

TABLE IV.B7: SUMMARY OF TOTAL ANNUAL BURDEN FOR COMPLETION OF TEMPORARY FLOOR FOR SMALL BIOTECH DRUGS ICR FORM

Requirement	Number of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Temporary Floor for Small Biotech Drugs	10	10	9.75	97.5	Varies	24,401.75

e. Counteroffer

A Primary Manufacturer must complete and submit the information requested on the Statutory Written Counteroffer ICR Form or the Renegotiation Written Counteroffer ICR Form, as applicable, if it both chooses not to accept CMS' initial offer and chooses to submit a Counteroffer for a selected drug. The Statutory Written Counteroffer ICR Form and the Renegotiation Written Counteroffer ICR Form are collectively referred to as the ''Counteroffer ICR Form'' due to CMS approximating the estimates for each form to be similar due to the questions on the forms requiring about the same amount of time for a manufacturer to collect and submit the information on the applicable form.

CMS estimates collecting up to 56 responses from Primary Manufacturers for burden estimate base year initial price applicability year 2029. CMS chose this number because by statute only up to 20 drugs payable under Medicare Part B and/or covered under Medicare Part D can be selected for negotiation for 2029 and a maximum of 36 drugs can be selected for renegotiation for initial price applicability year 2029, and for each selected drug CMS will undergo negotiation or renegotiation with only one Primary Manufacturer, so it is not possible that there would be more than 57 respondents for initial price applicability year 2029.

Using the wage rates in Table IV.A1 of this final rule, we expect, for a Primary Manufacturer, a business operations specialist or team of business operations specialists 27.00 hours to review CMS' initial offer and justification and compare it to current prices, revenue, and other market and clinical data for the selected drug and compare CMS' justification with the data the Primary Manufacturer submitted as part of the section 1194(e)(1) and 1194(e)(2) factors and the section 1194(e)(2) data from other interested parties shared by CMS with the Primary Manufacturer, if feasible, and put together recommendations on how the initial offer compares to what was submitted and develop Counteroffer options and justifications, a team of healthcare professionals (a pharmacist 15.00 hours, a registered nurse 5.00 hours, and a general internal medicine physician 5.00 hours) 25.00 hours to compare CMS' initial offer and justification to the section 1194(e)(2) factors around the selected drug and therapeutic alternatives and develop Counteroffer options and justifications, an economist or team of economists 64.00 hours to consider team recommendations of the business operations specialist(s) and healthcare professionals, model counteroffer options, and recommend Counteroffer options, a general and operations manager or team of general and operation managers 14.25 hours to review Counteroffer options and justifications and develop a Counteroffer proposal for the MFP and to examine the gathered information, populate the Counteroffer ICR Form, and submit the Counteroffer ICR Form to CMS, a lawyer or team of lawyers 64.00 hours to review counteroffer options and draft a justification for the selected Counteroffer proposal for the MFP, and a chief executive 10.00 hours to review the Counteroffer proposal for the MFP, make a decision on the Counteroffer proposal for the MFP, review the Counteroffer information prior to submission, and log in to the CMS HPMS to certify the submission.

In aggregate, we estimated an annual burden of 11,438 hours (56 Primary Manufacturers × 204.25 hr/response × 1 response/year) at a cost of $2,127,987.40 (56 responses × [(27.00 hr × $95.06/hr + (15.00 hr × $133.46/hr) + (5.00 hr × $71.14/hr) + (5.00 hr × $246.70/hr) + (64.00 hr × $119.92/hr) + (14.25 hr × $165.98/hr) + (64.00 hr × $285.14/hr) + (10.00 hr x $355.30/hr)].

TABLE IV.B8: SUMMARY OF TOTAL ANNUAL BURDEN FOR COMPLETION OF COUNTEROFFER ICR FORM

Requirement	Number of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Counteroffer	56	56	204.25	11,438	Varies	2,127,987.40

TABLE IV.B9: SUMMARY OF TOTAL ANNUAL BURDEN FOR DRUG PRICE NEGOTIATION ICR

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	Number of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Drug Price Negotiation for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act (using base year initial price applicability year 2029)	0938-1452 (CMS-10849)	447	447	Varies	64,235.50	Varies	7,793,807.55

C. Summary of Annual Burden Estimates

Table IV.C1 sets out the burden for this rulemaking's finalized provisions that are subject to the PRA. It does not score burden adjustments that are strictly based on updated data and are unrelated to any of the provisions.

TABLE IV.C1: ANNUAL REQUIREMENTS AND BURDEN ESTIMATES (WITH BASE YEAR INITIAL PRICE APPLICABILITY YEAR 2029)

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	Number of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 429.110, 429.610, and 429.615 Negotiation Program Drug Selection for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act	0938-1443 (CMS-10844)	46	46	Varies	4,760	Varies	582,859.20
§§ 429.110, 429.610 and 429.615 Drug Price Negotiation for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act	0938-1452 (CMS-10849)	447	447	Varies	64,235.50	Varies	7,793,807.55
TOTAL		**493**	**493**	**Varies**	**68,995.50**	**Varies**	**8,376,666.75**

V. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes and codifies, with limited modification, policies related to the implementation of certain provisions of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022), which were established in the final guidance for the Medicare Drug Price Negotiation Program (hereinafter the ''Negotiation Program''). The primary driver for this rulemaking is the statutory mandate to codify changes made by the IRA. Without regulatory implementation of the Negotiation Program, the Medicare program cannot comply with Federal law, reduce prescription drug costs for beneficiaries, or achieve cost savings provided under statute.

This rulemaking finalizes and codifies policies for the Negotiation Program at part 429 consistent with sections 1191 through 1198 of the Social Security Act (hereinafter ''the Act'') and to codify policies for the Medicare Prescription Drug Benefit Program at part 423 consistent with section 11001(b) of the IRA, which made certain amendments to the Act, including with respect to Medicare Part D. Our policies in this rulemaking specifically address: general provisions; identification of selected drugs; Negotiation Program Agreement; program administration; establishment of a single maximum fair price (MFP) and determination of the ceiling; negotiation process; renegotiation of an MFP; implementation of the MFP; manufacturer compliance and oversight; civil monetary penalties; and requirements related to qualified prescription drug coverage. In addition, we finalized new policies for the Negotiation Program as follows: a policy for specific fixed combination drugs that are new formulations; clarification for drugs that formerly qualified for the orphan drug exclusion; revisions regarding the process and schedule of CMS review of information in making determinations with respect to Bona Fide Marketing; additional details related to the Primary Manufacturer transfer of responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity; calculation of the 30-day equivalent supply for a selected drug that is typically administered one time; implementation of the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030; and clarification of off-label use in consideration for renegotiation eligibility and selection. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for lower prices for Medicare through negotiation or price competition by lowering drug prices and making Medicare prescription drugs more affordable for beneficiaries.

The absence of regulatory action would result in statutory non-compliance regarding IRA implementation and missed opportunities for program improvement and innovation. Therefore, this rulemaking is necessary to ensure the Negotiation Program operates effectively, efficiently, and in compliance with Federal law while serving the best interests of Medicare beneficiaries.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order

12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts.). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our estimates, Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant under section 3(f)(1). Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this rule meets the criteria set forth in 5 U.S.C. 804(2).

We have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

The CMS Office of the Actuary estimated the impacts of the drug provisions of the IRA using the 2024 President's Budget as a baseline early in calendar year 2023. These estimates were made prior to many policy decisions to implement the law, and independently from other components of CMS. Since the majority of these provisions have already been implemented through program instruction, including Medicare Drug Price Negotiation Program guidance with respect to initial price applicability years 2026, 2027, and 2028 (as discussed in further detail in section I.A.2. of this final rule), this estimate should be taken only in its historical context, not as a reflection on the experience since its effectuation. We will highlight certain components of this estimate where recent experience has diverged from our initial assumptions. The IRA has a range of Medicare provisions, including restraining price growth and negotiating drug prices for certain drugs payable under Part B and covered under Part D, as well as redesigning the Part D benefit structure to decrease beneficiary out-of-pocket costs. The provisions of the IRA take effect over several years, resulting in very different effects by year. Much of the Part D benefit redesign became effective in 2025, for example, before the Negotiation Program provisions can have any offsetting effects.

To model the negotiation provisions of the IRA, we first determined which drugs would be selected for negotiation in accordance with sections 11001 and 11002 of the IRA. Using 2022 experience for Part B and Part D claims, we ranked drugs by Part B and Part D expenditures and then applied the eligibility criteria specified in the IRA—verifying, in particular, that the ranked drugs had been on the market long enough to qualify for negotiation. From this list, we generated the potential list of drugs to be negotiated in each year for Part B and Part D.

To estimate the impact of negotiation and to measure the differences between the current prices and the ceiling price and other pricing parameters laid out in the IRA, we used 2021 data from a variety of sources, including PDE records, Medicaid AMP data, and Part B ASP data. We assumed, after comparing the Medicare prices to the ceiling prices in each projection year, that Medicare would be able to negotiate slightly below the ceiling price in Part D. We then adjusted for generic and biosimilar launches that, should they happen after the selection process, would potentially limit the impact of the MFP. Lastly, we adjusted for changes in the percentage of spending that the selected drugs would represent over time. The discounts relative to total 2021 Part D allowed cost, prior to manufacturer rebates and total Part B allowed cost, are shown in Table V.C1.

TABLE V.C1: CUMULATIVE NEGOTIATION DISCOUNT FROM ALLOWED COSTS

	2026	2027	2028	2029	2030	2031
Part B	0%	−1%	−5%	−6%	−9%	−12%
Part D	−9%	−16%	−20%	−23%	−24%	−25%

For Part D, the benefit is considerably enriched under the IRA, and the most impactful changes took effect in 2025. To estimate these effects inclusive of the Negotiation Program impacts, we incorporated the negotiated price at the drug level into a beneficiary- and claim-level detailed model. Then, we recalculated the new benefit on the negotiated prices to determine the combined result under the defined standard benefit design by year. To protect beneficiaries from large premium increases, the IRA limits the premium change in years 2024 through 2029 before ultimately readjusting the base beneficiary premium percentage to a minimum of 20 percent in 2030 and later years. The major benefit changes and beneficiary premium protections by year are shown in Table V.C2.

TABLE V.C2: IRA PART D BENEFIT AND PREMIUM CHANGES

	2023	2024	2025–2029	2030
Benefits	Reduced cost sharing for insulins and Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccines	No cost sharing in catastrophic phase	Removal of coverage gap, $2,000 out-of-pocket max (indexed), new manufacturer discount	No benefit changes
Premium	Funded by retrospective government subsidy	Base beneficiary premium (BBP) limited to 6% increase from prior year	BBP limited to 6% increase from prior year	BBP equal to lesser of prior year's BBP increased by 6% or the BBP calculated under section 1860D-13(a)(2) of the Act, with BBP not less than 20% of bid and reinsurance costs.

To complete the modeling of the Negotiation Program, prescription drug inflation rebates, and benefit provisions, we applied the results from the Part D claim-level detailed simulation to our total Part D benefit model. This model also incorporated changes to the per capita cost trends to reflect: (i) the impact of most existing brand-name drugs moving to a CPI-level increase; (ii) the expected growth in new drug costs; and (iii) the expected induced utilization due to the enriched benefit. We assumed that drugs with a significant amount of spending in Part D would temper their price increases rather than pay the inflation rebates required by the IRA. Additionally, we reduced our estimate of manufacturer rebates to compensate for the lower negotiated prices and lower price growth on existing drugs.

For drugs payable under Part B, we applied the negotiated price discounts to the OM spending for separately payable Part B drugs. We further adjusted these results to account for the impact to private health plan expenditures to obtain a total impact. While there are also inflation rebates required for certain drugs payable under Part B under the IRA, price increases on existing drugs payable under Part B historically have been close to the CPI in aggregate, and therefore we did not project an effect for this provision in the drugs payable under Part B. We also incorporated other, less significant changes from the IRA, such as the lower cost sharing for insulins furnished under durable medical equipment and the temporary payment increase for qualifying biosimilar products.

Our assumptions on the impacts of the IRA differed from those used in other public estimates in a few critical ways. Most importantly, we assumed that the inflation rebates required by the IRA would result in manufacturers owing relatively small inflation rebate amounts for drugs covered under Part D and nothing for drugs payable under Part B. We assumed that manufacturers would prefer to have lower price trends that would incentivize greater use than pay publicly reported fees for price increases that exceed inflation. Under this assumption, the effects of the inflation rebate provisions of the IRA are changed because the difference in price is shared across the benefit rather than accruing directly to the government. In other words, lower list price trends will reduce prices paid at the pharmacy relative to the baseline, which results in lower beneficiary cost-sharing and lower state clawback payments, thereby increasing the Federal cost for the Part D benefit. To compensate for the loss of price increases, we expected manufacturers to reduce rebates offered to plan sponsors.

Additionally, we expected that the initial pool of drugs covered under Part D selected for negotiation would have a large proportion of heavily rebated drugs. In these cases, we expected that the price net of rebate will be substantially lower than the other ceiling prices described in the IRA. We further estimated that the effect of negotiation in the early years would be similar to the impact of shifting rebates to the point of sale. This shift reduces beneficiary cost sharing as the price at the point of sale is lower but increases bid amounts and increases Federal expenditures.

In summary, the total effects were to reduce government expenditures for Part B, to increase expenditures for Part D through 2030, and to decrease Part D expenditures beginning in 2031. Part B savings were primarily due to: (i) the substantial lowering of payments, relative to current payment, as a result of MFPs; and (ii) small impacts from other provisions. Part D ultimately generated cost savings at the end of the budget window, but many of the gains from MFPs and lower trends were initially spent on increased benefits and the loss of manufacturer rebates. The impact on benefits and premiums and the impact in total are shown in Table V.C3 using the 2024 President's Budget as a basis.

TABLE V.C3: PART B AND PART D IRA IMPACTS
(IN BILLIONS)

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
Part B										
Total benefits	$0.1	$0.1	$0.1	−$0.2	−$0.3	−$5.8	−$8.4	−$14.7	−$21.4	−$28.4
Premium	0.0	0.0	0.0	−0.1	−0.1	−1.5	−2.1	−3.7	−5.3	−7.1
Total Federal impact	0.1	0.1	0.1	−0.2	−0.2	−4.4	−6.3	−11.0	−16.1	−21.3
Part D										
Total benefits	0.9	6.5	9.5	11.3	7.5	3.0	0.4	−4.5	−10.4	−12.5
Premium	0.0	−0.3	−0.6	−0.3	0.2	0.7	1.3	0.7	−0.1	−0.3
Inflation rebates	0.4	0.3	0.3	0.2	0.2	0.2	0.2	0.3	0.3	0.3
State transfer impact	0.0	−0.1	−0.4	−0.6	−1.7	−3.5	−5.1	−6.4	−7.6	−8.6
Total Federal impact[1]	0.4	6.6	10.2	11.9	8.8	5.6	3.9	1.0	−3.0	−3.9

[1] The Federal impact is calculated as the benefit impact less: (i) the premium impact; (ii) the inflation rebate impact; and (iii) the State transfer impact.

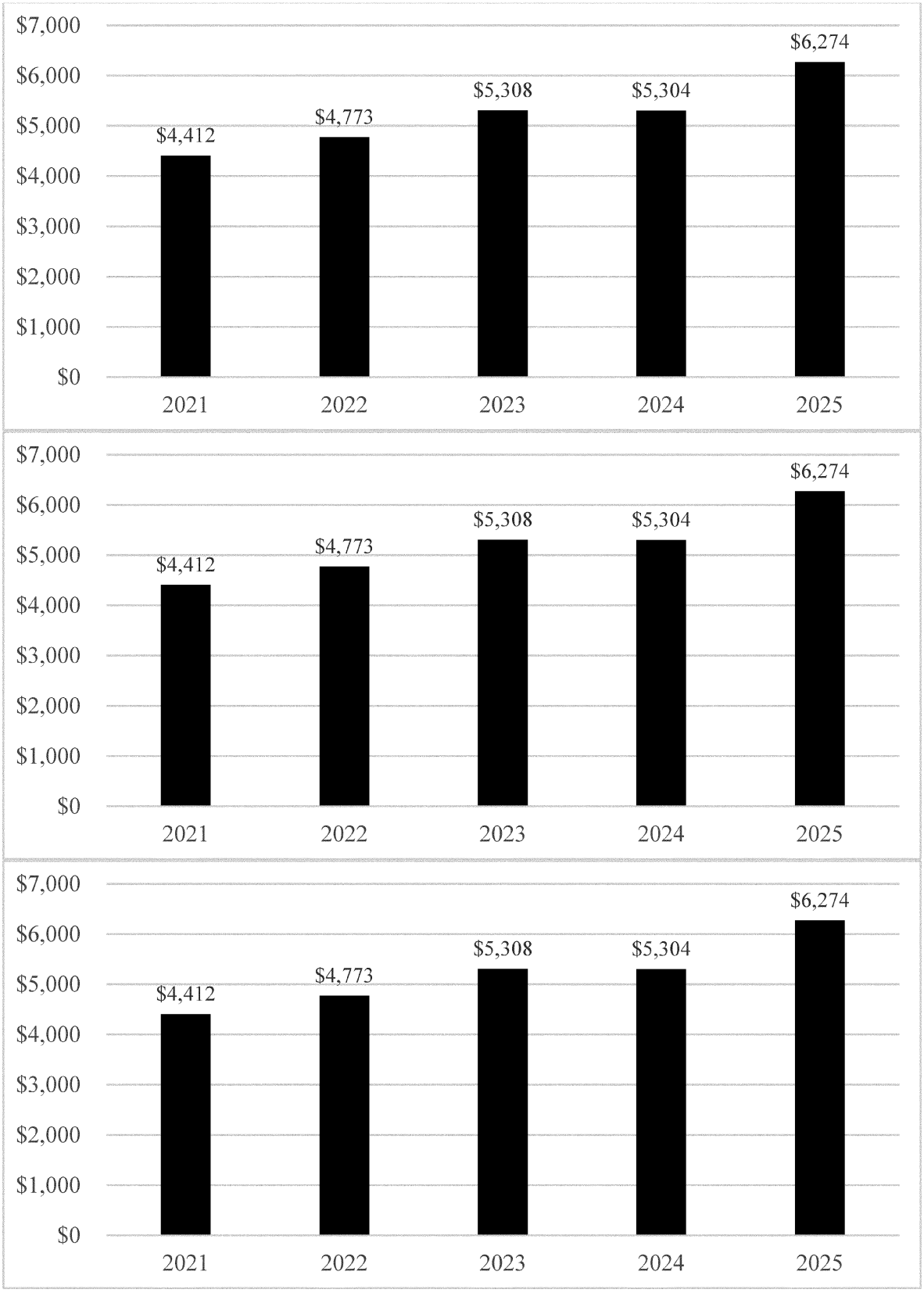
Note: Totals do not necessarily equal the sums of rounded components.

Since we produced these estimates, both the Part B and Part D programs have had large increases in drug expenditures. Part D trends have accelerated dramatically, with the per capita gross drug cost increasing more than 18 percent in 2025 over 2024, driven by higher glucagon-like peptide-1 (GLP–1) and specialty drug usage. Meanwhile, Part B drug trends have also increased, although the primary driver was skin substitutes that were payable as biological products for the purposes of Medicare payment. There are a variety of other causes contributing to observed changes in expenditures for both programs.

The Part D trends in per capita gross costs are shown in Figure V.C1. Much of the IRA Part D benefit redesign took effect in 2025, including limiting annual out of pocket expenditures to $2,000 per enrollee for 2025 (to be annually increased by the annual percentage increase, as described in section 1860D–2(b)(6) of the Act). While this new feature could have induced spending beyond the assumption we included in our initial estimate, it is worth noting that the 2024 benefit structure under the IRA also eliminated cost-sharing in the catastrophic phase of the benefit, effectively implementing an out-of-pocket maximum without a pronounced increase in costs. Additionally, some of the increase may be attributable to manufacturers reducing spending on patient assistance programs, which would cause more claims to run through the Part D program. Expanded indications for cancer drugs also contributed to the increase.

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FIGURE V.C1: PART D PER CAPITA GROSS DRUG COSTS



The observed discounts from MFPs for selected drugs also differed from what we initially assumed. For initial price applicability year 2026, the projected negotiated discount impact on allowed costs—ingredient cost,

dispensing fee, and sales tax—using 2025 experience data is 11.3 percent, while the projected impact for initial price applicability year 2027 is 18.2 percent. Compared with the original estimated effects shown in Figure V.C1, the actual negotiated discounts are more than 2 percent greater than the original modeling results. These differences reflect the deviation in price levels, updated information about generic and biosimilar launches, and the percentage of expense the negotiated drugs represent for each year. Part B MFPs for initial price applicability year 2028 are not currently available, so we do not quantify the change from our original assumptions. We also had assumed that MFPs for initial price applicability years 2026 and 2027 would also apply to Part B utilization. Final policies for those years contained the MFPs to the Part D benefit. This change from our assumption did not meaningfully affect overall estimates, due to multiple factors including limited observed utilization of most initial price applicability years 2026 and 2027 drugs in Part B and the timing of certain generic or biosimilar entrants. Until the entirety of 2026 Part D data is available, including Part D Direct and Indirect Remuneration data, we are unable to determine the ultimate impact of initial price applicability year 2026 MFPs. Even after such data is available, there will not be an accurate way to attribute elements of the experience to particular provisions. For example, the 2026 claims experience will undoubtedly be impacted by the benefit redesign changes implemented in 2025, but determining what portion of 2026 results are due to those benefit changes compared with the implementation of MFPs is unclear.

Part D drug inflation rebates were higher than originally assumed. Converting the published inflation rebates owed from the applicable period to a calendar year basis, 2023 inflation rebates were over $500 million dollars. This is higher than the $400 million dollar estimate shown in Table V.C3. This implies that drug prices increased slightly faster than originally assumed, generating higher inflation rebates. As a percentage of gross drug costs, the original estimate represents 0.01 percent, while the actuals amount to 0.02 percent.

For Part B, our original estimates assumed that the drug inflation rebates would be negligible. Actual drug inflation rebates due for calendar years 2023 and 2024 were $14 million and $121 million, respectively. These amounts represent approximately 0.01 percent and 0.04 percent of the incurred charges for OM in 2023 and 2024. Since drug inflation rebates are not incurred on MA utilization at this time, this is the most appropriate comparison.

Other, more nuanced elements of the IRA changes also differed from our original expectations. For example, the IRA Manufacturer Discount Program is likely larger than we initially assumed, but the PDE reporting is not yet complete for the discount's first year. Similarly, the impacts of the IRA on Part D DIR are unknown, as Part D plan sponsors have not yet submitted the 2025 DIR reports. These elements may have larger effects on overall Part D expense than the other assumption deviations previously described.

Additionally, this rule implements provisions of the ''Working Families Tax Cut'' legislation (Pub. L. 119–21) of 2025. This legislation expanded the IRA's orphan drug exclusion, allowing drugs that are designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act and approved by FDA only for indications within such designated rare disease(s) or condition(s) to be excluded from the Negotiation Program effective with respect to initial price applicability year 2028. Additionally, and also effective with respect to initial price applicability year 2028, the ''Working Families Tax Cut'' legislation amended how CMS identifies the day from which to measure the 7- and 11-year time since approval and licensure periods for drugs that formerly qualified for the orphan drug exclusion. These amendments lead to changes in projections of which drugs will be eligible for negotiation and corresponding changes to the overall effects of negotiation.

We analyzed these effects using baseline estimates from the 2026 Mid-Session Review budget exercise. Following the general procedures described previously for estimating the effects of the IRA negotiation provisions, we adjusted the projected drugs to be negotiated by year to account for the ''Working Families Tax Cut'' legislation amendments. Orphan drug exclusions were determined using data from the FDA on orphan drug designations. We did not forecast the likelihood of these drugs losing their orphan status, as we assume the relative value of orphan and non-orphan drugs remains stable over time. While it is possible that some drugs will avoid non-orphan indication approvals to take advantage of this exclusion, these situations will vary widely from drug to drug, and we do not have a basis to assume the future effects of such behavior.

Table V.C4 shows the impacts to Medicare Part B and Part D benefits and premiums. These impacts are reflected in accounting Table V.E.

TABLE V.C4: PART B AND PART D WORKING FAMILIES TAX CUT LEGISLATION IMPACTS
(IN BILLIONS)

	2028	2029	2030	2031	2032	2033	2034
Part B							
Total benefits	$2.8	$2.7	$0.2	$0.5	$0.4	$1.3	$1.6
Premium	0.7	0.7	0.1	0.1	0.1	0.3	0.4
Total Federal impact	2.1	2.0	0.2	0.3	0.3	0.9	1.2
Part D							
Total benefits	−0.2	0.0	0.1	0.0	0.4	0.8	1.0
Premium	0.0	0.0	0.0	0.0	0.1	0.1	0.2
Inflation rebates	0.0	0.0	0.0	0.0	0.0	0.0	0.0
State transfer impact	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Federal impact[1]	−0.2	0.0	0.1	0.1	0.4	0.6	0.9

1. Analysis of New Policies

In addition, we finalized new policies for the Negotiation Program as follows: a policy for specific fixed combination drugs that are new formulations; clarification related to drugs that formerly qualified for the orphan drug exclusion; revisions regarding process and schedule of CMS review of information in making determinations for Bona Fide Marketing; additional details related to the Primary Manufacturer transfer of responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity; calculation of the 30-day equivalent supply for a selected drug that is typically administered one time; how CMS would implement the Temporary Floor for Small Biotech Drugs for initial price applicability years 2029 and 2030; and clarification of off-label use in consideration for renegotiation eligibility and selection. Of these finalized provisions, only the policy for specific fixed combination drugs that are new formulations would potentially have an impact as the other provisions are technical changes that would not result in additional costs or savings to the Negotiation Program.

The fixed combination drug provision involves costs and savings that extend outside the budget window for this regulatory impact analysis. For purposes of this discussion, consider Product A, which contains the active ingredient X; and consider a later-developed Product B, which contains active ingredient X plus another active ingredient Y, and which meets the criteria finalized at § 429.125(b)(4)(ii). The final policy would aggregate Product A and Product B into the same potential qualifying single source drug and, if such potential qualifying single source drug were ultimately selected, result in Product A and Product B being part of the same selected drug. This would result in any agreed-upon MFP being applied earlier, with respect to the later-developed Product B, than under the current general fixed combination drug policy in which Product A and Product B would be treated as separate potential qualifying single source drugs. This may result in savings in the short term. This policy would also expand the number of products aggregated under a selected drug that would become deselected once a generic or biosimilar is subject to Bona Fide Marketing for any dosage form or strength of the selected drug, resulting in Product B potentially having an agreed-upon MFP applied earlier, but for a shorter period of time, than if it had been identified as a separate qualifying single source drug that was selected and negotiated separately, thus resulting in potential lost savings in the long term. Therefore, potential savings generated by aggregating more products into a qualifying single source drug to which, if selected, the agreed-upon MFP would apply could be limited due to corresponding potential savings lost by the larger number of products that would be deselected once a generic or biosimilar is subject to Bona Fide Marketing, though changes in price after the drug is deselected may be contained (and thus savings preserved) by the Medicare Prescription Drug Inflation Rebate Program for drugs payable under Part B.[113] In addition, a policy for specific fixed combination drugs that are new formulations that would aggregate Product A and Product B into the same potential qualifying single source drug could result in a scenario where Product A has a generic or biosimilar that is subject to Bona Fide Marketing before that qualifying single source drug's eligibility for selection, which could result in both Product A and Product B being ineligible for selection for negotiation, meaning that an MFP could not be negotiated for either product.

As an illustrative example, consider a biological product that has a new formulation that is a fixed combination drug containing hyaluronidase. Under the finalized policy, for drug selection with respect to initial price applicability year 2029, the formulations of that biological product both with and without hyaluronidase would be considered the same potential qualifying single source drug, and potentially selected drug, if the criteria in finalized § 429.125(b)(4)(ii) were met. In this case and with respect to this biological product if it were selected, the MFP, if one is agreed to by CMS and the Primary Manufacturer, would apply to all dosage forms and strengths of the selected drug, including the new formulation containing hyaluronidase, in initial price applicability year 2029 and each subsequent year until CMS makes a determination in accordance with § 429.135(a) that such drug ceases to be a selected drug because a manufacturer for a biosimilar for, most likely, the earlier-formulated non-hyaluronidase product has been licensed and is subject to Bona Fide Marketing. Alternatively, if we had not finalized the proposal, the new formulation containing hyaluronidase would not be considered the same potential qualifying single source drug as the original biological product, and so might be separately selected for negotiation in 2039 (an illustrative year to represent the earliest date when the 11-year timing criterion set forth in proposed § 429.125(c)(2) for a biological product has been reached). These effects would be outside the budget window, and we do not have a credible, drug-level forecast for that time period. Such a forecast would be required to estimate this provision, as the impacted set of drugs is small and the effects will depend on the level of utilization of this subset of drugs far in the future. Additionally, we are unable to accurately estimate the impact of finalizing the policy for specific fixed combination drugs that are new formulations within the budget window since the budgetary effects of the counterfactual (that is, not finalizing such proposal) are outside the budget window, and we do not have baseline estimates for that time horizon. We welcomed comments on methodologies to estimate these effects.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter supported the Negotiation Program being described as saving money and protecting the drug development pipeline. They suggested potential uses for the savings generated by the Negotiation Program.

Response: CMS appreciates the support from the commenter. However, the comment regarding how savings from the Negotiation Program should be used are out of scope for this final rule.

Comment: A commenter stated that the analysis does not account for impacts from other changes to Part D spending, such as benefit redesign, the Manufacturer Drug Program, and general drug utilization trends. This commenter stated that this lack of separation of impacts from different changes to Part D spending causes the true fiscal impact of the Negotiation Program to be unclear and may lead to misinterpreted conclusions about the impact of the Negotiation Program.

Response: We thank this commenter for their input. CMS clarifies that these estimates are inclusive of the Inflation Reduction Act provisions for the Negotiation Program, Part D benefit redesign, the Medicare Prescription Drug Inflation Rebate Program, and related sections. They do not address the Negotiation Program in isolation,

[113] As clarified in the CY 2026 Physician Fee Schedule Final Rule, the average sales price (ASP) reported by a manufacturer must include the MFP, and the ASP is typically the basis for calculating the Part B inflation rebate. (In contrast, the average manufacturer price [AMP] that is the basis for calculating the Part D inflation rebate excludes the MFP per section 1927(k)(1)(B)(i)(VI) of the Act.)

because we do not have estimates using a pre-statute baseline that isolates the impacts of that program. Furthermore, we clarify that the impact on benefits and premiums and the impact in total are shown in Table V.C3 using the 2024 President's Budget as a basis and reflect net impacts to the programs.

Comment: A commenter noted that the regulatory impact analysis is based on gross expenditures so it does not account for rebates that are not realized due to the Negotiation Program. They stated that use of gross expenditures overstates the Negotiation Program's fiscal impact and suggest CMS either restate the analysis using net expenditures or clarify that realized savings would be smaller by the amount of rebates displaced.

Response: We thank this commenter for their feedback. As clarified in the preceding response, the impacts shown in Table V.C3 are net impacts to the program. We recognize that the required formulary inclusion for selected drugs is likely to significantly reduce rebates on selected drugs. The paragraph preceding Table V.C3 also mentions that manufacturer rebate losses are accounted for in the estimates.

Comment: A commenter noted that the regulatory impact analysis does not account for dynamics that shift drug development costs to other products in a manufacturer's portfolio through adjustment of list prices, adjustment of launch prices, and deprioritization of formulations of drugs that are likely to be selected for the Negotiation Program. The commenter concludes that these actions cause the Negotiation Program to not create as much savings to the overall health care system as the RIA suggests. Another commenter stated that funding for small-molecule innovation has fallen since the passage of the IRA and that nothing in the proposed rule's impact analysis suggested CMS has weighed the cost of this dynamic.

Response: We thank this commenter for their feedback. We do not anticipate significant changes to market list price measures such as the Average Wholesale Price as a result of the IRA, so the direct shifting to commercially insured patients is unlikely. It is possible that manufacturers could reduce their rebates in the commercially insured business, but we anticipate that insurers will maintain their formulary leverage in negotiations. Regarding the comment on funding for small-molecule innovation, CMS is not aware of evidence indicating that the change stated by the commenter is widespread throughout the market. Therefore, we do not think it is appropriate to include in this analysis.

Comment: A few commenters raised concerns that the proposed policy for specific fixed combination drugs that are new formulations could reduce savings under the Negotiation Program because, once a generic or biosimilar emerges for the original product, both the original formulation and the new formulation will be deselected from the Negotiation Program, even though the reformulated products themselves may not yet face generic or biosimilar competition. One of these commenters stated that manufacturers could exploit this dynamic by shifting utilization to the reformulated version, leaving consumers and Medicare to pay monopoly prices on a product to which the MFP no longer applies. To address this concern, the commenter recommended that CMS monitor prescribing and pricing patterns for reformulated products after deselection, use the material-change and renegotiation authorities in § 429.605(d) to bring reformulated products back into the program when warranted, and work with Congress so that a reformulation without genuine generic or biosimilar competition cannot evade the MFP. A commenter noted CMS' statement in the Regulatory Impact Analysis that the relevant costs and savings of the proposed policy for specific fixed combination drugs that are new formulations extend outside the budget window for the analysis. The commenter stated that CMS' inability to quantify the proposal does not establish that its effects are negligible but rather demonstrates that CMS lacks an adequate basis to conclude that the proposal will improve the Negotiation Program without producing material unintended consequences. A few commenters requested that CMS analyze changes in research programs, clinical development, and regulatory applications to attempt to quantify the foregone innovation and regulatory cost if the proposal is finalized.

Response: We appreciate the input and reiterate our statement in the proposed rule (91 FR 36333) that the proposed policy for specific fixed combination drugs that are new formulations involves costs and savings that extend outside the budget window for the rule's regulatory impact analysis. There, we acknowledged that potential savings generated by aggregating more products into a qualifying single source drug to which, if selected, the agreed-upon MFP would apply could be limited due to corresponding potential savings lost by the larger number of products that would be deselected once a generic or biosimilar is subject to Bona Fide Marketing. However, we also noted that changes in price after the drug is deselected may be contained (and thus savings preserved) by the Inflation Rebate Program for drugs payable under Part B.[114] While we are unable to produce a quantitative estimate of the financial impacts on the Negotiation Program, we do not treat this uncertainty as evidence that such costs are negligible. We disagree that our inability to quantify these effects means CMS lacks an adequate basis for this policy and have carefully considered the costs qualitatively. We weighed the statutory requirement to aggregate new formulations under sections 1192(d)(3)(B) and 1196(a)(2) of the Act, the program integrity risks of not doing so, and the narrow scope of drugs affected, against the acknowledged but unquantifiable potential foregone savings in the long term were a new formulation to have an agreed-upon MFP applied earlier but for a shorter period of time due to an approved generic drug or licensed biosimilar for a product included in the qualifying single source drug engaging in Bona Fide Marketing, as compared to potential foregone savings in the short term if it had been identified as a separate qualifying single source drug. We weighed the potential responses to this policy against the risk that, absent this policy, manufacturers could use the development of new formulations that enable an alternative route of administration to avoid or delay MFP applicability, an outcome that would undermine the statutory purpose of sections 1192(d)(3)(B) and 1196(a)(2) and create the program integrity risk the policy proposed at § 429.125(b)(4)(i) is designed to address. On balance, we believe the qualitative benefit of closing this gap and the potential short-term savings generated outweigh the uncertain and likely limited foregone long-term savings under the Negotiation Program given that the policy applies only to a narrow set of new formulations meeting specific criteria proposed at § 429.125(b)(4)(i) and finalized at § 429.125(b)(4)(ii).

Regarding the recommendation that CMS monitor prescribing and pricing patterns for reformulated products following deselection, we intend to monitor utilization and pricing trends for such products as part of our ongoing

[114] As clarified in the CY 2026 Physician Fee Schedule Final Rule, the average sales price (ASP) reported by a manufacturer must include the MFP, and the ASP is typically the basis for calculating the Part B inflation rebate. (In contrast, the average manufacturer price [AMP] that is the basis for calculating the Part D inflation rebate excludes the MFP per section 1927(k)(1)(B)(i)(VI) of the Act.)

program oversight. Regarding the recommendation that CMS work with Congress to address reformulations that lack genuine generic or biosimilar competition, we appreciate the suggestion. However, statutory changes are outside the scope of this final rule. Regarding the request that CMS use the material-change and renegotiation authorities in § 429.605(d) to bring reformulated products back into the Negotiation Program when warranted, we understand this comment as a request that CMS use our renegotiation authorities under section 1194(f) of the Act to select for renegotiation a drug that has been deselected due to the approval or licensure and engagement in Bona Fide Marketing of a generic drug or biosimilar for a product included in the selected drug. We decline this request because section 1194(f)(2) of the Act limits renegotiation-eligible drugs to selected drugs.

Final Decision: After consideration of public comments, we are finalizing our regulatory impact analysis as proposed.

D. Alternatives Considered

In this section, CMS includes discussions of alternatives considered.

1. Fixed Combination Products (§ 429.105(b)(4))

The first alternative we considered would have further narrowed the scope of the policy for specific fixed combination drugs that are new formulations proposed at § 429.125(b)(4)(i) and finalized at § 429.125(b)(4)(ii) to biological products only. As compared to the policy proposed at § 429.125(b)(4)(i) and finalized at § 429.125(b)(4)(ii), this alternative may not meaningfully impact which products would be aggregated under a qualifying single source drug.

The second alternative we considered was an articulation of the policy as aggregating drugs for which one of the active moieties, active ingredients, or antigen components contained is not biologically active against the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference. We believe the policy proposed at § 429.125(b)(4)(i) and finalized at § 429.125(b)(4)(ii), provides a clearer and more administrable standard for CMS and manufacturers to apply consistently, which is why we did not pursue this alternative.

The third alternative we considered would have maintained the policy established for initial price applicability years 2026 through 2028, wherein, for a fixed combination drug with two or more active moieties, active ingredients, or antigen components, we would treat the distinct combination of active moieties, active ingredients, or antigen components as one active moiety, active ingredient, or antigen component. We did not adopt this alternative because we believe our proposed policy better applies, in a predictable and administrable way, our interpretation of the directives in sections 1192(d)(3)(B) and 1196(a)(2) of the Act, which require the aggregation of data across dosage forms and strengths of the drug, including new formulations of the drug, and not based on the specific formulation or package size or package type of such drug. As compared to the policy proposed at § 429.125(b)(4)(i) and finalized at § 429.125(b)(4)(ii), this alternative may reduce the number of products that would be aggregated under a qualifying single source drug. If we maintained the policy established for initial price applicability years 2026 through 2028, selection and negotiation for a new formulation of a qualifying single source drug, which would otherwise be aggregated with and subject to the MFP under the finalized policy at § 429.125(b)(4)(ii), could instead be delayed, which might reduce total savings under the Negotiation Program.

Because these alternatives considered involve financial impacts outside the 10-year budget window, and we do not have credible drug-level forecast that far out, quantifying longer-term effects would be speculative, and only considering impacts within the window would not adequately explain the full results of these alternatives.

Further discussion of the policy finalized at § 429.125(b)(4)(ii) is included in section II.B.6.a. of this final rule.

E. Accounting Statement and Table

Consistent with OMB Circular A–4 (available at *https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf*), we have prepared an accounting statement in Table V.E1 showing the classification of the impact associated with the provisions of this rule.

TABLE V.E1: ACCOUNTING STATEMENT ($millions)

Category	3% Discount Rate	7% Discount Rate	Period Covered	Notes:
COSTS				
Annualized monetized costs			CY 2029	$8.38
TRANSFERS				
From Federal Government and Medicare Enrollees to pharmaceutical manufacturers	$9,976	$8,695	CYs 2028-2034	Orphan drug provision

F. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief for small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. The RFA requires that CMS analyze regulatory options for small businesses and other entities unless CMS certifies that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the final rule effects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

HHS considers a significant impact on a substantial number of small entities to be one with a 3 percent revenue effect on 5 percent of small entities.[115] CMS would consider a ''significant impact'' to be 3 percent or more of the affected entities' costs or revenues, and a ''substantial number'' to mean 5 percent or more of affected small entities within the total number of the small businesses in that North American Industry Classification System (NAICS) industry description. As discussed in section II. of this final rule, the Medicare Drug Price Negotiation Program requires the Secretary to negotiate and renegotiate, for applicable periods, Medicare prices for certain high expenditure, single source drugs and biological products. Our analysis shows that this final rule may directly impact one category of small entities, Primary Manufacturers. Given the uncertainty on negotiation outcomes and available data, CMS concludes that this final rule may have an economic impact on small entities. This analysis as well as other sections in this final rule, serves as the Final Regulatory Flexibility Analysis, as required by the RFA. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We have determined that this threshold will not be reached by the requirements in this final rule. The resources needed to produce and distribute a drug with expenditures that exceed the low-spend Medicare drug exclusion described in section II.B.6.c.2. of this final rule is expected to require a workforce larger than the small entity threshold; thus, we expect that no Primary Manufacturer would qualify as a small entity. Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities.

1. Description and Number of Affected Small Entities

We use the NAICS to identify the industry potentially affected by this final rule. We also use the Small Business Administration (SBA) size standards in ''number of employees'' and ''millions of dollars'' to identify small entities.[116] The SBA considers any ''Pharmaceutical Preparation Manufacturing'' firm (NAICS code 325412) with fewer than 1,300 employees as a small business. As defined in section 1192(e)(3)(B)(i) of the Act, a selected drug must have total expenditures of $200 million or more during the defined measurement period, between June 1, 2022 and May 31, 2023, for initial price applicability year 2026, adjusted by inflation in subsequent years (hereinafter the ''low-spend Medicare drug exclusion'').

For purposes of this final analysis, we are unable to determine the actual employee size or revenue of all manufacturers that may ever have a selected drug in the Negotiation Program. Assuming the low-spend Medicare drug exclusion described previously, we estimate that no Primary Manufacturer would be considered to be a small entity because we expect that the resources needed to produce and distribute a drug with Medicare expenditures that meet this threshold would require a workforce larger than the small entity threshold of 1,300 employees. As Table V.F1 demonstrates, none of the drugs that were selected for negotiation, as set forth in § 429.105 of this final rule, were manufactured by small entities during the first 3 years of the Negotiation Program.

TABLE V.F1: PERCENT OF SMALL ENTITY PRIMARY MANUFACTURERS WITH SELECTED DRUGS DURING INITIAL PRICE APPLICABILITY YEARS 2026 – 2028[117]

Initial Price Applicability Year	Company Size	Total Number of Employees in the U.S.	Percent of Unique Companies
2026	Small	1,300 or fewer	0%
	Large	1,300+	100%
2027	Small	1,300 or fewer	0%
	Large	1,300+	100%
2028	Small	1,300 or fewer	0%
	Large	1,300+	100%

2. Description of the Potential Impacts on Small Entities

With the expiration of the Small Biotech Exception, which applies to initial price applicability years 2026, 2027, and 2028, and the implementation of the Temporary Floor for Small Biotech Drugs, which becomes effective for initial price applicability years 2029 and 2030, manufacturers of small biotech drugs could have a selected drug for initial price applicability year 2029 or a future year. It is possible that a manufacturer of a small biotech drug could have 1,300 or fewer employees, but CMS does not have credible information to forecast if or when such manufacturers would have a selected drug.[117]

CMS notes that the estimates of manufacturer size and impact of this rule are based on available data which could change in the future and as such, the estimated impacts could vary. Specifically, the estimates are based on the current status of drug negotiations, employment and revenue information using 2024 or other available data as of the publication of this final rule. Despite this uncertainty, CMS certifies that the final rule will not have a significant impact on a substantial number of small entity Primary Manufacturers because the resources needed to produce and distribute a drug with expenditures that meet the low-spend Medicare drug exclusion is expected to require a workforce larger than the small entity threshold, therefore, we expect that no Primary Manufacturer would qualify as a small entity. A timeline of potential impacts to small entities in the

[115] Department of Health and Human Services. Guidance on Proper Consideration of Small Entities in Rulemaking of the U.S. Department of Health and Human Services, 2003. Available at: *https://aspe.hhs.gov/reports/proper-consideration-small-entities-rulemakings-us-dhhs.*

[116] Small Business Administration. Table of Size Standards, Available at: *https://www.sba.gov/document/support-table-size-standards.*

[117] Data based on number of employees listed within the most recently publicly available Annual or Fourth Quarter Report for each Primary Manufacturer during the associated Initial Price Applicability Year at the time this NPRM was drafted.

Negotiation Program are shown in Table V.F2. CMS requested comments on our conclusion, approach, assumptions, and data used to estimate these impacts.

TABLE V.F2: POTENTIAL IMPACTS TO SMALL ENTITIES IN THE NEGOTIATION PROGRAM

	2026	2027	2028	2029	2030
Primary Manufacturers	No changes	No changes	No changes	Small Biotech Exception no longer applies; previously excepted small biotech drugs now eligible for Negotiation Program	Small Biotech Exception no longer applies; previously excepted small biotech drugs now eligible for Negotiation Program

3. Alternatives To Minimize the Impact on Small Entities

The vast majority of the policies discussed in this final rule, including timing for reporting and publications and effective dates of rates, are required by sections 1191 through 1198 of the Act. Due to the IRA establishing the requirements for the selection and identification of negotiation-eligible drugs and the requirements for the negotiation or renegotiation process rather than this final rule, CMS was unable to propose alternatives that will accomplish the purpose of the Negotiation Program in a manner consistent with law. In addition, to the extent practicable, processes were standardized and clarified to improve efficiency for Primary Manufacturers to comply with program requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A commenter disagreed with the expectation that no Primary Manufacturer would be considered to be a small entity because the resources needed to produce and distribute a drug with Medicare expenditures that meet the low-spend Medicare drug exclusion threshold would require a workforce larger than the small entity threshold of 1,300 employees. The commenter contended that there are small biotech drug manufacturers who could have fewer than 1,300 employees and over $200 million in Medicare expenditures.

Response: We thank the commenter for their feedback. The estimate in this analysis is based on the information currently available, which does not indicate a manufacturer of a drug selected for the Negotiation Program would meet the characteristics described by the commenter.

Final Decision: After consideration of public comments, we are finalizing our RFA analysis as proposed.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not have a significant impact on small rural hospitals because our analysis shows that this final rule may directly impact one category of entities, Primary Manufacturers, and small rural hospitals are not entities involved in the Negotiation Program. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately $193 million. This final rule is not anticipated to have an unfunded effect on State, local, or tribal governments, in the aggregate, or on the private sector of $193 million or more. The analysis of impacts on this final rule does not report an estimate of any unfunded effect on State, local, or tribal governments, in the aggregate, or on the private sector that exceeds the $193 million threshold. However, this final rule will result in additional impacts associated with changes in behavior; these are not quantified. Therefore, the Secretary has concluded that the requirements of section 202 of the UMRA have been met for this final rule. We requested comments, including on the potential magnitude of this impact. We did not receive public comments on this URMA conclusion, and therefore, we are finalizing as proposed.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this final rule does not impose any substantial costs on State or local governments, preempt State law or have Federalism implications, the requirements of Executive Order 13132 are not applicable.

I. Executive Order 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' This rule may generate substantial Federal savings. A regulatory action that generates substantial Federal budget savings may be exempt from Executive Order 14192's requirements.

J. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided a final Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 14, 2026.

List of Subjects

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 429

Administrative practice and procedure, Biologics, Medicare, Prescription drugs, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 1. The authority citation for part 423 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 2. Section 423.100 is amended by revising the definition of ''Corresponding drug'' and revising and republishing the definition of ''Negotiated price'' to read as follows:

§ 423.100 Definitions.

* * * * *

Corresponding drug means, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product. A corresponding drug does not include a selected drug.

* * * * *

Negotiated price means the price for a covered Part D drug that meets all of the following:

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug.

(2) Subject to paragraph (4) of this definition, meets all of the following:

(i) Includes all price concessions (as defined in this section) from network pharmacies or other network providers.

(ii) Includes any dispensing fees.

(iii) Includes any applicable sales tax.

(iv) Includes any applicable vaccine administration fee.

(v) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices.

(3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

(4) For a covered Part D drug that is a selected drug and for each year of a price applicability period with respect to such selected drug, the negotiated price used for payment, as defined in paragraphs (1) through (3) of this definition, must not exceed the maximum fair price, as defined at section 1191(c)(3) of the Act, for such drug, plus any applicable dispensing fees.

* * * * *

■ 3. Section 423.120 is amended by—

■ a. Revising the section heading; and

■ b. Adding paragraphs (b)(2)(vii) and (viii).

The revisions and additions read as follows:

§ 423.120 Requirements related to qualified prescription drug coverage.

* * * * *

(b) * * *

(2) * * *

(vii) Except as specified in paragraph (b)(2)(viii) of this section, for 2026 and each subsequent year, include each Part D drug that is a selected drug under section 1192 of the Act for which a maximum fair price (as defined in section 1191(c)(3) of the Act) is in effect with respect to the year.

(viii) Nothing in paragraph (b)(2)(vii) of this section may be construed as prohibiting a Part D plan sponsor from removing such a selected drug from its formulary if such removal meets the requirements specified in paragraph (e)(2)(i) of this section and the notice requirements specified in paragraphs (f)(2), (3), and (4) of this section.

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■ 4. Part 429 is added to read as follows:

PART 429—MEDICARE DRUG PRICE NEGOTIATION PROGRAM

Subpart A—General Provisions

Sec.

429.10 Basis and scope.
429.20 Definitions.
429.30 Limitation on review.

Subpart B—Identification of Selected Drugs

429.100 Publication of the selected drug list.
429.105 Selection of drugs for negotiation.
429.110 Request for a biosimilar delay.
429.115 Identification of negotiation-eligible drugs.
429.120 Calculation of total expenditures.
429.125 Identification of qualifying single source drugs.
429.130 Bona Fide Marketing.
429.135 Deselection of a selected drug.

Subpart C—Negotiation Program Agreement

429.200 Entrance into an agreement with CMS.
429.205 Termination.
429.210 Other provisions of the Negotiation Program Agreement.

Subpart D—Program Administration

429.300 Confidentiality policy and data use.

Subpart E—Establishment of a Single MFP and Determination of the Ceiling

429.400 Establishment of a single MFP for negotiation and renegotiation purposes.
429.405 Collection of non-FAMP.
429.410 Determination of the ceiling.
429.415 Calculation of the 30-day equivalent supply.
429.420 Determination of the sum of the plan-specific enrollment weighted amounts.
429.425 Determination of the payment amount under section 1847A(b)(4) of the Act.
429.430 Determination of the combined Part B and Part D amount.
429.435 Determination of the applicable average non-FAMP amounts and applicable percent of the average non-FAMP.
429.440 Temporary floor for Small Biotech Drugs.
429.445 Calculation information and suggestion of error.

Subpart F—Negotiation Process

429.500 General rule.
429.505 Negotiation factors.
429.510 Methodology for developing the initial offer.
429.515 Engagement with Primary Manufacturers and interested parties.
429.520 Provision of CMS' written initial offer and concise justification.
429.525 Statutory written counteroffers.
429.530 Additional price exchange opportunities.
429.535 Notification of final offer and conclusion of negotiations.

Subpart G—Renegotiation of an MFP

429.600 General rule.
429.605 Eligibility of drugs for renegotiation.
429.610 Selection of drugs for renegotiation.
429.615 Data collection to inform renegotiation eligibility, selection, and renegotiation of the MFP for a selected drug.
429.620 Renegotiation process.

Subpart H—Implementation of the MFP

429.700 Application of the MFP across dosage forms and strengths.
429.705 Publication of the MFP.
429.710 Establishment of MFPs after the negotiation deadline.

Subpart I—[Reserved]

Subpart J—Manufacturer Compliance and Oversight

429.900 Monitoring manufacturer compliance.

Subpart K—Civil Monetary Penalties

429.1005 Violations of the Negotiation Program Agreement.
429.1010 Provision of false information related to the biosimilar delay and Temporary Floor for Small Biotech Drugs.
429.1015 Failure to pay a biosimilar delay rebate.
429.1020 Notice and appeal procedures.

Authority: 42 U.S.C. 1302, 1320f, 1320f–1 through f–7, and 1395hh.

Subpart A—General Provisions

§ 429.10 Basis and scope.

(a) *Basis.* (1) This part is based on the indicated provision of the following sections of the Social Security Act (''the Act''):

(i) 1191. Establishment of the Program.

(ii) 1192. Selection of Negotiation-Eligible Drugs as Selected Drugs.

(iii) 1193. Manufacturer Agreements.

(iv) 1194. Negotiation and Renegotiation Process.

(v) 1195. Publication of Maximum Fair Prices.

(vi) 1196. Administrative Duties and Compliance Monitoring.

(vii) 1197. Civil Monetary Penalties.

(viii) 1198. Limitation on Administrative and Judicial Review.

(2) The following specific sections of the Inflation Reduction Act also address the Medicare Drug Price Negotiation Program:

(i) 11001. Providing for Lower Prices for Certain High-Priced Single Source Drugs.

(ii) 11002. Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry.

(b) *Scope.* This part sets forth the requirements of the Medicare Drug Price Negotiation Program, which requires the Secretary to negotiate and renegotiate, for applicable periods, Medicare prices for certain high expenditure, single source drugs and biological products.

(c) *Severability.* Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provision would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 429.20 Definitions.

As used in this part, unless otherwise specified, the following definitions apply:

Additional delay request means a request to delay the inclusion on the selected drug list of a reference drug for which an initial delay request has been granted for a second initial price applicability year consistent with § 429.110 and section 1192(f)(1)(B)(i)(II) of the Act.

Applicable program agreement means an agreement under the Manufacturer Discount Program as specified in section 1860D–14C of the Act or a rebate agreement described in section 1927(b) of the Act.

Authorized generic drug means a drug as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic (FD&C) Act and a biological product that has been licensed under section 351(a) of the Public Health Service (PHS) Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for institutions), product code, labeler code, trade name, or trademark than the reference product.

Authorized representative of the Primary Manufacturer means an individual that has the authority or capacity to legally bind the Primary Manufacturer and meets one of the following criteria:

(1) Chief Executive Officer of the Primary Manufacturer.

(2) Chief Financial Officer of the Primary Manufacturer.

(3) An individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer of the Primary Manufacturer.

(4) An individual that has been granted delegation of signature authority on behalf of one of the individuals specified in paragraphs (1) through (3) of this definition.

Authorized representative of a Biosimilar manufacturer means an individual that has the authority or capacity to legally bind the Biosimilar Manufacturer and meets one of the following criteria:

(1) Chief Executive Officer of the Biosimilar Manufacturer.

(2) Chief Financial Officer of the Biosimilar Manufacturer.

(3) An individual with equivalent authority to a Chief Executive Officer or Chief Financial Officer of the Biosimilar Manufacturer.

(4) An individual that has been granted delegation of signature authority on behalf of one of the individuals specified in paragraphs (1) through (3) of this definition.

Average manufacturer price (AMP) has the meaning set forth in section 1927(k)(1) of the Act.

Average non-Federal average manufacturer price (non-FAMP) has the meaning set forth in section 1194(c)(6) of the Act.

Average sales price (ASP) means the manufacturer's price for a quarter for a drug represented by a particular 11-digit National Drug Code (NDC–11) determined under § 414.804 of this chapter and as reported in section 1927(b)(3) of the Act.

Billing unit means the identifiable quantity of a drug or biological product associated with a billing and payment code (for example, a Healthcare Common Procedure Coding System code), as established by CMS.

Biologics License Application (BLA) means an application submitted under section 351 of the PHS Act.

Biosimilar biological product or biosimilar has the meaning set forth in section 1847A(c)(6) of the Act.

Biosimilar Delay Request means an Initial Delay Request or an Additional Delay Request.

Biosimilar Manufacturer means one of the following:

(1) The BLA holder for the Biosimilar;

(2) If a BLA has been submitted to the FDA for review but the Biosimilar has not been licensed, the sponsor of the BLA submitted for review by the FDA; or

(3) If the Biosimilar has not been licensed and the BLA has not been submitted to the FDA, the organization planning to be the sponsor when the BLA is submitted for review by the FDA.

BLA holder means the entity that is the holder of the license(s) permitting marketing of a biological product in accordance with section 351 of the PHS Act.

Bona Fide Marketing means that an approved generic drug or licensed biosimilar is marketed as determined by CMS based on the information considered in § 429.130(a).

Combined Part B and Part D amount means an amount equal to the weighted average of the payment amount under section 1847A(b)(4) of the Act and the sum of the plan-specific enrollment weighted amount as determined by CMS under § 429.430.

CPI–U means the monthly Consumer Price Index for All Urban Consumers (United States city average) index level for all items from the Bureau of Labor Statistics.

Direct and Indirect Remuneration (DIR) has the meaning set forth in § 423.308 of this chapter.

Drug covered under Part D means a covered Part D drug as defined in section 1860D–2(e) of the Act.

Drug payable under Part B means a drug or biological product for which payment may be made under part B of Title XVIII of the Act.

Estimated remuneration at point-of-sale amounts (ERPOSA) means the estimated amount of rebates or other price concessions that the Part D plan sponsor is required to apply, or has elected to apply, to the negotiated price

as a reduction in the drug price made available to the beneficiary at the point of sale.

Extended-monopoly drug has the meaning set forth in section 1194(c)(4) of the Act.

FDA-approved indication means the information included in drug labeling per 21 CFR 201.57(c)(2) or other FDA regulations as applicable.

Fixed combination drug has the meaning set forth in 21 CFR 300.50.

Generic drug means a drug approved in an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act.

Healthcare Common Procedure Coding System (HCPCS) code means a billing and payment code, as established by CMS for payment under Part B, used to describe a drug or biological and for which CMS may publish a payment amount.

High Likelihood Deadline means the date that is 2 years after the statutorily defined selected drug publication date for the initial price applicability year for which a reference drug would be included on the selected drug list absent a successful Initial Delay Request.

Initial Delay Period means the time period between the selected drug publication date—

(1) For the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request, as described in § 429.110(g); and

(2) With respect to the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug otherwise would have been included on the selected drug list but for the successful Initial Delay Request as set forth in section 1192(f)(2) of the Act.

Initial Delay Request means a request to delay the inclusion of a reference drug on the selected drug list by one initial price applicability year consistent with § 429.110(c) and section 1192(f)(1)(B)(i)(I) of the Act.

Initial price applicability year has the meaning set forth in section 1191(b)(1) of the Act.

Knowingly has the meaning set forth in 42 CFR 1003.110.

Long-monopoly drug has the meaning set forth in section 1194(c)(5) of the Act.

Manufacturer has the meaning set forth in section 1191(c)(1) of the Act.

Manufacturer Discount Program means the Medicare Part D Manufacturer Discount Program established under section 1860D–14C of the Act.

Maximum fair price (MFP) has the meaning set forth in section 1191(c)(3) of the Act.

Medicare Drug Price Negotiation Program (or Negotiation Program) means the program created by sections 11001 and 11002 of the Inflation Reduction Act and codified in sections 1191 through 1198 of the Act and as amended.

Medicare Drug Price Negotiation Program Agreement (or Negotiation Program Agreement) means the agreement between a Primary Manufacturer and CMS as set forth in § 429.200 and section 1193(a) of the Act.

NDA holder means the entity that is the holder of the approval(s) to market a drug product in accordance with section 505(c) of the FD&C Act.

Negotiation-eligible drug has the meaning set forth in section 1192(d) of the Act and is identified in accordance with § 429.115.

Negotiation period has the meaning set forth in section 1191(b)(4) of the Act.

Net Part D Plan Payment and Beneficiary Liability means, for purposes of the Medicare Drug Price Negotiation Program, the total gross covered prescription drug cost for a selected drug covered under Part D net of direct and indirect remuneration (DIR) and Manufacturer Discount Program payments and excluding prescription drug event (PDE) records for which a compound code indicates the PDE record is for a compounded drug.

New Drug Application (NDA) means an application submitted under section 505(b) of the FD&C Act.

Off-label use means use for a condition for a selected drug or a therapeutic alternative that is not an FDA-approved indication but is included in evidence-based clinical practice guidelines and is a medically accepted indication payable under Part B or covered under Part D or both, taking into consideration major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination thereof.

Orphan drug designation has the meaning set forth in 21 CFR 316.3(b)(11).

Outcomes means the impact of an intervention, which may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life.

Part B data means Original Medicare (OM) Part B claims data and Medicare Advantage (MA) encounter data for Part B items or services.

Partnership has the meaning set forth in section 1192(f)(1)(C)(ii) of the Act.

Personally identifiable information (PII) has the meaning set forth at 2 CFR 200.1.

Plasma-derived product has the meaning set forth in section 1192(e)(3)(C) of the Act.

Preliminary price means the numerical dollar amount used by CMS in developing an initial offer in accordance with § 429.510(e) by adjusting the starting point of a selected drug based on section 1194(e)(2) factors.

Price applicability period has the meaning set forth in section 1191(b)(2) of the Act.

Primary Manufacturer means the manufacturer identified by CMS as the NDA holder or the BLA holder for the selected drug.

Private label distributor has the meaning set forth in 21 CFR 207.1.

Protected health information (PHI) has the meaning set forth at 45 CFR 160.103.

Qualifying single source drug has the meaning set forth in section 1192(e) of the Act and is identified in accordance with § 429.125.

Rare disease or condition has the meaning set forth in section 526(a)(2) of the FD&C Act.

Reference Drug means a negotiation-eligible drug that includes the reference product for a Biosimilar that is named in a Biosimilar Delay Request.

Reference Manufacturer means the Primary Manufacturer of the Reference Drug that is named in a Biosimilar Delay Request.

Reference Product has the meaning set forth in section 1191(c)(4) of the Act.

Relabeler has the meaning set forth in 21 CFR 207.1.

Renegotiation-eligible drug has the meaning set forth in section 1194(f)(2) of the Act.

Repackager has the meaning given the term ''repacker'' set forth in 21 CFR 207.1.

Request to Terminate means a written request submitted by a Primary Manufacturer to CMS, that CMS determines meets the conditions described in § 429.205(b)(1), to request termination of its applicable program agreements in the context of a Primary Manufacturer's decision not to enter into or to terminate a Negotiation Program Agreement.

Secondary Manufacturer means a manufacturer of a drug product included in the selected drug, that is not the Primary Manufacturer for the selected drug, and that either—

(1) Is listed as a manufacturer in an NDA or BLA for the selected drug; or

(2) Markets the selected drug in accordance with an agreement with the Primary Manufacturer but is not listed on an NDA or BLA of the selected drug.

A Secondary Manufacturer includes any manufacturer of any authorized

generic drug(s) and any repackager or relabeler of the selected drug that meets either of these criteria.

Second Delay Period means the time period between the publication date of the selected drug list for initial price applicability year that is—

(1) One year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request; and

(2) Two years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list but for the successful Initial Delay Request.

Section 1194(e)(1) factors mean the factors described in section 1194(e)(1) of the Act.

Section 1194(e)(2) factors mean the factors described in section 1194(e)(2) of the Act.

Selected drug has the meaning set forth in section 1192(c) of the Act and is identified in accordance with § 429.105.

Selected drug publication date has the meaning set forth in section 1191(b)(3) of the Act.

Self-administered drug means a drug or biological product identified as self-administered by the U.S. Department of Health and Human Services Office of Inspector General (OIG) in accordance with section 1847A(g)(1) of the Act.

Sequestration payment adjustment means, when applicable, the amount that is applied to a Part B claim to determine the Medicare payment amount—after determining coinsurance, deductible, merit-based incentive payment adjustments, and any applicable Medicare Secondary Payment adjustments.

Small Biotech Drug means a drug that is determined by CMS under § 429.440(b)(2), in accordance with section 1192(d)(2) of the Act, as eligible for the Temporary Floor for Small Biotech Drugs.

Specified Manufacturer has the meaning set forth in section 1860D–14C(g)(4)(B)(ii) of the Act, as determined by CMS for the purposes of the Manufacturer Discount Program in accordance with §§ 423.2716, 423.2720, and 423.2724 of this chapter.

Starting point means the numerical dollar amount used by CMS in developing an initial offer in accordance with § 429.510(d) that is then adjusted by CMS based on section 1194(e)(2) factors to determine the preliminary price, per the process described in § 429.510(e).

Temporary Floor for Small Biotech Drugs has the meaning set forth in § 429.440(b)(3).

Therapeutic advance means a demonstrated improvement in one or more outcomes or other clinical considerations for an identified condition of a selected drug as compared to its therapeutic alternative(s), if any. For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS will consider the extent to which the drug represents a therapeutic advance at the time of consideration based on all available information at such time of consideration.

Therapeutic alternative means a pharmaceutical product or group of pharmaceutical products other than the selected drug that may be used to treat the same condition or disease state as the selected drug.

Total allowed charges means the amount that is inclusive of the beneficiary coinsurance and Medicare payment for the covered Part B item or service paid for under part B of Title XVIII of the Act, without a sequestration payment adjustment applied.

Total expenditures has the meaning set forth in section 1191(c)(5) of the Act, as determined under § 429.120.

Total expenditures measurement period means the 12-month period ending on October 31 of the year prior to the year of the selected drug publication date with respect to an initial price applicability year.

Total gross covered prescription drug costs has the meaning given the term ''gross covered prescription drug costs'' set forth in § 423.308 of this chapter.

Unit has the meaning set forth in section 1191(c)(6) of the Act.

Unmet medical need means a circumstance in which the relevant disease or condition is one for which no other treatment options exist, or existing treatments do not adequately address the disease or condition. For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS will consider the extent to which the drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration.

Wholesale Acquisition Cost (WAC) unit price means the manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC–11 level.

§ 429.30 Limitation on review.

There is no administrative or judicial review of any of the following:

(a) The determination of a unit, with respect to a drug or biological product, under section 1191(c)(6) of the Act.

(b) The selection of drugs under section 1192(b) of the Act, the determination of negotiation-eligible drugs under section 1192(d) of the Act, the determination of qualifying single source drugs under section 1192(e) of the Act, and the application of section 1192(f) of the Act.

(c) The determination of a maximum fair price under subsection (b) or (f) of section 1194 of the Act.

(d) The determination of renegotiation-eligible drugs under section 1194(f)(2) of the Act and the selection of renegotiation-eligible drugs under section 1194(f)(3) of the Act.

Subpart B—Identification of Selected Drugs

§ 429.100 Publication of the selected drug list.

(a) *General.* Each drug included on the selected drug list for an initial price applicability year is a selected drug with respect to such initial price applicability year and each subsequent year unless and until CMS makes a determination in accordance with § 429.135(a).

(b) *Publication of the selected drug list.* With respect to each initial price applicability year beginning with initial price applicability year 2029, CMS publishes a list with the following information no later than the selected drug publication date as defined in § 429.20 with respect to such initial price applicability year:

(1) The selected drug list, which includes the 20 (or all, if such number is less than 20) selected drugs with respect to such initial price applicability year, determined in accordance with § 429.105(c).

(2) The drugs selected for renegotiation, if any, determined in accordance with § 429.610.

(3) For each selected drug included on the selected drug list published in accordance with paragraph (b)(1) of this section, CMS adds the following information to the MFP file:

(i) The active moiety/active ingredient/antigen component (or the distinct combination thereof), identified in accordance with § 429.125(b).

(ii) The NDC–11s identified in accordance with paragraph (c)(1) of this section, and the corresponding NDC–9s and HCPCS codes (as applicable).

(4) For each drug selected for renegotiation published in accordance with paragraph (b)(2) of this section, if any, CMS adds the following information to the MFP file:

(i) The active moiety/active ingredient/antigen component (or the distinct combination thereof) previously identified for the initial price applicability year for which the drug was originally selected for negotiation.

(ii) The NDC–11s identified in accordance with paragraph (c)(1) of this section as updated to reflect information previously submitted by the Primary Manufacturer, including submissions in accordance with this section, and the corresponding NDC–9s and HCPCS codes (as applicable).

(c) *Identification of the list of NDC–11s of the selected drug.* CMS identifies a list of the NDCs of each selected drug, including for a drug selected for renegotiation, that is developed and maintained using the following process:

(1) CMS identifies a baseline list of NDC–11s associated with the NDA(s)/BLA(s) of the selected drug.

(2) CMS transmits the NDC–11s identified in paragraph (c)(1) of this section to the Primary Manufacturer.

(3) CMS revises its list of NDC–11s of each selected drug, as appropriate, including without limitation using information submitted by the Primary Manufacturer in accordance with this section.

(d) *Primary Manufacturer submission of information for CMS' list of NDC–11s.* In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, including to ensure CMS' list of NDC–11s of the selected drug developed in accordance with § 429.100(c) is complete and accurate, the Primary Manufacturer must submit all of the following information to CMS in a form and manner specified by CMS by 11:59 p.m. PST on March 1 of the calendar year of the selected drug publication date for the selected drug, inclusive of NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer:

(1) Any NDC–11s associated with the NDA(s)/BLA(s) of the selected drug that do not appear on CMS' list of NDC–11s of the selected drug, including any missing NDC–11s of a Secondary Manufacturer.

(2) Any NDC–11s on CMS' list of NDC–11s of the selected drug that are distributed by or under the name of a private label distributor.

(3) Any NDC–11s on CMS' list of NDC–11s of the selected drug that are not manufactured, marketed, controlled or sold by the Primary Manufacturer or a Secondary Manufacturer.

(4) Any NDC–11s on CMS' list of NDC–11s of the selected drug that represent a sample package.

(5) Any NDC–11s on CMS' list of NDC–11s of the selected drug that represent an inner package or an outer package.

(6) Any NDC–11s on CMS' list of NDC–11s of the selected drug that have been discontinued and the discontinuation date for each.

(e) *Primary Manufacturer requirement to timely report changes.* In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, including to ensure CMS' list of NDC–11s of the selected drug developed in accordance with § 429.100(c) remains complete and accurate, the Primary Manufacturer must update the information provided to CMS under paragraph (d) of this section, in a form and manner specified by CMS, at least 30 calendar days prior to the change taking effect.

(f) *CMS' list of NDC–11s of the selected drug.* CMS' list of NDC–11s of the selected drug identified in accordance with paragraph (c) of this section is used in the administration of the Negotiation Program, including all of the following:

(1) To identify the NDC–11s of the selected drug that are subject to the negotiation process set forth in subpart F of this part and the renegotiation process set forth in subpart G of this part, as applicable.

(2) To identify the NDC–11s of the selected drug to which the MFP applies for the price applicability period.

(3) To calculate the ceiling set forth in § 429.410(b) for drugs selected for negotiation.

(4) To calculate the ceiling set forth in § 429.620(b) for drugs selected for renegotiation.

(5) To calculate how to apply the MFP across dosage forms and strengths as set forth in § 429.700 for selected drugs and in § 429.600(b)(2) for drugs selected for renegotiation.

§ 429.105 Selection of drugs for negotiation.

(a) With respect to each initial price applicability year beginning with initial price applicability year 2029, CMS—

(1) Ranks the list of negotiation-eligible drugs identified in § 429.115 by combined total expenditures under both Part B and Part D, calculated using the methodology set forth at § 429.120; and

(2) Lists the ranked drugs in descending order, with the negotiation-eligible drug with the highest combined total expenditures under Part B and Part D listed first and the negotiation-eligible drug with the lowest combined total expenditures under Part B and Part D listed last.

(b) CMS removes from the ranked list of negotiation-eligible drugs determined in accordance with paragraph (a) of this section any biological products that qualify for delayed selection as determined in accordance with the biosimilar delay process set forth in § 429.110.

(c) With respect to each initial price applicability year beginning with initial price applicability year 2029, CMS selects for negotiation the 20 highest ranked (or all, if the number is less than 20) negotiation-eligible drugs remaining on the ranked list of negotiation-eligible drugs determined in accordance with paragraph (a) of this section and subject to paragraph (b) of this section. If two or more negotiation-eligible drugs have the same combined total expenditures under Parts B and D to the cent, and such combined total expenditures are the 20th highest (or the highest, if the number is less than 20) among negotiation-eligible drugs, CMS ranks those negotiation-eligible drugs based on which drug has the earlier approval or licensure date (as applicable) identified at § 429.125(c), and selects from among the drugs with the same combined total expenditures based on earliest approval or licensure date until there are 20 selected drugs (or until all drugs are selected, if the number of negotiation-eligible drugs is less than 20).

§ 429.110 Request for a biosimilar delay.

(a) *Applicable terms.* For purposes of this section, all references to ''marketed'' or ''marketing'' mean Bona Fide Marketing as defined in § 429.20 and set forth at § 429.130(a).

(b) *General.* A Biosimilar Manufacturer may submit a request, prior to the selected drug publication date, to delay the inclusion of a Reference Drug from the selected drug list for either of the following:

(1) One initial price applicability year based on the criteria specified in paragraph (c) of this section.

(2) A second initial price applicability year after such first initial price applicability year based on the criteria specified in paragraph (e) of this section.

(c) *First 1-year delay (Initial Delay Request).* To delay the inclusion of a Reference Drug for one initial price applicability year, CMS must determine the following:

(1) The Initial Delay Request meets all of the following criteria:

(i) The Reference Drug would be an extended-monopoly drug included on the selected drug list for the initial price applicability year, absent the Biosimilar Delay.

(ii) The Reference Drug includes the reference product identified in the Biosimilar's application for licensure under section 351(k) of the PHS Act that has either been—

(A) Approved by the FDA; or

(B) Accepted for review by the FDA.

(iii) If the Biosimilar has been licensed by FDA, no more than 1 year has elapsed since the licensure of the Biosimilar under section 351(k) of the PHS Act and marketing for the Biosimilar has not commenced.

(iv) The Biosimilar Manufacturer and the Reference Manufacturer—

(A) Are not the same manufacturer and must not be treated as the same manufacturer, where all persons treated as a single employer under subsection (a) or (b) of section 52 of the IRC, or in a Partnership, must be treated as one manufacturer; and

(B) Have not entered into any agreement that—

(*1*) Requires or incentivizes the Biosimilar Manufacturer to submit a Biosimilar Delay Request; or

(*2*) Directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States on or after the selected drug publication date of the applicable initial price applicability year.

(2) If the requirements in paragraph (c)(1) of this section are met, that there is a high likelihood, as specified in paragraph (d) of this section, that the Biosimilar will be licensed and marketed before the High Likelihood Deadline.

(d) *High likelihood.* There is a high likelihood the Biosimilar will be licensed and marketed before the High Likelihood Deadline if each of the following criteria are met:

(1) By no later than a date to be specified by CMS, which will be in January in the calendar year of the selected drug publication date for the initial price applicability year for which the Biosimilar Manufacturer requests the delay, an application for licensure under section 351(k) of the PHS Act for the Biosimilar has been either—

(i) Approved by the FDA; or

(ii) Accepted for review by FDA.

(2) CMS has identified clear and convincing evidence that the Biosimilar will be marketed before the High Likelihood Deadline through the following circumstances:

(i) Patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline, as CMS identifies within the documentation specified in paragraph (f)(1) of this section, meaning one or more of the following:

(A) There will be no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar.

(B) One or more court decisions or decisions by the United States Patent and Trademark Office (USPTO)'s Patent Trial and Appeal Board (PTAB) establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patents relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar.

(C) Neither a court nor PTAB has adversely ruled against the Biosimilar Manufacturer's patent assertion(s) pertaining to an unexpired patent or patent(s) relating to the reference product included in the Reference Drug applicable to the Biosimilar and the Biosimilar Manufacturer has publicly announced a precise launch date for the Biosimilar that is a calendar date before the High Likelihood Deadline and is not contingent on the outcome of pending litigation.

(D) The Biosimilar Manufacturer has a signed agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before the High Likelihood Deadline, without imposing improper constraints, that may include, but are not limited to, the circumstances listed in paragraphs (c)(1)(iv)(A) and (B) of this section (which prohibits the Biosimilar Manufacturer and the Reference Manufacturer being the same or being treated as the same, requiring or incentivizing the submission of a Biosimilar Delay Request, or directly or indirectly restricting the quantity of the Biosimilar sold in the United States on or after the selected drug publication date of the applicable initial price applicability year), on the Biosimilar Manufacturer.

(ii) The Biosimilar Manufacturer will be operationally ready to market the Biosimilar before the High Likelihood Deadline, as CMS identifies within the documentation specified in paragraph (f)(1) of this section, meaning the Biosimilar Manufacturer is taking the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of the Biosimilar.

(e) *Second 1-year delay (Additional Delay Request).* To delay the inclusion of a Reference Drug for a second initial price applicability year, CMS must determine the following:

(1) The Additional Delay Request meets all of the following criteria:

(i) The Biosimilar listed in the Additional Delay Request was identified in a successfully granted Initial Delay Request (consistent with paragraph (c) of this section).

(ii) During the time between the publication date of the selected drug list for the initial price applicability year for which the Initial Delay Request was granted and the date that is 1 year following that publication date, under section 351(k) of the PHS Act, the Biosimilar has not been both—

(A) Licensed; and

(B) Marketed.

(iii) The Additional Delay Request meets the requirements set forth in paragraphs (c)(1)(ii) through (iv) of this section.

(iv) The Reference Drug would not be a long-monopoly drug (as set forth in § 429.20) for the initial price applicability year for which the Biosimilar Manufacturer is submitting the Additional Delay Request.

(2) If the requirements in paragraph (e)(1) of this section are met, CMS must reevaluate and determine that there is a high likelihood, as specified in paragraph (d) of this section, that the Biosimilar will be licensed and marketed before the High Likelihood Deadline.

(3) If the requirements in paragraph (e)(2) of this section are met, CMS must determine based on a holistic review of the Additional Delay Request, including within the documentation specified in paragraph (f) of this section, there is clear and convincing evidence that the Biosimilar Manufacturer has made a significant amount of progress towards licensure and marketing of the Biosimilar since the Biosimilar Manufacturer's submission of the successful Initial Delay Request.

(f) *Biosimilar delay request submission.* A Biosimilar Manufacturer may submit a Biosimilar Delay Request to CMS in a form and manner specified by CMS, by no later than a date to be specified by CMS, which will be no later than the end of December of the calendar year prior to the selected drug publication date for such initial price applicability year for which the Biosimilar Manufacturer may submit a Biosimilar Delay Request, and must provide the information specified in paragraphs (f)(1) through (3) of this section, as applicable:

(1) With the Biosimilar Manufacturer's Initial Delay Request or Additional Delay Request to support the

determinations specified in paragraphs (c) and (e) of this section, as applicable:

(i) All agreements related to the Biosimilar filed with the Federal Trade Commission or the Assistant Attorney General under section 1112(a) and (c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(ii) To the extent available, the manufacturing schedule for the Biosimilar submitted to FDA during the review of the licensure application under section 351(k) of the PHS Act.

(iii) To the extent available, disclosures that pertain to the marketing of the Biosimilar (for example, in filings by the Biosimilar Manufacturer of the Biosimilar with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 or comparable documentation that is distributed to shareholders of privately held companies) about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before the marketing of a Biosimilar.

(2) Upon request from CMS after review of a Biosimilar Delay Request, including the information provided consistent with paragraph (f)(1) of this section, additional information and documents from the Biosimilar Manufacturer to be submitted in a form and manner specified by CMS as necessary for CMS to make a determination for an Initial Delay Request or an Additional Delay Request, as applicable.

(3) At the Biosimilar Manufacturer's option, after the deadline for submitting a Biosimilar Delay Request specified in this paragraph (f) but prior to the selected drug publication date for such initial price applicability year for which the Biosimilar Manufacturer may submit a Biosimilar Delay Request, updates on the status of the Biosimilar's application for licensure in a form and manner specified by CMS by no later than a date to be specified by CMS.

(g) *Notice of determinations.* (1) After review of a Biosimilar Delay Request, CMS provides in writing:

(i) A notice of determination, on or after the selected drug publication date for the applicable initial price applicability year, at a time specified by CMS, to:

(A) The Biosimilar Manufacturer that submitted a request, which includes:

(*1*) Whether the Biosimilar Delay Request was successful or unsuccessful; and

(*2*) If unsuccessful, the reason CMS determined the request was unsuccessful.

(B) If a Biosimilar Delay Request is successful, the Reference Manufacturer of the reference product named in a successful Biosimilar Delay Request.

(ii) [Reserved]

(2) CMS publishes the number of Reference Drugs that would have been selected drugs for the applicable initial price applicability year absent the successful Biosimilar Delay Requests as part of publishing the selected drug list (as set forth in § 429.100).

(3) After review for licensure and marketing consistent with paragraph (h) of this section, CMS provides in writing by a date to be specified by CMS, which will be no later than the end of October in the calendar year of the selected drug publication date for the initial price applicability year for which CMS determined the Biosimilar Manufacturer's Biosimilar Delay Request successful, a notice of determination to the Biosimilar Manufacturer of CMS' determination as to whether the Biosimilar is or is not licensed and marketed during the Initial Delay Period or the Second Delay Period, as applicable.

(h) *Review for failure of the biosimilar to be licensed and marketed.* (1) CMS determines whether a Biosimilar named in a successful Initial Delay Request has been licensed and marketed during the Initial Delay Period.

(i) If CMS determines that the Biosimilar has not been licensed and marketed during the Initial Delay Period, the Biosimilar Manufacturer may submit an Additional Delay Request consistent with paragraph (e) of this section.

(ii) Subject to the circumstance in paragraph (h)(3) of this section, CMS includes the Reference Drug on the selected drug list for the initial price applicability year that is 1 year after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request if either of the following occurs:

(A) The Biosimilar Manufacturer does not submit an Additional Delay Request for the Biosimilar included in the successful Initial Delay Request.

(B) CMS determines that the Additional Delay Request submitted by the Biosimilar Manufacturer for the Biosimilar named in the successful Initial Delay Request does not meet the requirements in paragraph (e) of this section.

(2) CMS determines whether a Biosimilar named in a successful Additional Delay Request has been licensed and marketed during the Second Delay Period.

(i) If CMS determines that the Biosimilar has not been licensed and marketed, subject to the circumstance in paragraph (h)(3) of this section, CMS includes the Reference Drug on the selected drug list for the initial price applicability year that is 2 years after the initial price applicability year for which the Reference Drug would have been included on the selected drug list if not for the successful Initial Delay Request.

(ii) [Reserved]

(3) If one or more different biosimilars of the Reference Drug for the Biosimilar named in a successful Initial Delay Request (for purposes of paragraph (h)(1) of this section) or a successful Additional Delay Request (for purposes of paragraph (h)(2) of this section) are licensed and marketed, the Reference Drug is not included on the applicable selected drug list.

(i) *Rebate owed for failure of a biosimilar to be licensed and marketed.* (1) The Reference Manufacturer is required to pay the rebate specified in paragraph (i)(4) of this section for the 1 or 2 years that the Reference Manufacturer would have provided access to the MFP for the Reference Drug but for the Biosimilar Delay, if—

(i) CMS delayed the selection and negotiation of a Reference Drug for 1 year due to a successful Initial Delay Request or 2 years due to a successful Additional Delay Request;

(ii) CMS determined that the Biosimilar was not licensed and marketed, as described in paragraph (h) of this section; and

(iii) The Reference Manufacturer agrees to an MFP.

(2) The Reference Manufacturer must pay any rebates owed under paragraph (i) of this section in a time and manner to be specified by CMS.

(3) The rebates paid are deposited in either of the following:

(i) The Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act, for drugs payable under Part B.

(ii) The Medicare Prescription Drug Account established under section 1860D–16 of the Act, within the Federal Supplementary Medical Insurance Trust Fund, for drugs covered under Part D.

(4) Except if the drug meets the circumstances in paragraph (i)(5) of this section, the rebate amount is calculated as follows:

(i) CMS applies the calculation under paragraphs (i)(4)(ii) through (iv) of this section, as applicable for all the previous initial price applicability years where the Reference Drug would have

been on the selected drug list if not for the delay, but for the initial price applicability year for which an Additional Delay Request was granted, CMS adjusts the MFP by the annual percentage increase in the CPI–U for the 12-month period ending with July of the calendar year that is 2 years before the initial price applicability year for which the Additional Delay Request was granted.

(ii) In the case of a Reference Drug that is a drug covered under Part D—

(A) Seventy-five percent of the difference between the AMP as reported by the Primary Manufacturer of the selected drug under section 1927 of the Act, or if not reported under section 1927 of the Act, as submitted to CMS in accordance with § 429.200(b)(5), with respect to each of the calendar quarters of the price applicability period that would have applied but for the delay, and the MFP negotiated for the Reference Drug; and

(B) Multiplied by the number of units dispensed under Part D for the Reference Drug in each calendar quarter of the price applicability period that would have applied but for the delay.

(iii) In the case of a Reference Drug that is a drug payable under Part B—

(A) Eighty percent of the difference between the payment amount under section 1847A(b) of the Act, with respect to each of the calendar quarters of the price applicability period that would have applied but for the delay, and the MFP negotiated for the Reference Drug; and

(B) Multiplied by the number of units of the billing and payment code of the Reference Drug administered or furnished under Part B (excluding units that are packaged into the payment amount for an item or service and are not separately payable under Part B) for each calendar quarter of the price applicability period that would have applied but for the delay.

(iv) In the case of a Reference Drug that is a drug covered under Part D and payable under Part B, CMS calculates the rebate amount for Reference Drugs payable under Part B and covered under Part D by summing the rebate amount for the units payable under Part B as specified in paragraph (i)(4)(iii) of this section and the rebate amount for units covered under Part D as specified in paragraph (i)(4)(ii) of this section.

(5) If CMS determines that the Reference Drug transitioned from an extended-monopoly drug to a long-monopoly drug at the time of its inclusion on the selected drug list for an initial price applicability year (as set forth in § 429.110(h)(1)(ii) or (h)(2)(i)), as applicable for the initial year delay—

(i) The rebate calculation as described in paragraph (i)(4) of this section will substitute the MFP negotiated for the Reference Drug with the amount specified in paragraph (i)(5)(ii) of this section.

(ii) The amount specified in this paragraph is an amount equal to 65 percent of the average non-FAMP for 2021 for the Reference Drug (or the first full year following market entry if there is no non-FAMP for 2021) increased by the percentage increase in the CPI–U from September 2021 (or December of such first full year following the market entry) to September of the year prior to the selected drug publication date for the initial price applicability year that would have applied but for the Initial Delay Request.

(6) If CMS determines that the Reference Drug transitioned from an extended-monopoly drug to a long-monopoly drug at the time of its inclusion on the selected drug list for an initial price applicability year (as set forth in § 429.110(h)(2)), as applicable for the second year delay the rebate calculation as described in paragraph (i)(4) of this section will substitute the MFP negotiated for the Reference Drug with the amount specified at paragraph (i)(5)(ii) of this section that is further adjusted by the annual percentage increase in the CPI–U for the 12-month period ending with July of the calendar year that is 2 years before the initial price applicability year for which the Additional Delay Request was granted.

§ 429.115 Identification of negotiation-eligible drugs.

(a) *Identification.* With respect to each initial price applicability year beginning with initial price applicability year 2029, a qualifying single source drug, identified as set forth in § 429.125, is a negotiation-eligible drug if CMS determines that such qualifying single source drug is on the list of 50 Part D high spend drugs, as set forth in paragraph (a)(1) of this section, or on the list of 50 Part B high spend drugs or both, as set forth in paragraph (a)(2) of this section.

(1) *Part D high spend drugs.* CMS identifies Part D high spend drugs as follows:

(i) CMS removes a qualifying single source drug if it is currently a selected drug.

(ii) For each remaining qualifying single source drug identified in § 429.125, CMS calculates total expenditures under Part D using the methodology set forth at § 429.120(a).

(iii) CMS ranks the remaining qualifying single source drugs by total expenditures under Part D.

(iv) Subject to paragraph (b) of this section and using the ranked list identified in paragraph (a)(1)(iii) of this section, CMS identifies as Part D high spend drugs the 50 qualifying single source drugs that have the highest total expenditures under Part D.

(2) *Part B high spend drugs.* CMS identifies Part B high spend drugs as follows:

(i) CMS removes a qualifying single source drug if it is currently a selected drug.

(ii) For each remaining qualifying single source drug identified in § 429.125, CMS calculates total expenditures under Part B using the methodology set forth at § 429.120(b).

(iii) CMS ranks the remaining qualifying single source drugs by total expenditures under Part B.

(iv) Subject to paragraph (b) of this section and using the ranked list identified in paragraph (a)(2)(iii) of this section, CMS identifies as Part B high spend drugs the 50 qualifying single source drugs that have the highest total expenditures under Part B.

(b) *Tie-breaker methodology.* If two or more qualifying single source drugs have the same total expenditures to the cent (and such total expenditures are the 50th highest among qualifying single source drugs under Part D (as specified in paragraph (a)(1)(iv) of this section) or Part B (as specified in paragraph (a)(2)(iv) of this section), CMS ranks those qualifying single source drugs based on which drug has the earlier approval or licensure date (as applicable) identified at § 429.125(c), until CMS has identified 50 high spend drugs for Part B and 50 high spend drugs for Part D, as applicable.

§ 429.120 Calculation of total expenditures.

(a) *Total expenditures under Part D.* CMS calculates total expenditures under Part D for a given potential qualifying single source drug, qualifying single source drug, negotiation-eligible drug, or selected drug, as the sum of gross covered prescription drug costs for each PDE record for such drug that meets all of the following criteria:

(1) The date of service is during the total expenditures measurement period.

(2) The gross covered prescription drug cost on the PDE record is greater than zero dollars.

(3) The PDE record is considered final action.

(4) The drug coverage status code indicates the PDE record is for a drug covered under Part D.

(5) The compound code indicates the PDE record is not for a compounded drug.

(b) *Total expenditures under Part B.* CMS calculates total expenditures under Part B for a given potential qualifying single source drug, qualifying single source drug, negotiation-eligible drug, or selected drug, as the sum of the amounts determined under paragraphs (b)(1) and (2) of this section:

(1) Subject to the methodology described in paragraph (b)(3) of this section, the sum of the total allowed charges for each Original Medicare Part B claim for such drug that meets all of the following criteria:

(i) The date of service is during the total expenditures measurement period.

(ii) The claim type code is associated with an Original Medicare Part B claim in an outpatient setting (including but not limited to clinics, Federally Qualified Health Centers, and ambulatory surgical centers), a professional services claim, or a durable medical equipment claim, as determined by CMS.

(iii) The total allowed charges for the claim line is greater than zero dollars.

(iv) The claim is considered final action.

(v) The claim is not billed as a compounded drug.

(vi) The claim is not for a drug or biological product that is bundled or packaged into the payment for another service. In instances where a claim for separate payment is submitted for a drug payable under Part B when such a claim is typically payable under Part B Original Medicare payment rules only as part of a bundled payment, such claim will be considered to be bundled or packaged into the payment for another service and will not be included in the total allowed charges calculation.

(2) Subject to the methodology described in paragraph (b)(3) of this section, the sum of the total allowed charges that would have been applicable under Original Medicare Part B for each MA encounter data record for Part B services for such drug that meets all of the following criteria:

(i) The date of service is during the total expenditures measurement period.

(ii) The claim type code is associated with an MA encounter record in an outpatient setting (including but not limited to clinics, Federally Qualified Health Centers, and ambulatory surgical centers), professional services, or durable medical equipment record, as determined by CMS.

(iii) The reported total number of units on the MA encounter data record line is greater than zero.

(iv) The encounter data record is considered final action.

(v) The encounter data record is not denied.

(vi) The encounter data record is not a chart review record.

(vii) The encounter data record line is not for a supplemental benefit.

(viii) The encounter data record is not reported as a compounded drug.

(ix) The encounter data record is not for a drug or biological product that is bundled or packaged into the payment for another service under Part B Original Medicare. In instances where an encounter data record for separate payment is submitted for a drug payable under Part B when such a claim is typically payable under Part B Original Medicare payment rules only as part of a bundled payment, such claim will be considered to be bundled or packaged into the payment for another service and will not be included in the total allowed charges calculation.

(3) In cases where such drug is assigned to a HCPCS code with other products, CMS calculates the total expenditures under Part B by using ASP sales volume data to apportion Part B expenditures based on the ratio of reported sales volume of the drug compared to reported sales volume of all products assigned to the HCPCS code.

§ 429.125 Identification of qualifying single source drugs.

(a) *General.* Subject to the statutory exclusions codified in paragraph (e) of this section, with respect to each initial price applicability year beginning with initial price applicability year 2029, a qualifying single source drug is a drug covered under Part D, a drug payable under Part B, or both that meets the following criteria:

(1) For drug products, a qualifying single source drug is a drug—

(i) That is approved under section 505(c) of the FD&C Act and marketed in accordance with such approval;

(ii) For which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years have elapsed since the date of such approval, determined as set forth in paragraph (c) of this section; and

(iii) That is not the listed drug for any drug approved and marketed in an ANDA under section 505(j) of the FD&C Act, determined as set forth in paragraph (d) of this section.

(2) For biological products, a qualifying single source drug is a biological product—

(i) That is licensed under section 351(a) of the PHS Act and marketed in accordance with such licensure;

(ii) For which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years have elapsed since the date of such licensure, determined as set forth in paragraph (c) of this section; and

(iii) That is not the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act, determined as set forth in paragraph (d) of this section.

(b) *Potential qualifying single source drugs.* In identifying qualifying single source drugs under paragraph (a) of this section, CMS first identifies potential qualifying single source drugs as follows:

(1) *Drug products.* Subject to paragraph (b)(4) of this section, for drug products, all dosage forms and strengths of the drug with the same active moiety as identified using public sources (such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file), and the same NDA holder, inclusive of all of the following:

(i) Products that are marketed under different NDAs.

(ii) Repackaged and relabeled products that are marketed under such NDA(s).

(iii) Authorized generic drugs, as defined in § 429.20, that are marketed under such NDA(s).

(iv) Multi-market approval (MMA) products imported under section 801(d)(1)(B) of the FD&C Act that are marketed under such NDA(s).

(2) *Biological products.* Subject to paragraphs (b)(3) and (4) of this section, for biological products, all dosage forms and strengths of the biological product with the same active ingredient as identified using public sources (such as, but not limited to, RxNorm, OpenFDA, FDALabel, DailyMed, and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file), and the same BLA holder, inclusive of all of the following:

(i) Products that are marketed under different BLAs.

(ii) Repackaged and relabeled products that are marketed under such BLA(s).

(iii) Authorized generic drugs, as defined in § 429.20, that are marketed under such BLA(s).

(iv) MMA products imported under section 801(d)(1)(B) of the FD&C Act that are marketed under such BLA(s).

(3) *Vaccines for infectious disease(s).* Subject to paragraph (b)(4) of this section, for purposes of the identification of potential qualifying single source drugs under paragraph (b)(2) of this section for vaccines for infectious disease(s), CMS identifies all dosage forms and strengths of the drug with the same antigen component on such vaccine's labeling.

(4) *Fixed combination products*—(i) *General.* Subject to paragraph (b)(4)(ii) of this section, for purposes of the identification of potential qualifying single source drugs under paragraphs (b)(1) and (2) of this section for a drug or biological product that is a fixed combination drug with two or more active moieties, active ingredients, or, for vaccines for infectious disease(s), antigen components, CMS identifies a potential qualifying single source drug using all dosage forms and strengths of the drug or biological product with the same distinct combination of active moieties, active ingredients, or antigen components.

(ii) *New formulations.* If CMS determines that a fixed combination drug with two or more active moieties, active ingredients, or, for a vaccine for infectious disease(s), antigen components shares one or more active moiety(ies), active ingredient(s), or antigen component(s) with another drug or biological product with the same NDA/BLA holder, and such products differ in active moiety(ies), active ingredient(s), or antigen component(s) due to the inclusion of an active moiety, active ingredient, or antigen component that creates a new formulation and enables an alternative route of administration for the co-administered active moiety(ies), active ingredient(s), or antigen component(s), CMS identifies a potential qualifying single source drug using all dosage forms and strengths of the drug or biological product with the shared active moiety(ies), active ingredient(s), or antigen component(s) and the same NDA/BLA holder.

(c) *Time since approval or licensure.* With respect to initial price applicability years beginning with initial price applicability year 2029, CMS determines if a potential qualifying single source drug, identified as set forth in paragraph (b) of this section, meets the time since approval or licensure criteria set forth in paragraphs (a)(1)(ii) and (a)(2)(ii) of this section, respectively, as follows:

(1) *Time since approval for drugs.* Subject to paragraph (c)(3) of this section, for a drug, at least 7 years must have elapsed between the date of approval of the potential qualifying single source drug and the selected drug publication date with respect to such initial price applicability year. To determine the FDA date of approval of a potential qualifying single source drug that is a drug, CMS uses the date of approval of the FDA application belonging to the NDA holder and containing the active moiety (or in the case of potential qualifying single source drugs identified under paragraph (b)(4)(i) of this section, the distinct combination of active moieties), or, if such drug has more than one FDA application, CMS uses the initial date of approval associated with the earliest-approved FDA application belonging to the NDA holder and containing the active moiety (or in the case of potential qualifying single source drugs identified under paragraph (b)(4)(i) of this section, the distinct combination of active moieties). For potential qualifying single source drugs identified under paragraph (b)(4)(ii) of this section, CMS uses the date of approval of the FDA application belonging to the NDA holder and containing the shared active moiety(ies) identified at paragraph (b)(4)(ii) of this section or if such drug has more than one FDA application, CMS uses the initial date of approval associated with the earliest-approved FDA application belonging to the NDA holder and containing such shared active moiety(ies).

(2) *Time since licensure for biological products.* Subject to paragraph (c)(3) of this section, for a biological product, at least 11 years must have elapsed between the date of licensure of the potential qualifying single source drug and the selected drug publication date with respect to such initial price applicability year. Subject to the exceptions set forth in paragraphs (c)(2)(i) and (ii) of this section, to determine the FDA date of licensure of a potential qualifying single source drug that is a biological product, CMS uses the date of licensure of the FDA application belonging to the BLA holder and containing the active ingredient (or in the case of potential qualifying single source drugs identified under paragraph (b)(4)(i) of this section, the distinct combination of active ingredients), or, if such biological product has more than one FDA application, CMS uses the initial date of licensure associated with the earliest-approved FDA application belonging to the BLA holder and containing the active ingredient (or in the case of potential qualifying single source drugs identified under paragraph (b)(4)(i) of this section, the distinct combination of active ingredients). Subject to the exceptions set forth in paragraphs (c)(2)(i) and (ii) of this section, for a potential qualifying single source drug identified under paragraph (b)(4)(ii) of this section, CMS uses the date of licensure of the FDA application belonging to the BLA holder and containing the shared active ingredient(s) identified at paragraph (b)(4)(ii) of this section, or, if such biological product has more than one FDA application, CMS uses the initial date of licensure associated with the earliest-approved FDA application belonging to the BLA holder and containing such shared active ingredient(s).

(i) For each unique potential qualifying single source drug that CMS identifies based on its antigen component(s) in accordance with paragraph (b)(3) of this section, CMS determines the date of licensure using the earliest date of licensure for any BLA or supplemental BLA for that unique potential qualifying single source drug for purposes of determining the FDA date of licensure of the potential qualifying single source drug for purposes of implementing this paragraph (c)(2).

(ii) For biological products with an approved NDA that was deemed to be a BLA under section 351 of the PHS Act on March 23, 2020, in accordance with section 7002(e)(4)(A) of Biologics Price Competition and Innovation Act of 2009 (BPCI Act), and that are currently licensed biological products under section 351 of the PHS Act, CMS considers March 23, 2020 to be the date of licensure of the potential qualifying single source drug for purposes of implementing this paragraph (c)(2). For a biological product with an approved application under section 505(c) of the FD&C Act that was deemed to be a BLA under section 7002(e)(4)(B) of the BPCI Act, as amended by the Further Consolidated Appropriations Act of 2020, CMS considers the approval date determined in accordance with section 7002(e)(4)(B) of the BPCI Act to be the date of licensure of the potential qualifying single source drug for purposes of implementing this paragraph (c)(2).

(3) *Certain former orphan drugs.* Notwithstanding paragraphs (c)(1) and (2) of this section to the contrary, for a drug or biological product that met or meets the criteria for the orphan drug exclusion at paragraph (e)(1) of this section as of the date of such drug or biological product's initial approval or licensure identified as set forth in paragraphs (c)(1) and (2) of this section, CMS measures the 7- and 11-year periods described in paragraphs (c)(1) and (2) of this section, respectively, starting from the first day after such initial date of approval or licensure that such drug or biological product does not, or did not, meet the criteria for the orphan drug exclusion. CMS identifies this day as the earlier of—

(i) The date on which the FDA approves such drug or biological product for an indication (irrespective of whether approval of such indication was or is withdrawn after its approval)

for a disease or condition that is not a rare disease or condition for which the drug or biological product is designated under section 526 of the FD&C Act; or

(ii) The date on which an orphan drug designation is withdrawn, if that withdrawal results in the drug or biological product no longer qualifying for the orphan drug exclusion. For orphan drug designations withdrawn prior to or on August 12, 2013, for which the FDA Orphan Drug Product designation database does not include the date of such withdrawal, CMS uses August 12, 2013, as the date on which the orphan designation is withdrawn for purposes of identifying the first day after the drug or biological product's approval or licensure that such drug or biological product does not qualify for the orphan drug exclusion.

(d) *Bona Fide Marketing of an approved generic drug or licensed biosimilar.* A potential qualifying single source drug is not a qualifying single source drug, if CMS determines that—

(1) Using FDA reference sources including the Orange Book and Purple Book, at least one generic drug is approved under section 505(j) of the FD&C Act using any dosage form or strength of the potential qualifying single source drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using any dosage form or strength of the potential qualifying single source drug as the reference product; and

(2) Such generic drug or biosimilar is subject to Bona Fide Marketing when CMS reviews such information at the point in time specified in § 429.130(c)(1).

(e) *Exclusions from qualifying single source drugs.* A potential qualifying single source drug identified in paragraph (b) of this section is not a qualifying single source drug if CMS determines that it qualifies for one or more of the following exclusions:

(1) *The orphan drug exclusion.* A potential qualifying single source drug qualifies for the orphan drug exclusion if, for all dosage forms and strengths of such potential qualifying single source drug, the following criteria are met:

(i) The potential qualifying single source drug is designated as a drug for one or more rare diseases or conditions under section 526 of the FD&C Act, determined by CMS as follows:

(A) CMS uses data sources such as the FDA Orphan Drug Product designation database; and

(B) CMS only considers orphan drug designations that have not been withdrawn or revoked.

(ii) The only indication(s) approved by FDA for the potential qualifying single source drug are for such designated rare disease(s) or condition(s), determined by CMS as follows:

(A) CMS uses information on FDA-approved indications from publicly available databases and documents (such as, but not limited to, FDALabel, FDA Online Label Repository, Drugs@FDA, and NLM DailyMed); and

(B) CMS only considers approvals of indications that FDA has not withdrawn.

(2) *The low-spend Medicare drug exclusion.* A potential qualifying single source drug qualifies for the low-spend Medicare drug exclusion if it has combined total expenditures under Part B and Part D, calculated as set forth in paragraph (e)(2)(i) of this section, less than the inflation-adjusted threshold, calculated as set forth in paragraph (e)(2)(ii) of this section.

(i) For a potential qualifying single source drug described in paragraph (b) of this section, CMS calculates combined total expenditures under Part B and Part D as the sum of total expenditures under Part B (calculated as set forth in § 429.120(b)) plus total expenditures under Part D (calculated as set forth in § 429.120(a)).

(ii) Starting from the inflation-adjusted threshold for initial price applicability year 2028 equal to $212,907,518.30, the inflation-adjusted threshold for an initial price applicability year is equal to the inflation-adjusted threshold for the prior initial price applicability year, increased by the annual percentage increase in the CPI–U for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to a given initial price applicability year.

(3) *Plasma-derived product exclusion.* A potential qualifying single source drug qualifies for the plasma-derived product exclusion if it is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling or product information (such as, but not limited to, FDALabel and the FDA Online Label Repository).

§ 429.130 Bona Fide Marketing.

(a) *General.* CMS considers whether an approved generic drug or licensed biosimilar is marketed according to this section based on CMS' evaluation of the following:

(1) Sales and utilization data for the generic drug or biosimilar from the following data sources for the following data periods:

(i) The most recent 12 months of PDE data available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section;

(ii) The most recent 12 months of AMP data available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section;

(iii) The most recent 4 quarters of ASP data available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section; and

(iv) For data sources other than those sources listed in paragraphs (a)(1)(i) through (iii) of this section, including, but not limited to, Medicaid State Drug Utilization Data and data from nationally representative and commercially available data sources, CMS may evaluate the most recent 12 months, 4 quarters, or 52 weeks of any such data source, if available and as applicable to such data source, at the time CMS reviews such data consistent with paragraph (c) of this section.

(2) Information related to additional factors, available to CMS at the time CMS reviews such data consistent with paragraph (c) of this section, including:

(i) Whether the generic drug or biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain; and

(ii) Whether any licenses or other agreements between a Primary Manufacturer and the manufacturer of the generic drug or biosimilar limit the availability or distribution of the generic drug or biosimilar.

(3) CMS may also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar, including sales and utilization data for the generic drug or biosimilar not otherwise captured by paragraphs (a)(1)(i) through (iv) of this section.

(b) *Conduct holistic inquiry.* In its evaluation of the information described in paragraph (a) of this section, CMS conducts a holistic inquiry based on the totality of the circumstances.

(c) *Timing.* CMS reviews the information set forth in paragraph (a) of this section at the following times:

(1) *Identification of potential qualifying single source drugs.* For any potential qualifying single source drug for initial price applicability year 2029 and any initial price applicability year thereafter, in January prior to each selected drug publication date.

(2) *Monitoring generic(s) or biosimilar(s) for drugs that were not considered qualifying single source drugs.* For any potential qualifying single source drugs that did not qualify as a qualifying single source drug for initial price applicability year 2029 or any initial price applicability year

thereafter because CMS determined that a generic drug was approved using the potential qualifying single source drug as the listed drug or a biosimilar was licensed using the potential qualifying single source drug as the reference product, and such generic drug or biosimilar is subject to Bona Fide Marketing (consistent with paragraph (a) of this section), periodically during each calendar year, including at least annually in January.

(3) *Identification of selected drugs ineligible to be selected for renegotiation.* For identifying that a drug previously selected for negotiation is not eligible for renegotiation for initial price applicability year 2029 and any initial price applicability year thereafter, in January prior to each selected drug publication date.

(4) *Selected drugs until the negotiation period ends or until the negotiation process ceases to apply.* For drugs selected for negotiation for initial price applicability year 2029 and any initial price applicability year thereafter, monthly starting in March during the negotiation period for the initial price applicability year for which the drug was selected for negotiation and until the earlier of either:

(i) November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for negotiation; or

(ii) the date as of which CMS determines that a selected drug meets the requirements at § 429.135(b)(1) to cease being subject to the negotiation process.

(5) *Drugs selected for renegotiation until renegotiation ends or until the renegotiation process ceases to apply.* For drugs selected for renegotiation (if any) for initial price applicability year 2029 and any initial price applicability year thereafter, monthly starting in March during the renegotiation period for the initial price applicability year for which the drug was selected for renegotiation and until the earlier of either:

(i) November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug was selected for renegotiation; or

(ii) The date as of which CMS determines that a selected drug meets the requirements at § 429.135(b)(2) to cease being subject to the renegotiation process.

(6) *Selected drugs following the negotiation period.* For all drugs selected for initial price applicability year 2029 and any initial price applicability year thereafter after reaching an agreed-upon MFP (consistent with § 429.200(b)(4)), and, starting January 1, 2029, for any drugs selected for initial price applicability years 2026, 2027, and 2028, biannually in March and October, starting in October of the calendar year after CMS and the Primary Manufacturer reached an agreement on the MFP for the initial price applicability year for which the drug was selected originally for negotiation and until CMS determines that a selected drug meets the requirements at § 429.135(b) to cease being considered a selected drug.

(7) *Monitoring generic(s) or biosimilar(s) for selected drugs that are no longer subject to negotiation or renegotiation or that have ceased to be selected drugs.* For drugs selected for initial price applicability year 2029 and drugs selected for any initial price applicability year thereafter (consistent with § 429.200(b)(4)) for which CMS makes a determination under § 429.135(b), and, starting January 1, 2029, for any drugs CMS determines cease being considered a selected drug for initial price applicability years 2026, 2027, and 2028, periodically during each calendar year, including at least annually in January prior to each selected drug publication date.

§ 429.135 Deselection of a selected drug.

(a) *General.* Each drug selected for negotiation for an initial price applicability year remains a selected drug with respect to such initial price applicability year and each subsequent year beginning before the first year that begins at least 9 months after the date as of which CMS determines that—

(1) Using FDA reference sources including the Orange Book and Purple Book, at least one generic drug is approved under section 505(j) of the FD&C Act using any dosage form or strength of the selected drug as the listed drug or at least one biosimilar is licensed under section 351(k) of the PHS Act using any dosage form or strength of the selected drug as the reference product; and

(2) Such generic drug or biosimilar is subject to Bona Fide Marketing.

(b) *Timing.* For clarity, the following circumstances apply to such selected drug based on the date as of which CMS determines the conditions described in paragraph (a) of this section are met—

(1) If the date is during the period beginning on the selected drug publication date (as defined in § 429.20) and ending on November 1 of the year that begins 2 years prior to the initial price applicability year for which the drug is selected for negotiation, then—

(i) The selected drug ceases to be subject to the negotiation process under section 1194 of the Act, as set forth in subpart F of this part;

(ii) The selected drug remains a selected drug for such initial price applicability year only;

(iii) The selected drug will not be replaced with another selected drug for the initial price applicability year that the selected drug is selected; and

(iv) No MFP will be published for, or apply to, such drug.

(2) If the date is during a period beginning on the selected drug publication date (as defined in § 429.20) of the year that begins 2 years prior to the initial price applicability year for which the drug is selected for renegotiation and ending on November 1 of such year, then the selected drug ceases to be subject to the renegotiation process under section 1194 of the Act, as set forth in subpart G of this part.

(3) If the date is during the period beginning on November 2 of the year that begins 2 years prior to the initial price applicability year for which the drug is selected for negotiation and ending on March 31 of that initial price applicability year, then—

(i) The selected drug will cease to be a selected drug on January 1 of the year following the initial price applicability year for which such drug was selected for negotiation; and

(ii) The MFP will apply only for the initial price applicability year for which such drug was selected for negotiation.

(4) If the date is during the selected drug's price applicability period and after March 31 of the initial price applicability year for which the selected drug is selected for negotiation:

(i) The selected drug will cease to be a selected drug on January 1 of the year that begins at least 9 months after the date as of which CMS determines the conditions described in paragraph (a) of this section are met; and

(ii) The MFP will apply until such date that the selected drug ceases to be a selected drug as described in paragraph (b)(4)(i) of this section.

(c) *Timing of determination for renegotiation eligibility.* A drug previously selected for negotiation is not eligible for renegotiation if CMS has made a determination described in paragraph (a) of this section, prior to the next selected drug publication date for the initial price applicability year for which any drug could be selected for renegotiation.

(d) *Public notice.* If CMS makes a determination described in paragraph (a) of this section, CMS will announce such determination in a timeframe and manner specified by CMS.

Subpart C—Negotiation Program Agreement

§ 429.200 Entrance into an agreement with CMS.

(a) *General.* The Negotiation Program Agreement between the Primary Manufacturer, as defined in § 429.20, and CMS contains provisions regarding the requirements specified in paragraph (b) of this section, and may contain other provisions as determined by CMS, in accordance with section 1193 of the Act, as necessary for purposes of administering and monitoring compliance with the Negotiation Program.

(1) The deadline for the Primary Manufacturer of a selected drug to enter into a Negotiation Program Agreement with respect to the selected drug is 11:59 p.m. PST on February 28 following the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation.

(2) The negotiation period with respect to a selected drug will begin on the earlier of February 28 following the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation or the date that the Negotiation Program Agreement is fully executed.

(b) *Agreement requirements.* In executing a Negotiation Program Agreement with respect to a selected drug, a Primary Manufacturer agrees to the following:

(1) To comply with all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including this part, implementing those provisions and any changes to the Act that affect the Negotiation Program.

(2) To negotiate to determine an MFP for the selected drug with CMS, during the negotiation period for the initial price applicability year for the selected drug, in accordance with section 1194 of the Act, including as described in subpart F of this part.

(3) As applicable, to renegotiate to determine an MFP for the drug selected for renegotiation with CMS, during the renegotiation period for the initial price applicability year for the drug selected for renegotiation, in accordance with section 1194 of the Act, including as described in subpart G of this part.

(4) To provide access to the MFP, including as renegotiated, with respect to the selected drug, during the selected drug's price applicability period, in accordance with section 1193(a)(3) of the Act, including as described in subpart B and subpart I of this part.

(5) To submit to CMS, in a form and manner specified by CMS, the information specified in sections 1191 to 1198 of the Act, the Negotiation Program Agreement, or this part, including, but not limited to, the information as specified at §§ 429.100(d), 429.405, 429.505(b), and, if applicable, 429.615(b)(1), in accordance with sections 1193(a)(4) and 1193(a)(5) of the Act, including as described in subparts B, E, F, and G of this part.

(6) To comply with requirements determined by CMS to be necessary for the purposes of administering the Negotiation Program and monitoring compliance with the Negotiation Program, in accordance with section 1193(a)(5) of the Act, including as described in subpart J of this part.

(c) *Execution of agreement.* The Negotiation Program Agreement must be signed, in a form and manner specified by CMS, by an Authorized Representative of the Primary Manufacturer, as defined in § 429.20, and by CMS.

(d) *Agreement term.* The Negotiation Program Agreement takes effect on the date that the Negotiation Program Agreement is signed both by an Authorized Representative of the Primary Manufacturer and by CMS. The term of the Negotiation Program Agreement is from such effective date until the Negotiation Program Agreement is terminated in accordance with § 429.205(a), including as described in subpart C of this part.

(e) *Agreement to an MFP.* Upon agreeing to an MFP for a selected drug, CMS and the Primary Manufacturer of a selected drug will formalize the agreement to an MFP through an Addendum to the Negotiation Program Agreement that must be signed, in a form and manner specified by CMS, by an Authorized Representative of the Primary Manufacturer and by CMS.

§ 429.205 Termination.

(a) *Termination of Negotiation Program Agreement.* The Negotiation Program Agreement terminates effective as of the date of the earlier of—

(1) The first date that the selected drug covered by the Negotiation Program Agreement is no longer a selected drug consistent with CMS' determination in accordance with section 1192(c) of the Act as described at § 429.135.

(2) The date of termination established in paragraph (b)(5) of this section in connection with a Request to Terminate by the Primary Manufacturer submitted under paragraph (b) of this section.

(b) *Primary Manufacturer-requested termination.* (1) A Primary Manufacturer that wishes to terminate a Negotiation Program Agreement may submit in writing a Request to Terminate, in a form and manner specified by CMS. Such Request to Terminate must include—

(i) A request for termination of the Primary Manufacturer's applicable program agreements; and

(ii) An attestation that through the end of the price applicability period for the selected drug, the Primary Manufacturer must not seek—

(A) To enter any subsequent applicable program agreement; or

(B) Coverage for any of its drugs under the Manufacturer Discount Program.

(2) If CMS determines that the Primary Manufacturer's Request to Terminate complies with paragraph (b)(1) of this section, CMS—

(i) Confirms receipt of the Primary Manufacturer's notice; and

(ii) Executes the actions with respect to termination of the Primary Manufacturer's applicable program agreements as described in paragraphs (b)(3) through (5) of this section, if applicable.

(3) If CMS determines that the Primary Manufacturer's Request to Terminate complies with paragraph (b)(1) of this section, the Request to Terminate will constitute good cause for CMS to terminate the Primary Manufacturer's applicable program agreement(s) under the Manufacturer Discount Program in accordance with section 1860D–14C(b)(4)(B)(i) of the Act and § 423.2752(c)(1) of this chapter, and to expedite the date on which none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program in accordance with § 423.2752(c)(1) of this chapter.

(4) If CMS determines that the Primary Manufacturer's Request to Terminate complies with paragraph (b)(1) of this section, the Request to Terminate will also constitute good cause for CMS to terminate the Primary Manufacturer's applicable program agreement(s) under the Medicaid Drug Rebate Program in accordance with section 1927(b)(4)(B)(i) of the Act and the Medicaid National Drug Rebate Agreement.

(5) Unless a Primary Manufacturer rescinds its Request to Terminate in accordance with paragraph (d) of this section, CMS terminates the Negotiation Program Agreement effective on the first date following the receipt of a Request to Terminate that CMS determines

complies with paragraph (b)(1) of this section on which none of the drugs of the Primary Manufacturer are covered by an agreement under the Manufacturer Discount Program in accordance with § 423.2752(c)(1) of this chapter.

(c) *A Decision by the Primary Manufacturer not to execute a Negotiation Program Agreement.* (1) A Primary Manufacturer that does not wish to enter into a Negotiation Program Agreement in accordance with § 429.200 may submit in writing a Request to Terminate, in a form and manner specified by CMS, that meets the requirements described in paragraph (b)(1) of this section.

(2) In response to the Request to Terminate, CMS takes the steps described in paragraphs (b)(2) through (4) of this section, as applicable.

(d) *Request by a Primary Manufacturer to Rescind the Request to Terminate.* If a Primary Manufacturer wishes to rescind the Request to Terminate it submitted under paragraph (b) or (c) of this section, it must file a written request for a hearing, in a form and manner specified by CMS.

(1) Upon such a request from the Primary Manufacturer, CMS provides a hearing concerning termination of the Primary Manufacturer's applicable program agreements, in accordance with sections 1860D–14C(b)(4)(B)(i) and 1927(b)(4)(B)(i) of the Act, as applicable.

(2) Such hearing will be held prior to the effective date of termination of the applicable program agreements with sufficient time for such effective date to be repealed.

(3) Such hearing will be held solely on the papers.

(4) The only question to be decided in the hearing is whether the Primary Manufacturer has asked to rescind its Request to Terminate prior to the effective date of termination of the applicable program agreements.

(e) *Effect of termination.* Notwithstanding termination of the Negotiation Program Agreement for a selected drug in accordance with either paragraph (a)(1) or (2) of this section, the Primary Manufacturer is responsible for making the MFP for the selected drug available, in accordance with subpart I of this part, with respect to dispenses, administrations, and furnishings of the selected drug prior to the effective date of termination under paragraph (a) of this section. Confidentiality, record retention and data requirements and requirements for Primary Manufacturer participation in audit and other Negotiation Program oversight activities continue to apply.

(f) *Reentry into the Negotiation Program.* A Primary Manufacturer that has terminated the Negotiation Program Agreement for a selected drug in accordance with paragraph (b) of this section and later seeks to re-enter any applicable program agreement or obtain coverage for any of its drugs under the Manufacturer Discount Program during the selected drug's price applicability period would be deemed to have provided an invalid attestation, described in paragraph (b)(1)(ii) of this section, and the Negotiation Program Agreement would once again become operative as of the date of re-entry into the applicable program agreement or coverage for any of its drugs under the Manufacturer Discount Program.

§ 429.210 Other provisions of the Negotiation Program Agreement.

(a) *General.* If any provision of the Negotiation Program Agreement is found to be invalid by a court of law with competent jurisdiction, the Negotiation Program Agreement will be construed in all respects as if any invalid or unenforceable provision(s) were eliminated, and without any effect on any other provision.

(b) *Update to the Negotiation Program Agreement.* CMS retains the authority to amend the Negotiation Program Agreement to reflect changes in law, regulation, or guidance as applicable.

(c) *Transfer of Negotiation Program Agreement.* If, after entering in a Negotiation Program Agreement with CMS, the Primary Manufacturer of a selected drug transfers ownership of one or more NDAs or BLAs, as applicable, of a selected drug to another entity, the Primary Manufacturer remains responsible for all requirements of the Negotiation Program Agreement associated with the transferred NDA(s) or BLA(s), including the requirement to provide access to the MFP in accordance with subpart I of this part, unless and until the Primary Manufacturer transfers all the NDAs or BLAs of the selected drug that it holds to an entity and such acquiring entity assumes responsibility as the new Primary Manufacturer in accordance with this paragraph (c).

(1) To transfer responsibility for all requirements of the Negotiation Program Agreement to an acquiring entity, the transferring Primary Manufacturer must—

(i) Transfer all NDA(s) or BLA(s) of the selected drug that it holds to the acquiring entity;

(ii) Provide CMS with documentation of the intended transfer of responsibility for all requirements of the Negotiation Program Agreement to the acquiring entity, in the form of a novation, at least 30 calendar days before the intended effective date of any such transfer for CMS review and approval. Such novation of the transferring Primary Manufacturer's Negotiation Program Agreement must be signed by the transferring Primary Manufacturer and the acquiring entity and must include, at minimum, the legal name of the acquiring entity, the effective dates of the transfer of ownership of all transferred NDAs or BLAs of the selected drug that the transferring Primary Manufacturer holds and of the transfer of responsibility for all requirements of the Negotiation Program Agreement, a list of all transferring NDAs or BLAs of the selected drug, and agreement that the acquiring entity assumes all obligations and liabilities under the transferring Primary Manufacturer's Negotiation Program Agreement as the successor in interest.

(2) If the transferring Primary Manufacturer submits a novation agreement that meets the requirements of paragraph (c)(1)(ii) of this section and is approved and signed by CMS, the acquiring entity becomes the successor in interest to the transferring Primary Manufacturer's Negotiation Program Agreement and the Primary Manufacturer of the applicable selected drug as of the novation's effective date of the transfer of responsibility for all requirements of the Negotiation Program Agreement.

(3) The transferring Primary Manufacturer remains responsible for any outstanding Negotiation Program rebate liabilities related to the Biosimilar Delay, under section 1192(f) of the Act, unless and until such liabilities are transferred to the acquiring entity as the new Primary Manufacturer, in accordance with this paragraph (c).

Subpart D—Program Administration

§ 429.300 Confidentiality policy and data use.

(a) *Confidentiality of proprietary information.* Information deemed proprietary under this section will only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program.

(b) *Confidentiality policy.* CMS deems proprietary information, including trade secrets and confidential commercial or financial information, as confidential information exempt from disclosure if the information meets the requirements set forth under Exemption 3 or Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(3),(4)).

(1) CMS would not disclose protected health information or personally identifiable information except in accordance with applicable laws, where received by CMS as set forth in §§ 429.505 and 429.615 or received by CMS in engagements with interested parties specified in §§ 429.515 and 429.620(e).

(2) [Reserved]

(c) *Primary Manufacturer data.* The following data when submitted by the Primary Manufacturer as set forth at §§ 429.405, 429.505(b), and 429.615(b)(1) would be deemed proprietary information by CMS, unless the information is publicly available:

(1) Non-FAMP and associated non-FAMP data collection;

(2) Research and development costs of the Primary Manufacturer for the selected drug;

(3) Current unit costs of production and distribution of the selected drug;

(4) Data on pending patent applications for the selected drug; and

(5) Market data and revenue and sales volume for the selected drug in the United States.

(6) A Common Technical File/Drug Master File/''drug dossier'' if submitted with the submission specified at § 429.505(d)(3) or § 429.615(b)(3) (if applicable).

(d) *Publication.* Any information deemed proprietary by CMS or covered by the confidentiality policy, in accordance with paragraphs (a) and (b) of this section, must be redacted from any publications related to the Negotiation Program, including the publication of the MFP, as described in § 429.705.

Subpart E—Establishment of a Single MFP and Determination of the Ceiling

§ 429.400 Establishment of a single MFP for negotiation and renegotiation purposes.

(a) *Establishment of a single MFP for negotiation and renegotiation purposes.* CMS identifies, for purposes of determining offers and counteroffers for use at each step of the negotiation process, as set forth in §§ 429.510 through 429.535, and for use at each step of the renegotiation process, as set forth in § 429.620, a single price for a selected drug, including for a selected drug with multiple dosage forms and strengths.

(1) CMS bases the single price on the cost of the selected drug per 30-day equivalent supply for all formulations weighted across dosage forms and strengths, as set forth in § 429.415.

(2) [Reserved]

(b) [Reserved]

§ 429.405 Collection of non-FAMP.

(a) In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, the Primary Manufacturer must submit the following information to CMS in a form and manner specified by CMS by 11:59 p.m. PST on March 1 of the year of the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation, inclusive of the NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer:

(1) Non-FAMP, unit type, and total unit volume for each NDC–11 of the selected drug (as determined in § 429.100(d)) for the four quarters of calendar year 2021 in which the selected drug was sold and non-FAMP data was reported (or, in the case that there is not an average non-FAMP available for such selected drug for calendar year 2021 (when non-FAMP data has not been reported for at least one NDC–11 of the selected drug for at least one quarter in calendar year 2021)), the Primary Manufacturer is required to report the non-FAMP, unit type, and total unit volume for the four quarters of the first full calendar year following the market entry for such drug); and

(2) Non-FAMP, unit type, and total unit volume for each NDC–11 of the selected drug (as determined in § 429.100(d)) for the four quarters of the calendar year prior to the selected drug publication date with respect to the initial price applicability year for which the selected drug was selected for negotiation.

(b) In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, if the information in paragraph (a) of this section is restated due to requirements of 38 U.S.C. 8126 and implementing regulations and guidance issued by the Department of Veterans Affairs, the Primary Manufacturer is required to update the information submitted in accordance with paragraph (a) of this section in a form and manner specified by CMS.

§ 429.410 Determination of the ceiling.

(a) *Limitations on offer amount.* In negotiating the MFP of selected drugs with respect to their initial price applicability year, beginning with initial price applicability year 2029, and in accordance with section 1194(b)(2)(F)(i) of the Act, CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the ceiling specified in section 1194(c) of the Act, as determined under this section, subject to § 429.440(b)(4), or is less than the Temporary Floor for Small Biotech Drugs specified in section 1194(d) of the Act, as determined under § 429.440(b)(3), if applicable.

(b) *Determination of the ceiling for the MFP.* With respect to each initial price applicability year beginning with initial price applicability year 2029, the MFP negotiated under the process set forth in §§ 429.510 through 429.535 for a selected drug with respect to the first initial price applicability year of the price applicability period with respect to such drug must not exceed the lower of the amount specified in paragraph (b)(1) or (2) of this section. The ceiling for renegotiation is set forth in § 429.620(b).

(1) The amount determined under this paragraph equals one of the following amounts, as applicable to the selected drug:

(i) For a selected drug that is covered under Part D but is not payable under Part B, the sum of the plan-specific enrollment weighted amounts, as set forth in § 429.420.

(ii) For a selected drug that is payable under Part B and paid according to section 1847A(b)(4) of the Act, but is not covered under Part D, the payment amount under section 1847A(b)(4) of the Act, as set forth in § 429.425.

(iii) For a selected drug that is payable under Part B and paid according to section 1847A(b)(4) of the Act, and covered under Part D, an amount equal to the combined Part B and Part D amount, as set forth in § 429.430.

(iv) For a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act, and is covered under Part D, the sum of the plan-specific enrollment weighted amounts, as set forth in § 429.420.

(v) For a selected drug that is payable under Part B but is not paid according to section 1847A(b)(4) of the Act, and is not covered under Part D, there is no amount under paragraph (b)(1) of this section.

(2) The amount determined under this paragraph is equal to the applicable percent, as applicable to the selected drug, of the lower of—

(i) The average non-FAMP for calendar year 2021, or, as applicable, the first full year after 2021 for which data is available, adjusted by inflation, as set forth in § 429.435(a)(1); or

(ii) The average non-FAMP for the year preceding the selected drug publication with respect to the first initial price applicability year of the price applicability period for which the drug is being negotiated, or, as applicable, the most recent year prior

for which data is available, as set forth in § 429.435(a)(2).

(3) CMS calculates a single amount, a 30-day equivalent supply as described in § 429.415, across all dosage forms and strengths of the selected drug for the amounts set forth in paragraphs (b)(1) and (2) of this section to determine which amount is lowest and will serve as the ceiling for the MFP.

(c) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (b) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.415 Calculation of the 30-day equivalent supply.

(a) *Determination of the 30-day equivalent supply for a selected drug.* CMS calculates the 30-day equivalent supply across all dosage forms and strengths of the selected drug using the following methodologies, as applicable:

(1) *30-day equivalent supply for a selected drug covered under Part D.* For a selected drug that is covered under Part D, CMS uses the methodology in accordance with § 423.104(d)(2)(iv)(A)(*2*) of this chapter.

(2) *30-day equivalent supply for a selected drug payable under Part B.* For selected drugs that are payable under Part B, CMS determines the 30-day equivalent supply using the following methodology:

(i) For Part B data for the selected drug's HCPCS code(s) that is/are for the year prior to the year of the selected drug publication date with respect to the initial price applicability year (for which the selected drug is selected for negotiation), CMS identifies any subsequent instances of Part B data or any PDE record that:

(A) Is associated with the same beneficiary; and

(B) Is for a drug or biological product with the same active moiety/active ingredient, identified as set forth at § 429.125(b), as the selected drug.

(ii) CMS calculates a ''days between services'' amount by counting the days between the date of service on the first instance of Part B data and the date of service on the immediately subsequent instance of Part B data or PDE record.

(A) Notwithstanding this paragraph (a)(2)(ii), if the beneficiary does not have a subsequent instance of Part B data or PDE record with the same active moiety/active ingredient, identified as set forth at § 429.125(b), as the selected drug, CMS assigns a ''days between services'' amount equal to the median ''days between services'' amount for all other instances of Part B data or PDE records for that selected drug associated with that beneficiary during the applicable claims period.

(B) Notwithstanding paragraph (a)(2)(ii)(A) of this section, if there are no other instances of Part B data or PDE records for that selected drug associated with that beneficiary during the year set forth in paragraph (a)(2)(i) of this section, CMS does not assign a ''days between services'' amount, and the claim will not be included in the calculations.

(iii) For each instance of Part B data or PDE record, the 30-day equivalent supply for the HCPCS code is equal to the ''days between services'' (as determined in paragraph (a)(2)(ii) of this section) divided by 30.

(iv) CMS allocates a portion of the HCPCS code's 30-day equivalent supply to each NDC within the HCPCS code for calculations that require a 30-day equivalent supply at the NDC level and will proceed in accordance with paragraph (v) of this section.

(v) To determine the total Part B 30-day equivalent supply at the NDC level, CMS takes the following steps:

(A) As set forth in § 429.100(f), use NDC–11s from the list of NDC–11s of the selected drug as set forth in § 429.100(c) to determine which NDC–11s of the selected drug are included in the calculations for the calendar year as set forth in § 429.425(a) that meet the following criteria:

(*1*) The NDC–11 is assigned to the Primary Manufacturer or manufactured, marketed, controlled, or sold by a Secondary Manufacturer(s);

(*2*) The NDC–11 does not represent a sample package;

(*3*) The NDC–11 is assigned to a HCPCS code;

(*4*) The NDC–11 does not represent a self-administered drug; and

(*5*) CMS observes any instances of Part B data for the HCPCS code to which the NDC–11 is assigned during the calendar year as set forth in paragraph (a)(2)(i) of this section.

(B) Determine the total billing units sold for each NDC–11 assigned to the HCPCS code (including NDC–11s that do not belong to the selected drug, if applicable) for each quarter of the calendar year set for in paragraph (a)(2)(i) of this section, by multiplying the number of units reported by a manufacturer in ASP data submissions at the NDC–11 package level by the number of billing units per NDC–11 reporting unit.

(C) For all NDC–11s assigned to the HCPCS code that is associated with the selected drug, sum the total billing units sold for such NDC–11s across all calendar quarters to calculate an annual total billing units sold for all NDC–11s assigned to the HCPCS code.

(D) For each NDC–11 assigned to the HCPCS code that is associated with the selected drug, divide the annual total billing units sold for that NDC–11 by the annual total billing units sold for all applicable NDC–11s of the same HCPCS code.

(E)(*1*) For each NDC–11 assigned to the HCPCS code that is associated with the selected drug, multiply the 30-day equivalent supply for the HCPCS code (as determined in paragraph (a)(2)(iii) of this section) by the quotient calculated in paragraph (a)(2)(v)(D) of this section, to yield the total 30-day equivalent supply for the NDC–11.

(*2*) Notwithstanding paragraph (a)(2)(ii)(B) of this section, CMS plans to assign a value of ''12'' for the 30-day equivalent supply for drugs typically administered one time (for example, some vaccines and cancer therapies).

(b) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (a) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.420 Determination of the sum of the plan-specific enrollment weighted amounts.

(a) *Data used to calculate the sum of the plan-specific enrollment weighted amount for selected drugs as set forth in § 429.410(b)(1)(i) and (iv).* CMS uses plan sponsors' reported Part D PDE data and direct and indirect remuneration data for all Part D plans found in such PDE data that meet the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (5) for the year as set forth in paragraph (b)(1) of this section.

(1) As set forth in § 429.100(f), CMS uses NDC–11s from the list of NDC–11s of the selected drug as set forth in § 429.100(c) to determine which NDC–11s of the selected drug are included in the ceiling calculations for the calendar year as set forth in paragraph (b)(1) of this section that meet the following criteria:

(i) The NDC–11 is assigned to the Primary Manufacturer or manufactured, marketed, controlled, or sold by a Secondary Manufacturer(s);

(ii) The NDC–11 does not represent a sample package;

(iii) CMS observes any PDE days' supply, PDE quantity dispensed, and PDE gross expenditures during the calendar year as set forth in paragraph (b)(1) of this section; and

(iv) CMS observes any associated direct and indirect remuneration amounts for the NDC–11 during the calendar year as set forth in paragraph (b)(1) of this section.

(v) The PDE record meets the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (5).

(2) [Reserved]

(b) *Determination of the sum of the plan-specific enrollment weighted amounts.* Using the 30-day equivalent supply methodology set forth at § 423.104(d)(2)(iv)(A)(*2*) of this chapter, CMS calculates the sum of the plan-specific enrollment weighted amount for selected drugs as set forth in § 429.410(b)(1)(i) and (iv) to determine the sum of the plan-specific enrollment weighted amounts for across all NDCs of the selected drug by conducting the following steps:

(1) For each Part D plan, CMS identifies the PDE data for the selected drug's NDC–11s, as identified using the criteria set forth in paragraph (a)(1) of this section, for the most recent year for which all data are available.

(2) For each Part D plan and each NDC–11, CMS separately sums the negotiated price amounts (as defined in § 423.100 of this chapter), the ERPOSA (as defined in § 429.20), and units dispensed.

(3) For each Part D plan and each NDC–11, CMS sums the total direct and indirect remuneration amounts found in the Detailed Direct and Indirect Remuneration Report for the year set forth in paragraph (b)(1) of this section and subtracts the total ERPOSA calculated in paragraph (b)(2) of this section.

(4) For each Part D plan and each NDC–11, CMS—

(i) Subtracts the total direct and indirect remuneration amounts minus ERPOSA amount calculated in paragraph (b)(3) of this section, from the total negotiated price amounts calculated in paragraph (b)(2) of this section; and

(ii) Divides by the total units dispensed as determined in paragraph (b)(2) of this section.

(5) Separately, CMS identifies the total number of individuals enrolled in all Part D plans in December for the year set forth in paragraph (b)(1) of this section and the total number of individuals enrolled in each Part D plan in that same month. The Part D plans included in the calculations of this step will be restricted to Part D plans with at least one PDE record for that NDC–11 identified in paragraph (b)(1) of this section.

(6) For each Part D plan and each NDC–11, CMS divides the total number of Part D beneficiaries enrolled in the Part D plan as identified in paragraph (b)(5) of this section by the total number of individuals enrolled in all Part D plans also as identified in paragraph (b)(5) of this section, and multiplies this quotient by the price per unit, net of all price concessions received by such plan or pharmacy benefit manager on behalf of such Part D plan (as calculated in paragraph (b)(4) of this section) to arrive at the plan-specific enrollment weighted amount.

(7) For each NDC–11, CMS sums the amounts calculated in paragraph (b)(6) of this section across all Part D plans to calculate the sum of the plan-specific enrollment weighted amounts.

(8)(i) For each NDC–11, CMS multiplies the sum of the plan-specific enrollment weighted amounts (as calculated in paragraph (b)(7) of this section), which are a per-unit price, by the NDC–11 average number of units per 30-day equivalent supply calculated from PDE data for the year set forth in paragraph (b)(1) of this section (that is, quotient of the total quantity dispensed and the total 30-day equivalent supply as described in this paragraph (b)(8)(i)) to yield the price of a 30-day equivalent supply. This calculation results in the sum of the plan-specific enrollment weighted amounts for each NDC–11 identified based on the criteria as set forth in (a)(1) of this section.

(ii) For each NDC–11, CMS calculates the quotient of total quantity dispensed and total 30-day equivalent supply to calculate the NDC–11 average number of units per 30-day equivalent supply.

(9) For each NDC–11, CMS divides the total 30-day equivalent supply for that NDC–11 by the total 30-day equivalent supply across all NDC–11s of the selected drug, both calculated from PDE data from the year set forth in paragraph (b)(1) of this section and multiplies this quotient by the sum of the plan-specific enrollment weighted amounts for a 30-day equivalent supply as calculated in paragraph (b)(8) of this section.

(10) CMS sums amounts calculated in paragraph (b)(9) of this section, across all NDC–11s of the selected drug to generate the sum of the plan-specific enrollment weighted amounts for the selected drug for a 30-day equivalent supply.

(c) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (b) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.425 Determination of the payment amount under section 1847A(b)(4) of the Act.

(a) *Determination of the payment amount under section 1847A(b)(4) of the Act.* CMS calculates the payment amount under section 1847A(b)(4) of the Act, for the year which is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation, for a 30-day equivalent supply across all dosage forms and strengths of a selected drug.

(1) *General.* As set forth in § 429.100(f), CMS uses NDC–11s from the list of NDC–11s of the selected drug as set forth in § 429.100(c) to determine which NDC–11s of the selected drug are included in the ceiling calculations for the calendar year as set forth in this paragraph (a) that meet the following criteria:

(i) The NDC–11 is assigned to the Primary Manufacturer or manufactured, marketed, controlled, or sold by a Secondary Manufacturer(s);

(ii) The NDC–11 does not represent a sample package;

(iii) The NDC–11 is assigned to a HCPCS code;

(iv) The NDC–11 does not represent a self-administered drug; and

(v) CMS observes any instances of Part B data for the HCPCS code to which the NDC–11 is assigned during the calendar year as set forth in this paragraph (a).

(vi) The Part B data meets the inclusion and exclusion criteria as set forth in § 429.120(b)(1)(ii) through (vi) and (b)(2)(ii) through (ix).

(2) *Calculating the payment amount under section 1847A(b)(4) of the Act.* CMS calculates the payment amount under section 1847A(b)(4) of the Act for each HCPCS code to which any NDC–11 identified in paragraph (a)(1) are assigned and then assigns such payment amount to each NDC–11 of the selected drug within such HCPCS code.

(i) CMS calculates separately, the annual ASP and WAC amounts for the HCPCS code, by converting quarterly ASP and WAC data for the year set forth in this paragraph (a), for each NDC–11 of a selected drug as set forth in § 429.100(c) that is associated with a HCPCS code, to an annual calendar year ASP and WAC amount for each HCPCS code by taking an average of the reported ASP and WAC amounts for the NDC–11s associated with the HCPCS code across all four quarters of such calendar year, weighted by the total number of billing units in the Part B data for that HCPCS code each quarter.

(A) If the total number of billing units in the Part B data for the HCPCS code are zero for a given quarter, CMS assigns

that quarter the lowest positive total units from among the other quarters in the same calendar year for that HCPCS code.

(B) For each of the separate ASP and WAC calculations, if the reported price is negative, zero, or missing for all applicable NDC–11s assigned to the HCPCS code in a given quarter for the calendar year as set forth in this paragraph (a), CMS excludes that quarter from the applicable calculation.

(C) If the WAC reported to the ASP portal is negative, zero, missing for all applicable NDC–11s assigned to the HCPCS code for all four quarters of the calendar year as set forth in § 429.425(a) but the reported ASP is positive for at least one of the NDC–11s assigned to the HCPCS code, CMS uses the WAC reported by the Primary Manufacturer of the selected drug to CMS under section 1194(e)(1) of the Act as described in § 429.505(a).

(ii) CMS determines the lesser of the annual ASP and the annual WAC as determined under paragraph (a)(2)(i) of this section to yield the payment amount under section 1847A(b)(4) of the Act for the associated HCPCS code. This amount will apply to all applicable NDC–11s assigned to the associated HCPCS code.

(iii) Notwithstanding paragraphs (a)(2)(i) and (ii) of this section, if ASP, WAC reported to the ASP payer portal, and WAC reported by the Primary Manufacturer pursuant to section 1194(e)(1) of the Act as described in § 429.505(b)(2) are negative, zero, or missing for all applicable NDC–11s assigned to the HCPCS code for all four quarters of the calendar year as set forth in this paragraph (a), CMS takes the average of the published payment limits in the ASP pricing file (or in the OPPS Addendum B file, if it is not available in the ASP pricing file) for the HCPCS code across all four quarters, weighted by the total number of billing units in the Part B data for that HCPCS code for the four quarters as described in paragraph (a)(2)(i) of this section (including the adjustments made when billing units are zero) to calculate the payment amount under section 1847A(b)(4) of the Act.

(3) *Allocating HCPCS code-level utilization from Part B data for Part B services.* CMS allocates HCPCS code-level utilization from Part B data across each NDC–11 of the selected drug, identified in paragraph (a)(1) of this section, assigned to such HCPCS code.

(i) CMS allocates HCPCS code-level utilization from Part B data using the proportion of ASP units reported by manufacturers to CMS for each NDC–11 that is assigned to the HCPCS code and converts the total billing units in Part B data for the HCPCS code that includes the selected drug to determine the units that are comparable to NCPDP units that are used in PDE records for the NDC–11 of the selected drug using the following steps:

(A) For each NDC–11 assigned to a HCPCS code to which an NDC–11 of the selected drug is assigned for each quarter (including NDC–11s that do not belong to the selected drug, if applicable), calculates the total number of billing units sold for each NDC–11 by multiplying the number of units reported by a manufacturer at the NDC–11 package level by the number of billing units per NDC–11 reporting unit.

(B) Divides the billing units sold for an NDC–11, as calculated in paragraph (a)(3)(i)(A) of this section, by the total billing units sold for all NDC–11s within the same HCPCS code.

(C) Multiplies the total billing units from Part B data for the HCPCS code by the quotient calculated in paragraph (a)(3)(ii)(B) of this section, to determine the total Part B billing units for each NDC–11 of the selected drug.

(D) Multiplies the total Part B billing units from Part B data for that NDC–11, as calculated in paragraph (a)(3)(i)(C) of this section, by the billing unit to NCPDP conversion ratio (calculated by dividing the product of the standard package size and package quantity for an NDC–11 by the number of billing units per NDC–11 reporting unit for the NDC–11) to determine the PDE equivalent of the total Part units for that NDC–11.

(E) Notwithstanding paragraphs (a)(3)(i)(A) through (D) of this section, if there are no units as measured on PDE records, the Part B unit type is not converted to a PDE unit type.

(ii) [Reserved]

(4) *Calculating the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of the selected drug.* CMS calculates the payment amount under section 1847A(b)(4) of the Act for a 30-day equivalent supply of each NDC–11 identified based on the criteria as set forth in paragraph (a)(1) of this section.

(i) For each selected drug, CMS identifies the NDC–11s and the unique HCPCS code(s) associated with the selected drug using the criteria set forth in paragraph (a)(1) of this section.

(A) CMS identifies the annual calendar year payment amount under section 1847A(b)(4) of the Act for each HCPCS code, set forth in paragraph (a)(2) of this section, and assigns it to each NDC–11 within that HCPCS code.

(B) [Reserved]

(ii) CMS sums the converted Part B units from Part B data attributed to each NDC–11 (as calculated in paragraph (a)(3) of this section), across all four quarters of the calendar year as set forth in paragraph (a) of this section to calculate the annual Part B units of that NDC–11.

(iii) CMS calculates the total Part B 30-day equivalent supply in Part B data attributed to that NDC–11 of calendar year as set forth in § 429.415(a)(2).

(iv) CMS calculates the quotient of the annual Part B units in Part B data for each NDC–11 of the selected drug (as calculated in paragraph (a)(4)(ii) of this section), and the total Part B 30-day equivalent supply in Part B data (as calculated in paragraph (a)(4)(iii) of this section) which is the average number of units per 30-day equivalent supply.

(v) CMS multiplies the payment amount under section 1847A(b)(4) of the Act (as determined in paragraph (a)(4)(i) of this section), by the average number of units per 30-day equivalent supply (as calculated in paragraph (a)(4)(iv) of this section), to yield the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for each NDC–11 of the selected drug.

(vi) CMS divides the total 30-day equivalent supply for each NDC–11 (as calculated in paragraph (a)(4)(iii) of this section) by the total 30-day equivalent supply across all NDC–11s of the selected drug and multiplies this quotient by the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC–11 (as calculated in paragraph (a)(4)(v) of this section).

(vii) CMS sums the amounts calculated in paragraph (a)(4)(vi) of this section, across all NDC–11s of the selected drug to generate the payment amount under section 1847A(b)(4) of the Act for the selected drug for a 30-day equivalent supply.

(b) *Sequestration.* CMS does not apply the sequestration payment adjustment (as defined in § 429.20) to the payment amount under section 1847A(b)(4) of the Act as part of this methodology to calculate the payment amount under section 1847A(b)(4) of the Act.

(c) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraphs (a)(2) through (4) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.430 Determination of the combined Part B and Part D amount.

(a) *Determination of the combined Part B and Part D amount.* CMS calculates a single amount referred to as the combined Part B and Part D amount for a selected drug as set forth in § 429.410(b)(1)(iii) using the following methodology.

(1) CMS calculates the sum of the plan-specific enrollment weighted amounts, as set forth in § 429.420, and the payment amount under section 1847A(b)(4) of the Act, as set forth in § 429.425, for all dosage forms and strengths of a selected drug that is payable under Part B and covered under Part D as a 30-day equivalent supply by:

(i) Separately calculating the sum of the plan-specific enrollment weighted amounts, as set forth in § 429.420, and the payment amount under section 1847A(b)(4) of the Act, as set forth in paragraph § 429.425, using the following steps:

(A) If an NDC–11 is only present in PDE data, CMS calculates only the sum of the plan-specific enrollment weighted amounts per 30-day equivalent supply for that NDC–11 as set forth in § 429.420.

(B) If an NDC–11 is only associated with a Part B HCPCS code that is present in Part B data, CMS calculates only the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC–11 as set forth in § 429.425.

(C)(*1*) If an NDC–11 is both present in PDE data and is associated with a Part B HCPCS code that is present in Part B data, CMS calculates both the sum of the plan-specific enrollment weighted amount per 30-day equivalent supply and the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply for that NDC–11.

(*2*) If an NDC–11 is present in both PDE data and associated with a HCPCS code present in Part B data, CMS treats each version as a distinct NDC–11 in this step of the calculation.

(ii) For each NDC–11 identified in paragraph (a)(1)(i)(A) of this section present in PDE data, CMS calculates the sum of the plan-specific enrollment weighted amounts per 30-day equivalent supply, as set forth in § 429.420(b)(1) through (8), and the total 30-day equivalent supply.

(iii) For each NDC–11 identified in paragraph (a)(1)(i)(B) of this section associated with a HCPCS present in Part B data, CMS calculates the payment amount under section 1847A(b)(4) of the Act per 30-day equivalent supply, as set forth in § 429.425(a)(4)(i) through (v), and the total 30-day equivalent supply.

(2) CMS calculates a combined sum of the weighted averages of the sum of the plan-specific enrollment weighted amounts and the payment amounts under section 1847A(b)(4) of the Act per 30-day equivalent supply for these NDC–11s, using the respective utilization for the NDC–11 in Part B and Part D as described in the following steps:

(i)(A) For each NDC–11 identified in paragraphs (a)(1)(ii) and (iii) of this section, CMS divides the total 30-day equivalent supply for that NDC–11 by the total 30-day equivalent supply across all NDC–11s (both those present in PDE data and those associated with HCPCS present in Part B data) of the selected drug, and multiplies this quotient by either the sum of the plan-specific enrollment weighted amounts or the payment amount under section 1847A(b)(4) of the Act, respectively, per 30-day equivalent supply of that NDC–11.

(B) If an NDC–11 is present in both PDE data and associated with a HCPCS code present in Part B data, CMS treats each version as a distinct NDC–11 in this step of the calculation.

(ii) CMS sums the amounts calculated in paragraph (a)(2)(i) of this section, across all NDC–11s of the selected drug (including both the Part B version and the Part D version of NDC–11s that are present in both PDE records and associated with HCPCS codes present in Part B data), to generate the combined sum of the plan-specific enrollment weighted amounts and payment amount under section 1847A(b)(4) of the Act for the selected drug for a 30-day equivalent supply.

(3) Paragraphs (a)(2)(i) and (ii) of this section, result in the combined sum of the plan-specific enrollment weighted amounts and payment amounts under section 1847A(b)(4) of the Act across all NDC–11s of the selected drug.

(b) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (a) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.435 Determination of the applicable average non-FAMP amounts and applicable percent of the average non-FAMP.

(a) *Determination of the average non-FAMP.* CMS calculates and determines the lower of the two applicable average non-FAMP amounts, as set forth in paragraphs (a)(1) and (2) of this section, and determines the applicable percent of the average non-FAMP to apply, as set forth in paragraph (a)(4) of this section, for all selected drugs, subject to § 429.440(b)(4), if applicable.

(1) *Average non-FAMP in calendar year 2021.* As described in section 1194(c)(1)(C)(ii)(I) of the Act, CMS calculates an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP in calendar year 2021 (or for the first full year following market entry for such drug if there is not a non-FAMP for such drug or an average non-FAMP cannot be calculated), increased by the percentage increase in the CPI–U from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation.

(i) As set forth in § 429.100(f), CMS uses NDC–11s from the list of NDC–11s of the selected drug as set forth in § 429.100(c) to determine which NDC–11s of the selected drug are included in the ceiling calculations for the calendar year as set forth in this paragraph (a)(1) that meet all of the following criteria:

(A) The NDC–11 is assigned to the Primary Manufacturer or manufactured, marketed, controlled, or sold by Secondary Manufacturer(s).

(B) The NDC–11 does not represent a sample package.

(C) CMS received non-FAMP data for the NDC–11 for at least one calendar quarter in calendar year as set forth in paragraph (a)(1) of this section.

(D) CMS observes any PDE days' supply and PDE quantity dispensed or any Part B data associated with the HCPCS code to which the NDC–11 is assigned in calendar year as set forth in this paragraph (a)(1).

(E) The PDE record meets the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (5) or the Part B data meets the inclusion and exclusion criteria as set forth in § 429.120(b)(1)(ii) through (vi) and (b)(2)(ii) through (ix).

(ii) CMS uses the non-FAMP price and unit volume data for each NDC–11 that meets the criteria as set forth in paragraph (a)(1)(i) of this section, to be included in this average non-FAMP calculation.

(iii) CMS uses the data that is submitted by the Primary Manufacturer in accordance with section 1193(a)(4)(A) of the Act, as set forth in § 429.405, for each quarter of calendar year 2021 to calculate an annual average non-FAMP per unit for calendar year set forth in this paragraph (a)(1).

(iv) CMS uses 2021 PDE quantity dispensed and days' supply data (or data for the first full year following

market entry for such drug if such data is not available for 2021) submitted to CMS at the NDC–11 level by Part D plan sponsors, and total Part B billing units from Part B data and 30-day equivalent supply data at the HCPCS code-level, as applicable, to calculate:

(A) An annual average non-FAMP per unit for each NDC–11 of the selected drug.

(B) The annual average non-FAMP per 30-day equivalent supply for each NDC–11 of the selected drug.

(C) The annual average non-FAMP per 30-day equivalent supply for the selected drug.

(2) *Average non-FAMP for the calendar year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation.* As described in section 1194(c)(1)(C)(ii)(II) of the Act, CMS calculates an amount equal to the applicable percent, with respect to the selected drug, of the average non-FAMP for the year prior to the selected drug publication date with respect to such initial price applicability year (that is, for the calendar year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation).

(i) As set forth in § 429.100(f), CMS uses NDC–11s from the list of NDC–11s of the selected drug as set forth in § 429.100(c) to determine which NDC–11s of the selected drug are included in the ceiling calculations for the calendar year as set forth in this paragraph (a)(2) that meet the following criteria:

(A) The NDC–11 is assigned to the Primary Manufacturer or manufactured, marketed, controlled, or sold by a Secondary Manufacturer(s);

(B) The NDC–11 does not represent a sample package;

(C) CMS received non-FAMP data for the NDC–11 for at least one calendar quarter during the calendar year and as set forth in this paragraph (a)(2); and

(D) CMS observes any PDE days' supply and PDE quantity dispensed or any Part B data associated with the HCPCS code to which the NDC–11 is assigned in the calendar year as set forth in this paragraph (a)(2).

(E) The PDE record meets the inclusion and exclusion criteria as set forth in § 429.120(a)(2) through (5) or the Part B data meets the inclusion and exclusion criteria as set forth in § 429.120(b)(1)(ii) through (vi) and (b)(2)(ii) through (ix).

(ii) CMS uses the non-FAMP price and unit volume data for each NDC–11 that meets the criteria as set forth in paragraph (a)(2)(i) of this section, to be included for the calendar year set forth in this paragraph (a)(2) using the same methodology described in paragraphs (a)(1)(ii) through (iv) of this section to calculate the average non-FAMP.

(3) *Applicable percent of the average non-FAMP.* For each calendar year set forth in paragraphs (a)(1) and (2) of this section, CMS calculates the applicable percent of the average non-FAMP as follows:

(i) For each NDC–11 of the selected drug as a 30-day equivalent supply (in accordance with the methodology described in § 429.415).

(ii) Across the NDC–11s of the selected drug as a 30-day equivalent supply.

(4) *Average non-FAMP across NDC–11s of the selected drug.* To determine the average non-FAMP for each NDC–11 and across all NDC–11s of the selected drug, CMS conducts the following steps separately for the calendar years set forth in paragraphs (a)(1) and (2) of this section:

(i) For each NDC–11 and for each quarter during the calendar year, CMS calculates the non-FAMP per unit by dividing the non-FAMP per package by the total number of NCPDP units per package.

(A) For the calendar year set forth in paragraph (a)(1) of this section only, if the non-FAMP is missing for all NDC–11s of the selected drug for such calendar year, as set forth in § 429.405, then CMS uses the non-FAMP for the quarters of the first full calendar year following the market entry for such drug.

(B) [Reserved]

(ii) For each NDC–11 and for each quarter during the calendar year, CMS divides the total unit volume (calculated as the product of the total number of packages sold from manufacturer-reported non-FAMP data and the number of units per package) in that quarter by the total unit volume across all four quarters during the calendar year (also calculated from manufacturer-reported non-FAMP data), and multiply this quotient by the non-FAMP per unit calculated in paragraph (a)(4)(i) of this section.

(A) For the calendar year set forth in paragraph (a)(1) of this section only, if the non-FAMP is missing for all NDC–11s of the selected drug for such calendar year, as set forth in § 429.405, then CMS uses the non-FAMP and total unit volumes for the quarters of the first full calendar year following the market entry for such drug.

(B) [Reserved]

(iii) For each NDC–11, CMS sums the amounts calculated in paragraph (a)(4)(ii) of this section across quarters to calculate the average non-FAMP per unit for that NDC–11 for the calendar year.

(iv) For the calendar year as set forth in paragraph (a)(1) of this section only: for each NDC–11, CMS then increases the average non-FAMP per unit calculated in paragraph (a)(4)(iii) of this section by the percentage increase in CPI–U (all items; United States city average) as set forth in paragraph (a)(1) of this section.

(A) Notwithstanding this paragraph (a)(4)(iv), CMS does not apply a CPI–U adjustment to the average non-FAMP per unit for the calendar year described in paragraph (a)(2) of this section.

(B) [Reserved]

(v) For each NDC–11, after CMS calculates the average non-FAMP per unit for the calendar year (as calculated in paragraph (a)(4)(iii) of this section for the calendar year as set forth in paragraph (a)(2) of this section and as calculated in paragraph (a)(4)(iv) of this section for the calendar year as set forth in paragraph (a)(1) of this section), CMS applies the applicable percent specified in section 1194(c)(3) of the Act for the monopoly type which are set forth in paragraphs (a)(1) through (3) of this section and are determined for the selected drug based on its initial approval date as set forth in § 429.125(a)(1)(i) and the initial price applicability year for which the drug is selected for negotiation.

(A) The monopoly types and applicable percent are:

(*1*) A short-monopoly drug or vaccine, as described in section 1194(c)(3)(A) of the Act, is a selected drug other than an extended-monopoly drug and a long-monopoly drug, for which the applicable percent is 75 percent.

(*2*) An extended-monopoly drug, as described in section 1194(c)(3)(B) of the Act and defined in § 429.20, for which the applicable percent is 65 percent.

(*3*) A long-monopoly drug, as described in section 1194(c)(3)(C) of the Act and defined in § 429.20, for which the applicable percent is 40 percent.

(B) [Reserved]

(vi) For each NDC–11, CMS then multiplies the average non-FAMP per unit for the calendar year, adjusted for inflation, if applicable per paragraph (a)(4)(iv) of this section, and with the applicable percent applied as determined in paragraph (a)(4)(v) of this section by the quotient of total units divided by the total 30-day equivalent supply.

(vii) For each NDC–11, CMS then divides the total 30-day equivalent supply for that NDC–11 by the total 30-day equivalent supply across all NDC–11s of the selected drug and multiplies

this quotient by the amount calculated in paragraph (a)(4)(vi) of this section.

(viii) CMS sums the amounts calculated in paragraph (a)(4)(vii) of this section, across all NDC–11s of the selected drug to calculate the average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, if applicable per paragraph (a)(4)(iv) of this section, and with the applicable percent applied as specified in paragraph (a)(4)(v) of this section, for the selected drug.

(ix) CMS compares the amount calculated in paragraph (a)(4)(viii) of this section for the applicable percent of the calendar year described in paragraph (a)(1) of this section average non-FAMP per 30-day equivalent supply for the calendar year, adjusted for inflation, with the amount calculated in paragraph (a)(4)(viii) of this section for the applicable percent of the calendar year described in paragraph (a)(2) of this section average non-FAMP per 30-day equivalent supply for the calendar year and determines which is lower.

(b) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (a) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.440 Temporary floor for Small Biotech Drugs.

(a) *Definitions.* For the purposes of this section, the following definitions apply:

(1) *Part B 2021 Manufacturer* means the NDA holder or the BLA holder for the qualifying single source drug on December 31, 2021.

(2) *Part D 2021 Manufacturer* means the entity that either had—

(i) A Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D–14A of the Act in effect for the qualifying single source drug on December 31, 2021; or

(ii) An arrangement whereby the manufacturer's labeler codes were listed on another manufacturer's Medicare CGDP Agreement, consistent with section 1860D–14A of the Act, in effect on December 31, 2021.

(3) *Part B 2021 Manufacturer and its controlled group* comprises all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part B 2021 Manufacturer.

(4) *Part D 2021 Manufacturer and its controlled group* comprises all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part D 2021 Manufacturer and had a CGDP Agreement in effect on December 31, 2021.

(b) *General rule.* For a drug selected for negotiation for initial price applicability year 2029 or 2030, or a drug selected for renegotiation for initial price applicability year 2029 or 2030, for which the Primary Manufacturer submits information in accordance with paragraph (b)(1) of this section and CMS determines that such drug meets the requirements set forth in paragraph (b)(2) of this section, CMS will not make an offer (or agree to a counteroffer) for an MFP (as described in § 429.500(b)) that is lower than the Temporary Floor for Small Biotech Drugs, which must be equal to the amount specified in paragraph (b)(3) of this section.

(1) *Temporary Floor for Small Biotech Drugs submission.* For a selected drug to be considered for eligibility for the Temporary Floor for Small Biotech Drugs, such drug's Primary Manufacturer must submit information to CMS regarding the eligibility criteria described in paragraph (b)(2) of this section as relevant to such drug, in the form and manner specified by CMS.

(2) *Eligibility for the Temporary Floor for Small Biotech Drugs.* To be eligible for the Temporary Floor for Small Biotech Drugs, CMS must determine either that the selected drug is covered under Part D and meets the requirements of the Part D Track set forth in paragraph (b)(2)(i) of this section or that the selected drug is payable under Part B and meets the requirements of the Part B Track set forth in paragraph (b)(2)(ii) of this section.

(i) *Part D Track.* To meet the requirements of the Part D Track, the total expenditures under Part D during 2021 for the selected drug (calculated using the methodology set forth in § 429.120(a), except the date of service as described in § 429.120(a)(1) is during 2021) must be—

(A) Equal to or less than 1 percent of the total expenditures under Part D for all covered Part D drugs during 2021; and

(B) Equal to or greater than 80 percent of the total expenditures under Part D for all covered Part D drugs during 2021 for which the Part D 2021 Manufacturer and its controlled group had an agreement in effect under section 1860D–14A on December 31, 2021.

(ii) *Part B Track.* To meet the requirements of the Part B Track, the total expenditures under Part B during 2021 for the selected drug calculated using the methodology set forth in § 429.120(b), except the date of service as described in § 429.120(b)(1)(i) and (b)(2)(i) is during 2021, must be—

(A) Equal to or less than 1 percent of the total expenditures under Part B for all qualifying single source drugs payable under Part B during 2021; and (B) Equal to or greater than 80 percent of the total expenditures under Part B during 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group that are payable under Part B during 2021.

(iii) *Limitation.* A selected drug will not be eligible for the Temporary Floor for Small Biotech Drugs if the Primary Manufacturer of such drug was acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii) of the Act, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

(3) *Determination of the Temporary Floor for Small Biotech Drugs.* CMS calculates the Temporary Floor for Small Biotech Drugs with respect to each selected drug that CMS determines to be eligible, under paragraph (b)(2) of this section, as 66 percent of the following amount, as applicable:

(i) Subject to paragraph (b)(3)(ii) of this section, the average non-FAMP in calendar year 2021, increased by the percentage increase in the CPI–U from September 2021 to September of the year prior to the selected drug publication date for which the drug is selected for negotiation or, as applicable, renegotiation, calculated using the methodology set forth in § 429.435.

(ii) In the case that there is not an average non-FAMP available for such drug for 2021, the average non-FAMP for the first full year following market entry, increased by the percentage increase in the CPI–U from December of such first full year following market entry to September of the year prior to the selected drug publication date for which the drug is selected for negotiation or, as applicable, renegotiation, calculated using the methodology set forth in § 429.435.

(4) *Determination of the adjusted ceiling for the MFP exception.* In the event that the ceiling identified in § 429.410(b) (or § 429.620(b) as applicable) for a Small Biotech Drug is below the Temporary Floor for Small Biotech Drugs for such Small Biotech Drug, as described in paragraph (b)(3) of this section, then, notwithstanding

§ 429.410 (or § 429.620 as applicable), CMS will not make an offer (or agree to a counteroffer) for an MFP that exceeds the adjusted ceiling determined under paragraph (b)(4)(i), (ii), or (iii) of this section, as applicable, and calculates such adjusted ceiling amount as follows:

(i) CMS excludes the average non-FAMP in 2021 identified under section 1194(c)(1)(C)(ii)(I) of the Act from the ceiling determination made under § 429.410(b) or § 429.620(b), as applicable, with respect to such selected drug. If the resulting ceiling amount is equal to or above the Temporary Floor for Small Biotech Drugs established in paragraph (b)(3) of this section, then, notwithstanding § 429.410(b) or § 429.620(b), such resulting ceiling amount applies as the ceiling.

(ii) If the resulting ceiling amount determined under paragraph (b)(4)(i) of this section is lower than the Temporary Floor for Small Biotech Drugs established in paragraph (b)(3) of this section, then, notwithstanding § 429.410(b) or § 429.620(b), CMS excludes the average non-FAMP for the year preceding the selected drug publication with respect to the first initial price applicability year of the price applicability period for which the drug is being negotiated, or, as applicable, the most recent year prior for which data is available, as set forth in §§ 429.410(b)(2)(ii) and 429.435(a)(2), identified under section 1194(c)(1)(C)(ii)(II) of the Act, from the ceiling determination made under § 429.410(b) or § 429.620(b), as applicable, with respect to such selected drug. If the resulting ceiling amount is equal to or above the Temporary Floor for Small Biotech Drugs established in paragraph (b)(3) of this section, then, notwithstanding § 429.410(b) or § 429.620(b), such resulting ceiling amount applies as the ceiling.

(iii) If the resulting ceiling amount determined under paragraph (b)(4)(ii) of this section is below the Temporary Floor for Small Biotech Drugs established in paragraph (b)(3) of this section, then, notwithstanding § 429.410(b) or § 429.620(b), the adjusted ceiling equals the Temporary Floor for Small Biotech Drugs established in paragraph (b)(3) of this section.

(5) *Notice of determination.* After review of an application made in accordance with paragraph (b)(1) of this section, CMS provides a notice in writing to the Primary Manufacturer, alongside the calculation information provided as set forth in § 429.445(a), of—

(i) A determination of whether the selected drug is a Small Biotech Drug; and

(ii) If the selected drug is eligible for the Temporary Floor for Small Biotech Drugs, the calculation of the Temporary Floor for Small Biotech Drugs set forth in § 429.440(b)(3) and the calculation of the ceiling (or adjusted ceiling, if applicable), set forth in § 429.440(b)(4).

(6) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (b)(3) or (4) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.445 Calculation information and suggestion of error.

(a) *Calculation Information.* CMS provides a Primary Manufacturer with the following, as applicable:

(1) Information on CMS' calculation of the ceiling, as described in §§ 429.410 through 429.435;

(2) The computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug, as described in § 429.700(b) and (c); and

(3) Information on CMS' calculation of the Temporary Floor for Small Biotech Drugs (and adjusted ceiling, as applicable), as described in § 429.440(b)(3) and (4).

(b) *Timing.* (1) CMS intends to provide the information specified in paragraphs (a)(1), (2), and (3) (as applicable) of this section:

(i) Following the Primary Manufacturer's submission of data set forth in §§ 429.100(d), 429.405(a), 429.440(b)(1), and 429.505(b)(2); and

(ii) Following the Primary Manufacturer's submission of data set forth in § 429.615(b)(1).

(2) CMS intends to provide the information specified in paragraph (a)(2) of this section:

(i) Following the Primary Manufacturer's submission of data set forth in § 429.100(e); and

(ii) Following the determination by CMS that an NDC with insufficient data, as described in § 429.700(c)(3), has sufficient data as described in § 429.700(c)(4)(i)(B)(*2*).

(c) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraph (a)(1), (2), or (3) of this section may submit a Suggestion of Error pertaining to such calculations for CMS' consideration.

(1) A Primary Manufacturer must submit a Suggestion of Error within 10 days of receiving information under paragraph (a) of this section from CMS.

(2) The Suggestion of Error process does not affect a Primary Manufacturer's obligation to comply with Negotiation Program requirements and does not alter or change any timelines or requirements of the Negotiation Program.

(d) *Method and process.* A Primary Manufacturer must submit any Suggestion of Error, as described in paragraph (c) of this section, in a form and manner specified by CMS.

Subpart F—Negotiation Process

§ 429.500 General rule.

(a) CMS has a consistent methodology and process for negotiating MFPs as set forth in this subpart. For purposes of negotiating or renegotiating the MFP of a selected drug in accordance with such methodology and process, CMS:

(1) Aims to achieve agreement on the lowest MFP for each selected drug consistent with section 1194(b)(1) of the Act; and

(2) Considers the factors set forth in section 1194(e) of the Act and § 429.505, as applicable to the selected drug, in determining offers and counteroffers.

(b) To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in § 429.200(e) that sets forth the agreed-upon MFP.

§ 429.505 Negotiation factors.

(a) *General.* For purposes of negotiating the maximum fair price of a selected drug with the Primary Manufacturer, CMS considers the Primary Manufacturer-required data specified in paragraph (b)(2) of this section and evidence about the selected drug and therapeutic alternatives specified in paragraph (d)(3) of this section, as applicable to the drug, as the basis for determining the offers and counteroffers for the selected drug.

(b) *Primary Manufacturer-required data.* (1) In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, the Primary Manufacturer must submit the information in paragraph (b)(2) of this section to CMS in a form and manner specified by CMS by 11:59 p.m. PST on March 1 of the year of the selected drug publication date for the selected drug, inclusive of the NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer.

(2) Primary Manufacturer required data includes—

(i) Research and development costs of the Primary Manufacturer for the

selected drug and the extent to which the Primary Manufacturer has recouped research and development costs;

(ii) Current unit costs of production and distribution of the selected drug;

(iii) Prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug;

(iv) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration (FDA), and applications and approvals under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) or section 351(a) of the PHS Act (42 U.S.C. 262(a)) for the selected drug; and

(v) Market data and revenue and sales volume data for the selected drug in the United States.

(c) *Primary Manufacturer requirement to timely report updates.* In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, a Primary Manufacturer is required to provide updates to the information described in paragraph (b)(2) of this section for the drug selected for negotiation in a form and manner prescribed by CMS if the Primary Manufacturer becomes aware that any of such information has changed or is otherwise inaccurate.

(d) *Evidence about the selected drug and therapeutic alternatives.* (1) Any interested party, including the Primary Manufacturer of a selected drug, may choose to submit the information set forth in paragraph (d)(3) of this section to CMS in a form and manner specified by CMS.

(2) Interested parties must submit the information in paragraph (d)(3) of this section by 11:59 p.m. PST on March 1 of the year of the selected drug publication date for a selected drug in a form and manner specified by CMS.

(3) Evidence about the selected drug and therapeutic alternatives includes—

(i) The extent to which a selected drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives;

(ii) Prescribing information approved by the FDA for a selected drug and therapeutic alternatives to such selected drug;

(iii) Comparative effectiveness of a selected drug and therapeutic alternatives to such selected drug, taking into consideration the effects of the selected drug and therapeutic alternatives to such selected drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations; and

(iv) The extent to which a selected drug and therapeutic alternatives to such selected drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

(e) *Limitation on evidence.* CMS will not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

(1) CMS reviews cost-effectiveness measures used in studies relevant to a selected drug to determine whether the use of the measure is permitted in accordance with section 1194(e)(2) of the Act as described in this paragraph (e), as well as section 1182(e) of the Act and other applicable law.

(2) CMS may use content in a study that uses a cost-effectiveness measure if it determines that the cost-effectiveness measure used is permitted in accordance with section 1194(e)(2) of the Act as described in this paragraph (e) of this section, as well as section 1182(e) of the Act and other applicable law.

§ 429.510 Methodology for developing the initial offer.

(a) *Identification of conditions for which the selected drug is used.* CMS identifies the condition(s) for which the selected drug is used that are covered under Part D, payable under Part B, or both.

(1) CMS considers the prescribing information for the selected drug in accordance with section 1194(e)(2)(B) of the Act.

(2) CMS may consider off-label use as defined in § 429.20.

(3) CMS excludes FDA-approved indications and off-label use, if applicable, from its analysis when CMS believes that utilization of the selected drug within such indication(s) and for such uses is intended solely for use in a setting in which the selected drug is not payable under Part B and not covered under Part D.

(b) *Information used to identify a therapeutic alternative(s) for the selected drug.* (1) CMS identifies the therapeutic alternative(s) for each condition(s) for which the selected drug is used as determined under § 429.510(a) using any combination of the following, as available:

(i) Information submitted by the Primary Manufacturer and the public as described in § 429.505(b)(2) and (d)(3).

(ii) Prescribing information as approved by the FDA.

(iii) Drug classification systems commonly used in the public and private sector for formulary development.

(iv) Major drug compendia.

(v) Widely accepted clinical practice guidelines.

(vi) Evidence identified through a CMS-led literature review.

(vii) Published drug or drug class reviews.

(viii) Peer-reviewed studies or other clinical evidence and information submitted by the Primary Manufacturer and the public.

(ix) Medicare claims or other data sets.

(2) The therapeutic alternative(s) may be a brand name drug, a brand name biological product, a generic drug, or a biosimilar, including specific formulations or dosage forms and strengths of such brand name drug, brand name biological product, generic drug, or biosimilar.

(c) *Process for determining the potential therapeutic alternative(s) for a selected drug.* (1) CMS may consult with FDA, clinicians, patients or patient organizations, and researchers.

(2) When determining a therapeutic alternative(s) for a selected drug, CMS considers all of the following:—

(i) Off-label use(s) for potential therapeutic alternatives as defined in § 429.20.

(ii) Prescribing information as approved by the FDA.

(iii) Potential therapeutic alternatives within the same pharmacologic class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action.

(iv) Potential therapeutic alternatives in a different pharmacologic class than the selected drug.

(v) Formulations or dosage forms and strengths of a potential therapeutic alternative.

(3) CMS may focus on a subset of therapeutic alternatives that are clinically comparable to the selected drug.

(4) CMS prioritizes clinical appropriateness when identifying the therapeutic alternative(s) for a selected drug.

(d) *Determining a starting point for the initial offer.* (1) CMS determines the price of each therapeutic alternative determined under paragraph (c) of this section:

(i) For a therapeutic alternative covered under Part D, the price is the lower of the following:

(A) The Net Part D Plan Payment and Beneficiary Liability of the therapeutic alternative.

(B) The MFP of the therapeutic alternative, if applicable.

(C) The WAC of the therapeutic alternative.

(ii) For a therapeutic alternative payable under Part B, the price is the lower of the following:

(A) The ASP of the therapeutic alternative.

(B) The MFP of the therapeutic alternative, if applicable.

(C) The WAC of the therapeutic alternative.

(iii) For a therapeutic alternative that is both covered under Part D and payable under Part B, CMS combines the prices determined in paragraphs (d)(1)(i) and (ii) of this section using an approach similar to the methodology used to combine the sum of the plan-specific enrollment weighted amounts and the payment amount under section 1847A(b)(4) of the Act to calculate the combined Part B and Part D amount, as described in § 429.430.

(2) The prices determined in accordance with paragraph (d)(1) of this section will be expressed as a 30-day equivalent supply.

(i) For a therapeutic alternative(s) covered under Part D, the 30-day equivalent supply will be calculated as described in § 429.415(a)(1), unless CMS determines it is appropriate to apply an alternative methodology under paragraph (d)(2)(iv) of this section.

(ii) For a therapeutic alternative(s) payable under Part B, the 30-day equivalent supply will be calculated as described in § 429.415(a)(2), unless CMS determines it is appropriate to apply an alternative methodology under paragraph (d)(2)(iv) of this section.

(iii) For a therapeutic alternative(s) payable under Part B and covered under Part D, the 30-day equivalent supply will be calculated separately for the prices determined in paragraphs (d)(1)(i) and (ii) of this section using the methodology described in paragraphs (d)(2)(i) and (ii) of this section, unless CMS determines it is appropriate to apply an alternative methodology under paragraph (d)(2)(iv) of this section. The separate prices expressed as a 30-day equivalent supply for the therapeutic alternative as payable under Part B and as covered under Part D are then combined using the methodology described in paragraph (d)(1)(iii) of this section to result in one combined price expressed as a 30-day equivalent supply for the therapeutic alternative.

(iv) For a therapeutic alternative(s) covered under Part D, payable under Part B, or both, for which CMS has determined it is appropriate to apply an alternative methodology, the 30-day equivalent supply may be calculated using a tailored methodology that promotes comparability between the therapeutic alternative(s) and the selected drug.

(3) CMS uses the price(s) determined in paragraph (d)(1) of this section to determine the starting point for developing the initial offer.

(i) If there is no therapeutic alternative for the selected drug or if there is no price(s) of the therapeutic alternative(s) determined under paragraph (d)(1) of this section below the ceiling determined under § 429.410(b), then the starting point for developing the initial offer is the lower of the following:

(A) The pharmaceutical price for the selected drug as included in the Federal Supply Schedule as managed by the Department of Veterans Affairs per 48 CFR part 38 as most recently submitted by the Primary Manufacturer under § 429.505(b).

(B) The maximum price a manufacturer can charge for a selected drug under 38 U.S.C. 8126 as most recently submitted by the Primary Manufacturer under § 429.505(b).

(C) The ceiling for the selected drug as determined in § 429.410(b).

(ii) If there is more than one therapeutic alternative for the selected drug, and at least one price determined under paragraph (d)(1) of this section is below the ceiling determined under § 429.410(b), CMS determines a starting point for developing the initial offer within a range based on the lower of the prices listed in paragraph (d)(1) of this section and the ceiling determined under § 429.410(b).

(iii) If there is one therapeutic alternative for the selected drug with a price that is below the ceiling, the price of such therapeutic alternative is the starting point.

(e) *Adjusting the starting point based on section 1194(e)(2) factors.* (1) CMS uses a qualitative approach to broadly evaluate the body of available evidence related to section 1194(e)(2) factors listed at § 429.505(d)(3) in totality, including any combination of the following, as available:

(i) Information submitted by the Primary Manufacturer and the public as described in § 429.505(b)(2) and (d)(3) and provided in public events described in § 429.515(b), as available.

(ii) Evidence identified through a CMS-led literature review.

(iii) Medicare claims or other datasets, potentially including evidence related to health care resource utilization and usage patterns of the selected drug and its therapeutic alternative(s) as determined in paragraph (c) of this section, if any.

(iv) Clinical data.

(v) Other information relevant to the selected drug and its therapeutic alternative(s), if any.

(2) CMS may consult with FDA, clinicians, patients or patient organizations, and researchers.

(3) CMS identifies outcomes of interest to evaluate for each condition identified under § 429.510(a).

(i) The types of outcomes and contextual factors that CMS considers include all of the following:

(A) Clinical outcomes.

(B) Patient-centered outcomes, patient experience data, and patient-reported outcomes, if available.

(C) Additional outcomes and contextual factors or patient and caregiver preferences to the extent these outcomes and factors correspond with benefits or harms to individuals taking the selected drug or therapeutic alternative(s), if any.

(D) Caregiver perspective to the extent that such perspective reflects directly upon the experience or relevant outcomes of the patient taking the selected drug.

(ii) CMS identifies outcomes using both of the following:

(A) A CMS-led literature review.

(B) Information submitted by the Primary Manufacturer and the public as described in § 429.505(b)(2) and (d)(3) and provided in public events described in § 429.515(b), as available.

(4) Based on the evaluation of evidence described in paragraphs (e)(1) through (3) of this section, CMS adjusts the starting point by considering the applicable evidence related to section 1194(e)(2) factors collectively and within the context of the course of care for each condition for which the selected drug is used.

(i) This assessment includes but is not limited to examining the improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) by considering both of the following:

(A) The costs of the selected drug and its therapeutic alternative(s).

(B) The magnitude of differences in outcomes of interest determined in paragraph (e)(3) of this section conferred by the selected drug compared to its therapeutic alternative(s) for each condition for which CMS has identified a therapeutic alternative.

(ii) Notwithstanding paragraph (e)(4)(i) of this section, if a condition identified under paragraph (a) of this section does not have a therapeutic alternative as identified under paragraphs (b) and (c) of this section, then CMS considers all of the following:

(A) The totality of available information described in paragraph (e)(1) of this section.

(B) Any existing treatment option(s) to determine the extent to which the selected drug addresses an unmet medical need as defined in § 429.20 for each identified condition.

(C) The magnitude of differences in outcomes of interest determined in paragraph (e)(3) of this section conferred by the selected drug to determine the extent to which the selected drug represents a therapeutic advance.

(5) The starting point may be adjusted upward, adjusted downward, or not adjusted based on considerations described in paragraphs (e)(1) through (4) of this section to determine the preliminary price.

(f) *Adjusting the preliminary price based on section 1194(e)(1) factors.* (1) CMS considers the section 1194(e)(1) factors, specified in § 429.505(b)(2) and provided by the Primary Manufacturer, in totality in determining whether to adjust the preliminary price.

(2) The preliminary price may be adjusted upward, adjusted downward, or not adjusted based on CMS' consideration of the section 1194(e)(1) factors in totality as described in paragraph (f)(1) of this section.

(3)(i) The price resulting from paragraphs (f)(1) and (2) of this section is the initial offer.

(ii) Notwithstanding this paragraph (f)(3), if the amount determined in accordance with the process described in this section is above the ceiling as determined in § 429.410(b), then the initial offer will be equal to the ceiling, and if the amount determined in accordance with this section is below the Temporary Floor for Small Biotech Drugs (as determined in § 429.440(b)), if applicable, then the initial offer will be equal to the temporary floor.

§ 429.515 Engagement with Primary Manufacturers and interested parties.

(a) *Engagement with Primary Manufacturers.* In a form and manner specified by CMS and in accordance with the rules set forth in this section, CMS hosts up to four optional meetings with Primary Manufacturers of selected drugs that have submitted the information set forth in § 429.505.

(1) *Meeting scope.* The first meeting that CMS offers Primary Manufacturers the option to attend is intended for the Primary Manufacturer to provide additional context on their data submission of the section 1194(e)(1) factors and section 1194(e)(2) factors as set forth in § 429.505 as CMS begins evaluating the data submission and developing an initial offer as described in § 429.510.

(i) The remaining three meetings that CMS offers Primary Manufacturers the opportunity to attend focus on the section 1194(e)(1) factors and section 1194(e)(2) factors described in § 429.505 and other topics aimed at working towards an agreement on an MFP.

(ii) Notwithstanding this paragraph (a)(1), new manufacturer-required data as described in § 429.505(b)(2) is not considered if it is submitted after the March 1 deadline.

(iii) Discussion of disputes and program policies regarding the negotiation process are considered out of scope.

(2) *Meeting attendance.* Meetings are attended solely by representatives of the Primary Manufacturer and of CMS. The number of attendees are limited as specified by CMS.

(3) *Meeting materials.* For the purposes of each meeting—

(i) Primary Manufacturers may provide the following to be presented and discussed at each meeting in a form and manner specified by CMS:

(A) New information on the section 1194(e)(2) factors; and

(B) Materials, including pages, slides, charts, and graphs, to facilitate discussion, which must comply with limits on the amount or format of such materials as specified by CMS; and

(ii) CMS may request that the Primary Manufacturer provide copies of any presented or discussed materials before the meeting in which they are presented or discussed.

(4) *Meeting timing.* The first optional meeting, if accepted by the Primary Manufacturer, occurs, at a time to be specified by CMS, after the data submission deadline specified in § 429.505(b)(1) and (d)(2) and before the provision of CMS' initial offer, as set forth in § 429.520. Up to three optional meetings are offered by CMS to occur after the provision of CMS' initial offer. If the Primary Manufacturer accepts the meeting invitation(s), such meeting(s) occur, at a time to be specified by CMS, after the provision of CMS's initial offer as set forth in § 429.520 and before the provision of CMS' final offer, if applicable, as set forth in § 429.535.

(5) *Meeting rules.* A Primary Manufacturer—

(i) May maintain a written record of the negotiation process; and

(ii) Is prohibited from making an audio or video recording of any negotiation meeting.

(b) *Engagement with interested parties.* CMS may hold event(s) in a form and manner and at times to be specified by CMS to seek information from patients and other interested parties about selected drugs, therapeutic alternatives to the selected drugs, and other information. CMS may incorporate drugs selected for renegotiation into these events or may hold separate events, as applicable.

§ 429.520 Provision of CMS' written initial offer and concise justification.

(a) *Written initial offer.* CMS provides the Primary Manufacturer with the written initial offer no later than June 1 following the selected drug publication date as defined in § 429.20.

(1) This written initial offer is accompanied by an Addendum to the Negotiation Program Agreement, as described in § 429.200(e), populated with the proposal for the MFP. To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in § 429.200(e) that sets forth the agreed-upon MFP as described in § 429.500(b).

(2) [Reserved]

(b) *Concise justification.* With the written initial offer, CMS includes a concise justification for the written initial offer based on the data set forth in § 429.505. The concise justification—

(1) Includes a qualitative description of the factors from section 1194(e) of the Act as set forth in § 429.505 and a description of the methodology that CMS used to develop the written initial offer as set forth under this subpart; and

(2) Provides the Primary Manufacturer with information on the range of evidence and other information considered in accordance with section 1194(e) of the Act that CMS found compelling during the development of the written initial offer.

(3) May include information obtained through events with interested parties as described at § 429.515(b).

§ 429.525 Statutory written counteroffers.

(a) *Primary Manufacturers' statutory written counteroffer.* The Primary Manufacturer must respond in writing within 30 days of receipt of the written initial offer from CMS by either accepting the written initial offer for the selected drug or making a statutory written counteroffer and providing a justification for such counteroffer based on the data set forth in § 429.505.

(b) *Required components.* (1) Any statutory written counteroffer must do all of the following:

(i) Provide a proposal for the MFP for the selected drug and a justification for such proposal.

(ii) Respond to the justification provided in CMS' written initial offer.

(iii) Indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer described in § 429.505, or other available data as described in § 429.505(d), supports the Primary Manufacturer's statutory written counteroffer or otherwise does not support CMS' written initial offer.

(2) Primary Manufacturers must complete an Addendum to the Negotiation Program Agreement, as described in § 429.200(e), and must submit the statutory written counteroffer in a form and manner specified by CMS.

(c) *CMS response to statutory written counteroffer.* CMS responds in writing to a statutory written counteroffer made by the Primary Manufacturer.

(1) CMS considers the statutory written counteroffer and either accepts or rejects it in writing within 30 days of receipt of the statutory written counteroffer or within 60 days of sharing the initial offer, whichever is later.

(2) To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in § 429.200(e) that sets forth the agreed-upon MFP as described in § 429.500(b).

§ 429.530 Additional price exchange opportunities.

(a) *Additional price exchange opportunities.* CMS and Primary Manufacturers may initiate additional, written offers and counteroffers in a form and manner specified by CMS during the period of time between CMS' rejection of the Primary Manufacturer's statutory written counteroffer, if applicable, and the parties reaching an agreement on the MFP, or at least 8 business days before the deadline by which CMS must issue the final offer, whichever is earlier, via the additional price exchange opportunities described in this section.

(1) The additional price exchange opportunities allow for the optional upload of materials which must comply with limits on the amount or format of such materials as specified by CMS, and include an optional text field to enable the offering or counteroffering party to include additional contextual information for the offer or counteroffer.

(2) Only one written offer or counteroffer per selected drug may be active at a time.

(3) An offering or counteroffering party may archive its written offer or counteroffer in the period before the other party accepts or rejects it, but not afterwards.

(4) Parties do not need to alternate making written offers and counteroffers.

(5) To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in § 429.200(e) that sets forth the agreed-upon MFP as described in § 429.500(b).

(b) [Reserved]

§ 429.535 Notification of final offer and conclusion of negotiations.

(a) *Notification of final offer.* In the event neither CMS' initial offer nor the Primary Manufacturer's statutory written counteroffer were accepted, and an MFP was not agreed to during the negotiation meetings or via the additional price exchange functionality, CMS sends the Primary Manufacturer a ''Notification of Final Maximum Fair Price Offer'' and an Addendum with the final offer MFP by September 30 following the selected drug publication date defined in § 429.20.

(1) If a final offer is sent, the Primary Manufacturer must respond in writing to this final offer by either accepting or rejecting the final offer by October 31 following the selected drug publication date defined in § 429.20.

(2) To formalize agreement on an MFP, CMS and the Primary Manufacturer both must sign an Addendum to the Negotiation Program Agreement as described in § 429.200(e) that sets forth the agreed-upon MFP as described in § 429.500(b).

(b) *Conclusion of negotiations.* All negotiations between CMS and the Primary Manufacturer of the selected drug must end prior to November 1 following the selected drug publication date, with respect to the initial price applicability year.

Subpart G—Renegotiation of an MFP

§ 429.600 General rule.

(a) *General.* With respect to initial price applicability years beginning with initial price applicability year 2029, the process of renegotiation will include the following actions.

(1) CMS identifies renegotiation-eligible drugs, if any, as described in § 429.605.

(2) CMS selects drugs for renegotiation from among such renegotiation-eligible drugs, if any, as described in § 429.610.

(3) CMS renegotiates the MFP applicable to any such drugs selected for renegotiation in accordance with the process set forth in § 429.620.

(b) *Applicability of a renegotiated MFP.* (1) Once the Primary Manufacturer and CMS have agreed upon a renegotiated MFP under the process set forth under § 429.620 with respect to a selected drug, the Primary Manufacturer is responsible for making the renegotiated MFP for the selected drug available, in accordance with subpart I of this part, with respect to dispenses, administrations, and furnishings of the selected drug on or after January 1 of the initial price applicability year for which the selected drug is selected for renegotiation (subject to § 429.135) until termination of the Negotiation Program Agreement in accordance with § 429.205.

(2) CMS applies a renegotiated MFP to all formulations across dosage forms and strengths of the selected drug by applying the methodology set forth at § 429.700, and notwithstanding § 429.700(b)(1) and (b)(2)(i), CMS uses the initial price applicability year of the renegotiated MFP to determine the applicable year of data.

(3) The Primary Manufacturer of a selected drug with a renegotiated MFP must provide access to the initial agreed-upon MFP in accordance with section 1193(a)(3) of the Act, including as described in subpart I of this part, prior to the effective date of the renegotiated MFP as specified in paragraph (b)(1) of this section.

(c) *Publication of the list of drugs selected for renegotiation.* CMS publishes the drugs selected for renegotiation with respect to an initial price applicability year, if any, consistent with § 429.100(b)(2).

§ 429.605 Eligibility of drugs for renegotiation.

(a) *For a selected drug with an agreed-upon MFP from a prior initial price applicability year.* For any selected drugs with an agreed-upon MFP from a prior initial price applicability year for which CMS does not make a determination described in § 429.135(c), CMS reviews such drugs for renegotiation eligibility in accordance with section 1194(f)(2) of the Act as described in paragraphs (b) through (d) of this section.

(b) *Selected drugs for which there is a change in monopoly status.* With respect to initial price applicability years beginning in 2029, CMS determines a selected drug to be renegotiation-eligible based on a change in monopoly status as described in paragraph (b)(1) or (2) of this section.

(1) A selected drug with an agreed-upon MFP will be determined to be a renegotiation-eligible drug if there has been a change in its monopoly status from a drug that is not an extended-monopoly drug, as defined in § 429.20, or a long-monopoly drug, as defined in

§ 429.20, to an extended-monopoly drug by January 1 of the initial price applicability year for which such selected drug would be selected for renegotiation.

(2) A selected drug with an agreed-upon MFP will be determined to be a renegotiation-eligible drug if there has been a change in status from a drug that is not a long-monopoly drug, as defined in § 429.20, to a long-monopoly drug by January 1 of the initial price applicability year for which such selected drug would be selected for renegotiation.

(c) *Selected drugs for which a new indication is added.* A selected drug with an agreed-upon MFP will be determined to be a renegotiation-eligible drug if a new indication, which may be a new indication added to the FDA-approved labeling or a new off label use, is added for the selected drug since the selected drug was last negotiated or renegotiated, as applicable.

(1) A selected drug will not be determined to be renegotiation-eligible based on the addition of a new indication if the FDA-approved labeling update or off-label use is related to a previously considered disease or condition.

(2) CMS determines if a new indication has been added as described in paragraph (c)(1) of this section by evaluating:

(i) FDA-approved labeling for the selected drug; and

(ii) Voluntary submissions from the Primary Manufacturer of the selected drug as described in § 429.615(a), if any.

(A) If a Primary Manufacturer voluntarily submits information through the process described in § 429.615(a), then CMS may consider off-label use when determining if a new indication has been added for renegotiation eligibility.

(B) [Reserved]

(3) To inform CMS determination of renegotiation eligibility under paragraph (c) of this section, a new indication must be added to the FDA-approved labeling for the selected drug on or before a time specified by CMS and any information regarding off-label use must be voluntarily submitted under § 429.615(a).

(d) *Selected drugs for which there has been a material change in any factor listed in section 1194(e) of the Act.* A selected drug with an agreed-upon MFP will be determined to be a renegotiation-eligible drug if there has been a material change in any factor listed in section 1194(e) of the Act.

(1) A change(s) to any factor listed in section 1194(e) of the Act will be considered to be material if the change(s) would reasonably be expected to meaningfully alter CMS' consideration of the factor within the context of renegotiation offers and counteroffers, including the initial offer as described in subpart F of this part, as compared with CMS' consideration of the factor within the context of offers, including the initial offer, and, if applicable, counteroffers, during the most recent prior negotiation or renegotiation for the selected drug.

(2) CMS reviews information available prior to a time specified by CMS pertaining to section 1194(e)(1) or section 1194(e)(2) factors in accordance with §§ 429.505(b)(2) and (d)(3) and 429.510(e) and (f) to determine if there has been a material change.

(3) CMS considers information provided in voluntary submissions described at § 429.615(a), if any, to determine if there has been a material change.

§ 429.610 Selection of drugs for renegotiation.

(a) *Selection of renegotiation-eligible drugs due to a change in monopoly status.* All selected drugs determined to be renegotiation-eligible per § 429.605(b) will be selected for renegotiation.

(b) *Selection of renegotiation-eligible drugs due to a new indication or a material change in any factor listed in section 1194(e) of the Act.* Selected drugs determined to be renegotiation-eligible per § 429.605(c) and (d) will be selected for renegotiation if CMS expects renegotiation is likely to result in a significant change to the previously negotiated or renegotiated MFP of such drug.

(1) CMS expects renegotiation is likely to result in a significant change to the MFP if the criteria described in paragraphs (b)(1)(i) and (ii) of this section are both met.

(i) CMS determines the new indication(s) or material change(s) to any factor(s) listed in either section 1194(e)(1) of section 1194(e)(2) of the Act would be likely to result in a renegotiated MFP that represents at least a 15 percent or greater change to the current MFP of the selected drug upon engaging in renegotiation with the Primary Manufacturer.

(A) The percent change may be an increase or a decrease in the MFP.

(B) [Reserved]

(ii) CMS determines that a 15 percent or greater change in the MFP following renegotiation would have a significant impact on the Medicare program.

(2) To determine if the criteria in paragraph (b)(1) of this section are met, CMS conducts a holistic inquiry based on the totality of the information available and the circumstances of the renegotiation-eligible drug.

(i) The scope of information considered may extend beyond the scope of information reviewed for renegotiation eligibility as described at § 429.605(c) and (d) to include consultations with FDA, clinicians, patients, patient organizations, and researchers, a CMS-led review of the information sources described at § 429.510(b)(1), (c)(1), (e), and (f) pertaining to the factors listed at section 1194(e) of the Act or any other information to support CMS' determination.

(ii) [Reserved]

§ 429.615 Data collection to inform renegotiation eligibility, selection, and renegotiation of the MFP for a selected drug.

(a) *Voluntary information submission from Primary Manufacturers to inform renegotiation eligibility and selection for selected drugs.* A Primary Manufacturer of a selected drug may voluntarily submit information to CMS regarding the addition of a new indication to the selected drug or new information regarding the factors listed in section 1194(e) of the Act to CMS in the form and manner and by the deadline specified by CMS. Information submitted by a Primary Manufacturer will be used to inform renegotiation eligibility, selection, and renegotiation of the MFP for a selected drug.

(b) *Data collection from Primary Manufacturers and other interested parties for renegotiation of the MFP.* After publication of the drugs selected for renegotiation, if any, in accordance with § 429.100(b)(2), information as specified in paragraphs (b)(1) and (3) of this section must be submitted to CMS, in a form and manner to be specified by CMS, and by 11:59 p.m. PST on March 1 of the year of the selected drug publication date for the initial price applicability year for which the drug was most recently selected for renegotiation.

(1) In accordance with the requirements of the Negotiation Program Agreement as set forth in § 429.200, the Primary Manufacturer of a drug selected for renegotiation must submit the following information for such drug for the initial price applicability year for which the drug was selected for renegotiation, inclusive of the NDC–11s of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer, to CMS in a form and manner specified by CMS:

(i) The information specified at § 429.505(b)(2)(i) through (v); and

(ii) For drugs selected for renegotiation that were selected originally for negotiation for initial price applicability year 2026 or 2027 and have not previously been selected for renegotiation for initial price applicability year 2028 or thereafter, the information specified below for all NDC–11s of the selected drug payable under Part B, not covered under Part D, and for which the Primary Manufacturer did not include such information with the Primary Manufacturer's data submission for the initial price applicability year for which the selected drug was first selected for negotiation.

(A) Non-FAMP, unit type, and total unit volume for each NDC–11, if available, for the same calendar years for which non-FAMP data was reported in the Primary Manufacturer's data submission for the negotiation period in which the selected drug's MFP was negotiated.

(B) When there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in a calendar year, the non-FAMP submitted for that calendar quarter in paragraph (b)(1)(ii)(A) of this section should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data.

(2) In accordance with the requirements of its Negotiation Program Agreement as set forth in § 429.200, a Primary Manufacturer is required to update the information submitted in accordance with paragraph (b)(1) of this section if the Primary Manufacturer becomes aware that any such information has changed or is otherwise inaccurate.

(3) Interested parties may submit the data specified in § 429.505(d)(3).

§ 429.620 Renegotiation process.

(a) *General.* CMS establishes a renegotiation process consistent with the negotiation methodology and process established under section 1194(b) of the Act, to the extent practicable.

(b) *Determining the ceiling for renegotiation.* CMS will not make an offer or agree to a counteroffer for an MFP that exceeds the ceiling specified in section 1194(c) of the Act. Subject to § 429.440(b)(4), CMS calculates the ceiling for drugs selected for renegotiation using the following process:

(1) With respect to selected drugs negotiated for initial price applicability years 2026 and 2027 and have not been renegotiated in initial price applicability year 2028 or thereafter, CMS incorporates NDC–11s that are payable under Part B, if applicable. Specifically, CMS—

(i) For a selected drug that is both covered under Part D and payable under Part B, calculates the payment amount under section 1847A(b)(4) of the Act, as set forth in § 429.425, for the calendar year that is 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation of the previously agreed-upon MFP and the sum of the plan-specific enrollment weighted amounts calculated at the time of the previous negotiation; and

(ii) Calculates the average non-FAMP amount(s) used in the calculation set forth in paragraph (b)(2) of this section using the non-FAMP and Part B utilization data for NDC–11s set forth in § 429.615(b)(1)(i) for the same calendar years for which non-FAMP data was reported during the original negotiation and the non-FAMP and Part D utilization data previously used to calculate the average non-FAMP at the time of the previous negotiation.

(2) CMS updates, as necessary, the applicable percent specified in section 1194(c)(3) of the Act to reflect the monopoly status, which is set forth in § 429.435(a)(4)(v)(A)(*1*) through (*3*), of the drug selected for renegotiation and is determined based on its initial approval date, as set forth in § 429.125(a)(1)(i), and the initial price applicability year for which the drug is selected for renegotiation.

(3) With respect to all selected drugs with an agreed-upon MFP that are renegotiated, CMS, as applicable, updates the amounts considered for the ceiling as set forth in § 429.410, subject to § 429.440(b)(4), for inflation by adjusting for the percent increase in the CPI–U (as defined in § 429.20) from July of the calendar year that is 2 years prior to the initial price applicability year of the most recently published MFP through July of the calendar year prior to the selected drug publication date for the initial price applicability year for which the drug is selected for renegotiation.

(c) *Negotiation factors.* CMS considers the negotiation factors listed at section 1194(e)(1) and (e)(2) of the Act and as set forth in § 429.505 as the basis for determining the offers and counteroffers in the renegotiation process inclusive of information submitted or shared about the factors listed at sections 1194(e)(1) and (e)(2) of the Act in any prior negotiation or renegotiation(s).

(d) *Methodology for developing an initial offer.* CMS follows the process as set forth in § 429.510 to the extent practicable to develop the initial offer for renegotiation.

(e) *Engagement with Primary Manufacturers and interested parties.* CMS follows the process as set forth in § 429.515 for drugs selected for renegotiation to the extent practicable.

(f) *Provision of CMS' initial offer and concise justification.* CMS follows the process as set forth in § 429.520 to the extent practicable.

(g) *Renegotiation written counteroffers.* The renegotiation written counteroffer follows the process as set forth in § 429.525 to the extent practicable.

(h) *Additional price exchange opportunities.* The additional price exchange opportunities follow the process as set forth in § 429.530 to the extent practicable.

(i) *Notification of final offer and determination that renegotiations have finished.* CMS follows the process as set forth in § 429.535 to the extent practicable.

(j) *Application of the MFP across dosage forms and strengths.* CMS applies the renegotiated MFP across dosage forms and strengths as set forth in § 429.600(b)(2) to the extent practicable.

(k) *Publication of the MFP.* For drugs for which there is agreement on a renegotiated MFP, CMS publishes the renegotiated MFP and related information as set forth in § 429.705 to the extent practicable.

(l) *Establishment of MFPs after the negotiation deadline.* CMS follows the process set forth in § 429.710 in circumstances where a renegotiated MFP is agreed upon after the deadline for the conclusion of negotiations as set forth in § 429.535(b) to the extent practicable.

Subpart H—Implementation of the MFP

§ 429.700 Application of the MFP across dosage forms and strengths.

(a) *General principles for MFP application.* CMS has the administrative duty to establish procedures to compute and apply the MFP across different dosage forms and strengths of the selected drug and not based on the specific formulation, package size, or package type of such drug.

(1) A single MFP will be applied across NDC–9s and HCPCS codes, as set forth in § 429.100(d), as applicable, for a 30-day equivalent supply and will be used to calculate an MFP per unit for each NDC–9 of the selected drug and an MFP per billing unit for each billing and payment code associated with the selected drug, as applicable.

(2) [Reserved]

(b) *Procedures to compute and apply the MFP across dosage forms and*

strengths. CMS calculates and applies the MFP across dosage forms and strengths as follows:

(1) *Calculate Annual WAC per Unit.* For each selected drug and calendar quarter of the year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation, CMS—

(i) For each NDC–11—

(A) Divides the WAC quarterly units by the total WAC annual units (as reported by the Primary Manufacturer under § 429.505(b)(2)(v)); and

(B) Multiplies the quotient determined in paragraph (b)(1)(i)(A) of this section by the quarterly WAC per unit for such NDC–11 (as reported by the Primary Manufacturer under § 429.505(b)(2)(v)) to calculate the weighted quarterly WAC per unit.

(ii) For each selected drug, sums the resulting weighted quarterly WAC per unit amounts from paragraph (b)(1)(i)(B) of this section for all NDC–11s to calculate the annual WAC per unit.

(2) *Calculate average number of units per 30-day equivalent supply.* (i) For each NDC–11, CMS calculates the total units dispensed/administered, as reported on PDE data or Part B data for the year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation.

(A) For NDCs only present in PDE data: total units dispensed/administered are defined as the total quantity dispensed for an NDC–11, summed across the calendar year.

(B) For NDCs only associated with HCPCS codes present in Part B data: total units dispensed or administered are defined as the total billing units sold for an NDC–11 as determined using the unit allocation and standardization methodology described in § 429.425(a)(3), summed across the calendar year.

(C) For NDCs that are both present in PDE data and associated with HCPCS codes present in Part B data: total units dispensed/administered are defined as the sum of the quantity dispensed for the NDC–11 and the total billing units sold for the NDC–11 as determined using the unit allocation and standardization methodology described in § 429.425(a)(3), summed across the calendar year.

(ii) For each NDC–11, CMS divides the total units dispensed/administered, as calculated in paragraph (b)(2)(i) of this section, by the total 30-day equivalent supply, as determined using the 30-day equivalent supply methodology described at § 423.104(d)(2)(iv)(A)(*2*) of this chapter for Part D and at § 429.415(a)(2)(v) for Part B, to calculate the average number of units per 30-day equivalent supply.

(3) *Calculate WAC per 30-day equivalent supply ratio.* (i) For each NDC–11, CMS multiplies the annual WAC per unit, calculated as described at paragraph (b)(1) of this section, by the average number of units per 30-day equivalent supply, as described at paragraph (b)(2) of this section, to calculate the WAC per 30-day equivalent day supply for that NDC–11.

(ii) For each NDC–11, CMS divides the total 30-day equivalent supply from paragraph (b)(2)(ii) of this section for such NDC–11 by the total 30-day equivalent supply summed across all applicable NDC–11s within an NDC–9 and then multiplies such quotient by the amount calculated in paragraph (b)(3)(i) of this section to calculate the weighted WAC per 30-day equivalent supply per NDC–11.

(iii) For each NDC–9, CMS sums the resulting amounts from paragraph (b)(3)(ii) of this section across all NDC–11s to calculate the WAC per 30-day equivalent supply for that NDC–9.

(iv) For each NDC–9, CMS divides the total 30-day equivalent supply for that NDC–9 by the total 30-day equivalent supply summed across all NDC–9s and then multiplies this quotient by the resulting amount from paragraph (b)(3)(iii) of this section to calculate the weighted WAC per 30-day equivalent supply per NDC–9.

(v) CMS sums the resulting amounts from paragraph (b)(3)(iv) of this section across all NDC–9s of the selected drug to calculate the WAC per 30-day equivalent supply for the selected drug.

(vi) For each NDC–9, CMS divides the amount from paragraph (b)(3)(iii) of this section by the amount from paragraph (b)(3)(v) of this section to calculate the WAC per 30-day equivalent supply ratio for that NDC–9.

(4) *Calculate NDC–9 MFP per Unit and MFP per Billing Unit.* (i) To determine the NDC–9 MFP per unit, CMS takes the following steps:

(A) For each NDC–9, CMS multiplies the single MFP for the selected drug by the amount resulting from paragraph (b)(3)(vi) of this section to calculate the MFP per 30-day equivalent supply for that NDC–9.

(B) For each NDC–9, CMS divides the amount resulting from paragraph (b)(4)(i) of this section by the quotient of the total number of units dispensed/administered divided by the total 30-day equivalent supply to calculate the NDC–9 MFP per unit at the NCPDP unit (for example, tablet).

(ii) For NDC–11s associated with HCPCS codes present in Part B data, CMS further converts the MFP per NCPDP unit of each NDC–9 into an MFP per billing unit using the following steps:

(A) For each NDC–9, CMS converts the resulting amount from paragraph (b)(4)(i)(B) of this section to an NDC–11 MFP per billing unit, as necessary. First by multiplying NDC–9 MFP per unit calculated in paragraph (b)(4)(i)(B) of this section by the manufacturer submitted total NDC–11 package NCPDP unit quantity, for NDC–11s associated with a HCPCS code, to get an NDC–11 MFP per package. Then, by dividing this product by the HCPCS billing units per package for that NDC–11 to get an NDC–11 MFP per billing unit.

(B) For each NDC–11, CMS sums the units reported by manufacturers in the ASP portal for all quarters for the calendar year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation for each NDC–11 associated with a given HCPCS code.

(C) For each NDC–11, CMS divides the resulting amount from paragraph (b)(4)(ii)(B) by the sum of units reported by manufacturers in the ASP portal for all quarters for the calendar year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation for all NDC–11s that share the same HCPCS code and belong to the selected drug.

(D) For each NDC–11, CMS multiplies the resulting amount from paragraph (b)(4)(ii)(A) of this section by the resulting amount from paragraph (b)(4)(ii)(C) of this section.

(E) For each HCPCS code, CMS sums the resulting amount from paragraph (b)(4)(ii)(D) of this section across all NDC–11 associated with the HCPCS code to yield the MFP per billing unit.

(c) *Application of the MFP to NDC–11s and HCPCS codes associated with a new NDA or BLA of the selected drug, new NDC–11s and HCPCS codes for existing NDAs or BLAs of the selected drug, and NDC–11s of the selected drug with insufficient PDE, Part B data, or WAC data for the calendar year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation.* CMS applies the MFP to NDCs associated with new NDAs or BLAs of the selected drug, new NDC–11s and HCPCS codes for existing NDAs or BLAs of the selected drug, and to NDCs of the selected drug with insufficient PDE, Part B data, or WAC data as follows:

(1) *NDC–11s and HCPCS Codes associated with new NDAs or BLAs of*

the selected drug. If the Primary Manufacturer of a selected drug receives approval or licensure for a new NDA or BLA, as applicable, for the same active moiety/active ingredient/antigen component (or in the case of a potential qualifying single source drug identified under § 429.125(b)(4)(i), the distinct combination thereof), as identified as set forth at § 429.125(b)(1) through (4), as the selected drug, CMS—

(i) Uses available information to determine the 30-day equivalent supply and the WAC ratio; and

(ii) Includes the NDCs and HCPCS codes associated with the new NDA or BLA, as set forth in § 429.100(c), as appropriate, on the list of NDCs and HCPCS codes of the selected drug and requires that the MFP apply to such NDCs and HCPCS codes.

(2) *New NDC–11s and HCPCS codes for existing NDAs or BLAs of the selected drug.* If new NDC–11s and HCPCS codes for existing NDAs or BLAs of the selected drug are marketed after the initial calculation of WAC ratios, as set forth in paragraph (b)(3) of this section, CMS–

(i) Uses available information to determine the 30-day equivalent supply and the WAC ratio; and

(ii) Includes the new NDCs and HCPCS codes, as set forth in § 429.100(c), as appropriate, on the list of NDCs and HCPCS codes of the selected drug and requires that the MFP apply to such NDCs and HCPCS codes.

(3) *NDC–11s of the selected drug with insufficient data.* If an NDC–11 (or all NDC–11s assigned to a HCPCS code) that has been included on the list of NDCs of the selected drug under § 429.100(c) lacked sufficient PDE, Part B data, or WAC data for the year that begins 3 years prior to the initial price applicability year with respect to which the selected drug was selected for negotiation, CMS—

(i) Uses available information to determine the 30-day equivalent supply and the WAC ratio; and

(ii) Includes the NDCs and HCPCS codes, as appropriate, on the list of NDCs and HCPCS codes of the selected drug and requires that the MFP apply to such NDCs and HCPCS codes.

(4) *WAC ratio.* To determine the 30-day equivalent supply and the WAC ratio using available information for NDC–11(s) (and all NDC–11s assigned to a HCPCS code) of the selected drug described at paragraphs (c)(1) through (3) of this section, CMS takes the following steps:

(i) Determines whether there is an existing NDC that is comparable to such NDC (or comparable to the NDCs associated with such HCPCS code) with sufficient data for the MFP application calculations to be performed as set forth in paragraph (b) of this section.

(A) If an existing, comparable NDC exists, CMS uses the quotient of total units dispensed or administered to 30-day equivalent supply (adjusted as necessary to reflect dosing or unit type differences between the comparable NDCs and the new NDCs as described at paragraphs (c)(1) and (2) of this section or NDCs with insufficient data as described at paragraph (c)(3) of this section), as described at paragraph (b)(2) of this section, and the WAC ratio, as described at paragraph (b)(3) of this section, that was calculated for the existing, comparable NDC for the application of MFP to the new NDC or NDC that lacks sufficient data.

(B) If a comparable NDC does not exist, CMS imputes the quotient of total units dispensed or administered to 30-day equivalent supply using sources such as the FDA-approved labeling and other sources associated with the new NDC as described at paragraph (c)(1) or (2) of this section or NDC that lacks sufficient PDE, Part B data, or WAC data as described at paragraph (c)(3) of this section, but uses a WAC ratio of 1.0 to apply the MFP to the new NDC as described at paragraph (c)(1) or (2) of this section or NDC that lacks sufficient PDE, Part B data, or WAC data, but uses a WAC ratio of 1.0 to apply the MFP to the NDC that lacks sufficient PDE, Part B data, or WAC data as described at paragraph (c)(3) of this section.

(*1*) When CMS accrues sufficient data for NDCs for which CMS imputed the quotient of total units dispensed or administered to 30-day equivalent supply as described in this paragraph (c)(4)(i)(B), CMS adjusts the MFP application by updating the quotient of total quantity dispensed or administered to 30-day equivalent supply based on observed PDE data and Part B data for existing NDCs (or NDCs associated with such HCPCS code) that lacked sufficient WAC, PDE data, or Part B data to be included in the initial calculation of WAC ratios (described in paragraphs (a) and (b) of this section), and new NDCs (and all NDC–11s assigned to such HCPCS code) launched after the initial calculation of WAC ratios.

(*2*) CMS determines that sufficient data was accrued as follows:

(*i*) One year has elapsed since the NDCs first appeared in PDE records or the HCPCS codes associated with the NDCs appeared in Part B data.

(*ii*) The NDC or HCPCS code has accrued the same number of units dispensed/administered as the NDC–11 that had the fewest units dispensed/administered at the time that the WAC ratios were originally calculated.

(ii) If a new NDC (or NDC that lacks sufficient PDE, Part B data, or WAC data) is assigned to a HCPCS code for which CMS has already calculated an MFP per billing unit, the MFP per billing unit for that HCPCS code will not change, and the new NDC (or NDC that lacks sufficient PDE, Part B data, or WAC data) will be subject to that existing MFP per billing unit.

(d) *Suggestion of Error.* A Primary Manufacturer that believes in good faith that CMS has made an error in the calculations specified in paragraphs (b) and (c) of this section may submit a Suggestion of Error, as set forth in § 429.445(c) and in a form and manner specified by CMS, as set forth in § 429.445(d).

§ 429.705 Publication of the MFP.

(a) *Publication.* With respect to an initial price applicability year for which a drug is selected for negotiation or renegotiation, as applicable, CMS publishes by November 30 of the year that is 2 years prior to such initial price applicability year the MFP for each such drug for which CMS and the Primary Manufacturer have reached an agreement on an MFP.

(1) CMS publishes all of the following on the CMS website:

(i) The selected drug.

(ii) The initial price applicability year.

(iii) The MFP file which contains the single MFP for a 30-day equivalent supply of the selected drug, NDC–9 MFP per unit price and HCPCS code dosage price and is updated annually to show the inflation-adjusted MFP for the selected drug as set forth in paragraph (a)(2)(i) of this section.

(iv) Whether an MFP between a Primary Manufacturer and CMS is not agreed upon.

(v) Whether a drug is no longer a selected drug and the reason for that change.

(2) For each selected drug and for each year subsequent to the first initial price applicability year of the price applicability period (unless renegotiation occurs as set forth under subpart G of this part), CMS publishes an updated MFP no later than November 30 of the year that is 2 years prior to such subsequent year.

(i) The updated MFP for each selected drug is equal to the MFP that was published for such drug for the previous year, increased by the annual percentage increase in the CPI–U for the 12-month period ending with the July immediately preceding such November 30.

(ii) [Reserved]

(3) In the case of a selected drug with respect to an initial price applicability year for which the MFP is agreed upon after the MFPs are published for other selected drugs in accordance with § 429.710, CMS publishes the MFP no later than 30 days after the date such MFP is so agreed upon.

(b) *Explanation for the MFP.* CMS publishes explanations for the MFPs no later than March 1 of the year prior to the initial price applicability year.

(1) The explanation for the MFP of each selected drug, or drug selected for renegotiation, subject to the requirements for treatment of confidential and proprietary information described in § 429.300 includes—

(i) The narrative explanation of the MFP;

(ii) Redacted information regarding the negotiation meetings, as applicable, including exchanges of offers and counteroffers, as applicable; and

(iii) The redacted information submitted by a Primary Manufacturer, as set forth in § 429.505(b)(2) or § 429.615(b)(1), as applicable, and the redacted information submitted by interested parties, as set forth in § 429.505(d)(3) or § 429.615(b)(3), as applicable.

(2) If agreement upon an MFP is not reached for a selected drug, neither an MFP nor an MFP explanation is published. CMS indicates on the CMS website that an MFP has not been agreed upon between the Primary Manufacturer and CMS for the selected drug as set forth in paragraph (a)(1)(iv) of this section.

§ 429.710 Establishment of MFPs after the negotiation deadline.

If actions or delays by the Primary Manufacturer delay the negotiation process such that the MFP may be agreed to after the end of the negotiation period as described in § 429.535(b), CMS continues to engage in the negotiation process set forth in subpart F of this part. In accordance with the requirement to have a consistent methodology and process for negotiating MFPs, CMS follows timelines consistent with the negotiation process set forth in subpart F of this part and takes the time to complete the established process so described as appropriate for the selected drug.

(a) If actions or delays by the Primary Manufacturer delay the negotiation process, when CMS initiates or resumes the negotiation process, CMS applies the consistent methodology and process with respect to the selected drug based on its status at the time the negotiation process occurs, including with respect to renegotiation, as applicable, as described in subpart G of this part.

(b) If the manufacturer and CMS have completed each step of the negotiation process as detailed in subpart F of this part, including the issuance of a final offer in accordance with § 429.535(a), and then, after the statutory end of the negotiation period as described in § 429.535(b), the Primary Manufacturer of a selected drug wishes to agree to an MFP, the Primary Manufacturer must notify CMS in writing that it would like to accept the final offer from CMS.

Subpart I—[Reserved]

Subpart J—Manufacturer Compliance and Oversight

§ 429.900 Monitoring manufacturer compliance.

(a) *Monitoring and assessment.* CMS monitors and evaluates Primary Manufacturer compliance with the Negotiation Program Agreement as described in § 429.200, including compliance with all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including this part, implementing those provisions and any changes to the Act that affect the Negotiation Program.

(b) *Primary Manufacturer cooperation with CMS compliance monitoring activities.* Primary Manufacturers must cooperate with CMS compliance monitoring activities. In accordance with the Negotiation Program Agreement as set forth in § 429.200, Primary Manufacturers must cooperate with CMS monitoring and evaluation of Primary Manufacturer compliance as specified in paragraph (a) of this section, including, but not limited to, providing complete and accurate responses to CMS written requests for clarifications, corrections, and additional information, and complying fully with all requests for corrective action, in a form and manner specified by CMS. Such requests will include a date by which the Primary Manufacturer must submit a complete, accurate, and relevant response, or take any other corrective action requested. Non-responsive, incomplete, or inaccurate responses will not be considered compliant. Failure to provide a timely, accurate, and complete response is a violation of the Negotiation Program Agreement as described in § 429.200, and may result in the Primary Manufacturer being subject to a civil monetary penalty as described in § 429.1005.

(c) *Actions to address Primary Manufacturer noncompliance.* If CMS concludes that the Primary Manufacturer is noncompliant with one or more of the requirements of the Negotiation Program Agreement, including all applicable requirements and conditions set forth in sections 1191 through 1198 of the Act and all applicable guidance and regulations, including this part, implementing those provisions and any changes to the Act that affect the Negotiation Program, CMS may take one or more of the following actions:

(1) Provide a written notice to the Primary Manufacturer of the violation(s).

(2) Request the Primary Manufacturer take specific corrective action to address the noncompliance, in a form and manner, and by the deadline specified by CMS.

(3) Impose a civil monetary penalty on the Primary Manufacturer as set forth in subpart K of this part.

Subpart K—Civil Monetary Penalties

§ 429.1005 Violations of the Negotiation Program Agreement.

(a) *General.* CMS must impose a civil monetary penalty on a Primary Manufacturer that has entered into a Negotiation Program Agreement as set forth in § 429.200, and that fails to comply with a requirement determined by CMS to be necessary for the purposes of administering and monitoring compliance with the Negotiation Program including without limitation the requirement to submit information in accordance with section 1193(a)(4) of the Act.

(b) *Determination of the civil monetary penalty amount.* CMS must impose a civil monetary penalty for such violation as set forth in paragraph (a) of this section in the amount of $1,000,000 as adjusted annually under 45 CFR part 102, for each day of such violation as set forth in paragraph (a) of this section.

(c) *Accrual of civil monetary penalty.* The civil monetary penalty accrues for each day of such violation as set forth in paragraph (a) of this section, starting on the first day of such violation, until—

(1) The Primary Manufacturer has provided all required information or otherwise taken any corrective action determined by CMS to be necessary to address such violation, including, as applicable, providing documentation to evidence that the Primary Manufacturer has provided all past due information; or

(2) The Negotiation Program Agreement is terminated as described in § 429.205(a).

(d) *Notice.* When a civil monetary penalty is imposed under this section, CMS sends a notice to the Primary Manufacturer in accordance with § 429.1020(a) after the civil monetary penalty stops accruing under paragraph (c) of this section.

§ 429.1010 Provision of false information related to the biosimilar delay and Temporary Floor for Small Biotech Drugs.

(a) *General.* CMS must impose a civil monetary penalty as follows:

(1) On a Biosimilar Manufacturer for each item of false information the Biosimilar Manufacturer knowingly provides to CMS for use in applying the aggregation rule described at § 429.110(c)(1)(iv)(A).

(2) On a Primary Manufacturer for each item of false information the Primary Manufacturer knowingly provides to CMS for use in applying the test to determine if a selected drug is eligible for the Temporary Floor for Small Biotech Drugs described at § 429.440(b)(2).

(b) *Determination of the civil monetary penalty amount.* CMS must impose a civil monetary penalty in the amount of $100,000,000 as adjusted annually under 45 CFR part 102, per item of false information described in paragraph (a) of this section.

(c) *Notice.* When a civil monetary penalty is imposed under this section, CMS sends a notice to the Biosimilar Manufacturer or Primary Manufacturer, as applicable, in accordance with § 429.1020(a).

§ 429.1015 Failure to pay a biosimilar delay rebate.

(a) *General.* CMS must impose a civil monetary penalty on a Reference Manufacturer that fails to pay the rebate amount set forth in § 429.110(i)(4) by the payment deadline as set forth in section § 429.110(i)(2) for such selected drug.

(b) *Determination of the civil monetary penalty amount.* CMS must impose a civil monetary penalty for each violation described at paragraph (a) of this section in an amount equal to 10 times the amount of the biosimilar delay rebate as set forth at § 429.110(i)(4) that the Reference Manufacturer failed to pay.

(c) *Notice.* When a civil monetary penalty is imposed under this section, CMS sends a notice to the Reference Manufacturer in accordance with § 429.1020(a).

§ 429.1020 Notice and appeal procedures.

(a) *Notice of imposition of civil monetary penalties.* If CMS makes a determination to assess a civil monetary penalty described in this subpart, CMS sends a written notice of its decision to impose a civil monetary penalty to include the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) For civil monetary penalties imposed in accordance with § 429.1005, the start date of the penalty accrual.

(4) For civil monetary penalties imposed in accordance with § 429.1005, the end date of the penalty accrual.

(5) The total amount of the penalty assessed.

(6) The date the penalty is due.

(7) The manufacturer's right to a hearing as specified under 42 CFR part 423, subpart T.

(8) Information about where to file the request for a hearing.

(b) *Collection.* (1) A manufacturer must pay the civil monetary penalty in full within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS as set forth in paragraph (a) of this section.

(2) In the event a manufacturer requests a hearing, in accordance with 42 CFR part 423, subpart T, the manufacturer must pay the amount in full within 60 calendar days after the date of a final decision by the Departmental Appeal Board, to uphold, in whole or in part, the civil monetary penalty.

(3) If the 60th calendar day described in paragraphs (b)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(c) *Appeal procedures for civil monetary penalties.* Section 1128A(c)(2) of the Act provides that CMS may not collect a civil monetary penalty until the affected party has had notice and the opportunity for a hearing. Any appeal proceedings will be governed by the provisions of 42 CFR part 423, subpart T.

(1) Primary Manufacturers may appeal the following determinations, subject to the limitations on administrative and judicial review in section 1198 of the Act:

(i) A CMS determination to assess a civil monetary penalty under §§ 429.1000 through 429.1015.

(ii) The calculation of the amount of the civil monetary penalty.

(2) If CMS decides to impose a civil monetary penalty, CMS provides the manufacturer with notice in accordance with the process set forth in paragraph (a) of this section.

(3) A manufacturer has a right to a hearing following a decision by CMS to impose a civil monetary penalty following the administrative appeal process and procedures established in 42 CFR part 423, subpart T.

(d) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section 1128A of the Act) apply to civil monetary penalties under this section to the same extent that they apply to a civil monetary penalty or procedures under section 1128A of the Act.

(e) *Bankruptcy.* In the event that a manufacturer declares bankruptcy, as described in title 11 of the United States Code, and fails to pay either the biosimilar delay rebate amount owed or the total sum of civil monetary penalties imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid amount of the rebates and civil monetary penalties owed by the manufacturer.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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